

BMJ Open Experiences of Venous Leg Ulcer persons following an individualised nurse-led education: protocol for a qualitative study using a constructivist grounded theory approach

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ABSTRACT

Introduction Venous leg ulcers are slow-healing wounds with a high risk of recurrences. To prevent recurrences and promote healing, different nurse-led educational interventions have been developed. The impact of these interventions on self-management is ambiguous. Also, how persons with a venous leg ulcer experiences these educational sessions are poorly described.

Aim This study protocol presents the methodology to provide a comprehensive explanation of participants' journeys—of how they experience their individualised education sessions concerning self-management.

Methods and analysis A constructivist grounded theory approach according to Charmaz involving 30 participants will be used. Data will be collected through semistructured face-to-face interviews. Interviews will be transcribed verbatim and analysed with initial and focus coding using MAXQDA. Data collection and data analysis will occur iteratively, focusing on constant comparison to obtain well-developed categories. Categories will be reinforced using existent literature.

Ethics and dissemination This pre-results study is embedded in a clinical trial (NCT04019340) and approved by ethical committee of the canton of Geneva (CCER: 2019-01964). A theory will emerge from participants' journeys informing future education sessions for patients with venous leg ulcers. The findings will be disseminated through peer-reviewed publications and communications.

INTRODUCTION

Venous leg ulcers (VLUs) are defined as a loss of skin on the lower leg or foot taking more than 6 weeks to heal.¹ They are the most frequent aetiology of leg ulcer (70%) and are associated with chronic venous insufficiency.² The estimated prevalence of VLUs is approximately 0.9% of the global population,^{3 4} is higher in women⁴ and rises above 2% in the population aged >85 years.^{4–6} Management of VLUs is costly. In the UK, annual costs associated with VLUs are estimated at £941 million.⁷ All these numbers will increase over the next years due to the ageing of the population.⁸

Strengths and limitations of this study

- This study protocol demonstrates how a constructivist grounded theory approach highlights patients' voices.
- A systematic and iterative approach with constant comparative analysis will enable the refinement of relevant categories.
- The results of the study will be a production of inductively derived generalisations about patients with venous leg ulcer following a standardised education programme.
- Theoretical sampling is challenging for a grounded theory study protocol.

VLUs are slow-healing wounds as only 53% of VLUs heal within 1 year.⁹ Once healed, they are associated with a high recurrence rate estimated at 39% at 6 months and 57% at 1 year.¹⁰ Persons with VLUs experience symptoms including pain, insomnia, exudate and odour.¹¹ Qualitative data identified pain as the worst symptom and described it as burning, shooting or itching.¹² Moreover, up to 64% of persons with VLUs will experience four or more symptoms at the same time.¹³

Persons with VLUs have to cope with other chronic conditions such as hypertension, musculoskeletal disease or atrial fibrillation, which are frequently (90%) associated with VLUs.¹⁴ This complex situation has a big impact on quality of life¹⁵ and provides challenges for individuals when managing their multiple diseases.

The gold standard used to enhance healing and prevent VLU recurrence is compression therapy.¹⁶ Heyer *et al*¹⁷ stated that only 40.6% of patients with VLU received compression therapy. Non-adherence to therapy is frequently described in this population.^{18 19}

Reasons for non-adherence are multidimensional,²⁰ including discomfort and pain associated with compression therapy^{21 22} or conflicting advice by healthcare professionals,²³ and frequently lead back to misunderstanding the underlying causes of their VLUs^{24 25} or the benefits of self-care activities such as walking or resting in an optimal position.²⁶ Knowledge deficit is a frequent hypothesis for why chronic venous disease develops into a first VLU²⁷ or a recurrence.²⁸ Conversely, adherence to compression therapy improves with participants' knowledge level.²⁹

To address knowledge deficit, promote healing and prevent VLU, patient-education has to be multifaceted and oriented towards protective factors intended to prevent recurrence. This includes increasing knowledge about their disease and skills such as why and how to wear compression stockings^{16 30 31} and promoting mobility,³² leg elevation, walking, and ankle and foot exercises,^{33 34} as well as the benefits of micronutrients including a vitamin-rich diet.³⁵ Providing written materials such as brochures for patients with VLU could improve their knowledge.³⁶ Protz *et al*³⁶ suggest that written information must be used in an educational setting in which patients have the opportunity to ask questions. When they arise, nurses mostly respond to these questions as they provide most of the wound care interventions.^{7 9} Moreover, nurses have developed multiple individualised patient education programmes.^{37–42}

However, different systematic reviews^{31 43} reveal a lack of high-quality randomised controlled trials (RCTs) that address the effectiveness of these interventions on adherence to therapy or wound healing. For this reason, Probst *et al*^{44 45} developed an interprofessional educational intervention to promote wound healing and self-management strategies. This individualised nurse-led education programme will start with face-to-face meetings between a tissue viability nurse and participants. During the first meeting, the study nurse will provide an evidence-based brochure. This first step of the educational process will provide participants with an opportunity to learn about various aspects of their disease and receive evidence-based recommendations for individualised treatment. To evaluate the effectiveness of this intervention, an RCT design with 124 participants will be used.⁴⁵ However, these results will not provide information about the process and the reasons for its effectiveness.³⁷

Van Hecke *et al*³⁷ described cognitive changes associated with understanding what lifestyle adaptations to implement and why, as well as implementing behaviour changes through creative lifestyle and emotional efforts associated with gaining hope and a new perspective. Learning and implementing change is not a simple task for patients. Moreover, the intervention itself, its context, the environment and conditions can affect the learning process.⁴⁶ The nurse–patient relationship is important in face-to-face educational sessions. Phillips *et al*¹² reviewed contradictory data and revealed that good communication was perceived positively. In fact, a good

communication and a trusting relationship seem to promote compliance.⁴⁷

However, nothing is known about how patients with VLUs experience nurse-led educational programmes and implement lifestyle changes.

AIMS AND OBJECTIVES

This study aims to develop a comprehensive contextualised explanation of how patients with VLU experience an individualised patient education programme regarding self-management of VLUs (hereafter their journey).

The study's objectives are as follows:

1. Qualitatively map journeys.
2. Identify self-management strategies and decisions within these journeys.
3. Identify the contextual and personal perception of behaviour change shaping their journey
4. Provide a comprehensive explanation of the participants' experiences/process of individualised educational session.

METHOD

A grounded theory (GT) is best suited to investigate a process, interactions between individuals or journeys through an illness condition.⁴⁸ GTs are used in health and social sciences to generate theoretical accounts of psychosocial processes.⁴⁹ However, philosophical perspectives of GTs varied across authors.⁵⁰ To provide a congruent method between the principal investigator and the research field, a constructivist grounded theory (CGT)^{51 52} was chosen. This inductive approach is widely used in nursing and allows for exploring the process of patient education. It takes into consideration the concerns of participants who are involved in the process and the researcher's preliminary knowledge and experiences about the clinical field. According to the PhD project, a preliminary literature review and scoping review⁵³ were conducted to expose the gap of existent knowledge. These preliminary reviews are congruent with a CGT methodology to reveal how this subject has been addressed previously⁵⁴ and could be engaged critically and comparatively in the process.⁵² CGT offers researchers the ability to provide interpretative aspects and to co-construct the research via the shared experiences of the researcher, participants and readers.^{48 55}

STUDY TEAM

This study protocol is a PhD project from PB, a novice qualitative researcher, that is embedded within a larger trial (Clinical Trial Number: NCT04019340). The research team consists of two senior researchers: one (SP) with expertise in VLUs, patient education and qualitative designs, and another (PJL) with expertise in methodology for qualitative designs.

STUDY SETTING

This multicentre study will be conducted in three outpatient wound care clinics in the French-speaking part of Switzerland.

Participants and recruitment

Participants from the RCT intervention group will be eligible for this study when they have followed five individualised education sessions. The following inclusion criteria will be applied: an existing open VLU, an ankle brachial pressure index between 0.8 and 1.3, aged >18 years and proficiency in French language. Participants will be excluded for not providing consent.⁴⁵ After participants complete five individualised education sessions, the intervention study nurse will inform them that PB will contact them to organise an interview.

In GT, the use of theoretical sampling enables well-developed, defined and delimited categories to be obtained.⁵⁶ However, this method contends that it is not possible to know the precise sample size in advance.⁵² Theoretical sampling is ambiguously used or described in published GT.⁵⁷ In CGT, the sample size is determined on the basis of credibility, context and inquiry purpose.^{51 52} Evidence demonstrates sample sizes ranging from 20 to 35 participants.^{55 58} Taking into consideration the study's aim, the skills of the interviewer and the extant literature, we expect that 30 participants will provide rich data for an initial sample.

Patient and public involvement

This is a study protocol for a CGT method, and therefore no patients or consumer's groups are yet involved.

Data collection

PB will collect data using semistructured interviews. This approach encourages articulation of experiences and views of the participants. We have developed initial open-ended questions based on our clinical experience, the scope of the intervention and a literature review. These provide the openness necessary to obtain a broader overview of the field of investigation and listen to participants recounting their journey.⁵² **Box 1** lists some initial questions translated from French. Charmaz⁵² describes intensive interviewing as a method suited for the flexibility and adaptability of CGT and the field of inquiry. It

Box 1 Initial questions translated from French to English

- ▶ You followed five consultations with a tissue viability nurse. What was your experience of these consultations?
- ▶ What was your experience of these meetings in terms of care and treatment?
- ▶ Could you describe what it changed in your day?
- ▶ Tell me, how do these sessions influence your journey living with venous leg ulcer (VLU)?
- ▶ What has been most helpful during this process?
- ▶ After your experiences, what would you recommend to people with VLUs?

permits data collection adjustments directly during interview as well as during the iterative data collection and analysis process.⁵² The interviews were initially planned to take place according to participants' preferences at their home or the outpatient clinic. However, due to the COVID-19 outbreak in our country, data collection began via telephone call or videoconference to preserve participants' safety and maintain the study period. Ward *et al*⁵⁹ described the use of telephone interviews as congruent with GT with some strengths, as participants reported feeling more relaxed or not feeling judged for their comments. Reported inconveniences included that telephone interviews did not offer the possibility to observe non-verbal behaviours. The interviews are planned for 45–60 min. If participants agree, the interviews will be recorded digitally for verbatim text transcription. Data collection started in April 2020 and is planned for 12 months.

Data management

All data will be saved on a secured, password-protected server at the HES-SO University of Applied Sciences and Arts, Geneva. Only the investigators will have access to the data. In addition, data will be deidentified and archived on the Geneva YARETA portal,⁶⁰ which meets Findable Accessible Interoperable Reusable (FAIR) requirements. Sociodemographic data will be analysed using IBM SPSS V.25.0⁶¹ for descriptive statistics. After verbatim transcription and anonymisation of the data, participants will be assigned pseudonyms.

Data analysis

MAXQDA⁶² will be used to assist qualitative data analysis. According to Charmaz,⁵² coding will be performed using two steps: (1) initial coding process using line-by-line coding to label these fragments with codes and (2) focus coding using codes that recur frequently and seem to be most relevant. These codes include data interpretation, and with further analysis identify relationships between categories and their orientation on theoretical development.^{49 52 55} This systematic and iterative approach with constant comparative analysis of data with data or data with categories will permit refinement of relevant categories during the data collection process. To engage in the analytical process, define links between codes⁵² and enhance reflexivity on the process,⁶³ memo writing will be used. This process will be documented in a 'memo bank' stored in MAXQDA.⁶² Software-assisted analysis will allow for transparent analysis⁴⁹ even if it could take the researcher 'away' from his data and lead to a 'mechanical activity' in place of a cognitive process.⁵⁵ To improve the process, data analysis will be supervised by SP and PJJ.

Quality criteria and expected outcomes

GT evaluation criteria depend on the approach.⁶³ Charmaz⁵² defined criteria for quality as credibility, resonance, originality and usefulness. Credibility will be assumed based on the scope and depths of the interviews

and the quality of the iterative process to obtain links between data and categories. Resonance will, first, be discussed during intensive interviewing with participants to obtain well-developed categories and, second, when sharing the outcomes with persons involved in the patient education process and during literature reviews aiming to extend and challenge theoretical development.⁵² Finally, as this is a PhD thesis and the data are collected via person's experiences, interactions and existent literature, we hope that this project will provide a well-developed theory that includes refined concepts to better understand patient experiences and the development of clinical practices regarding the outcomes.

Ethics and dissemination

The ethics committee of canton of Geneva approved this study (CCER: 2019-01964). All participants will receive an informational document and a consent form detailing the objectives of the study, the procedures involved, insurance and data confidentiality. All participants must provide their written consent prior to data collection.

This is the first study focusing on the process of how participants experience an individualised patient education programme related to self-management. Supervision by senior researchers for method and rigour during the process will allow this project to propose an image of a reality that will be co-created between the research team, participants and actual knowledge. Outcomes will be disseminated via publication papers, oral presentations or posters to provide a new insight and support VLU patient education. Quality of the publications will be ensured using Guidelines for Reporting GT research studies (GUREGT).⁶⁴

Contributors PB designed the study and wrote the initial manuscript. SP originated the concept of the project, supervised the design and acquired the funding. PJL provided support for design. PB, PJL and SP contributed to writing or reviewing the manuscript. All authors revised the manuscript and approved the final version to be published.

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Competing interests None declared.

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