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A SYSTEMATIC REVIEW OF QUALITATIVE RESEARCH; EXPERIENCES OF LIVING WITH VENOUS LEG ULCERS:

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A SYSTEMATIC REVIEW OF QUALITATIVE RESEARCH; EXPERIENCES OF LIVING WITH VENOUS LEG ULCERS:

ABSTRACT:

Aim: To systematically identify, evaluate and synthesise qualitative research that examined the symptoms and health related quality of life themes that are important from the perspective of patients with venous leg ulceration.

Background: Venous leg ulceration is a common chronic condition; the symptoms and associated treatments have a negative effect on health-related quality of life. Qualitative research methods can provide insight into the personal experiences of patients with venous leg ulceration.

Design: Qualitative evidence synthesis (using framework synthesis).

Data Sources: Multiple electronic databases including MEDLINE, EMBASE, PsycINFO and CINAHL were comprehensively searched from inception to November 2015.

Review Methods: Systematic identification, quality assessment and synthesis of existing qualitative research were performed; framework synthesis was conducted on included studies. An inductive approach was used and emergent themes were identified. The final stage in the synthesis involved the development of new interpretations.

Results: Thirteen studies met the inclusion criteria; the overall quality of the included studies was good. Four overarching themes were identified; physical impact, psychological impact, social impact and treatment and, within these, further sub-themes were identified. Ulcer and treatment related pain, as well as odour and exudate appeared to have significant and direct negative effects on quality of life, with additional and cumulative effects on sleep, mobility and mood.

Conclusion: The themes identified in this review should be considered by professionals providing services, care and treatment for venous leg ulcer patients and in the selection, or development, of patient reported outcome measures for use with this population.

Key Words:

Nursing; Venous leg ulcer; Framework Synthesis; Literature Review; Systematic review; Qualitative; Quality of life; Patient experience.

SUMMARY STATEMENT:

Why is this research or review needed?

- This review was needed to ensure that the development of a new online, condition specific patient reported outcome measure (Electronic Personal Assessment Questionnaire- Vascular (ePAQ-VAS)) was conducted rigorously and had adequate content validity.
- This review was needed to identify and synthesise the published data about patient's experiences of living with venous leg ulcers.
- This review was needed to provide a comprehensive description of patient's experiences of living with a venous leg ulcer.

What are the key findings?

- Four overarching themes were identified; physical impact, psychological impact, social impact and treatment.
- Ulcer and treatment related pain; odour and exudate have direct negative effects on venous leg ulcer patient's quality of life, with additional cumulative effects on sleep, mobility and mood.
- The issues faced by individuals with venous leg ulceration are complex and interrelated.

How should the findings be used to influence policy, practice, research, education?

- These findings are being used in the development of the Electronic Personal Assessment Questionnaire for use with vascular patients (ePAQ-VAS).
- Clinicians, researchers and service providers should use these findings to ensure that new and existing patient reported outcome measures used with venous leg ulcer patients have adequate content validity.
- Clinicians and commissioners of care should use these findings to inform individual consultations and the design, development and evaluation of services.

INTRODUCTION:

A leg ulcer is defined as the loss of skin below the knee on the leg or foot, which takes more than two weeks to heal (NICE 2013). Venous leg ulcers (VLUs) are caused by sustained venous hypertension, which results from chronic venous insufficiency and/or an impaired calf muscle pump (Grey et al 2006). VLUs are a chronic and often debilitating condition with an estimated point prevalence for open venous ulcers in European populations of between 0.1 and 0.3% (SIGN 2010, Nelzen 2008), and an overall prevalence in the developed world (for healed and unhealed) venous ulcers of around 1% of the population (Nelzen 2008). Limited data is available for developing world populations (O'Meara et al 2013). Epidemiological studies suggest that prevalence is positively associated with increased age and female sex (O'Meara et al 2013).

Chronicity is a major issue with 60% of VLUs lasting for more than six months, and 20% for more than five years (Price and Harding 1996). When a VLU does heal recurrence is common, with rates of around 45% (Harrison et al 2001). The cost of care and management of VLU is high, and as the population ages, associated healthcare costs will increase. Costs in the USA rose from \$US 1 billion in the early 1990s to almost 15 billion in 2011, and costs in the UK are estimated at between £300 and £600 Million per year (Lin et al 2016).

Much previous research has focused on cure and management of VLU (Green et al 2014), rather than impact on health-related quality of life (HRQoL). However it is likely that VLUs have an impact on HRQoL (Persoon et al 2004, Briggs and Fleming 2007, Green et al 2014), which is not adequately addressed by healthcare professionals (Green et al 2014); scoping searches have identified the existence of relevant qualitative research which considered systematically could significantly contribute to our understanding of the impact of VLU on HRQoL.

Background

This review was conducted to ensure that a new electronic personal assessment questionnaire (ePAQ-VAS) has adequate content validity to accurately measure the HRQoL issues of importance to individuals with VLU. Quantitative researchers use patient-reported outcome measures (PROMs) to collect information about the impact of a disease, or treatment, from a patients' perspective; PROMs can be generic or disease specific.

Preliminary findings from a recent systematic review (Poku et al 2017 unpublished) conducted to identify valid and reliable PROMs used in populations with VLU identified seven PROMs whose psychometric properties had been assessed in this population. There were three generic PROMs; the Twelve Item Short Form Health Survey (SF-12 - Iglesias et al 2005), the Nottingham Health Profile

(NHP - Frank and Moffat 2001) and the EuroQol Five Dimensions Questionnaire (EQ-5D - Jull et al 2010, Walters et al 1999), and a further four disease specific Proms; Sheffield Preference-based Venous Ulcer questionnaire (SPVU-5D - Palfreyman et al 2007, Palfreyman 2008), Leg and Foot ulcer Questionnaire (Hyland et al 1994, Iglesias et al 2005), the Venous Leg Ulcer Self Efficacy Tool (VeLUSET - Brown et al 2014) and Venous Leg Ulcer Quality of Life (VLUQOL - Hareendran et al 2007). The extent to which these instruments had been validated in populations with VLU was variable; VLU-QoL underwent the most rigorous development and psychometric validation, with some evidence of content, criterion and construct validity, internal consistency and test-retest reliability (Hareendran et al 2007).

PROMs need to be relevant and appropriate to the population they are used with; qualitative research methods can be used to ensure the content validity of such instruments (US Department of Health 2009). Qualitative research provides a rich patient reflection on life with VLU (Green et al 2014), the synthesis of such research can contribute to the validation of new and existing PROMs but equally can inform clinical practice and commissioning decisions.

THE REVIEW:

Aim:

The primary aim of this qualitative evidence synthesis was to examine the symptoms and quality of life themes that are important from the perspective of patients with VLU to facilitate the assessment of content validity of existing PROMs and inform the development of a new PROM (ePAQ-VAS) for use in this population.

Review Question:

What are the symptoms and quality of life issues that are important to individuals living with venous leg ulcers?

Design:

This qualitative evidence synthesis (using framework synthesis) was conducted according to a pre published protocol (Duncan et al 2016) and is reported according to the ENTREQ statement (Tong et al 2012).

Search Methods:

Published and unpublished papers reporting primary qualitative research were included in this review if the qualitative data were reported, and could be considered separately from quantitative

data, and methods of data collection and analysis were described. Populations of participants with a diagnosis of chronic venous insufficiency (CVI) presenting with venous leg ulcers, oedema or skin discolourations were included. Quantitative studies with no primary qualitative data were excluded, as were studies of undefined populations of CVI patients or patients with acute venous obstruction, such as acute deep vein thrombosis.

Comprehensive searches were conducted in Cinahl, Embase, Medline, PsycINFO, Science Citation Index, Social Science Citation Index, and ProQuest dissertations and theses, from inception to November 2015, no language or date restrictions were applied. Additionally reference lists of included studies and related reviews were examined and citation searches were conducted (see appendix 1 for search strategies).

Two authors (PP and EL) independently screened the title and abstract of all papers identified by the searches with reference to the published inclusion/ exclusion criteria. Potentially eligible full text papers were read and discussion was used to resolve any difference of opinion. A third researcher (AA) was available for consultation if consensus could not be reached.

Search Outcome:

A total of 1804 references were identified, following the removal of duplicates 1318 citations were screened; 56 full text articles were retrieved and screened for eligibility, 40 of these were excluded. Study selection is detailed in The PRISMA Flow Diagram (Figure 1).

Quality Appraisal:

Quality assessment was independently conducted by two researchers (EL and PP) using the CASP criteria; a 10-item checklist designed for use in the appraisal of qualitative research studies (CASP 2014); any discrepancies were resolved through discussion.

Data abstraction

A study specific data extraction form was used to collect descriptive data from included studies, details of author; date; country; research design; method of analysis; aims and objectives; sample, including age and gender; diagnosis and eligibility criteria were collected. Detailed data extraction was integral to the coding process and is described in the synthesis section below.

Synthesis:

Framework synthesis (Barnett-Page et al 2009 and Oliver et al 2008) was used to direct the analysis and synthesis of data. This is an iterative process used in systematic reviews of qualitative research and is analogous to, and was developed from, framework analysis as applied to primary research data. This approach explicitly allows *a priori* identification of themes.

Included full text papers were uploaded electronically into NVIVO 10 (QSR International, Burlington, USA). Reviewers familiarised themselves with the literature and subsequently initial coding of the results and discussion was conducted independently line-by-line (PP and EL) with relevant sections and quotations highlighted and assigned to the specific nodes of a provisional thematic framework (Appendix 3). This provisional framework was developed based on themes from the PROMS identified in preliminary findings from a related review (Poku et al 2016 unpublished). Domains included in identified PROMs that had undergone some degree of validation in populations with VLU were identified (Appendix 4) and through a process of interpretation and translation a single framework of putative themes was developed.

An inductive approach to synthesis of studies included in this review was used with on-going revision of the framework as data was systematically analysed. Comparisons were made across the included studies matching emergent themes to those already established in the framework. As themes and subthemes were identified additional themes were created while some provisional themes were discarded or amalgamated and previously coded papers were re-visited to establish if any aspects of their findings matched the revised framework (Figure 2).

RESULTS:

Thirteen studies reported in 16 papers met the inclusion criteria and were included in the review (Table 1). The studies were published between 1995 and 2014 and were conducted in the UK (n=8), the USA (n=3), South Africa (n=1) and Ireland (n=1).

Samples all adhered to eligibility criteria however the differences in specific criteria across the studies resulted in a range of participants with diverse characteristics. Included studies used, age, comorbidities, treatment setting, ulcer duration, associated symptoms and social circumstances as inclusion/exclusion criteria.

Quality assessment:

The overall quality of the included studies was good with 11 of 13 studies adequately addressing nine or 10 out of the 10 items on the CASP checklist (Appendix 6) suggesting a high degree of rigour. The main problem with quality was the lack of consideration given to the relationship between the

researcher and study participants with only 7 of 13 studies demonstrating that this relationship had been considered; however this could be due to lack of reporting rather than deficiencies in conduct. This is illustrated by comparison of two included papers by Jones reporting the same study; a PhD thesis (Jones 2007) discusses positionality in some detail, whereas a much shorter published account (Jones 2005) omits any discussion of this. Studies were not excluded or weighted based on quality assessment.

The quality of the included studies could have been enhanced by clearer links between the material quoted in the studies and details of individual respondents. Palfreyman et al (2007) clearly linked evidence, in the form of direct quotations, with specific study respondents including reference to age, sex, employment status, intravenous drug use, current ulcer duration, recurrence and overall number of years living with ulceration. This approach is followed to a lesser extent by Brown (2005b) and Jones et al (2008) but this transparency, which aids interpretation and allows the reader or reviewer to identify possible links between specific personal characteristics and issues, is less evident in the other included studies.

Findings:

Following analysis of included papers the number of main themes was reduced from five to four; physical impact, psychological impact, social impact and treatment. Within the main themes sub-themes, including emergent themes, were used to code data. Table 2 shows the themes and sub-themes identified and the associated papers.

Quotes from participants have been used to illustrate the findings.

Physical Impact:

The physical impact of VLU was apparent across all included papers; pain, exudate, odour, mobility and activities of daily living were particularly prominent issues.

Pain

Pain was identified as a particularly distressing and disabling symptom that had significant effects on quality of life. Many participants reported that pain was the worst of any of the symptoms.

“Well for me it’s the pits, all I have to say is it’s the worst thing that could happen to anybody”,
(Patient 1) Byrne and Kelly 2010)

“...the worst thing that I have ever gone through in my life. And believe me, I’ve had surgery, multiple surgeries, I’ve never had nothing hurt like this. Never. It feels like someone’s sticking a hot poker in

you." (Krasner 1998b)

Pain varied in type, intensity and duration and whilst it could be attenuated by a variety of strategies, it was also frequently exacerbated by infection, treatment and activity, with some patients dreading debridement and re-dressing of wounds. For some participants pain was more or less a constant but others described experiencing pain free periods interspersed with periods of sudden onset of severe pain with no apparent precipitating factors.

"I cannot understand why yesterday was nearly a pain-free day until 4 am, when a very severe pain occurred, waking me from a good sleep not often enjoyed." (('Charles') Hopkins 2004).

For some specific patients (IV drug users) pain seemed less tolerable (Palfreyman et al 2007) while for a small minority their ulceration was not associated with any pain at all (Flaherty 2005). Pain was variously described as burning, shooting, stabbing, knife like, throbbing, dull, niggly, gnawing, aching, annoying, dull, hot poker, pins, nerve pain, sticky and stinging. There is a suggestion that pain relief is often inadequate (Douglas 2001, Hareendran et al 2005, Krasner 1998b) with many patients not prescribed or not taking analgesia. In addition pain affected sleep, mobility and psychological wellbeing, significantly contributing to a reduced QoL. It seems that there was an implicit assumption that pain is something that has to be tolerated; descriptions of stoicism and acceptance or diversion recur throughout the included studies.

"I think you can harp on, and I am, the sort of person who just gets on with it, and if it helps you go and see about it and that is that." ((Participant 3) Flaherty 2005).

"Kept working, working all the hours in the day ... when I did stop the pain was back with vengeance." (Douglas 2001).

Other Symptoms

A wide variety of other symptoms were reported across the papers, not all were common to every paper however the majority of studies included reference to more than one other symptom. The most common were exudate, odour, skin irritation, and sleep disturbances. Exudate and odour appear to be related, and a cause of distress in themselves. They were linked to reports of embarrassment and shame with attendant effects on social interaction, often contributing to isolation due to avoidance of social activities.

"The odour has been unbearable ... I used to go to church but the person next to me could smell my leg so I don't go now." (Douglas 2001).

“The thing was leaking out through my leg and you know he would get this terrible smell more than I would because I am used to it, I would start crying cause there is nothing you could do about it. Nothing at all.” ((Participant 7) Byrne and Kelly 2010).

“It (the ulcer) limits what you can do....it makes you want to hide. Because if you go into a room and someone says “oh there is a funny smell in here” (long pause)...it might not be you, but oh God is it? You feel conspicuous.” ((Participant with a 5-year history of ulceration) Jones et al 2008)

Graphic descriptions of the smell are common with participants likening the smell to rotting flesh and faeces. (Douglas 2001, Palfreyman et al 2007)

Swelling is mentioned in four of the papers but seemed to be a less significant problem in comparison to pain, odour and exudate. Sleep problems were often secondary to pain and itching, but the associated tiredness contributed to social isolation as participants described feeling a need to catch up on rest (Theron 2008). Insomnia was frequently associated with frustration and a sense of not being in control.

“If it happens to hit in the night, there’s a quiet despair because you’re going to lose a night and there isn’t a thing in creation you feel you can do.” ((Participant 4) Byrne and Kelly 2010).

Itching and pruritus also affected sleep but these symptoms were seen by some as a positive as it was associating with healing.

Mobility

Mobility was described by participants as being affected by multiple factors; VLU was reported as being associated with reduced mobility primarily because of associated pain (Byrne and Kelly 2010, Douglas 2001, Hareendran 2005, Palfreyman et al 2007). Treatment was also reported as having an effect as bandages restricted movement (Brown 2005b, Hareendran 2005, Krasner 2005b); in addition participants also described a restriction in clothing choice and appropriate footwear due to the dressings (Byrne and Kelly 2010, Douglas 2001, Hareendran 2005). Comorbidities (particularly arthritis) also played a role in reducing activity levels.

“Well, I’ve got knee problems as well and this arthritis, it restricts me. What with the ankles being in the four layer, I can’t bend my ankles or knees. I can’t cope with it all”, ((78 year old female) Brown 2005b)

One author also found that some participants believed that they had been instructed to reduce activity levels (Douglas 2001). Fear of falling or of traumatic injury causing further ulceration also

influenced the amount of activity undertaken (Brown 2005b). Mobility problems also had an effect on employment and recreational activities.

Activities of Daily Living (ADLs)

Participants in nine papers discussed restriction of activities in terms of restricted mobility; additionally VLU appear to have a significant impact on study participant's ability to maintain their own hygiene. Bathing seems particularly problematic (Douglas 2001, Hareendran et al 2005, Wellborn and Mocerri 2014), complicated by compression bandaging, and in the context of the previous discussion about the effects of odour and exudate is an issue that if unresolved can have a cumulative effect on quality of life. Participants in two papers described relying on family and friends for help with cooking and cleaning, sometimes placing a perceived strain on relationships (Douglas 2001, Hareendran et al 2005).

Employment

There were a number of issues involved in getting and maintaining employment (five papers Douglas 2001, Krasner 1998b, Palfreyman et al 2007, Theron 2008, Wellborn and Mocerri 2014). The main problems were associated with restricted mobility (specifically standing for long periods) with one respondent reporting that she had closed her store because she couldn't stand and work all day (Wellborn and Mocerri 2014). Other specific issues related to employment included driving (Krasner 1998b) and managing exudate at work:

"Used to try all sorts but in the end wore wellington boots at work ... anything to hide the leakage",
(Douglas 2001)

This had an effect on financial and social wellbeing for some respondents with some retiring early or becoming unable to work because of their ulcer (Charles 1995, Krasner 1998a, Wellborn and Mocerri 2014).

Comorbidities

Comorbidities included arthritis and drug use and these added to problems of mobility and social isolation (Palfreyman et al 2007, Brown 2005b, and Theron 2008).

Psychological Impact:

VLU had a significant psychological impact including discussion of suicidal thoughts by a single participant in one paper (Byrne and Kelly 2010); themes of mood, acceptance, body image and self-esteem were identified.

Symptoms particularly pain, odour and exudate had a direct effect on mood, but also led to avoidance of social situations and activity because of the smell and/or physical inability to get out and about, which contributed to social isolation.

"I don't have a social life. I stay in most nights. I don't go out anywhere when it's like this. With it smelling, I think to myself (that) I will just stop in", ((57 year old unemployed male with a 9 year history of ulceration) Palfreyman et al 2007)

"I couldn't stand up for more than a few minutes. I didn't go out", (Charles 1995)

Lack of sleep and subsequent fatigue contributed to depression, despair and hopelessness (Jones 2007, Hopkins 2004, Theron 2008). Alleviation of depression seems to be related to concepts of control, with professionals who introduced hope being credited with having a positive effect on mood (Hopkins 2004, Douglas 2001). There were few references to formal psychological assessment or the effect of pharmaceutical or behavioural approaches to treating depression.

Some participants were able to accept their situation and had adapted their expectations and were able to find some satisfaction in their changed circumstances:

"No I've got a nice lifestyle now, even with the ulcers. I can't see that that would change dramatically", (Douglas 2001).

Whereas others were unable to accept the loss of their former lives, one female study participant when asked what area of her former life had been affected by ulcer disease responded:

"My whole life. I cannot do anything I want to do. I cannot go anyplace", ((76 year old female) Chase et al 1997)

Anxiety was associated with fear of falling or suffering an injury that might lead to the development of further ulcers:

"I'm so scared to go out, in case, you know, my legs, even in the garden. When I think of the pain I suffered, I just want to cry. (Tears well up in his eyes). I couldn't bear it to come back again", ((80 year old male participant) Brown 2005b)

It was also associated with fear that others could smell the ulcer or that there would be a leakage of exudate, again there was little discussion of formal healthcare mediated management of anxiety.

Embarrassment and shame were felt by some participants and discussed in relation to odour and exudate:

“You’re having a drink, a social drink with your mates and it is smelling and drifting up. It is wafting up – everyone can smell it. And they’re saying ‘What’s that...smell?’ You have to confess and say, ‘It’s me leg, it’s me ulcer.’ It’s embarrassing!” (27 year old, unemployed, male, IV drug user with less than one year history of ulceration) Palfreyman et al 2007).

“I realized that I smelt like the clinic smelled ... I didn’t want to go to keep in touch with Friends ... you would get a whiff of yourself and think god ... I was miserable and morbid and then occasionally I would get so frustrated that I would get verbally aggressive” ((Male 69 years old) Jones et al 2008)

Reduced self-esteem was also an issue, particularly for women, some of whom who were also troubled by restrictions on choice of clothing and footwear (Hareendran et al 2005, Douglas 2001).

Social Impact:

The impact on social functioning consisted of the sub-themes relationships, social activities, social isolation and clothing. All papers reported the effect of VLU on patient’s relationships, either with family and friends, or health-care professionals, or both.

The primary professional relationship discussed was with nursing staff (nine papers). Positive relationships were characterised by continuity and good communication, with nurses becoming important not only as participants in the management of the ulcer but also socially.

“You do get very attached to some of them, some of them talk to you for ages, ask you about your fears and problems, are really interested in you as a person. Then they get back to you about it and try to resolve your problems, as if they really care!” ((78 year old female) Brown 2005b)

In contrast the nurse-patient relationship was sometimes seen as a mechanical relationship, with patients, or their ulcer, reduced to the status of passive recipients of treatment.

“I have no idea what type of ulcer it is ... an ulcer is an ulcer surely ... nurses just dress it and go ... I used to ask is it getting better ... but no one seems to know ... so I don’t ask now ... Just can’t understand why we were not told anything about these ulcers in the past ... we really have been kept in the dark about it all ...”, (Douglas 2001)

Where the nurse patient relationship is sometimes described in a positive light, the impact of VLU on relationships with family and friends is predominantly perceived negatively and a source of strain (Chase 1997, Douglas 2001, Hareendran 2005, Jones 2007, Palfreyman et al 2007). There was one report of a marital breakdown due to a VLU (Jones 2007), however, it is unknown if there were any other factors involved. For a substantial number of VLU patients their condition puts a strain on

relationships as they become increasingly reliant on partners for assistance with ADLs, Holidays and leisure activities are cancelled (Brown 2005b, Byrne and Kelly 2010, Hareendran 2005, Hopkins 2004, Palfreyman et al 2007) social activities are avoided and pain and odour limit physical intimacy (Palfreyman et al 2007) while some patients become emotionally isolated not discussing fears, for instance about deterioration (Jones 2007).

Treatment:

This theme was common to all papers and encompassed sub themes of compliance, knowledge and understanding of treatments. The mainstay of treatment is compression, however elevation, lifestyle advice and analgesia are all aspects of treatment that were reported in studies.

Compression appeared to be tolerated well by some patients, but tolerance appears to be related to an understanding of the relationship between compression, the underlying causes of VLU and a belief that it promotes healing and symptom control (Douglas 2001, Hareendran et al 2005, Krasner 1998b). In some cases even where the consequences in terms of effects on healing are known patients choose to abandon the treatment because of discomfort:

“I just kept telling the nurse it was too painful ... but she insisted it was the right treatment ... After she left I took it all off.” (Douglas 2001)

The positive effects of physical activity are not discussed at any length other than in terms of advice given to some patients, where they received apparently contradictory advice on the one hand to reduce activity levels but conversely are also encouraged to increase activity levels:

“Doctor said she must keep legs up all the time ... then the nurse comes and says she must walk and exercise ...” (Douglas 2001)

DISCUSSION:

The aim of this review was to examine the symptoms and quality of life themes that are important from the perspective of patients with VLU and to identify themes that should be included PROMs for used with VLU patients. We suggest that items related to the themes and subthemes identified in this review should be included in new and existing PROMs depending on the nature and scope of the PROM.

Analysis was based on themes included in existing PROMs, this novel approach, combined a preliminary translation of apparently diverse items and themes to produce a framework with which to categorise themes identified within included studies. The use of the initial framework, whilst

potentially acting as a limiting or constraining factor, did not pre-determine the final main or sub themes, though the final framework is recognisably related to the preliminary framework. The synthesis resulted in the identification and categorisation of four main themes (physical, psychological and social impact, and treatment) and numerous sub themes. These themes reflect the findings of existing research but, as the results emerged from an iterative process of analysis and synthesis, they represent new and important findings for use in the design of future PROMs and in the provision of care to patients with VLU.

We categorised themes discretely for discussion and presentation but our analysis and synthesis suggests that elements of each are inter-related and cumulative in their effect on QoL. The range of symptoms experienced is broad, unique to individuals and sometimes transient and reflects the complexity of caring for this patient group and in developing instruments to measure the effects of VLU on patient's symptoms and quality of life. For instance the range of descriptors used for pain adds credibility to the suggestion that VLU pain is sometimes a combination of nociceptive and neuropathic pain (Krasner 1998b) requiring a sophisticated assessment and pain relief strategy.

Participants called on a range of internal resources in managing the impact of VLU and demonstrated a range of strategies such as stoicism, acceptance, coping and avoidance, they described: not giving in, maintaining a positive attitude, keeping cheerful, not moaning, keeping working, hiding leakage, changing clothing, positive comparison and attempting to reduce ulcer thinking time. But other than reference to accepted treatments such as compression and nursing care there was limited discussion of the role of external resources for instance pharmaceutical or behavioural therapies such as cognitive behavioural therapy, perhaps reflecting a lack of clear, accessible evidence based guidance available to clinicians. For instance, there is an acceptance by SIGN (2010) in their guidance on the management of venous leg ulceration that pain management is a complex issue requiring 'structured discussion and frequent reassessment' but continues that it is outside the remit of their published guidance. Similarly NICE (2013) discuss underlying causes of pain but in terms of management signpost clinicians towards generic guidelines on the management of mild to moderate pain.

Reference to the findings of this review will be used in the development of a new PROM (ePAQ-VAS) for use with individuals living with the full range of vascular conditions (similar research has been conducted with patients with abdominal aortic aneurysm, peripheral arterial disease and carotid artery disease) but it is of equal importance that professionals consider the range and impact of these symptoms on quality of life when delivering care. Further research should be conducted to identify and evaluate interventions that alleviate the suffering of these patients.

Addressing symptoms and quality of life issues are essential components of encouraging concordance with treatments directed at ulcer healing but are also goals worth pursuing in their own rights. Education and communication as part of a continuing and consistent relationship with health care professionals are key factors in shared decision making about treatment options contributing to realistic expectations related to patients and professionals shared objectives (Hoffman et al 2014).

This research has limitations, most notably the lack of reported consideration of the relationship between researcher and study participant in the primary research included in this review, though this is mitigated by the inclusion of studies from different countries and settings using different forms of analysis which after comparison and translation of themes were found to have substantial commonalities. Comprehensive searches of seven electronic databases were performed but grey literature searching was restricted to searches of the ProQuest Dissertations and Theses Database. It is possible that searches of conference proceedings, other grey literature sources and alternative electronic databases such as the British Nursing Index and CENTRAL might have proved productive in identifying additional studies that met the review inclusion criteria, however in common with most contemporary research it was necessary to make pragmatic decisions in relation to the allocation of resources.

CONCLUSION:

The themes and subthemes identified in this review should be given consideration by professionals providing care and treatment for VLU patients and in the selection or development of PROMs for use with this population.

Venous leg ulcers have a significant negative impact on the quality of life of sufferers, symptoms such as pain, odour, exudate and swelling combine with side effects of the primary treatment (compression therapy) to affect many aspects of life (sleep, mobility, relationships, self-image), which in turn increase the psychological distress experienced by many people with VLU.

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TABLE 1: TABLE OF INCLUDED STUDIES*:

Author, Year and Country	Research Design	Sample	Main Findings
Brown A (2005a&b) UK	Phenomenological	n=8; gender ratio and ages not given; Purposive sample	Three main themes emerged from the data analysis: Pain, Social Disconnectedness and Coping.
Byrne and Kelly (2010) Ireland	Phenomenological,	n=12; no further information given	The findings identified four interlinked themes: Physical Experiences, Psychological Experiences, Social Experiences, Experiencing the Therapeutic Relationship.
Charles et al (1995) UK	Phenomenological	n=4 (3 male, 1 female); no further information	The interviews demonstrated that patients with chronic leg ulcers suffered negative effects in the physical, psychological and social areas of their lives.
Chase (1997) USA	Phenomenological	n=7; no further information given	Four major themes: a Forever Healing Process, Limits and Accommodations, Powerlessness and Who cares?
Douglas (2001) UK	Qualitative Grounded Theory	n=8 (6 females, 2 males); aged 65-94; purposive sample	Five major categories, Physical Experience, Loss of Control, Vision of the Future, Carer's Perspective and Health-care Professional and Patient Relationship'.
Flaherty (2005) UK	Descriptive non-experimental design	n=10 (5 male, 5 female); aged 52-91; purposive sample	Three main theme emerged: Symptoms, Treatment and Coping mechanisms
Hareendran et al (2005) UK	Mixed Methods	n=38 (12 male, 26 female); aged 46-91 (mean 71.5)	Categories identified: Appearance, Sleep, Functional Limitations, Emotional/ Psychological, Symptoms and Disappointment with Treatment.
Hopkins (2004) UK	Phenomenology	n=5 (4 male, 1 female); aged 47-78 (mean 75); purposive sample	The core themes identified were: Biographical Disruption, Ways of Coping, Social Implications and Therapeutic Relationships.
Jones et al (2005) and Jones (2007) UK	Mixed Methods	n=20 (8 male, 12 female); aged 52-86 (mean 68); purposive sample	Jones 2005: Three key themes around odour were identified: Emotional Response to Odour; Limitation of Social Activities and the Ways in which Odour, or Fears about the Presence of Odour, were Managed by Nurses. Jones 2007: HCP attribute symptoms such as fatigue, insomnia, a sense of loss and hopelessness to venous disease rather than to the depression of which they are classic symptoms.
Krasner (1998a and b) UK	Phenomenology	n=14 (7 male, 7 female); aged 30-86; purposive sample	Eight key themes overall: Expecting Pain, Feeling Frustrated, Swelling equals Pain, Not Standing, Interfering with the Job, Starting the Pain Over Again (painful debridements), Having to Make Significant Life Changes, Finding Satisfaction in New Activities.
Palfreyman et al (2007) UK	Qualitative	n=19 (14 male, 5 female); aged 27-79; purposive sample	A complex interaction between three key themes: Symptoms, Social Restriction and Attribution.
Theron (2008) South Africa	Mixed methods	n=30 (11 male, 19 female); aged 52-90 (mean 71)	Three themes: Freedom vs. Imprisonment, Gain vs. Loss, and Hope vs. Despair
Wellbourn and Morceri (2014) USA	Phenomenology	n=10 (4 male, 6 female); mean age 66; convenience sample	Four themes: Knowledge Deficit, Discomfort, Inconvenience, and Coping.

* A more detailed table of included studies is available as a supplementary file (appendix 5)

TABLE 2: THEMES AND SUB-THEMES:

THEMES AND SUB-THEMES	Study reference												
	Brown (2005 a and b)	Byrne and Kelly (2010)	Charles (1995)	Chase et al (1997)	⁵ Douglas (2001)	Flaherty (2005),	Hareendran et al (2005)	Hopkins (2004)	Jones (2007) and Jones et al (2008)	Krasner (1998 a and b)	Palfreyman et al (2007)	Theron (2008)	Weilborn and Morceri (2014)
1. Physical impact	X	X	X	X	X	X	X	X	X	X	X	X	X
Pain	X	X	X	X	X	X	X	X	X	X	X	X	X
Severity	X	X	X	X	X		X	X	X	X	X		X
Type		X	X	X	X	X	X		X	X	X		X
Relief			X	X	X	X	X		X	X	X	X	
Other symptoms	X	X	X	X	X	X	X	X	X	X	X	X	X
Skin irritation	X	X	X	X			X		X				X
Exudate	X	X		X	X	X	X		X				
Odour		X		X	X		X	X	X		X		
Sleep		X	X		X		X	X	X	X		X	X
Healing	X		X	X	X		X	X	X	X		X	
Re-occurrence	X		X	X	X	X	X	X	X	X		X	
Swelling			X	X						X			
Energy			X						X			X	
Mobility	X	X	X	X	X	X	X	X	X	X	X	X	X
Standing			X						X	X			X
Walking	X		X	X	X		X	X	X	X	X	X	X
Exercising			X	X		X		X	X	X			
ADLs	X	X	X	X	X		X		X	X	X	X	X
Employment			X	X	X				X	X	X	X	X
Co-morbidities	X			X					X		X	X	
2. Psychological impact	X	X	X	X	X	X	X	X	X	X	X	X	X
Mood	X	X	X	X	X	X	X	X	X	X	X	X	X
Depression	X	X	X		X		X		X	X	X	X	X
Anxiety	X	X	X	X	X	X	X	X	X	X	X	X	X
Hopelessness	X	X	X	X	X		X	X	X	X	X	X	X
Embarrassment		X	X	X	X	X	X	X	X	X	X		
Frustration and Control		X	X	X	X	X	X	X	X	X	X	X	X
Acceptance	X	X	X	X	X	X	X	X	X	X	X	X	X
Change and loss			X	X		X		X	X	X		X	X
Coping strategies	X	X	X	X	X	X	X	X	X	X	X	X	X
Hope		X			X			X	X	X		X	
Body image			X	X	X	X	X	X	X	X	X	X	
Self esteem			X	X	X		X	X	X		X		X
3. Social Impact	X	X	X	X	X	X	X	X	X	X	X	X	X
Relationships	X	X	X	X	X	X	X	X	X	X	X	X	X
Family and friends	X	X	X	X	X	X	X	X	X	X	X		X
Professionals	X	X	X	X	X	X		X	X	X	X	X	X

Social activities	x	x	x	x	x		x	x	x	x	x	x	x
Leisure	x	x	x	x	x		x	x	x	x	x		x
Holidays				x			x		x				
Social isolation	x	x	x	x	x		x	x	x	x	x	x	
Avoidance	x	x		x	x		x	x	x		x		
Inability to participate	x						x	x	x	x	x	x	x
Clothing		x		x	x	x	x		x	x			
Restrictions				x		x	x		x	x			
Adaptations					x	x	x		x				
4. Treatment	x	x	x	x	x	x	x	x	x	x	x	x	x
Compliance	x		x	x	x	x		x	x	x	x		x
Knowledge and understanding	x		x	x	x	x	x	x	x	x	x	x	x
Type of treatment	x	x	x	x	x	x	x	x	x	x	x	x	x
Home		x						x					
Clinic						x				x	x		x
Compression or bandaging	x	x	x	x	x	x	x	x	x	x	x	x	x

Figure 1. PRISMA Flow Diagram:

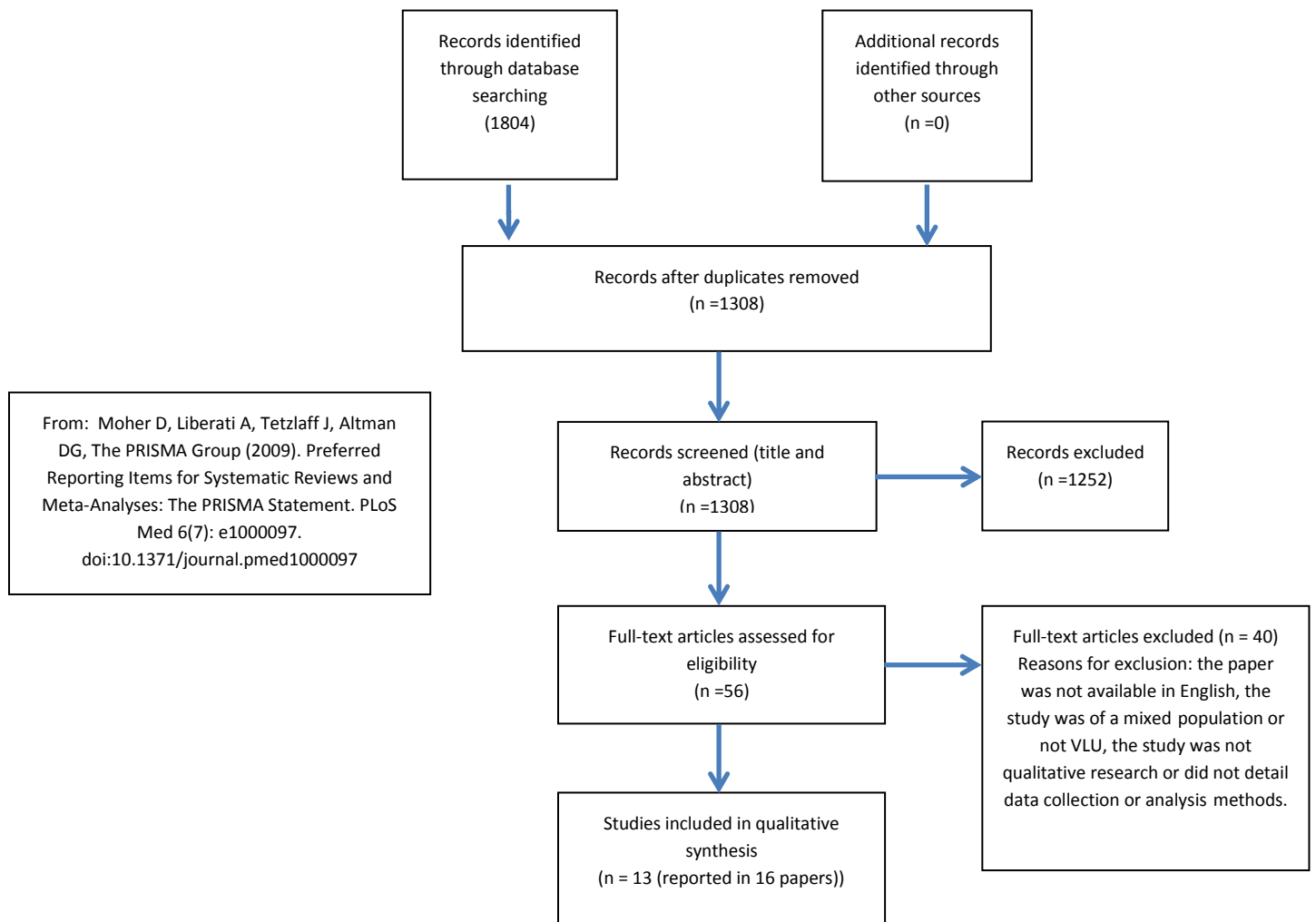
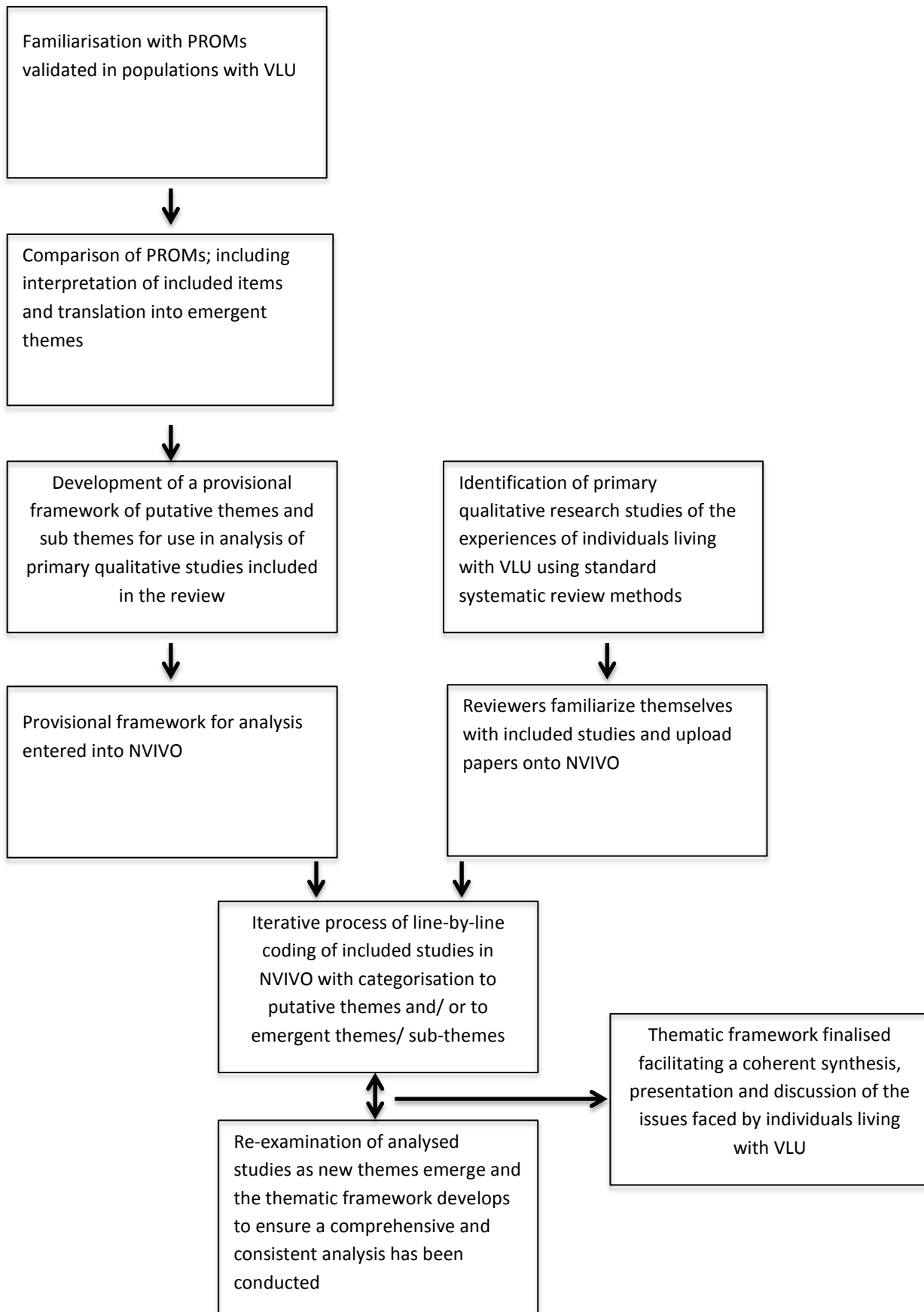


Figure 2: Application of framework synthesis:



APPENDIX 1 – SEARCH STRATEGY:

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

-
- 1 ((Venous or vein) adj2 (disease or stasis or obstruction or incompetence or insufficiency or syndrome or thromboembolism)).tw. (25881)
 - 2 (Venous ulcer\$ or leg ulcer\$ or venous leg ulcer\$).tw. (6752)
 - 3 (Venous insufficiency or Venous incompetence or Venous thromboembolism or VTE or Venous outflow obstruction or VOO or Venous valvular incompetence or VVI).tw. (20317)
 - 4 exp Venous Insufficiency/ (6251)
 - 5 exp Varicose Veins/ (16173)
 - 6 (Venous adj2 (edema or oedema)).tw. (267)
 - 7 Venous disorder\$ of the leg\$.tw. (16)
 - 8 (Varicose vein\$ or spider vein\$ or varicosity or varices or telangiectasia\$).tw. (28766)
 - 9 Endovenous occlusion.tw. (11)
 - 10 post-thrombotic syndrome.tw. (742)
 - 11 Venous Thrombosis/ or Venous Thromboembolism/ (25218)
 - 12 or/1-11 (84718)
 - 13 *Attitude to Health/ (38618)
 - 14 *Self Care/ (13923)
 - 15 *Health Knowledge, Attitudes, Practice/ (42825)
 - 16 (patient* adj4 (feeling* or emotion* or view* or symptom* or perception* or attribute*)).ti,ab. (175843)
 - 17 ("health related quality of life" or "health related qol" or "health related ql" or hrqol or hql or "patient reported outcome*" or "patient-reported outcome*" or prom or proms or "disease reported outcome*").ti,ab. (33984)
 - 18 ("quality of life" or "qol" or "outcome measure*" or "health outcome*").ti,ab. (354573)
 - 19 *"Quality of Life"/ (60353)
 - 20 *"Outcome Assessment (Health Care)"/ or *"Outcome and Process Assessment (Health Care)"/ (30619)

- 21 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 (632316)
- 22 (qualitative* or findings or interview*).mp. (1839410)
- 23 focus groups/ or interviews as topic/ (62635)
- 24 exp qualitative research/ (25171)
- 25 22 or 23 or 24 (1845336)
- 26 12 and 21 and 25 (714)

Database: Embase <1974 to 2015 November 20>

Search Strategy:

- 1 ((Venous or vein) adj2 (disease or stasis or obstruction or incompetence or insufficiency or syndrome or thromboembolism)).tw. (37296)
- 2 (Venous ulcer\$ or leg ulcer\$ or venous leg ulcer\$).tw. (8767)
- 3 (Venous insufficiency or Venous incompetence or Venous thromboembolism or VTE or Venous outflow obstruction or VOO or Venous valvular incompetence or VVI).tw. (32246)
- 4 exp Vein Insufficiency/ (8885)
- 5 varicosis/ or leg varicosis/ or leg ulcer/ or spider vein/ (33685)
- 6 (Venous adj2 (edema or oedema)).tw. (400)
- 7 Venous disorder\$ of the leg\$.tw. (28)
- 8 (Varicose vein\$ or spider vein\$ or varicosity or varices or telangiectasia\$).tw. (37046)
- 9 Endovenous occlusion.tw. (9)
- 10 post-thrombotic syndrome.tw. (1206)
- 11 vein thrombosis/ or post thrombosis syndrome/ or venous thromboembolism/ (52548)
- 12 or/1-11 (133928)
- 13 *attitude to health/ (44517)
- 14 *self care/ (12199)
- 15 (patient* adj4 (feeling* or emotion* or view* or symptom* or perception* or attribute*)).ti,ab. (257226)
- 16 ("health related quality of life" or "health related qol" or "health related ql" or hrqol or hql or "patient reported outcome*" or "patient-reported outcome*" or prom or proms or "disease reported outcome*").ti,ab. (48597)

- 17 ("quality of life" or "qol" or "outcome measure*" or "health outcome*").ti,ab. (478159)
- 18 *"quality of life"/ (66900)
- 19 *outcome assessment/ (13667)
- 20 13 or 14 or 15 or 16 or 17 or 18 or 19 (781647)
- 21 12 and 20 (7265)
- 22 (qualitative* or findings or interview*).mp. (2229865)
- 23 exp interview/ (179591)
- 24 exp qualitative research/ (34228)
- 25 22 or 23 or 24 (2237748)
- 26 21 and 25 (1092)

Database: PsycINFO <1967 to November Week 3 2015>

Search Strategy:

-
- 1 ((Venous or vein) adj2 (disease or stasis or obstruction or incompetence or insufficiency or syndrome or thromboembolism)).tw. (369)
 - 2 (Venous ulcer\$ or leg ulcer\$ or venous leg ulcer\$).tw. (77)
 - 3 (Venous insufficiency or Venous incompetence or Venous thromboembolism or VTE or Venous outflow obstruction or VOO or Venous valvular incompetence or VVI).tw. (373)
 - 4 cerebrovascular disorders/ (1939)
 - 5 thromboses/ (683)
 - 6 Venous disorder\$ of the leg\$.tw. (0)
 - 7 (Venous adj2 (edema or oedema)).tw. (7)
 - 8 (Varicose vein\$ or spider vein\$ or varicosity or varices or telangiectasia\$).tw. (258)
 - 9 Endovenous occlusion.tw. (0)
 - 10 post-thrombotic syndrome.tw. (2)
 - 11 embolisms/ (365)
 - 12 or/1-11 (3508)
 - 13 *health attitudes/ (7012)
 - 14 *self care skills/ (2812)

- 15 *health knowledge/ (4945)
- 16 (patient* adj4 (feeling* or emotion* or view* or symptom* or perception* or attribute*)).ti,ab. (35622)
- 17 ("health related quality of life" or "health related qol" or "health related ql" or hrqol or hql or "patient reported outcome*" or "patient-reported outcome*" or prom or proms or "disease reported outcome*").ti,ab. (8471)
- 18 ("quality of life" or "qol" or "outcome measure*" or "health outcome*").ti,ab. (85067)
- 19 *"Quality of Life"/ (24944)
- 20 13 or 14 or 15 or 16 or 17 or 18 or 19 (132586)
- 21 12 and 20 (276)
- 22 (qualitative* or findings or interview*).mp. (785063)
- 23 interviews/ (6987)
- 24 exp qualitative research/ (6235)
- 25 22 or 23 or 24 (785063)
- 26 21 and 25 (73)

CINAHL - search

1. ((Venous or vein) adj2 (disease or stasis or obstruction or incompetence or insufficiency or syndrome or thromboembolism)).tw.
2. (Venous ulcer\$ or leg ulcer\$ or venous leg ulcer\$).tw.
3. (Venous insufficiency or Venous incompetence or Venous thromboembolism or VTE or Venous outflow obstruction or VOO or Venous valvular incompetence or VVI).tw.
4. exp Venous Insufficiency/
5. exp Varicose Veins/
6. (Venous adj2 (edema or oedema)).tw.
7. Venous disorder\$ of the leg\$.tw.
8. (Varicose vein\$ or spider vein\$ or varicosity or varices or telangiectasia\$).tw.
9. Endovenous occlusion.tw.
10. post-thrombotic syndrome.tw.
11. Venous Thrombosis/ or Venous Thromboembolism/
12. or/1-11

Science Citation Index

“vein disease” or “vein stasis” or “vein obstruction” or “vein incompetence” or “vein insufficiency” or “vein syndrome” or “vein thromboembolism” or “Venous ulcer*” or “leg ulcer*” or “venous leg ulcer*” or “Venous insufficiency” or “Venous incompetence” or “Venous thromboembolism” or “Venous disease” or “Venous stasis” or “Venous syndrome” or VTE or “Venous outflow obstruction” or VOO or “Venous valvular incompetence” or VVI or “Varicose Vein*” or “Venous edema” or “Venous oedema” or “spider vein*” or

varicosity or varices or telangiectasia* or “Endovenous occlusion” or “post-thrombotic syndrome” or “Venous Thrombosis” or “Venous Thromboembolism”

Proquest search

(qualitative* or findings or interview*) AND ti(“vein disease” or “vein stasis” or “vein obstruction” or “vein incompetence” or “vein insufficiency” or “vein syndrome” or “vein thromboembolism” or “Venous ulcer*” or “leg ulcer*” or “venous leg ulcer*” or “Venous insufficiency” or “Venous incompetence” or “Venous thromboembolism” or “Venous disease” or “Venous stasis” or “Venous syndrome” or VTE or “Venous outflow obstruction” or VOO or “Venous valvular incompetence” or VVI or “Varicose Vein*” or “Venous edema” or “Venous oedema” or “spider vein*” or varicosity or varices or telangiectasia* or “Endovenous occlusion” or “post-thrombotic syndrome” or “Venous Thrombosis” or “Venous Thromboembolism”) AND (ti((patient* AND feeling*) OR (patient* AND emotion*) OR (patient* AND view*) OR (patient* AND symptom*) OR (patient* AND perception*) OR (patient* AND attribute*)) OR ti("health related quality of life" or "health related qol" or "health related ql" or hrqol or hql or "patient reported outcome*" or "patient-reported outcome*" or prom or proms or "disease reported outcome*" or "quality of life" or "qol" or "outcome measure*" or "health outcome*"))

Appendix 3: Initial Coding Framework

1. Physical Impact	1.1. Pain
	1.2. Other Symptoms
	1.3. Mobility
	1.4. ADLs
	1.5. Employment
	1.6. Co-morbidities
2. Psychological Impact	2.1. Mood
	2.2. Acceptance
	2.3. Altered Body Image
	2.4. Self-esteem or Self-worth
3. Social Impact	3.1. Relationships
	3.2. Social Activities
	3.3. Social Isolation
	3.4. Clothing
4. Treatment	4.1. Compliance/ Non-compliance
	4.2. Understanding – of Ulcer or Treatment
	4.3. Type or setting of Treatment
5. Coping Strategies	

Appendix 4 Domains from PROMS for VLU

PROM	Domains/ Themes
SF-12	General Health
	Physical Function

	Mental Health
	Pain
	Energy/Fatigue
NHP	Energy level
	Pain
	Emotional Reaction
	Sleep
	Social Isolation
	Physical Activities
	Life Areas Affected –
	Work/employment
	ADLs
	Social Life
	Home Life (relationships)
	Interests/Hobbies
	Sex Life
	Vacations
EQ5D	Mobility
	Self-Care
	Usual Activities
	Pain/Discomfort
	Anxiety/Depression
SPVU-5D	Physical – Pain
	Mobility
	Personal care
	Sleep
	Psychological – 2x Mood questions
	Social – Leisure
	Personal Relationships
	Social Activities
	Social Isolation
	Clothes
	Ulcer Impact –
	Smell – 2 x questions
	Exudate
Leg and Foot Ulcer Questionnaire	Pain
	Sleep
	Mobility
	Socialising
	Travel
	ADLs
	Relationships
	Mental Health/Emotions
	Treatment
	Adaptations
VeLUSET	General Self-care – I understand why I need to wear my compression stockings for the rest of my life

	<p>I will check my compression stockings regularly to make sure they still fit me</p> <p>I will wear my hosiery even though my ulcer may come back</p> <p>I will try to see my nurse every 3/6 months to get new hosiery</p> <p>I understand why compression stockings will help stop my ulcer coming back</p> <p>Daily Self-care Tasks –</p> <p>Putting feet up daily for 2 hours</p> <p>Putting stockings on/off daily</p> <p>Asking for help if can't do stockings</p> <p>Wearing stockings even with other health problems</p> <p>Do exercises daily</p> <p>Lose weight if needed</p> <p>Avoid Standing/sitting too long</p> <p>Walk >30mins</p> <p>Going Out</p> <p>Normal Life</p> <p>Wear Clothes I want even with stockings.</p> <p>Going out and enjoy self even with stockings</p>
VLUQOL	<p>Activities (12 items) –</p> <p>Activities outside home restricted</p> <p>Hard to do regular activities (i.e. work)</p> <p>Do not go out</p> <p>Activities in the home restricted</p> <p>Difficult to move around</p> <p>Dependent on other people</p> <p>Cannot do things I enjoy</p> <p>Activities take longer</p> <p>Social life affected</p> <p>Do activities by myself</p> <p>Treatment disruptive</p> <p>Bathing/washing difficult</p> <p>Psychological (12 items) –</p> <p>Feel embarrassed</p> <p>Feel self-conscious</p> <p>Feel angry</p> <p>Lack of self-confidence</p> <p>Depressed over rate of healing</p> <p>Worry that will never be free of ulcers</p> <p>Feel depressed</p> <p>Feel frustrated</p> <p>Worry about ulcer deteriorating</p> <p>Feel irritable</p> <p>Feel unattractive</p> <p>Cannot wear what I like</p> <p>Symptom Distress (10 items) –</p> <p>Ulcer burns/stings</p> <p>Ulcer hurts</p>

	Skin irritated Ulcer itches Skin sensitive Do not sleep well Difficult to relax Ulcer makes me tired Ulcer weeps/oozes Ulcer smells
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Key: - Potential domains for coding framework

Pain

Physical/mobility/ADLs

Social

Relationships

Work/employment

Energy

Other Symptoms i.e.sleep

Mental/Emotional

Clothes

Treatment

Personal care

APPENDIX 5: TABLE OF INCLUDED STUDIES:

Author, Year and Journal	Country	Research Design	Method of Analysis	Study Aims and Objectives	Sample	Diagnosis of Participants	Eligibility Criteria	Main Findings
Brown A (2005a&b)	UK	Phenomenological	Transcriptions were repeatedly read to allow total immersion in the data. Commonalities and frequently recurring themes were highlighted and grouped together in order to develop the themes	1) To explore whether the presence of a VLU impacts negatively on a patients social life 2) To determine whether or not 'knitting needle syndrome' exists.	8 Purposive sample Gender ratio and ages not given	VLU recruited from community nursing caseloads	Inclusion: Male/female Aged 65 years and over, no cognitive impairment, e.g. dementia VLU living Alone Perceived to have few social contacts English speaking Exclusion: Uncertain aetiology, receiving psychological counselling. Recently bereaved, i.e. within 6 months	Three main themes emerged from the data analysis: Pain, Social Disconnectedness and Coping.
Byrne and Kelly (2010)	Ireland	Phenomenological, Heidegarian, Hermeneutic approach	Giorgi's Thematic Analysis Framework	No clear aims/objectives- 'Focus on lived experience of VLU and its effects on lives'	12 No further information given	Living at home with VLU	Not given	The findings identified four interlinked themes: Physical Experiences, Psychological Experiences, Social Experiences, Experiencing the Therapeutic Relationship.
Charles et al (1995)	UK	Phenomenological	Giorgi's Thematic Analysis Framework	How are the physical, psychological and social areas of a person's life affected by chronic leg ulceration?	4 3 male 1 female No further information	Chronic VLU	Not given (Range of ulcer existence 5-35 years)	The interviews demonstrated that patients with chronic leg ulcers suffered negative effects in the physical, psychological and social areas of their lives.
Chase (1997)	USA	Phenomenological	Used Van Manen's approach to phenomenological analysis	To determine the lived experience of healing a venous ulcer for patients in an ambulatory surgical clinic.	7	Patients whose wounds were managed with weekly dressing changes in the clinic.	Not given	Four major themes: a Forever Healing Process, Limits and Accommodations, Powerlessness and Who cares?
Douglas (2001)	UK	Qualitative Grounded Theory	In grounded theory, data collection and data analysis occur simultaneously. There are three stages of coding with this	To ascertain patient need and help healthcare professionals to understand the effects of chronic leg	8 (Purposeful sample) 6 females	VLU	Inclusion; VLU > 1 year DN care at home Capacity for informed consent.	Results: Five major categories, Physical Experience, Loss of Control, Vision of the Future, Carer's Perspective and Health-care Professional and Patient Relationship'.

			<p>approach:</p> <ul style="list-style-type: none"> - Open - Axial - Selective 	<p>ulceration from a patient's perspective.</p>	<p>2 males</p> <p>Aged 65-94</p>			
Flaherty (2005)	UK	Descriptive non-experimental design	<p>No specific method – data was transcribed and analysed for themes and patterns,</p>	<ul style="list-style-type: none"> - Gain insight into the experience of living with a healed VLU - Explore patients knowledge of their condition - Gain insight into patient's expectations for the future. - Explore patients long-term expectations of HCP and HC 	<p>10</p> <p>(Purposive sample)</p> <p>5 male</p> <p>5 female</p> <p>Aged 52-91</p>	Healed VLU	<p>Past diagnosis of VLU from a community based healed LU clinic.</p>	<p>Three main theme emerged: Symptoms, Treatment and Coping mechanisms</p>
Hareendran et al (2005)	UK	Mixed Methods	<p>No specific method named. Transcripts were examined to identify recurring themes and develop a coding system. using QSR NUD*IST TM software (version 4) to identify key issues.</p>	<p>To identify health-related quality-of-life (HRQoL) issues in patients with VLU, with the aim of generating items for a treatment outcome measure.</p>	<p>38</p> <p>12 male</p> <p>26 female</p> <p>Aged 46-91 (mean 71.5)</p>	VLU	<p>Inclusion; proven venous disease Ulceration between the knee and ankle Ulcer duration of > 16 weeks. Exclusion; ulceration from other aetiologies Comorbidities that could exacerbate ulceration Significant arterial disease Inability to read or respond in English. Patients identified in community and outpatient clinics.</p>	<p>Categories identified: Appearance, Sleep, Functional Limitations, Emotional/ Psychological, Symptoms and Disappointment with Treatment.</p>
Hopkins (2004)	UK	Hermeneutic Phenomenology	<p>Interpretative phenomenological analysis.</p>	<p>To explore the lived experience of people who have non-healing venous ulcers</p>	<p>5</p> <p>Purposive sample</p> <p>4 male</p> <p>1 female</p> <p>Aged 47-78 (mean 75)</p>	Non-healing VLU identified through district nurse caseloads.	<p>Inclusion; venous ulceration No known significant arterial disease Non-healing ulceration of >1 year Recurrent ulceration of >6 months Regular treatment from practice or district nurse Exclusion:</p>	<p>The core themes identified were: Biographical Disruption, Ways of Coping, Social Implications and Therapeutic Relationships.</p>

							Significant arterial disease Lack of regular nursing treatment Ulceration present for <1 year Recurrent ulceration <6 months Unable to give informed consent.	
Jones et al (2005) and Jones (2007)	UK	Mixed Methods	Qualitative analysis framework used part of Colaizzi and Van Manen's structure.	- To explore the experience of depression in people living with chronic leg ulceration - To explore patients experience of living with VLU - To assess the impact of excessive exudate, leading to leakage and odour, on their daily lives, overall health and QoL.	20 interviews Purposive sample 8 male 12 female Aged 52-86 (mean 68)	Clinical NS and leading clinicians in LU management or TV at 9 NHS trusts recruited participants with VLU.	Inclusion: over 18, active ulceration of >3 months, determined by history, clinical appearance and ABPI reading ruling out arterial insufficiency. Exclusion: people with RA or DM, ulcers caused by medical condition other than VI.	Jones 2005: Three key themes around odour were identified: Emotional Response to Odour; Limitation of Social Activities and the Ways in which Odour, or Fears about the Presence of Odour, were Managed by Nurses. Jones 2007: HCP attribute symptoms such as fatigue, insomnia, a sense of loss and hopelessness to venous disease rather than to the depression of which they are classic symptoms.
Krasner (1998a and b)	USA	Heideggarian Hermeneutic Phenomenology	Diekmann's approach to phenomenological analysis.	To describe, to understand and to interpret the experience of living with painful VU.	14 Purposive sample 7 male 7 female Aged 30-86	Outpatient wound centre patients with active VU and pain.	All had active venous ulceration and ulcer pain at the time of the initial interview	Eight key themes overall: Expecting Pain, Feeling Frustrated, Swelling equals Pain, Not Standing, Interfering with the Job, Starting the Pain Over Again (painful debridements), Having to Make Significant Life Changes, Finding Satisfaction in New Activities.
Palfreyman et al (2007)	UK	Qualitative	Framework Analysis	To examine, from the perspective of patients, the impact of VLU on HRQoL in current and former intravenous drug users and the general population.	19 Purposive sample 14 male 5 female Aged 27-79 (IVDU mean age 32)	General population with VLU. Current or ex-IVDU with VLU.	LU patients at primary care clinic. Purposive sampling ensured a range of ages, sex, and ethnicity. IVDU were included to reflect the study area had a high index of health inequalities and deprivation.	A complex interaction between three key themes: Symptoms, Social Restriction and Attribution.

					(Non-IVDU mean age 61)			
Theron (2008)	South Africa	Mixed methods For the qualitative part the epistemological framework was that of constructivism.	Identification of themes was based on Owens' (1978) criteria of recurrence of ideas within the narrative data	What aspects of HRQoL are affected by the subjective experience of living with a VLU?	Qualitative part - 30VLU 11 male 19 female Aged 52-90 (mean 71) Non-VLU also completed questionnaire for comparison	Adults with VLU	VLU patients 50 and 90 years. Inclusion: established history of VLUs > six months. Exclusion: VLU patients diagnosed when < age 50.	Three themes: Freedom vs. Imprisonment, Gain vs. Loss, and Hope vs. Despair
Wellbourn and Morceri (2014)	USA	Interpretive phenomenology	Interpretive phenomenological analysis	To describe the lived experience of chronic venous insufficiency (CVI) sufferers. To explore how this chronic disease affected their health-related quality of life.	10 (convenience sample) 4 male 6 female Mean age 66 years. Nine were white and 1 was African American. All were currently retired, disabled, or unemployed.	Participants had a history of VI and VLU, or active VI patients. Research setting: Hospital based OP clinic in a small naval community.	Inclusion: History of CVI and LU, or VLU history. Speak/read English, live in community dwelling. Exclusion: < 18 years, current use of illicit drugs, lower extremity wounds associated with other aetiologies..	Four themes: Knowledge Deficit, Discomfort, Inconvenience, and Coping.

APPENDIX 6: QUALITY ASSESSMENT

Paper	CASP Quality Appraisal									
	1. Was there a clear statement of the aims?	2. Is a qualitative methodology appropriate?	3. Was the research design appropriate to address the aims of the project?	4. Was the recruitment strategy appropriate to the aims of the research?	5. Was the data collected in a way that addresses the research issue?	6. Has the relationship between researcher and participants been adequately considered?	7. Have ethical issues been taken into consideration?	8. Was the data analysis sufficiently rigorous?	9. Is there a clear statement of findings?	10. How valuable is the research?
Brown (2005a and b)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Byrne and Kelly (2010)	X	✓	✓	X	✓	X	X	?	✓	✓
Charles (1995)	✓	✓	✓	X	✓	X	✓	✓	✓	✓
Chase et al (1997)	✓	✓	✓	?	✓	X	X	✓	✓	✓
Douglas (2001)	✓	✓	✓	✓	✓	X	✓	✓	✓	✓
Flaherty (2005)	✓	✓	✓	✓	✓	X	✓	✓	✓	✓
Hareendran et al (2005)	✓	✓	✓	✓	✓	X	✓	✓	✓	✓
Hopkins (2004)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jones (2007)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jones et al (2008)	✓	✓	✓	✓	✓	X	✓	✓	✓	✓
Krasner (1998a and b)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Palfreyman et al (2007)	✓	✓	✓	✓	✓	X	✓	✓	✓	✓
Theron (2008)	✓	✓	?	✓	?	✓	✓	?	✓	✓
Wellbourne and Morceri (2014)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓