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**A mixed methods study of patient centred care in
people with chronic venous leg ulceration.**

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Abstract.

Aims:

To explore the lived experience of patients with chronic venous leg ulceration and to establish whether themes that impact on quality of life are addressed during wound care consultations. To develop a consultation template based on these themes and to evaluate the feasibility of a future randomised controlled trial to evaluate template utility.

Methods:

Three phases were undertaken. The first comprised qualitative interviews with 9 patients to identify how themes impacted on the daily lives of those with chronic venous leg ulceration. The second phase used non-participant observation for 5 of the 9 patients to establish whether these themes were disclosed and addressed during consultations. A nominal group meeting of experts was undertaken to construct a new consultation template, which was verified by patient participants. The template was piloted with 9 new patient participants during the final phase to ascertain if a future randomised controlled trial to evaluate efficacy would be feasible.

Results:

Phase 1 established a range of themes and subthemes that served to diminish the quality of life of participants. Phases 2 revealed that many of these themes were either not disclosed by patient participants or, when raised, were often not fully addressed by the nurse during wound care consultations. The new consensus consultation template was developed and piloted during phase 3.

Conclusion:

Chronic venous leg ulceration impacts on every area of the patient's life but often such concerns were not disclosed or effectively addressed during wound care consultations. Although the pilot of the consultation template demonstrated that a future randomised controlled trial would not be feasible, valuable information was provided to inform potential future study design.

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Glossary of terms.

Glossary of terms:

Ankle brachial pressure index (ABPI)

An ABPI measurement provides a ratio of the systolic blood pressure in the arm, as an estimate of central systolic pressure, and the highest systolic pressure of three named vessels (the anterior and posterior tibial arteries and the dorsalis pedis artery), in the lower leg for each limb. An ankle brachial pressure index (ABPI) of 0.8 is seen as the lowest reading to apply high compression bandaging (Vowden & Vowden, 2001).

Chronic venous insufficiency (CVI)

Is a long standing medical condition in which the veins have problems returning blood back to the heart. Valves may be incompetent, the veins may be partly blocked, blood may be leaking from the vessels and there may be deep vein thrombosis or phlebitis as a precursor to this condition. Skin reactions include varicose eczema, discoloration, thickening and an increased risk of ulceration.

Chronic venous leg ulceration (CVLU)

Chronic venous leg ulcer is defined as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease (SIGN, 2010).

Department of Health (DH)

The Department of Health (DH) lead across health and care by creating national policies and legislation, providing the long-term vision and ambition to meet current and future challenges, putting health and care at the heart of government, and being a global leader in health and care policy.

District Nurse (DN)

The DN is a key member of the primary health care team and plays a crucial role, visiting people in their own homes or in residential care homes, providing care for patients and supporting family members.

Evidence based practice (EBP)

EBP is an interdisciplinary approach to clinical practice based on the principle of the importance of research to support clinical decisions.

General Practitioner (GP)

A medical practitioner, who treats both acute and chronic disease, provides preventative care and health promotion most often in a primary care environment.

Health care professional (HCP)

In the context of this thesis, HCP refers to all health care professionals who have face-to-face patient contact, including doctors, nurses, physiotherapists and occupational therapists.

Health related quality of life (HRQoL)

HRQoL is a multi-dimensional concept that includes physical, psychological and social functioning and focuses on the impact conditions and illnesses on quality of life.

Nursing and Midwifery Council (NMC)

The NMC is the regulator for nursing and midwifery in England, Wales, Scotland, Northern Ireland and the Islands. They safeguard public health and wellbeing of the public; they set the standards for education, training, conduct and performance so that nurses and midwives; they ensure that skills, knowledge and professional standards are upheld.

Patient centred care (PCC)

PCC supports the active engagement of the patient and their family in their care and decision making.

Patient reported outcome measures (PROMs)

PROMs provide an assessment of the quality of care delivered to NHS patients from the patient perspective.

Primary care

Primary care is healthcare provided outside acute hospitals, it is often the first point of contact and is most often general practice focused.

Quality of life (QoL)

QoL refers to the general well-being of individuals and society and is often used interchangeably with HRQoL.

Shared decision making (SDM)

SDM refers to a patient being actively involved in decisions relating to their care, as opposed to decisions being made for them by their HCP.

Key to transcripts in Chapter 4.3:

- [] Background information to make the context, meaning or dialect clear.
- Pause
- (.....) Words or phrases have been edited out.
- * Comment from field notes (not interview transcript).

Transcript conventions have been adapted from the ethnographic text by P. E. Willis (1977, page viii).

Chapter 1: Introduction.

Chapter 1: Introduction.

Chapter 1 provides an introduction to the thesis and includes an overview of the area of study, accompanied by the personal and professional motivation for the exploration of this topic area. In addition, the construction of the specific research questions, the background to study design and an outline of the structure of the thesis is provided (figure 2, page 22).

1.1 Introduction.

Chronic venous leg ulceration (CVLU) is a long term condition that affects many thousands of people worldwide, most often as a result of chronic venous insufficiency (CVI) (Posnett & Franks, 2007). The annual costs for the care and management of the condition are high and, with a global ageing population, are expected to continue to rise since prevalence increases with age (Moffatt et al, 2004; Persoon et al, 2004; Posnett & Franks, 2007). The majority of care for these patients is delivered in the community, at a clinic location or at home, principally by teams of district nurses (DN) (Nelzen et al, 1997; McGuckin et al, 2000). Research suggests that this care often has an exclusive wound management focus and is of varying quality, with little attention paid to the impact that the ulceration poses for the individual (Callam et al, 1985; McGuckin et al, 2000; Persoon et al, 2004). The personal cost to the patient and their carers as a result of the CVLU is significant and is often either underestimated or simply overlooked by their health care professional (HCP) (Franks & Moffatt, 2007).

1.2 Rationale for the study.

The delivery of nursing care within the community has, over recent years, undergone considerable 'modernisation' which has expanded the remit of DN teams to include responsibility for more acute patients and an increasingly busy schedule (QNI, 2009; DH, 2013, RCN, 2013). In addition to these increasing 'acute' demands, each DN continues to have day-to-day responsibility for the care of many patients who suffer from debilitating long term and palliative conditions. Balancing these competing demands, often accompanied by diminishing staff numbers, presents every DN team with daily challenges (QNI, 2013). As a result, DNs are increasingly having to take a reactive approach to their expanding workload, 'juggling' the challenge of new, dependent patients with their regular patients, in order to ensure that risks are managed and care is optimised (QNI, 2009). These changes, according to the Queen's Nursing Institute (QNI, 2009; 2013), often result in delayed visits, hurried consultations and potentially compromised care.

Patients with CVLU are generally, but not exclusively, elderly and often present with long periods of ulceration and, when healing does occur, frequently there is recurrence as a result of their underlying CVI (Lindsay, 2000; Ebbeskog & Ekman, 2001a; Yarwood-Ross & Haigh, 2013). Regular DN visits of considerable length are required for such patients, which places significant pressure on an already strained service and its limited resources (Ouien et al, 2000). Such increasing pressure on the service may be a factor that contributes to the reported wound management focus of consultations and the variability of the quality of the care provided (Callam et al, 1985; McGuckin et al, 2000; Persoon et al, 2004).

Many DN teams, as a way of managing these increasing demands, have adopted the approach of providing wound care consultations at central clinic bases. Such clinics often employ a variety of

innovative models such as the Leg Club Model (Lindsay, 1999), which aims to provide holistic care in non-clinical surroundings, and out of hours clinics that improve access to services (Lindsay, 2000; DH, 2013). These steps go some way to managing increasing demands; however, it is often the CVLU patients specifically who are unable to attend such clinics due to the effects of co-morbidities and the impact of their increasing age (Lindsay, 2000; SIGN, 2010). Effective service redesign is essential and is high on the Government agenda, but in the meantime it appears that the needs of CVLU patients are often not being met during their current wound care consultations (DH, 2013; QNI, 2013).

1.2.1 Personal motivation for the study.

Having been a DN Caseload Manager for eight years, I had seen at first hand the increasing pressure on the service; including reductions in staffing levels, earlier discharges of very dependent patients from hospital into the community and an expansion of the caseload. The challenge of allocating and managing this daily workload was mounting and my ability to deliver high quality care was gradually being challenged; consultation times were subsequently reduced and the allocation of time was being closely monitored by managers.

Following a move into nurse education in 2003, I maintained my links with local DN teams by accompanying students on their placements in clinical practice. It was on one of these accompanied student visits that this research was inspired. During one such visit, I met Nellie who was 82 years of age and had a long history of CVLU. On this visit the student nurse had been asked to renew Nellie's bilateral leg bandages and it was during this visit that I had an opportunity to discuss with Nellie the impact that leg ulceration had made on her life.

I asked Nellie to tell me about her leg ulcers, to which she sighed and recounted her experience of 60 years of ulceration. On her wedding photograph on the wall she had bilateral bandages on her legs and on this day, 60 years later, we were in attendance, again replacing her bilateral bandages. I was astounded; despite knowing of the longevity of CVLU, this was certainly the longest I had ever known anyone suffer from CVLU. Nellie reported having experienced some periods of healing but her ulcers had inevitably returned: sometimes after months, occasionally after a year but most often after only a few weeks following healing.

Throughout this 60 year period Nellie spoke of being a wife and a mother; she had worked at a local pottery company; she had seen her children marry and have children of their own and she had been widowed 10 years earlier. Throughout all of these episodes of her life she had suffered from CVLU; and now at the age of 82 years, she was dependent on carers, immobile and still required bilateral bandages to her lower legs. Nurses were currently visiting three times weekly for up to 45 minutes per visit to redress her ulcers.

Nellie's life had been completely defined by her ulceration. This made me consider the care she had received over this prolonged period and whether, on the many occasions she had contact with the HCPs to care for her leg ulcers over these 60 years, had we, as HCPs, ever really explored what Nellie's life was like on a day-to-day basis. Had we ever considered whether anything could be put in place to improve her symptoms and ease the impact of her CVLU, however simple? Healing without recurrence may never have been an achievable goal in Nellie's case, but easing of her symptoms and attempting to reduce the impact on her daily functioning may well have been a more appropriate priority for her care.

Nellie's visit certainly made an impact on me and profoundly influenced my choice of study topic for future research. I came away from the visit knowing that the current priority of care for CVLU patients, which so often was focussed on the achievement of healing in an almost blinkered fashion, even when, for many, this was not an achievable goal was not always the most appropriate priority (Heit et al, 2001). I wanted to explore whether a shift in the focus of the consultation away from an exclusive healing focus towards a more patient centred approach (PCC), where the daily needs of the patient were central, would enhance quality of life (QoL) and satisfaction with care provision for this patient group.

1.3 Background to the study area.

This thesis presents a mixed methods study that explores a patient centred approach to care for people with chronic venous leg ulceration. The study question was formulated using the PICO approach to ensure that it was relevant and sufficiently focussed (Richardson et al, 1995; Huang et al, 2006). The overall study question is:

Does a patient focus to consultations in the care of patients with chronic venous leg ulceration improve patient satisfaction and quality of life?

PICO (Richardson et al, 1995) is an acronym which stands for the population or patient problem (P); the intervention (I); the comparator (C) and the outcome (O). The following sections (1.3.1 – 1.3.4.2) provide explanations of the key PICO elements which have informed the development of both the overall and the individual research questions for this study:

- the population (P): adult patients in the community setting with CVLU;
- the intervention (I): PCC;
- the comparison (C): usual care (applied during phase 3 of the study) (chapter 8;page 247) and
- the outcomes (O): patient satisfaction and quality of life.

1.3.1 Population (P) – adults with chronic venous leg ulceration in the community setting.

A leg ulcer is defined as a wound below the knee which fails to heal within six weeks (Nelzen et al, 1997; SIGN, 2010). Prevalence of ulcers internationally is high and up to 80% of cases have a venous component and, as a result of the underlying CVI; such ulcers are difficult to heal and have a high tendency to recur (Callam et al, 1985; Moffat et al, 1992; Nelzen et al, 1997; Posnett & Franks, 2007). Leg ulcers are classified as venous, mixed or of arterial aetiology following a thorough clinical assessment and the recording of an ankle-brachial pressure index (ABPI) ratio using a Doppler ultrasound (Vowden & Vowden, 2001). The clinical assessment is the key feature of assessment, with the ABPI ratio an adjunct to diagnostic process (Ruff, 2003). The ABPI reading is the ratio of the systolic blood pressure at the ankle divided by the brachial systolic blood pressure and, along with

the clinical assessment, informs the optimal management of the range of leg ulcer classifications (Vowden & Vowden, 2001; Ruff, 2003; SIGN, 2010).

Table 1: Ankle brachial pressure index classification and interpretation (Vowden & Vowden, 2001).

<u>ABPI value</u>	<u>Interpretation.</u>
> 1.2	Vessels abnormally hardened due to peripheral vascular disease: routine specialist referral.
0.8 - 1.2	Normal range. Classified as venous aetiology.
0.5 - 0.8	Moderate arterial disease: specialist referral. Classified as mixed aetiology.
< 0.5	Severe arterial disease: urgent specialist referral. Classified as arterial aetiology.

Table 1 (above) provides detail of potential ABPI ratio results and subsequent ulcer classification. Ulcers are deemed to be of venous aetiology following a clinical assessment and an ABPI ratio of between 0.8-1.2. Such a ratio indicates that high compression bandaging; a method of venous ulcer management evidenced to improve healing rates, may be safely applied (Moffat, 1998; 2004; SIGN, 2010). Arterial ulcers, in contrast to venous, differ in their cause, location and presentation, and account for 13 - 15% of all leg ulcers (Callam et al, 1985; Kippel & Dieppe, 1998). An arterial ulcer presents with an ABPI ratio of below 0.5 (Vowden & Vowden, 2001). Healing for such patients is dependent on the surgical restoration of circulation and oxygenation and an urgent specialist referral is required; the use of any compression bandaging is contraindicated as it would compromise an already limited blood supply (Vowden & Vowden, 2001). In between these two aetiologies, 10 - 15% of ulcers have an element of arterial impairment (Callam et al, 1985) and are classified as being of

'mixed aetiology', presenting with an ABPI ratio of between 0.5 and 0.8. Such patients require a routine specialist referral, but following further assessment, are often managed in a similar way to their venous counterpart, albeit with reduced compression (Vowden & Vowden, 2001). Patients with either venous and mixed aetiology ulcer classifications were included within this study, as their presentation, symptoms and management are similar. Patients with arterial ulceration differ considerably in both their presentation, symptoms and management and often have a multitude of other co-morbidities to deal with; in view of this, patients with arterial ulceration were excluded from the study.

CVLUs are the most commonly occurring wound with the most recent estimates of up to one in 500 of the UK population experiencing an ulcer (Yarwood-Ross & Haigh, 2013). Heit et al (2001) demonstrated an annual recurrence rate of between 33-42%, a statistic that has not improved over the last 20 years. The condition is expensive, with annual costs for care and management conservatively estimated in 2007 to be in the region of £200 million (Posnett & Franks, 2007); a sum mostly directed to primary care where the majority of the care for such patients is delivered (Posnett & Franks, 2007; SIGN, 2010). Indeed studies estimate that DNs provide care for 82-87% of patients with CVLU (Callam et al, 1985; Nelzen et al, 1990; SIGN, 2010). CVLU impact on all areas of the life of the patient and their carers (Hyde et al, 1999; Rich & McLachlan, 2003); with lives complicated by issues such as intractable pain, restricted mobility, odour, depression, anxiety and social isolation (Jones & Nelson, 2005). QoL is diminished both as a result of the debilitating symptoms of the ulceration but also due to the recalcitrant nature of the condition (Persoon et al, 2004; Briggs & Flemming, 2007).

1.3.2 Intervention (I) - patient centred care (PCC).

The concept of PCC underpins this study and is explored more fully in chapter 2 (page 23) but also describes the intervention for the study. PCC depicts a move from seeing the patient in terms of their disease or pathology to thinking in terms of the person and their problems (Henbest & Stewart, 1989; McCormack & McCance, 2006). A PCC approach embraces the development of an environment where healthcare decisions are made jointly between the practitioner and the patient (Légaré et al, 2009); indeed Stewart (2001) described this as an attempt to make

“...the implicit in patient care explicit.” (Stewart, 2001; p. 444)

The clinical consultation is considered to be the central focus of HCP-patient communication, with the development of a therapeutic relationship between the professional and the patient considered an essential component to PCC (Dieppe et al, 2002; Entwistle & Watt, 2006; Lewin et al, 2009). The relationship between the HCP and the patient, it is said, should be based on,

“...mutual trust, understanding and shared knowledge being paramount.” (McCormack & McCance, 2006; p.472)

A number of studies report that PCC is valued by patients and demonstrate that it results in improved communication, optimised patient participation, enhanced concordance and improved adherence to treatment plans, better health outcomes, enhanced satisfaction with care and improvements in QoL (Stewart et al, 2000; Stewart, 2001; Dieppe et al, 2002; Michie et al, 2002; Swenson et al, 2004; Irwin & Richards, 2006; Poochikian-Sarkissian et al, 2010). There also appear to be significant advantages for the health care professional, with research asserting that the delivery of PCC improves job satisfaction and enhances feelings of empowerment (Thorne, 2005; Brown et al, 2006).

1.3.3 The comparator (C) –usual care.

Usual care is frequently adopted as the care delivered to a control group during a randomised controlled trial and provides a baseline with which to compare results (Hicks, 2004). It is said that usual care

“...depends heavily on the knowledge, skills and resources of the health care professionals delivering it” (Hotopf, 2002; p. 329)

For the purpose of the final phase of the study, a pilot study, the intervention (I) to enhance PCC was compared (C) to usual care for the same group of patients.

1.3.4 The outcomes (O) – patient satisfaction and quality of life.

Following a review of the literature, two outcomes were considered to be appropriate for the final phase of the study. Patient satisfaction is an important and widely used outcome measure often applied to evaluate the effectiveness of interventions that manipulate care provision (Kinmonth et al, 1998; Pill et al, 1998). Such studies are explored in more detail in chapter 6 (page 194). QoL, as an outcome measure, has also been used extensively not only to explore the effectiveness of care interventions but also to capture the impact of a variety of conditions on the patient's life (Jull et al, 2004; Franks et al, 2006; Faria et al, 2011). QoL studies in relation to CVLU are explored in the literature review in chapter 3 (page 50).

1.3.4.1 Patient satisfaction.

Patient satisfaction is defined as,

“...the extent of an individual’s experience compared with his or her expectations.” (Asadi-Lari et al, 2004; p. 33)

Assessing and monitoring such satisfaction within health care has become increasingly important and constitutes a significant focus within the NHS, especially with the recent emphasis on patient-reported outcome measures (PROMs) which aim to reflect what a patient sees as significant from their care (McDonald & Langford, 2000; DH, 2006; Marshall et al, 2006). Such patient satisfaction is seen as an important outcome of care; indeed patients who are satisfied are increasingly likely to be concordant with their treatment plan and to perceive their care to be of good quality (Donadedian, 1988; Baker, 1990; Asadi-Lari et al, 2004; Moffatt, 2004). The evaluation of patient satisfaction is seen as an essential feature to improving service provision (Gill & White, 2009); however many satisfaction studies have tended to focus on the development and validation of measurement tools, which, to date, are said to be of varying quality (Hawthorne, 2006).

Few studies have explored and evaluated patient satisfaction in relation to the care provided in the community setting generally or, more specifically, patient satisfaction with their DN consultations (Poulton, 1996; Gilleard & Reed, 1998; McDonald & Langford, 2000; Tornvist et al, 2000). Tornvist et al (2000), however, undertook one such study in Sweden and demonstrated that, overall, patients reported that they were extremely satisfied with the care from their DN, although deficits were demonstrated in the areas of patient involvement in SDM, pain management and continuity of care. Even fewer studies have sought to review satisfaction with care specifically for patients with CVLUs; indeed Tornvall and Wilhelmsson’s (2010) study was thought to be the first study to specifically evaluate the perspective of patients with CVLU with the quality of their DN care provision. This study

similarly concluded that there was a high degree of satisfaction with DN care (Tornvist et al, 2000) but patients expressed a need for improved patient centredness in their consultations, enhanced pain management and enriched continuity of care delivery. Again this study was undertaken in Sweden and, as such, may reflect the design of Swedish community services which are markedly different than our United Kingdom (UK) service design. To date, no UK studies have aimed to evaluate care delivery for this client group and, since CVLU is a longstanding condition that demands a lengthy and intense relationship with the nurse, there is an urgent need for more research to evaluate care delivery for this client group (Chase et al, 1997; Douglas, 2001; Tornvall & Wilhelmsson, 2010).

1.3.4.2 Quality of life (QoL).

The World Health Organisation (WHO) (1997) defines quality of life (QoL) as an

“...individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected by the person's physical state of health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of the environment” (WHO, 1997; p. 1).

The concept when related to health and health care is often termed health related quality of life (HRQoL) and refers to the self reported appraisal of health - in physical, psychological and social domains – by an individual, over time (Bowling, 2005). Such an assessment is helpful when assessing the effects of chronic illness and in developing an understanding of how illness affects a person's day-to-day life (Walters et al, 1999; Fayers & Machin, 2000; Franks & Moffatt, 2001; Charles, 2004; van Korlaar et al, 2003).

Over the last 20 years there has been a growing interest in exploring and attempting to quantify the QoL of people across the whole range of healthcare delivery (Bowling, 2005). This interest has been attributed to a number of factors including the development of professional roles, a growing reliance on the evidence base for practice (EBP) and a need to foster patient empowerment; especially in the management of long term conditions (DH, 2005; O'Boyle, 2008; Moore & Cowman, 2009). These factors have served to heighten an awareness of the need to explore the impact of a variety of chronic illnesses on the QoL of the patient, both to understand the impact of the illness and also to investigate the effects of various treatment modalities on the life of the sufferer (Bowling, 2005).

QoL evaluation is frequently applied as an outcome measure in research that evaluates the impact of treatment or care delivery (DH, 2013). In the area of CVLU care, research unequivocally demonstrates a decline in the QoL of the patient, with significant effects demonstrated across physical, psychological and social dimensions (Chase et al, 1997; Franks & Moffatt, 2001; Persoon et al, 2004; Briggs & Flemming, 2007). Studies that explore QoL for this client group apply a range of research methods. Qualitative studies serve to develop our understanding of how life is for the leg ulcer patient, in their words (Persoon et al, 2004; Briggs & Flemming, 2007); the rich data produced provides a clear insight into the opinions and feelings behind the participants' responses, which are supported by the use of powerful quotations. In contrast, the quantitative studies focus on enumerating characteristics, using instruments to assess QoL which are generic in their design, devised to assess the population in general or disease-specific, devised to focus on a particular disease and to be sensitive to precise aspects of that condition (Bowling, 2005). The generic QoL measures are broad ranging and well established, often having been used extensively with many conditions (Bowling, 2005) and include the Medical Outcome Study Short Form-36 (SF-36) (Ware & Sherbourne, 1992), the Nottingham Health Profile (NHP) (Hunt et al, 1986) and the EuroQol (EQ) (EuroQol Group, 1990). The disease-specific QoL questionnaires are designed specifically to focus

on characteristics of a particular condition and aspire to be responsive to even minor changes in the health of the sufferer (Bowling, 2005). In order for these disease-specific tools to be effective, the validity and reliability of the instrument has to be tested and established along with their practicality, sensitivity and specificity (Hareendran et al, 2005; Palfreyman, 2007a). A number of the studies utilise both disease-specific QoL tool and generic tools (Smith et al, 2000; Price and Harding, 2004; Iglesias et al, 2005; Palfreyman, 2008) and, as a result, aim to provide a wide range of information and often a more complete picture of the patient experience.

1.4 The study hypotheses.

The care of the patient with CVLU tends to overlook the impact of the condition on day-to-day functioning, with the nurse appearing to favour a wound care focus for the consultation (Persoon et al, 2004). Such a focus may preclude the consulting nurse from effectively evaluating the impact of ulceration beyond the provision of wound care and thus may limit their ability to address the needs of the patient effectively. Since this study involves a number of qualitative phases and a pilot study, hypothesis testing is not appropriate (Leon et al, 2011), however, a number of hypotheses would underpin a future randomised controlled study (RCT), if such a study were deemed to be feasible. Such hypotheses, for a full RCT, are described as being experimental (H_1) and null (H_0). The experimental hypothesis (H_1)

“predicts a relationship between two or more variables.” (Hicks, 2004; p. 66)

while the null hypothesis (H_0) describes a situation when the relationship described by the experimental hypothesis does not exist, with any change being attributed to chance or other unrelated factors. In any ensuing study, the researcher’s aim is to reject the null hypothesis and thus evidence sufficient support for the experimental hypothesis (Hicks, 2004; Denscombe, 2007). As

said, hypothesis testing would not be undertaken within this study since the final phase is designed as a pilot study, however the following hypotheses would be appropriate for a future full RCT:

H₁ Patients with chronic venous leg ulceration will demonstrate improvements in satisfaction with their care as a result of a patient centred consultation when compared to their usual consultation.

H₀ Patients with chronic venous leg ulceration will not demonstrate improvements in satisfaction with their care as a result of a patient centred consultation when compared to their usual consultation.

H₁ Patients with chronic venous leg ulceration will demonstrate improvements in their quality of life as a result of a patient centred consultation when compared to their usual consultation.

H₀ Patients with chronic venous leg ulceration will not demonstrate improvements in their quality of life as a result of a patient centred consultation when compared to their usual consultation.

1.5 The research questions.

In response to the above hypotheses, a three phased mixed method study was proposed in order to answer the following four research questions:

1. What are the significant factors that impact on the day-to-day lives of people with chronic venous leg ulceration (Phase 1)?

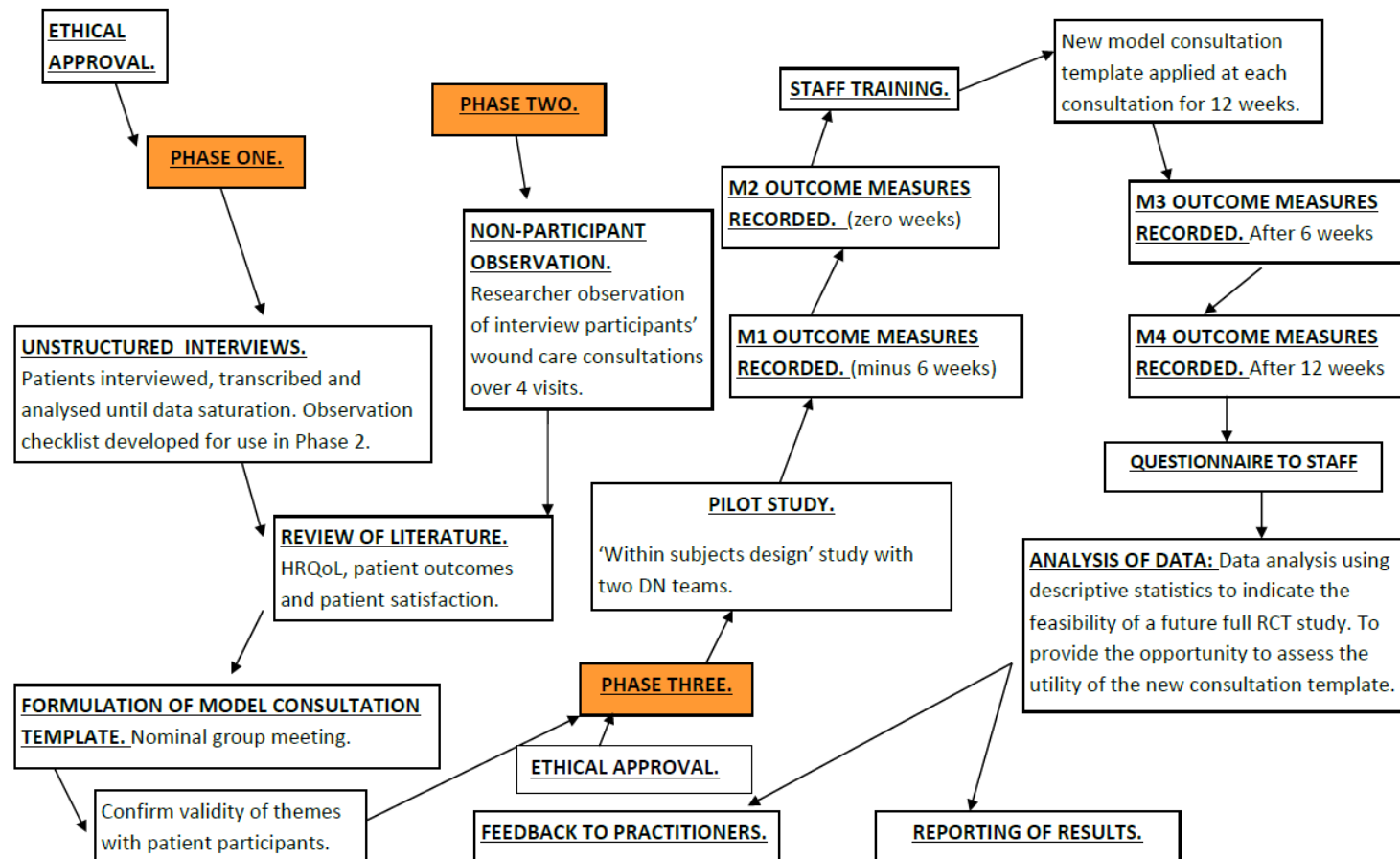
2. To what extent are these factors elicited and addressed during the patients' consultations (Phase 2)?
3. Can expert and patient consensus create a model consultation template for patients with chronic venous leg ulceration (Nominal group)?
4. Is a future full randomised controlled trial (RCT) of the new model consultation template feasible (Phase 3)?

A mixed methods approach has been adopted in order to effectively answer these research questions. Qualitative methods have been applied during the initial phases (phase 1 and 2 and the nominal group) in order to provide a preliminary base; qualitative methods are often used in this way, most often when there is a scarcity of relevant prior knowledge (Hicks, 2004). For the final phase, quantitative methods were employed to pilot the newly developed consultation template (Pope & Mays, 1995). Such a mixed methods approach ensures the accuracy of study findings, allows for the triangulation of results and provides a pragmatic approach to the research problem (Meadows, 2003; Denscombe, 2007).

Following a review of the literature available in this area (chapter 3, page 50), this study design was felt to represent an original approach to the development of a patient focus to the care and management of patients who suffer from CVLU. This project builds on previous research and generates new knowledge in relation to factors that impact on the day-to-day life of patients with CVLU. This study develops a patient centred approach to care for patients with CVLU and pilots this

in terms of patient satisfaction and QoL outcomes, using a number of previously validated measurement tools. The overall study design is illustrated in figure 1 overleaf.

Figure 1: Whole study flow chart



1.6 Structure and content of the thesis.

As discussed (page 4), the questions that formed the basis for this study were embedded in the clinical context in which they were formulated. This study has not only been a research journey for myself, as a clinical practitioner and novice researcher, but also for the nurse and patient participants who formed part of my study, to whom grateful thanks are extended. This thesis documents this journey and conveys the learning and development which occurred along the way. Figure 2 (page 22) provides an illustration of the overall layout of the thesis. Each of the distinct phases has been reported within a single chapter to include a combined methodology and methods section, a results section and discussion relating to the findings for that study phase. It was felt that such an approach would provide structure and clarity for the reader.

Chapter 1 has provided an introduction to the study and has described the clinical context of the condition under scrutiny and its associated care delivery. It has provided an outline of the professional and personal impetus to develop and undertake the study, often during very difficult times in a rapidly changing National Health Service (NHS) (QNI, 2009; DH, 2013). It has also provided explanations of key terms related to CVLU and introduced the research questions. Chapter 2 provides an introduction to the theoretical underpinnings and explores both the central and interrelated theories that support the methods, design and development of the study. The third chapter presents a review of the literature to date that has explored the impact of CVLU on QoL and includes detail of the systematic literature search and the narrative synthesis process that was undertaken.

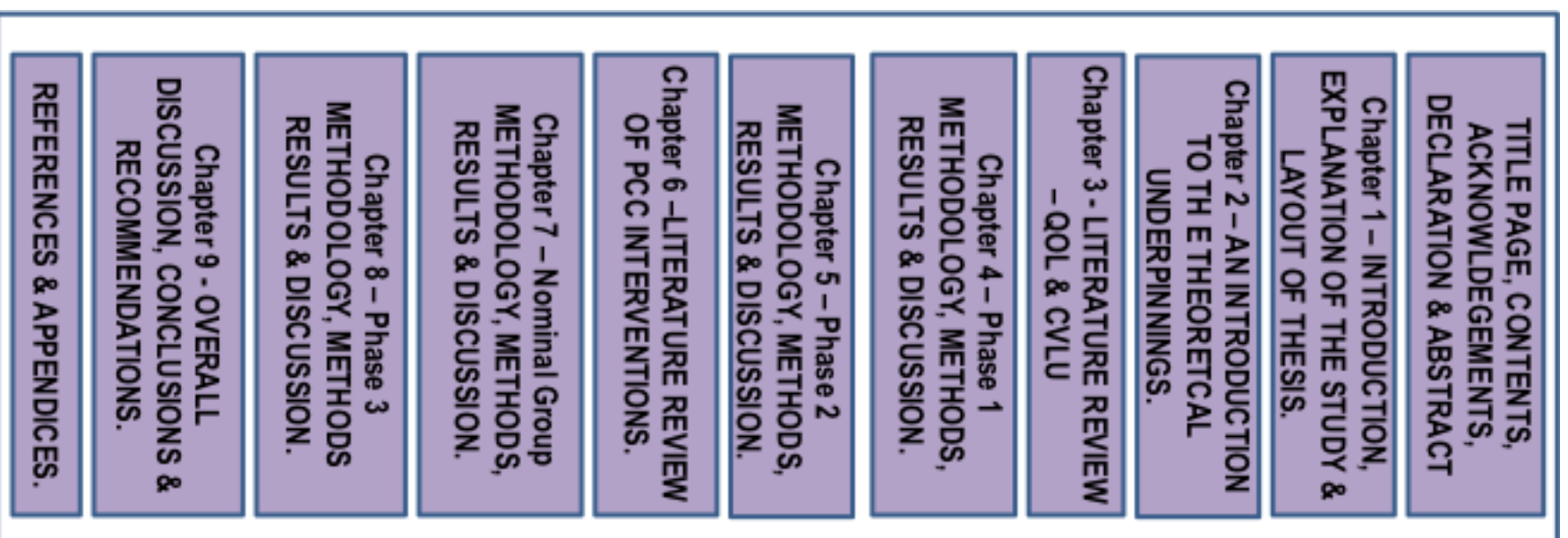
Chapters 4 and 5 focus on phase 1 and 2 of the study respectively and are each presented to include the methodology and methods, results and discussion. The sixth chapter presents a succinct

review of the literature relating to consultation-based nurse interventions designed to improve the patient centredness of clinical encounters. Chapter 7 provides an exploration of the nominal group technique and reports the development of the new consultation template. Chapter 8 is again presented to include the methodology and methods, results and discussion for phase 3, the final phase of the study. Finally, chapter 9 presents an overall synthesis and discussion of the findings of the study as a whole, its inherent strengths and weaknesses of the study and the conclusions drawn. This chapter also provides recommendations for improvements in patient care, developments to clinical practice and ideas for further research. References and appendices complete the thesis.

1.7 Conclusion.

This chapter has provided the background to the study area and has detailed explanations of some of the key terms. It has explored the motives that underpin the study and described the construction of the research questions. An explanation of the layout of the thesis chapters has also been provided. The next chapter presents an exploration of the theoretical underpinnings of the thesis.

Figure 2: Overall PhD structure.



Chapter 2: An introduction to the theoretical underpinnings.

Chapter 2: An introduction to the theoretical underpinnings.

This chapter provides the background to patient centred care (PCC), the main underpinning theory for the study. In addition a number of interrelated theories and concepts that have also underpinned and strengthened the design, analysis and interpretation of this study are explored. Links are made, where appropriate, throughout the thesis to these theories and concepts.

2.1 Introduction.

As presented in chapter 1 (page 1 - 21), the basis of this study originated within clinical care and was based on the premise that putting the patient at the centre of the consultation would improve their experience, their satisfaction and, potentially, their QoL. The centrality of the patient within their care provision is fundamental to a number of theories and is often described as either patient or person centred care (PCC) (Henbest & Stewart, 1989; McCormack & McCance, 2006); terms that have been applied interchangeably within this thesis. PCC is important in both the UK and international healthcare agenda and has recently been acknowledged as a key measure of the quality of health care provision (DH 2000, 2001a, 2004; Dieppe et al, 2002; Entwistle et al, 2004; WHO, 2005; de Haes, 2006; McCormack & McCance, 2006; Robinson et al, 2008; Timmins & Astin, 2009).

2.2 Patient centred care.

The concepts embedded in PCC were initially described in the 1950s by a Hungarian psychoanalyst, Michael Balint. Balint (1957) outlined a biopsychosocial approach, specifically related to medical care, which he labelled 'patient-centred medicine'. This, at the time, was in direct contrast to the firmly established biomedical model which was dominated by a disease focus and was historically paternalistic in its approach (Henbest & Stewart, 1989; Teutsch, 2003). In the 1950s, practice was completely provider-focussed and patients received care with little or no consideration for their preferences (Robinson et al, 2008).

The development of PCC was also influenced by the work of the psychologist Carl Rogers, a renowned humanistic psychologist who proposed a 'person centred approach' in order to facilitate the psychological progression of his clients (Rogers & Stevens, 1967). Rogers (1967) emphasised that clients should be fully involved in their care, with a genuine, empathetic relationship between the client and their HCP at the centre; a relationship Rogers (1967) described as 'the helping relationship'. This principle is a central characteristic of many models of PCC today (Salvage, 1990) and at the core of a number of nursing models and theories across specialities (Orem, 1971; Roy, 1976; Benner, 1984; Watson, 1985). The work of an American, George Engel (1977), also a psychologist, also influenced the development of PCC with proposals for a new medical model based on the bio-psychosocial rather than the widely held biomedical model in medicine.

More recently, Stewart et al (2000), a general practitioner (GP) renowned for her research exploring the nature of consultations in primary care, defined PCC as a relationship between the HCP and the patient that has as its focus the well-being of the patient, with their psychological and social situation and their experience of illness central to the interaction. Stewart et al (2000) claimed that such a PCC relationship could be achieved by ensuring patient involvement in all treatment decisions and with improved communication. The Cochrane Collaboration (Lewin et al, 2009) provides a more recent definition of PCC stating that it is based on two main features: the sharing of decisions regarding health problems with the patient and the provision of care that focuses on the patient as a person not just a disease.

Conceptual developments surrounding PCC have stalled, partly because of a lack of consensus on a clear definition of PCC and little evidence of benefit (Mead & Bower, 2000; de Haes, 2006; Lewin et al, 2009). There are distinct similarities with other 'theories' that surround the HCP-patient relationship, which, de Haes (2006) has suggested, may also have limited distinct PCC theory development and may have led to it being seen as a "...fuzzy' or elusive concept" (de Haes, 2006; p. 292). This view, de Haes (2006) claims, has resulted in a temptation to group all that is 'good' about care and communication as being PCC, a feature that has not been helpful in establishing the effectiveness of a PCC approach.

Despite the centrality of the consultation within PCC and the availability of some evidence to support that a patient centred clinical encounter has benefits including improvements in functional status, enhanced self-care and enriched patient satisfaction (Mead & Bowers, 2000; Lewin et al, 2009; Poochikian-Sarkissian et al, 2010); practitioners continue to fail to elicit patients' concerns or to negotiate their treatment options consistently during consultations (Ley et al, 1976; Griffin et al,

2004; de Haes, 2006). Research also demonstrates that patients are frequently reluctant to disclose their concerns (Bugge et al, 2006). This lack of effective two-way communication during the consultation has been the feature of a number of research studies. In 1979, Stewart, McWhinney and Buck undertook a study of GP consultations and demonstrated that 54% of patient problems and 45% of patient concerns were either not elicited by the physician or disclosed by the patient during the consultation. Tuckett et al (1985) reported that during only 6% of observed consultations the doctor made an active effort to elicit patient views about the significance of their diagnosis and in 1995, Stewart observed that the physician and patient failed to agree on the presenting problem during 50% of consultations. More recently, in 2002, an MRCGP study that utilised video to evaluate consultations found that established criteria to demonstrate patient-centredness were rarely achieved (Campion et al, 2002; McLean & Armstrong, 2004).

Thorne (2005) highlighted that communication between the HCP and the patient presents a pivotal opportunity within the consultation, which could have either negative or positive effects. Historically, HCP communication has been seen as a 'soft science', an 'extra' that may be bestowed upon a fortunate patient by their HCP but not an essential feature of the delivery of effective healthcare (Stewart, 2001; Thorne, 2005). More recent research into chronic illness however, has presented HCP-patient communication as having great potential to facilitate coping, self-care and to optimise the patient's QoL (DH, 2005; Thorne, 2005). The partnership approach required for PCC is seen to have the potential to empower and enhance independence, enabling clients to be involved in managing their life and health (Mead & Bowers, 2000; Stewart, 2001). Such factors are especially important within the home care environment where the aim of healthcare is to optimise autonomy, maintain independence and to avoid hospitalisation (DH, 2005). PCC is said to represent true collaborative working, where health care professionals share their knowledge and, as a result, their decision making power with their patient (Stewart, 2004). However, patients continue to report

feeling marginalised within the illness discourse and powerless to make their own decisions about care (Henderson, 2003; Helman, 2007). Beck (1997) claimed that it was not possible for the nurse and the patient to have equal power in the practice setting; the patient is sick and vulnerable and, unless the nurse actively seeks to promote patient empowerment, the patient is unlikely to make decisions about their care.

Failure to provide PCC is not confined to doctors; McCabe in 2004 reported that nurses frequently failed to communicate effectively and tended to only approach their patients to deal with either administrative tasks or functional activities. Patients reported that on occasions they felt intimidated by their HCP and, as a result, were reluctant to express their needs (Henderson, 2003; Helman, 2007); a problem compounded by poor clinical communication (McCabe, 2004; Wong & van der Horst, 2010). Historically, a nurses' approach to care provision has been one of 'doing for' the patient, which tends to reinforce an unequal power base since the nurse has more power than the patient (Brickman et al, 1982; Godfrey, 2001; McWilliam et al, 2001). This power imbalance base has traditionally shaped the nurse-patient relationship and is often grounded in an expectation of client compliance (Godfrey, 2001).

An 'effective' PCC consultation, aims to promote SDM but is also reliant on the patient disclosing their concerns, which research demonstrates, is not always an approach that is activated by the nurse or appreciated by the patient (Swenson et al, 2004). Indeed, Henderson (2003) found that despite nurses knowing that optimal patient involvement required them to give information and share their decision-making powers, many remained reluctant. Most of the nurses in her study reflected that they wanted to make decisions rather than assist their patients to do this which created a power imbalance within the HCP-patient interaction and allowed the patient only minimal input in their care

beyond their activities of daily living. Henderson (2003) found that the nurses in her study felt that they often knew best and identified three types of communication.

1. Nurses giving information.

Most often undertaken using a closed question approach which simply required the patient to provide a yes or no answer (Gibb & O'Brien, 1990). Henderson (2003) concluded that this was a strategy employed by the nurse in order to increase patient compliance by limiting the depth of any ensuing conversations and ensuring that the nurse retained their control of the interaction (Lanceley, 1985).

2. Nurses controlling the amount and type of interactions with their patient.

Here communication focused entirely on physical care needs and again employed a predominance of closed questions. Care was characterised by a conscious avoidance of any lengthy conversations with the patient that may lead to a lack of control (Henderson, 2003).

3. Nurses using power with their patients.

These encounters left patients concerned that a failure to comply with any requests made by the nurses may preclude them from receiving good care or could result in them being labelled 'difficult' patients. In their earlier research, Prodasky and Sexton (1988) had similarly described the reaction of nurses to patients who they perceived as being 'difficult', claiming that this could lead to a further restriction in communication with information withheld and the provision of only minimal care. Findings supported by Stockwell (1972) and Moscrop (2010).

Henderson (2003) highlighted a need for nurses to proactively share information and thus encourage a positive relationship with their patients; achieved by joking, being friendly, actively listening and encouraging patient input; not features that were often observed in her study (Henderson, 2003). Smith (2004), a nurse consultant, found often that despite some blurring of boundaries within the consultation, effective social interaction between the patient and the health care professional remained a major predictor of the success of the consultation, judged in terms of patient satisfaction and the achievement of clinical outcomes.

A number of initiatives have aimed to equalise the balance of power within the HCP-patient relationship, to encourage the adoption of a partnership approach and to enhance the sharing of decisions about care (DH, 1991; DH, 2001c). One of the first such documents was published in 1991 by the Department of Health (DH) and was entitled 'The Patient's Charter' (DH, 1991). This document (DH, 1991) outlined the rights of National Health Service (NHS) patients, highlighting a need for patients to exercise these rights and encouraging them to become involved in decisions about their care, with important caveats that patients were well enough and wanted to be involved.

Ridsdale et al (1992) found that a 'willingness' to become involved within the consultation was often reliant on both the state of health of the patient and the complexity of the decisions that needed to be made. Not all patients wanted to be 'fully' involved in decisions about their care; indeed, Ridsdale et al (1992) found that many patients wanted information about their condition and treatment, but may not, necessarily, want to fully participate in making complex treatment choices. Elwyn et al (2000) similarly found that optimal SDM behaviour was most likely to occur where there was a situation of equipoise regarding decisions and that the treatment choices required having albeit different, but equally acceptable outcomes; a situation that is often not the case in clinical practice.

With similar intentions to enhance SDM, and against a backdrop of the increasing prevalence of long-term health conditions (LTC), in 2001, the DH published 'The Expert Patient' (DH, 2001c). This document set out an objective to encourage patients, especially those with a LTC, to become more actively involved in their treatment decisions in order to improve compliance and, thus, enhance their QoL. At the time, it was acknowledged that this venture very much depended on the extent to which the patient could be seen as an expert and, often more importantly, whether the patient wanted and the HCP would allow the patient a more equitable and positive role within the consultation (DoH, 2001c). Despite the commendable goals of expert patient programmes (DoH, 2001c), many patients with a LTC continued to report a lack of PCC with impolite, demeaning and often upsetting episodes of communication with their health care professionals. Thorne (2005) condemned such incidents as wholly unacceptable and claimed that they are damaging and create scepticism about the healthcare system. The majority of complaints from patients involving their HCP relate to communication and include a failure to listen, to provide the information that was required and even a lack of respect for the patient. Such communication issues result in patients leaving the consultation without asking the important questions which had been troubling them and had prompted the request for the consultation or without having received a satisfactory response (Pendleton et al, 2003). Such reports come from a variety of settings and across a range of conditions, and thus demonstrate the widespread attitudinal and structural barriers to PCC which presents a potential cause of dissatisfaction and, often, non-compliance (Ley, 1988; Pendleton et al, 2003; Thorne, 2005).

Shared decision making presumes a two-way flow of information, from the HCP to the patient and from the patient to the HCP and should include both medical and personal information. Research surrounding PCC and patient involvement often highlights the need for SDM within the consultation. Bugge et al (2006) undertook a study in which they recorded HCP-patient consultations, followed by interviews with both the patient and the HCP. Analysis revealed incidences when either the patient

or the HCP failed to disclose relevant information and the reasons offered for this non-disclosure. Bugge et al (2006) identified 34 episodes of non-disclosure relating to patient problems, with 52 relating to either treatment or management. They found that some of the observed incidents had an impact on the quality of subsequent decision making or negatively impacted on the patient's healthcare. Bugge et al (2006) concluded that patients often did not provide their HCP with sufficient information regarding their history or concerns and similarly that the HCP often did not provide important information required to enable the patient to be fully involved in the interaction; findings evidenced in other studies (Langewitz et al, 2002; Henderson, 2003; Pendleton et al, 2003). Reasons for patient non-disclosure included an environment that was not conducive to sharing information; that the HCP displayed off-putting behaviour, appearing hurried or actually blocked or interrupted any the patient attempts to share information; they felt the information was not necessary or they consciously withheld the information in order to increase their chance of achieving the goals that they desired (Bugge et al, 2006). HCP reasons for their non-disclosure also included a non-conducive environment; a lack of sufficient knowledge; a feeling that the required decision should be based on their knowledge and skills or they felt that the information was inappropriate at the time of the consultation. Bugge et al (2006) concluded that if either the patient or the HCP refrained from fully disclosing relevant information, shared understanding would not be achieved.

Entwistle and Watt (2006) stressed the need for the HCP to agree about the value of patient involvement in decision making, proposing that there was a lack of consensus about what optimal patient involvement actually constituted and how this varied across different health care situations. They felt that there was agreement that patient involvement was essential to the achievement of good healthcare outcomes and found that increasing use of decision aids were being used as a method of supporting patients to make informed health decisions (McCaffery et al, 2007). Decision aids serve to increase knowledge and facilitate patients to disclose their preferences in order that

their values are incorporated into the subsequent consultation and any treatment decisions. It has been demonstrated that decision aids increase patient involvement in the decision making process and are viewed, by many, as superior to normal care (Entwistle & Watt, 2006). The use of decision aids fits well with the model of SDM, providing that the patient wishes to be involved in the decision making process. Entwistle and Watt (2006) however, warn that healthcare decisions are often extremely complex and, on the whole, are new to the patient. Such decisions are emotional and require that the patient predict how they will feel in a future unknown health situation; as a result, they are not simple and may be something that the patient wishes to avoid (Swenson et al, 2004).

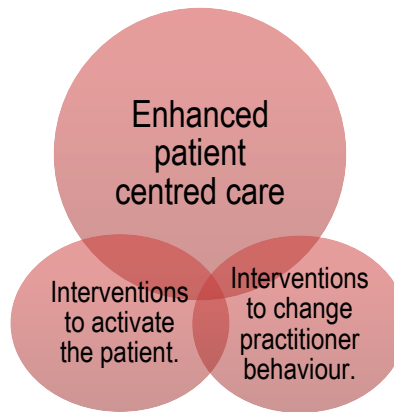
Every person experiences his or her illness uniquely, reacting in a distinctive way and they confront their disease-related stressors in relation to their life context (Thorne, 2005). Effective communication in such situations represents the HCP's recognition of the limits of what they can offer in terms of science in trying to solve the everyday problems that the patient is experiencing. At this point the HCP is recognising the patients' authority in understanding what their life is like with their condition (McCaffery et al, 2007). It is said that at this point, the HCP surprisingly becomes more useful to their patient as advisors within a shared care context (McCaffery et al, 2007).

2.3 Measures to enhance PCC.

In 1957 Balint first described what we know as PCC and, despite the purported benefits for the patient (Stewart et al, 2000; Irwin & Richards, 2006) and the HCP (Thorne, 2005; Brown et al, 2006), over the ensuing 55 years improvement has been slow, with patient complaints relatively commonplace (Pendleton et al, 2003). There continues to be a need for measures and interventions to enhance PCC and to evaluate their efficacy so that improvements can be made at every consultation, for every patient or, to coin a Department of Health phrase, to ensure we "...make every contact count" (DH, 2012; page 12).

McCormack (2003) provided a conceptual framework to support PCC with the principle of, what he termed, "....being in relation." (McCormack, 2003; p. 205). He proposed that such a HCP-patient relationship would be based on informed flexibility, mutuality, transparency and negotiation. To date, recommendations to enhance PCC have focussed on two separate approaches or a combination of the two: interventions that aim to change practitioner behaviour, such as enhancing consultation style (EPOC, 2008) or patient mediated interventions, which aim to activate the patient such as decision aids (Kinnersley et al, 2007; McCaffery et al, 2007; O'Connor, 2009) (figure 3).

Figure 3: Interventions to enhance patient centred care.



A number of studies have demonstrated that training HCPs can enhance PCC, especially with interventions that focus on their consultation style, encouraging empathy, listening skills and improved identification and handling of emotional problems (Lewin et al, 2009; Fischer & Ereaut, 2011). Such HCP-patient communication has been the focus of research with barriers to effective communication being attributed to a number of factors: 'the asymmetry of the physician-patient relationship' (Jordan, 1997; page 32); poor communication (Jarrett & Payne, 1995); organisational constraints (Pritchard, 1992); delays in answering patient's questions (Roberts, 2000); a focus on functional activities (Heit et al, 2001; Henderson, 2003). Work, to date, has mainly focused on the practitioner with, de Haes (2006) claims, insufficient attention as to why patients may not express their concerns.

A number of studies have considered the factors that constitute PCC from patients' perspectives. Factors that were consistently identified in such studies were: knowing about the patient's progress,

being responsive to needs, encouraging patient participation in planning care, providing information on condition and treatment plan and treating the patient with respect (Poochikian-Sarkissian et al, 2010). Further studies have provided evidence to support the benefits of PCC and its impact on levels of patient satisfaction and the quality of care received; despite a wide range of studies reported, there is minimal evidence that PCC consistently leads to better patient outcomes (Henbest & Stewart, 1989; McLean & Armstrong, 2004).

In view of these findings, investigators have increasingly adopted the concept of PCC as an indicator of good quality consulting; with patient satisfaction with care the most frequently assessed and thought to be the most reliable measure of PCC (Mead et al, 2002; Robinson et al, 2008). Few researchers have attempted to evaluate approaches to enhance PCC in nursing and its associated outcomes, either for the HCP or the patient (McCormack & McCance, 2006). McCormack and McCance (2006) postulated that such a study would require a shift in thinking about the role of the patient within healthcare,

“Being patient centred requires the formation of a therapeutic narrative between professional and patient that is built on mutual trust, understanding and a sharing of collective knowledge.” (McCormack & McCance, 2006; p. 473)

McCormack et al (2010) demonstrated a need for more research to evaluate specific nursing outcomes as a result of PCC interventions. Descriptive accounts do reveal a positive impact on the patient’s experience of care but there is further need to reach convincing conclusions.

2.4 PCC and this study.

This study, with its aim to evaluate whether a patient centred focus to consultations for CVLU patients improves their satisfaction and QoL, has its foundations in the concepts of PCC. The study is based on Langewitz et al's (1998) definition of the patient at the centre of the consultation with,

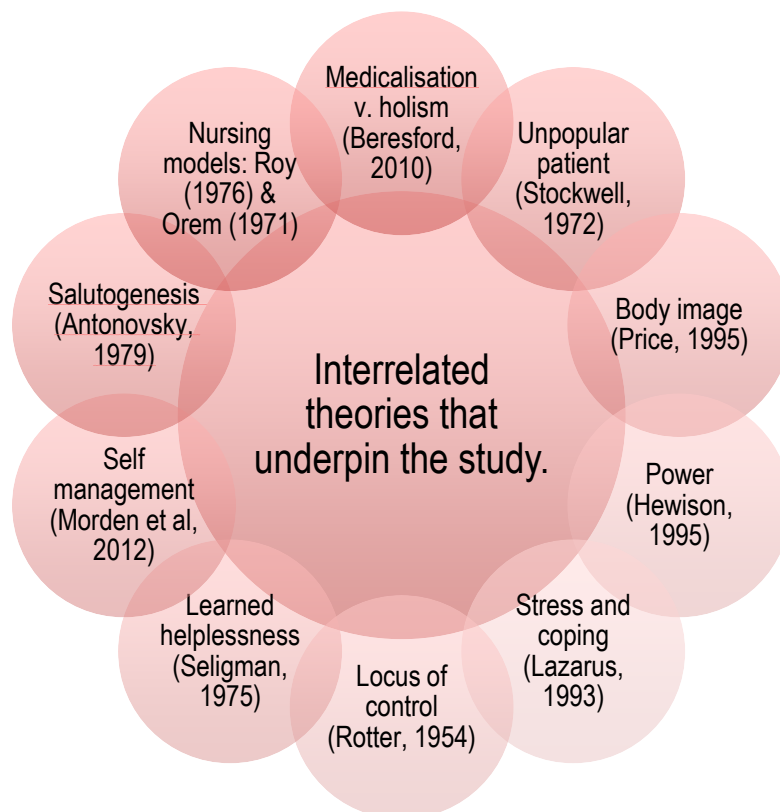
“....communication that invites and encourages the patient to participate and negotiate in decision-making regarding their own care.” (Langewitz et al, 1998; p.268)

Throughout the thesis, PCC and other interrelated theories will be applied to the design, analysis and interpretation of results.

2.5 Theories and concepts that are interrelated to the study design.

Although PCC is the central tenet of this study, a number of theories and concepts relate to the conceptual developments that underpin PCC and also this study. These theories serve to enhance our understanding of the HCP-patient relationship and, at times, go some way to explain the actions and reactions of each party within this complex relationship. These theories are discussed briefly here, and potential links to both PCC and this study are highlighted here and throughout the thesis (figure 4).

Figure 4: Interrelated theories and concepts that underpin the study.



2.5.1 Medicalisation and holism.

The term medicalisation is used to describe a 'reductionist' philosophy that some authors claim has been adopted by medicine in its quest to describe and define disease processes (Ahn et al, 2006; Beresford, 2010). Although the aim of medicalisation is to develop our understanding and management of disease, it is frequently criticised for its tendency to focus on the minutiae which results in research that is extremely focused and lacks subsequent insight into the 'bigger' picture of the impact of the condition on the patient (Ahn et al, 2006). Consequently the risk, in such situations, is that the actual phenomenon being studied becomes disassociated from the patient (Beresford, 2010). This problem is said to be intensified by the increasing reliance on evidence based practice (EBP), which emphasises the need to reduce clinical problems to a level that permits the investigation of efficacy, using such methods as randomised controlled trials (RCT) rather than their effectiveness within a real life context (Beresford, 2010). Beresford (2010) warns that the resultant advice from such 'reductionist' research may be so specific that any subsequent individual application to real patients could lead to potential harm.

Such medicalised reductionism can be seen as a feature of the care of patients with CVLU, where research is increasingly focused on the nature of the wound itself, the science, the cell biology of the healing process and the chemical components of the dressings used, often to the exclusion of the patient's experiences and preferences (Lansdown & Williams, 2005; Davydov, 2011). This 'wound' focus to HCP-patient interactions, alluded to in chapter 1, can be interpreted as medicalisation of CVLU.

In contrast, holism represents the opposite approach to medicalisation, with an emphasis on the centrality of the patient within the disease process and the need for the whole person to be

accounted for within research and the delivery of care. Beresford (2010) effectively sums up holism as

“.... looking at the patient and disease as a whole rather than focusing on interactions at cellular level.” (Beresford, 2010; p. 721)

The first holistic practitioner in nursing was said to be Florence Nightingale herself, who emphasised a need to focus care on the whole patient and to have an awareness of the influence of environmental factors on their health and recovery (Dossey, 2005). Contemporary issues in healthcare raise questions about whether our current approach to nursing is indeed holistic especially since care is increasingly delivered within specialisms, which emphasise a single disease focus, despite the growing prevalence of multimorbidity (Smith et al, 2011). The themes stressed within holism include the centrality of the patient as a whole, positioned at the centre of the care dialogue and are at the heart of PCC and underpin the research questions at the centre of this study.

2.5.2 Unpopular patient.

In 1972, Stockwell published her seminal text, ‘The Unpopular Patient’, which aimed to describe and explore the interpersonal relationship between the nurse and their patient within hospital wards. The focus of Stockwell’s (1972) section of a larger study was the interaction between the patient’s personality and nurse’s personality and it aimed to investigate the meaning behind why some patients were classified as “difficult” by their nursing staff. Stockwell (1972) described these ‘unpopular’ patients as

“...patients whom the nursing team enjoys caring for less than others.” (Stockwell, 1972; p. 11)

The impact of this classification on patient care in the study was surprising, with results identifying a middle group of patients who were categorised as being neither popular nor unpopular patients, who were subsequently deprived of attention (Stockwell, 1972). Stockwell's (1972) research, at the time, was extremely contentious and challenged the widely held view that nurses were non-judgmental in their care.

More recently, the description of patients as 'heartsink' was coined within general practice (O'Dowd, 1988) in reference to patients who caused their HCP, generally the GP in the studies described, to feel 'heartsink' when they consulted with them (Moscrop, 2010). Ellis (1986) had previously described such patients and this feeling as 'dysphoria', which he described as:

“....the feelings felt in the pit of your stomach when their (the patients') names are seen on the morning's appointment list”. (Ellis, 1986; p. 318)

O'Dowd (1988) described such patients as being dissatisfied, manipulative, demanding and frequent complainers but, on closer inspection, they actually represented a disparate group of often quite complex patients; views O'Dowd is said to have amended during ensuing years (Moscrop, 2010). This 'heartsink' description displayed many similarities to Stockwell's (1972) 'unpopular patients' and her revelations about nurse attitudes. 'Heartsink' patients, studies demonstrate, may experience ineffectual management of their condition as a result of their impact on the HCP concerned, who may be frustrated and act in an unprofessional manner during clinical contact (O'Dowd, 1988; Moscrop, 2010).

Such research suggests that patients may fall into the category of being unpopular, difficult or a heartsink patient, without actually being aware of such marginalisation and the impact that this may

have on their subsequent care (Stockwell, 1972; O'Dowd, 1988). As discussed in the introduction (page 9), patients with CVLU are longstanding and present a considerable and on-going demand on the DN and the caseload, which may predispose to their classification as 'heartsink' or unpopular patients, which may directly impede the likelihood of care that is patient centred.

2.5.3 Body image.

Everyone has a personal perception of his or her body. This refers to the picture of our body held in our mind which ultimately defines how we see ourselves (Schilder, 1935). Changes to our physical appearance due to illness or disease have an impact on our personal identity and may displace this view (Price, 1999; 2000). Price (1999) claims that initial steps to correct this distorted view early in an illness trajectory may be successful but, as the course of the illness or disease progresses, the effectiveness of interventions diminish. As a result, the illness actually stigmatised the person due to their changed appearance and a general loss of bodily control (McIntyre, 1995; Price, 1999).

Price (1995) describes altered body image as,

“....a state of personal distress, defined by the patient, which indicates that the body no longer supports self-esteem and which is dysfunctional to individuals, limiting their social engagement with others.” (Price, 1995; page 180)

Such altered body image is extremely common in, although not limited to, palliative cancer care. It may result from a person's diminished ability to manage the impact of their illness or as a result of the reactions of others to their condition (Cook, 1999), but it is generally associated with a loss of control (Price, 1998). CVLU impacts extensively on the patients' self image with complications such as bandaged legs, copious exudate and unwanted odour and as a result may limit social

engagement, self-esteem and daily functioning (Hyde et al, 1999; Rich & McLachlan, 2003). The impact on the patient's body image is considerable and will be revisited.

2.5.4 Power in the health care professional-patient relationship.

As has been suggested (page 30), the HCP-patient relationship is not necessarily one of equals (Beck, 1997; Henderson, 2003); a factor which may subsequently have an impact on the effectiveness of any ensuing dialogue. Power in the nurse-patient relationship was explored using by Hewison (1995) by analysing and exploring the language used during nurse-patient interactions. He (Hewison, 1995) concluded that nurses used language to exert power over their patients, a behaviour that was generally accepted as normal, which in itself presented a barrier to the development of a collaborative nurse-patient relationship and prevented open and meaningful communication. Hewison's (1995) study also confirmed that the majority of nurse-patient interactions were trivial, routine and related to tasks and is in line with other studies discussed such as Henderson (2003) and McCabe (2004). The impact of power in HCP-patient dialogue serves to limit disclosure and thus the application of appropriate interventions.

2.5.5 Stress and coping.

Theories of stress, coping and health are often derived from Lazarus' (1993) original Transactional Model, which was developed in response to an increasing interest in the area of stress in the 1960s and 1970s. Responses to stress, Lazarus (1993) believed, depend on the meaning that the individual attributes to a stressful stimulus and ultimately, has an effect on both health behaviour and coping. Lazarus (1993) proposed that coping efforts were dependent on primary and secondary appraisals of an impending stressor. Primary are said to refer to an assessment of the threat of a

situation, and secondary, a review of the resources available to cope with the stressor. These responses, Lazarus (1993) believed, are problem-focused strategies, such as information seeking or emotionally focused strategies such as changing personal thinking about a situation, avoidance and denial. Lazarus' (1993) Transactional Model supports the positive benefits of social support in respect of both well-being and health, which links with the theories of both salutogenesis (Antonovsky, 1979; page 46) and locus of control (Seligman, 1975; page 44).

2.5.6 Locus of control.

Many studies explore personal characteristics in order to establish why patients act in a certain way; one such psychological theory, known as locus of control, was expounded by Rotter (1954) in order to describe the degree that a person believes that they can control the events that impact on their life. A person's locus, or place, is described as being either internal or external. When a person has an internal locus of control they believe that they are in control of their life. In contrast, a person with an external locus of control feels that they and their decisions are controlled by factors that are beyond their control (Rotter, 1954). The significance of the theory of locus of control is the potential impact that an external locus poses to a person's ability to self-care and their belief about whether they can make effective changes in order to improve their health outcomes.

The concept of locus of control (Rotter, 1954) has been investigated in relation to CVLU (Charles, 1995) who found that those who had an internal locus assumed a more active approach to their ulcer management, believing that they had control over events whereas, in contrast, those with an external locus believed that they were under the control of others.

2.5.7 Learned helplessness.

Another personal characteristic that is relevant to PCC and the effectiveness of consultations is learned helplessness, a trait used by Seligman (1975) to describe why some people, when faced with a negative situation, have a tendency to behave helplessly and remain passive, despite having an opportunity to correct the situation.

Seligman (1975) conducted experiments on dogs and humans and adopted the phrase learned helplessness to describe the expectation that events were out of the individual's control. In addition to the negative expectations held by those with learned helplessness, such feelings were often accompanied by feelings of low self-esteem and persistent failure. As with locus of control (Rotter, 1954), the theory of learned helplessness is significant in relation to the consulting characteristics of patients with a number of long term conditions including CVLU.

2.5.8 Self-management theories.

The theory of self-management is embedded in much current policy and practice (DH, 1991; 2001a) and is defined as care that is directed and led by the patient themselves (Morden et al, 2012). The term self-management is often used interchangeably with self-care, it is key to a patient centred health care system and a fundamental element in the management of LTC (DH, 2005). The theory of self-management is underpinned by patient's motivation to engage in their care and is linked to the theories of locus of control (Rotter, 1954; page 44) and learned helplessness (Seligman, 1975; page 45).

Elements that are key to the adoption of self-management are encapsulated in the theory of self-determination, initially developed by Deci and Ryan (2000), which focuses on two types of motivation for health: controlled and autonomous. People who demonstrate controlled motivation tend to undertake interventions for extrinsic reasons, for example for a specific reward or to make people happy. In contrast, those with autonomous motivation act for intrinsic reasons and undertake things for the benefit of themselves. Autonomous motivation, as with the similar internal locus of control (Rotter, 1954; page 44), is seen to be predictor of positive changes for health benefit and key in self-management, weight loss and other positive health interventions (Deci & Ryan, 2000). Social learning theory, or self efficacy as it is also known (Bandura, 1977), is also implicated in a patient's motivation to engage in self-management and focuses on an individual perceiving that they are able to undertake the behaviours necessary in order to improve their health and is said to be predictive of self-management behaviour (Bandura, 1977; Skinner et al, 2003).

When faced with the longevity of a chronic condition such as CVLU, patient engagement, self efficacy (Bandura, 1977) and concordance with an agreed treatment plan are crucial. The personal belief in one's own ability to improve health outcomes is often predictive of the success of treatment interventions and impacts on compliance with such regimes (Deci & Ryan, 2000). These issues are considered in the light of the research findings for patients with CVLU throughout the thesis.

2.5.9 Salutogenesis.

Antonovsky (1979; 1987), as Balint (1957) had done before (page 25), also contested the widely held biomedical model of health of the time and proposed a new 'continuum model' of health where each person was positioned, at any point in time, along a health (salutogenesis) / disease

(pathogenesis) continuum. Antonovsky (1987) distinguished factors that he felt maintained an individual's health and their ability to adapt to disease, stressing the importance of their sense of coherence, a unique attribute held by each individual. Sense of coherence describes an orientation towards the world which perceives it as a continuum and as 'comprehensible, manageable and meaningful' (Johnson, 2004; page 420); a factor that Antonovsky (1987) felt was of significance in facilitating an individual's movement toward the health end of the continuum when faced with a particular stressor. Those with a strong sense of coherence would understand the challenge, be motivated to cope and would apply the resources necessary (Antonovsky, 1987).

Antonovsky (1979) also expounded the importance of generalised resistance resources, properties necessary to enable a person to cope and to view the world as making sense - cognitively, instrumentally and emotionally - thus facilitating movement towards the health pole of the continuum. Generalised resistance resources were described by Antonovsky (1979; 1987) as biological, material and psychological factors which make it easier for people to see their lives as consistent, structured and understandable and include money, knowledge, experience, self-esteem, being loved, healthy behaviour, commitment, social support, cultural capital, intelligence, traditions and view of life (Antonovsky, 1979). Antonovsky (1979; 1987) proposed that if a person has some or all of these factors at their disposal they would have a better chance of them coping with the challenges of life (Antonovsky, 1979; 1987; Lindstrom & Eriksson, 2005; 2006). Research demonstrates that in all age groups, socioeconomic backgrounds and across cultures, those who demonstrate a strong sense of coherence experience better perceived health, improved mental well-being, healthier ageing and enhanced quality of life and conversely, those with a weak sense of coherence have poorer perceived health and low mood (Antonovsky, 1987; Lindstrom & Eriksson, 2006). Clear links can also be seen with locus of control (Rotter, 1954; page 44), learned helplessness (Seligman, 1975; page 45) and self-management theories (Morden et al, 2012; page 45).

2.5.10 Nursing models: Roy (1976) and Orem (1971).

The foundations of PCC are said to transcend many nursing theories including Roy's Adaptation Model (1976) and Orem's Self-Care Model (1971). Orem's Self-Care Model of nursing (1971) is a model often used in primary care and rehabilitation areas. Orem (1971) proposed that all people needed to be self-reliant, responsible for their own care and that of their family. The model focuses on the patient's perspective of their illness; with the aim of nursing care being to assist them to meet their own self-care needs, whilst encouraging independence. If the patient is unable to meet their self-care needs, Orem's model (1971) purports that it is the role of the Registered Nurse (RN) to define their deficits and to provide sufficient support, until self-care is achieved.

Roy (1976), in her adaptation model, described individuals as biopsychosocial beings who were constantly interacting with various environmental challenges. In order to cope, Roy (1976) suggested, individuals use both innate and acquired mechanisms and adapt to the challenges in four modes: physiological, self-concept, role function and interdependence. The goal for nursing in Roy's model (1976) is to assist the person to adapt to the challenges that they face, thus improving their health and QoL.

Both nursing models have their basis in patient adaptation to disease, the encouragement of independence and adaption to the challenges of disease with the aim of achieving self-care (Orem, 1971; Roy, 1976). Care for patients with CVLU has been criticised as often having a wound care focus to the exclusion of patient concerns, hence the importance of considering these models in relation to care for patients with CVLU (Callam et al, 1985; McGuckin et al, 2000; Persoon et al, 2004; page 2).

2.6 Conclusion.

All of the related theories and concepts presented within this section have the potential to diminish PCC and to limit communication between the HCP and the patient during their consultation. They lead to potentially mismatched goals and limit patient expectations of improved self-management. Throughout the thesis these theories, along with PCC, will be linked to study design and the interpretation of results.

This chapter has provided an overview of theories relating to PCC. Key research publications have been included along with an exploration of the advantages of this approach both for the patient and the HCP. As mentioned, there is a paucity of literature that evaluates explicit PCC interventions in nursing care and their outcomes and this is an area highlighted for further research (McCormack & McCance, 2006). Other related theories and concepts that enhance our knowledge of PCC and the role of both the patient and the HCP in this dialogue have also been summarised. The next chapter, chapter 3, provides a review of the literature surrounding CVLU and HRQoL. This review synthesises the body of literature in this area and establishes those areas where CVLU impacts on the life of the patient.

Chapter 3: Literature Review

Chapter 3: Does chronic venous leg ulceration impact on the quality of life of the patient? A systematic review.

This chapter provides a review of the literature that explores the factors that impact on QoL for a patient with CVLU. The introductory chapter clearly demonstrated the prevalence of CVLU and the wide-ranging limitations that this condition imposes on the patient's functioning. This chapter provides a review of the literature in this area and positions this study within the scope of what is already understood.

3.1 Introduction.

In the area of CVLU research demonstrates that QoL is limited (Chase et al, 1997; Briggs & Flemming, 2007); often a factor that is intensified by a 'wound' focus to DN consultations in the community (Callam et al, 1985; McGuckin et al, 2000). The chronicity of ulceration impacts on all areas of life for the patient and, often, their carers (Hyde et al, 1999; Rich & McLachlan, 2003). Qualitative studies in this area provide the patient's perspective of living with a CVLU (Persoon et al, 2004; Briggs & Flemming, 2007); with the rich data providing a clear insight the feelings behind participants' responses, which are supported by the use of powerful quotations. In contrast, the quantitative studies enumerate these characteristics, using instruments to assess QoL. Findings have been presented separately (section 3.8; page 70 & 3.9; page 77) and then have been synthesised (section 3.10; page 89) to provide a more complete picture of the patient experience.

3.2 Aim.

The aim of this rapid review was to explore the impact of CVLU on the patients' QoL. Systematic methods have been adopted including a search strategy that aimed to identify,

“...the findings of all relevant individual studies” (CRD, 2009; p. v)

and in so doing, provide a review that is replicable, robust, comprehensive and scientific (CRD, 2009). In order to synthesise the sourced studies, a narrative synthesis was undertaken as is standard in systematic reviews and, where the level of heterogeneity has allowed, a meta-analysis has been included (Popay et al, 2005; Lucas et al, 2007; Rodgers et al, 2009; Booth et al, 2012).

3.3 Review question.

The PICO approach (Richardson et al, 1995; Booth, 2006), introduced in chapter 1 (page 7), was used to devise the study question. For the purpose of this literature review, the adapted acronym PECO (National Collaboration Centre for Methods & Tools (NCCMT), 2012) was applied to assist in the development of the review title: population (P), exposure (E), comparator (C), outcome (O) and study type (s). PECO (NCCMT, 2011) is the acronym of choice where there is no specific intervention under investigation (Booth et al, 2012) and, for this review, PECO (NCCMT, 2012) stands for:

- P – adult patients based in the community.
- E – chronic venous leg ulceration.
- C – no chronic venous leg ulceration.
- O – quality of life.
- s – any study type.

As a result, the question developed and addressed by this review is:

Does chronic venous leg ulceration impact on the quality of life of the patient?

3.4 Methods.

A systematic search of articles was undertaken using the Health Databases Advanced Search (HDAS) engine, an interface of 'NHS Evidence' (www.evidence.nhs.uk/) that provides access to a range of bibliographic databases across a range of disciplines including medicine, nursing and psychology. Each database was searched individually, applying search terms line by line (detailed on page 57), with inclusion and exclusion criteria applied to the articles sourced (page 55). A fellow reviewer agreed the final selection of articles and a range of data was extracted (page 63) and summarised (page 67 onwards). A meta-analysis of quantitative data has been undertaken where heterogeneity has allowed (page 79) (Franks & Moffatt, 1998; Franks & Moffatt, 2001; Franks et al, 2006; Furtado et al, 2008).

3.4.1 Literature databases.

A range of database resources were searched for the purpose of this review, with each providing access to various collections of material. The databases were:

- MEDLINE (Medical Literature Analysis and Retrieval System Online), a life science database from the United States (US) National Library of Medicine, which provides access to an extensive range of journals. To ensure comprehensive searching MEDLINE also utilises Medical Subject Headings (MeSH®), a controlled vocabulary thesaurus that facilitates searching using terminology at various levels of specificity.

- CINAHL (Cumulative Index to Nursing and Allied Health Literature) is a comprehensive nursing and allied health professional database and has been available since 1985. Similar to MeSH®, CINAHL headings are available to ensure that the most inclusive search is achieved.
- The British Nursing Index (BNI) is a United Kingdom (UK) nursing and midwifery database and has been available since 1992.
- EMBASE (Excerpta Medica Database) is a large pharmacological and biomedical database, which commenced in 1980.
- PsycINFO (Psychological Information Database) provides wide-ranging access to mental health and behavioural science material.
- AMED (Allied and Complementary Medicine) provides access to literature from three subject areas: professions allied to medicine, complementary medicine and palliative care.
- Health Business Elite is a database of health care administration and non-clinical aspects of healthcare management.
- HMIC (Health Management Information Consortium), which provides access to King's Fund and DH records.

It was felt that by accessing the eight databases above all relevant material would be retrieved and reviewed. In addition the Cochrane Collaboration database was searched in order to access any relevant systematic reviews and Google Scholar was searched using key terms in order to check all relevant material had been sourced. Once the search was complete, hand searching, reference and citation tracking was undertaken.

3.4.2 Article inclusion criteria.

In order for an article to be selected for inclusion within the review, a range of criteria in relation to PECO's (NCCMT, 2012) was applied (table 2 below). Only study participants over the age of 18 years were included, since CVLU almost exclusively affects adults, most often of increasing age (Posnett & Franks, 2007; page 2). Since care for those with CVLU is predominantly delivered by a DN, it was felt that study participants would be located in a community environment (Callam et al, 1985; page 9), rather than within secondary care. In view of this, secondary care was excluded from the search.

Table 2: Criteria for inclusion in the review.

Inclusion criteria	Description
Age (P)	Adult patients over 18 years.
Study type (s)	Qualitative, quantitative and mixed methods studies.
Populations (P)	Primary care / Community based.
Disease (E)	Venous leg ulcers or mixed aetiology.
Outcome measure (O)	QoL exploration or evaluation.

An accepted 'leg ulcer' definition was applied to aid study selection requiring selected participants to have suffered from active ulceration for in excess of six weeks (Nelzen et al, 1997; SIGN, 2010), ideally defined by an ankle brachial pressure index (ABPI) of more than 0.5 (Vowden & Vowden, 2001; page 8). Where this level of detail was not available within study information, if the sample was referred to as having venous or mixed aetiology ulcers they were included for further review. Arterial

ulcers (with an ABPI of less than 0.5), pressure ulcers and neuropathic ulcers were excluded from the study since their presentation, symptoms and impact on the patient differ considerably.

Only articles available in English were sourced since there was no funding available for translation; it was, however, noted that this might have limited the completeness of the review. Finally the review was restricted to research published since 1990; studies completed prior to this would be of doubtful relevance in view of advances in research and improvements in the management of patients with CVLU since this time. Studies were included irrespective of methodology or design.

3.4.3 Article exclusion criteria.

Studies were excluded from the review if the participants were 17 years of age or under, as leg ulceration is rare in this age group (Persoon et al, 2004). Studies were also excluded if they focussed purely on a single domain, such as pain (Krasner, 1998; Guarnera et al, 2007), as it was felt that such studies would fail to fully explore the range of factors that impact on the daily lives of patients with CVLU. Where the study focussed on a specific therapy, such as ultrasound for wound healing and its impact on QoL (Watson et al, 2011), again the study was excluded as the patients' QoL was only evaluated in response to the therapy under review. Where studies investigated a product, such as a new dressing (Bjellerup et al, 1993; Kirby, 2008) or an intervention, such as a novel approach to the delivery of community services (Collins et al, 1998; Edwards et al, 2005); these were excluded as the focus of the study was an aspect rather than the full realm of effects on QoL and often such studies were funded by industry. Finally, where a study was designed to evaluate or compare QoL instruments (Hyland & Thomson, 1994; Price & Harding, 1996; Walters et al, 1999; Price & Harding, 2004; Hareendran et al, 2005 & 2007; Iglesias et al, 2005; Palfreyman,

2007a & 2008; Jull et al, 2010), these studies were excluded. Such studies focus on measurement tool validation or item generation rather than a specific patient focus and were felt not to be relevant. This is not an exclusion criterion that has necessarily been applied across other reviews (Persoon et al, 2004; Herber et al, 2007a) but such exclusion has enhanced the patient focus of this review.

3.4.4 Search strategies.

As already outlined, this systematic search accessed eight databases, the Cochrane Collaboration database and Google Scholar, with each bibliographic database searched individually, line by line and replicated in every source (full detail is included in appendix 1). A series of comprehensive search terms, developed using the PECO approach (NCCMT, 2012), were systematically applied along with Boolean operators (AND / OR) (Hicks, 2004). The search terms are detailed in table 3 below.

Table 3: Search terms.

1	venous ulcer*
2	chronic venous insufficiency
3	varicose ulcer*
4	stasis ulcer*
5	leg ulcer*
6	chronic wound*
7	MeSH leg ulcer
8	OR all of the above
9	quality of life
10	"quality of life"
11	health related quality of life
12	"health related quality of life"
13	MeSH quality of life
14	OR 9 – 13
15	combine 9 AND 14

In order to ensure a focus on venous or mixed aetiology ulcers, a number of alternate search terms were combined including MeSH® terms: “varicose ulcer” and synonyms: “stasis ulcer”, “leg ulcer” and “chronic wound”. In addition the term “chronic venous insufficiency” was added, since this is most often the underlying cause of the ulceration and could potentially lead to the identification of other relevant studies. The outcome measure of interest was the QoL of patients with CVLU. QoL is a term that is often interchangeably used with HRQoL, so the terms “quality of life” and “health related quality of life” were searched separately. In addition MeSH® terms for “leg ulcer” and “quality of life” were applied ensuring that articles sharing these common themes were retrieved at the appropriate point of the search.

3.4.5 Screening, selection and quality assessment of articles.

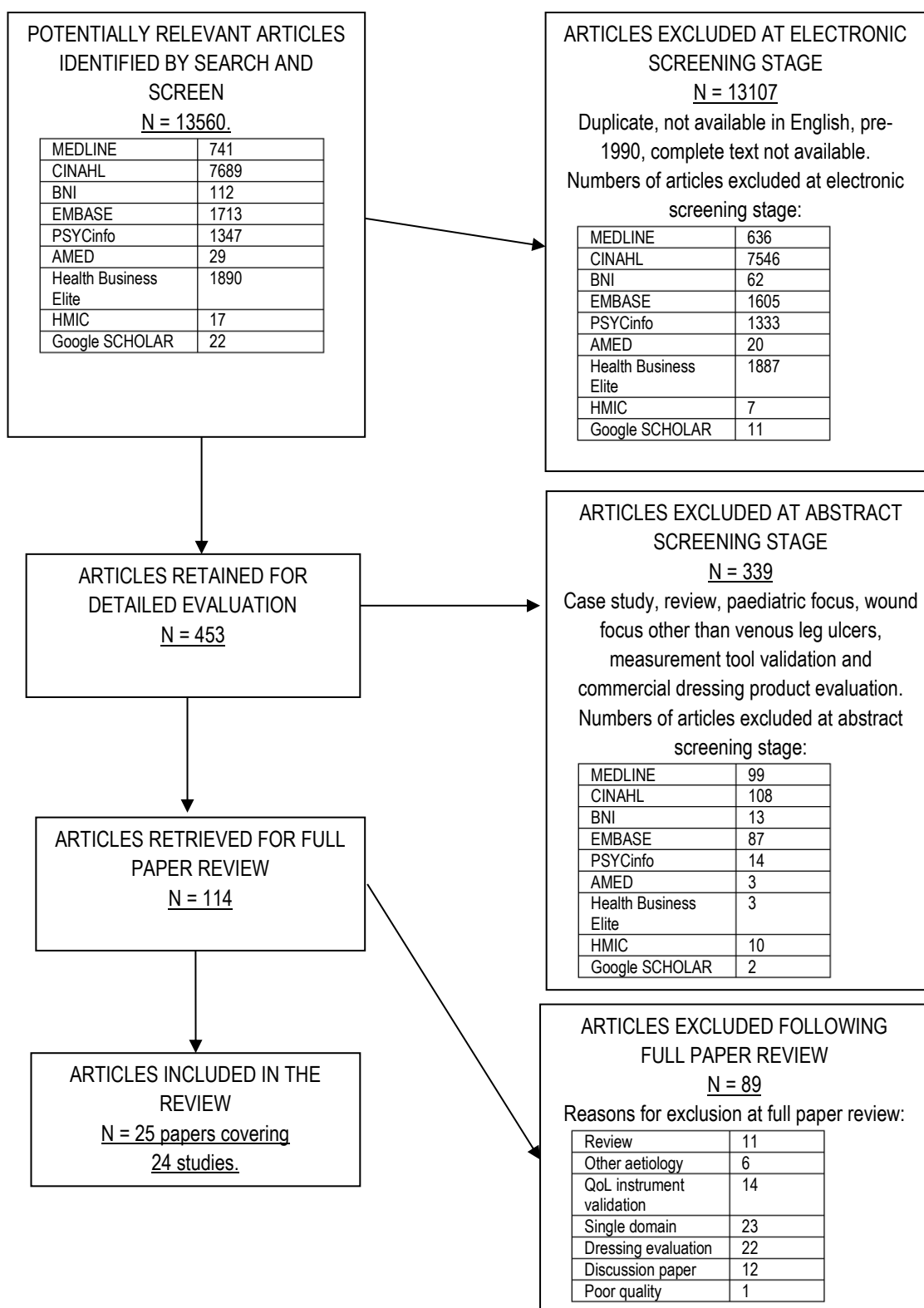
This stage of the search process involved the screening of titles, abstracts and, finally, full texts against the eligibility criteria by the researcher, with duplicates and unsuitable articles removed at this point. An educational supervisor independently assessed a proportion of those rejected in order to verify the decisions made. Following this process of selection, a proportion of the studies deemed to meet the inclusion criteria were independently reviewed by both the researcher and an educational supervisor. Good inter-rater reliability was demonstrated (Hicks, 2004) and once consensus was reached, final inclusion was agreed.

3.5 Search results.

The search initially resulted in a total of 13560 articles. Following removal of duplicates and a review of the relevancy of the study titles, 4453 were retained for more detailed review. Of these 453,

following review of the abstract, 114 were retained and reviewed by two reviewers. A review of the full articles resulted in the exclusion of 89 articles and the retention of 25 for final synthesis. The selected 25 articles covered 24 studies in total and were the subject for the full review (figure 5).

Figure 5: Stages of article selection – PRISMA flow chart (Moher et al, 2009; CRD, 2009).



3.5.1 Data extraction.

For each study, data was extracted and summarised on data extraction sheets, produced separately for the qualitative and quantitative studies (table 5; page 64). This process was undertaken by the researcher and again checked for accuracy. The data extracted was the author, year of publication and the location of the study. The design of the study was summarised, including the duration of the study and the frequency of data collection. Participant information of interest included sample size, participant age (range where available) and participant gender. The outcome measures of interest for each study were recorded and a brief summary of the results recorded. In order to provide a clear overview, thorough analysis and complete review of the selected studies, the Critical Appraisal Skills Programme (CASP, 2010) to the critical analysis of literature was applied to ensure the quality, validity and relevance of the information sourced. Finally any study limitations and ethical approval status were recorded along with the quality score (QS) discussed earlier (Hawker et al, 2002).

3.5.2 Quality assessment.

Appraisal of the quality of quantitative studies, generally RCTs, within systematic reviews is well established; indeed Moher et al (1995) identified 34 such tools in 1995, a total which is ever increasing and includes tools recommended by CRD (2009), CASP (2010) and a domain-based evaluation currently recommended by Cochrane (Higgins and Green, 2011). In terms of the quality appraisal of qualitative studies there remains much debate of the value of such appraisal, although such an approach is, on the whole, encouraged (Goldsmith et al, 2007; Mays et al, 2005; CRD, 2009; Higgins & Green, 2011). Where a review involves 'disparate data' from differing research methods (Hawker et al, 2002; page 1291), quality appraisal potentially becomes much more complicated. In response to this, Hawker et al (2002) developed a framework to assess the quality of incongruent studies, whilst acknowledging that some would question whether qualitative and

quantitative studies could be reviewed against the same criteria. The subsequent scoring system (Hawker et al, 2002) was based around similar scoring systems, such as an earlier CASP tool (1998) (CASP, 2010) and sets out to provide an explicit indication of the strengths and weaknesses of each of the studies included in a review. In view of its simplicity, the Hawker et al (2002) was selected as the tool of choice to assess the quality of both the qualitative and quantitative studies included in this review, thus providing an overall impression of study quality irrespective of method. Since the application of such a generic approach is potentially contentious (Dixon-Woods et al, 2004), no studies were excluded as a result of their score but such scores were taken into account during the data synthesis.

The Hawker et al (2002) system provides a summed score for nine aspects of study reporting including study methodology, each rated from 10 (very poor), 20 (poor), 30 (fair) and 40 (good). Scores are summed and evaluated in terms of Hawker et al (2002) guidelines: with scores of less than 90 deemed to indicate the study was of very poor quality; scores of 90-180 deemed to indicate poor quality; scores of 180-270 deemed of fair quality and 270-360 indicated good quality (Hawker et al, 2002).

The elements of reporting assessed for each publication were the abstract and title, introduction and aims, method and data, sampling, data analysis, ethics and bias, findings/results, transferability/generalisability and implications and usefulness. Full details of the assessment and scores for each of the elements are provided in appendix 2; however, the studies included in the review ranged from none of very poor quality, four of poor quality, six of fair quality and 14 of good quality with scores displayed in table 4 overleaf.

Table 4: Quality appraisal scores (chronological order).

Author & year	Total Score (Range: 90-360)
Lindholm et al (1993)	240 (F)
Charles, H. (1995)	170 (P)
Walshe, C. (1995)	330 (G)
Bland, M. (1996)	130 (P)
Chase et al (1997)	240 (F)
Franks, P.J. & Moffatt, C. (1998)	310 (G)
Hyde et al (1999)	280 (G)
Chase et al (2000)	230 (F)
Douglas, V. (2001)	270 (G)
Ebbeskog, B. & Ekman, S. (2001)	320 (G)
Franks, P.J. & Moffatt, C. (2001)	330 (G)
Wissing et al (2002)	230 (F)
Franks, P. J. et al (2003)	310 (G)
Rich, A. & McLachlan, L. (2003)	340 (G)
Charles, H. (2004)	230 (F)
Hopkins, A. (2004)	270 (G)
Jull et al (2004)	330 (G)
Brown, A. (2005 a, b)	290 (G)
Yamada, B. & Santos, V. (2005)	180 (P)
Franks et al (2006)	350 (G)
Heinan et al (2006)	340 (G)
Furtado et al (2008)	320 (G)
Byrne, O. & Kelly, M. (2010)	160 (P)
Faria, E. et al (2011)	250 (F)

Table 5: Detail of included qualitative studies (11):

Author, year & location	Design of study	Participant characteristics	Outcome measure	Results	Limitations & ethical approval
Bland, M. (1996) New Zealand	Heideggerian phenomenology Single interview	n=9 Gender: 5 male Age: 56-81 years Aetiology not defined	Loosely structured interviews to explore the personal experience of condition.	Themes included: 1) impact on life; 2) pain, odour, infection & exudate were constant issues; 3) rest; 4) compliance issues mentioned.	Lacks study detail. Ulcer aetiology stated. Ethical approval not documented. QS: 130
Brown, A. (2005 a, b) UK	Phenomenology Single interview	n=8 Gender not defined Age: Over 65 All of venous aetiology	To explore the social impact of living with a leg ulcer.	Three themes: 1) pain; 2) social disconnectedness; 3) coping.	Age range not defined. Gender is not stated. Ethical approval is documented. QS: 290
Byrne, O. & Kelly, M. (2010) ROI	Heideggerian, hermeneutic phenomenology Single interview	n=12 Gender not defined Age: Older people All of venous aetiology	To explore the lived experience of venous leg ulceration.	Four themes: 1) physical; 2) psychological; 3) social experience; 4) the experience of the therapeutic relationship.	Age range not defined. Gender not stated. Ethical approval not stated. QS: 160
Charles, H. (1995) UK	Phenomenology Single interview	n=4 Gender: 3 male Age: 43-62 years All of venous aetiology	To explore the effects of ulceration on the patient's life.	Three themes: 1) physical; 2) psychological; 3) social areas all suffered negative effects.	Ethical approval stated. QS: 170
Chase et al (1997) USA	Phenomenology Single interview with 12 month review	n=7 Gender not defined Age: no detail All of venous aetiology	To explore the experience of leg ulceration.	Four themes: 1) a forever healing process; 2) limits & accommodations; 3) powerlessness; 4) who cares?	Focus on mobile, clinic attenders. No age or gender detail. Ethical approval not stated. QS: 240
Douglas, V. (2001) UK	Qualitative grounded theory Single interview	n=8 Gender: 2 male Age: 65-94 years All of venous aetiology	To explore the patients' experiences of leg ulceration.	Five categories: 1) HCP & patient relationship; 2) physical experience; 3) loss of control; 4) vision of the future; 5) carers' perspective	Change of interview criteria – working or lived with carer. Ethical approval not stated. QS: 270
Ebbeskog, B. & Ekman, S. (2001) Sweden	Phenomenological-hermeneutical approach Single interview	n=15 Gender: 3 men Age: 74-89 years All of venous aetiology	To explore the meaning of the lived experience of leg ulceration.	Four themes: 1) emotional consequences of altered body image; 2) living a restricted life; 3) achievement of well-being with a painful wound & bandages & 4) struggle between hope & despair with regard length of healing process.	Female dominance Consent stated but not ethical approval. QS: 320

Hopkins, A. (2004) UK	Hermeneutic phenomenology Single interview & diary completion over 2 weeks	n= 5 Gender: 4 male Age: 47-78 years All of venous aetiology	To explore what it is like to live with a non-healing ulcer.	Four themes: 1) biographical disruption, 2) ways of coping, 3) social implications; 4) therapeutic relationships.	Participants known to researcher. Ethics approval stated. QS: 270
Hyde et al (1999) Aus	Qualitative descriptive study 1 hour interview & 30 min follow up to verify themes	n=12 Gender: all female Age range: 70-93 years Aetiology not defined	To gain an insight into the lives of older women living with leg ulcers.	Two themes: 1) gaining and maintaining control over vulnerable limbs: 2) lifestyle consequences of ulcers & mobility.	Female focus. Ethical approval not stated. QS: 280
Rich, A. & McLachlan, L. (2003) UK	Phenomenology. Single interview	n=8 Gender: 3 male Age: 55-89 years All of venous aetiology	To explore patients' experiences of living with a leg ulcer.	Four themes: 1) symptoms; 2) treatment; 3) perceptions, emotions & coping strategies; 4) restrictions.	Researcher known to patients. Ethics approval stated. QS: 340
Walshe, C. (1995) UK	Phenomenology One occasion	n=13 Gender: 1 male Age: elderly All of venous aetiology	To describe the experience of living with a leg ulcer.	Four themes: 1) symptoms; 2) description of treatment; 3) restrictions caused by ulceration; 4) perceptions of & coping with ulceration.	Age range not defined. Ethics approval stated. QS: 330

Detail of include quantitative studies (13):

Author, year & country	Design of study	Participant characteristics	Outcome measures	Results	Limitations & ethical approval
Charles, H. (2004) UK	Prospective quantitative review 12 weeks duration with data collected at start & end	n=65 Gender: 43% male Age: Median 72 years Aetiology not defined	SF-36 used to compare health domains with AEN at start & 12 weeks whether healed or not.	SF-36 & compared to AEN (where available) gave lower scores in CVLU patients. Significant improvement in all SF36 domains for all patients over 12 weeks. Where healed showed statistically significant improvement in the vitality domain. Where healing did not occur also showed some improvement.	Not all AEN available. Age range detail not available. Consent stated but not ethics. QS: 230
Chase et al (2000) USA	Quantitative descriptive study SF-36 on single occasion	n=21 Gender: 3 men Age: 39-73 years All of venous aetiology	SF-36 to compare functional health status to US AEN	Preliminary assessment of knowledge & functional status of CVLU patients demonstrated that limitations in physical function & vitality were moderate to severe.	Small sample Consent stated but not ethics. QS: 230

Faria, E. et al (2011) Brazil	Quantitative study Single completion of SF36	n=160 Gender: 30% male Age: 46-85 years All of venous aetiology	SF-36, self-esteem & Stanford questionnaire on one occasion to assess HRQoL, self-esteem & functional status of CVLU patients	All SF-36 domains received low scores for CVLU patients. Self-esteem scores were the same as control. Stanford questionnaire (HAQ-20) revealed negative impact of CVLU on functional status.	Single occasion. Clinic patients. Ethics approval stated. QS:250
Franks, P.J. & Moffatt, C.J. (2006) UK	Cross sectional quantitative study Single completion of NHP questionnaire	n=758 Gender: 272 male Age: 74.6 Venous: 66%	Nottingham health profile (NHP) to cross section compared to AEN. (2006 – secondary analysis).	Scores indicated poorer health for CVLU patients, esp. mobility, pain & energy. Less pain & better sleep quality for those seen at DN clinic. Greater impairment was revealed for male & younger age groups respondents. Large & long duration ulceration leads to poorer HRQoL. Nurse led clinic patients had better HRQoL.	Single completion. Ethics approval not stated. QS: 310
Franks., P.J. & Moffatt, C. (2001) UK	Quantitative study 12 week study, data collected at start & end with NHP	N=383 Gender: 37% male Age: median 74 years All of venous aetiology	To evaluate the responsiveness of NHP (and compare to Walters et al (1999) results with the SF-36)	Improvements in all dimensions for NHP. Study authors argue that the NHP may be better tool for use with this group of patients.	Complex comparison. Self-completion. Ethics approval not stated. QS: 330
Franks, P.J., McCullagh, L. & Moffatt, C.J. (2003) UK	Prospective quantitative study SF36 start & 12 weeks.	n=118 Gender: 27% male Age: mean 78 years Aetiology not defined	Interview and SF-36 recorded at baseline & 12 weeks to assess QoL in LU patients	HRQoL worse LU patients compared AEN. Improvement in results when ulcer healed, especially bodily pain. Statistical difference between those with healed and non-healed ulcers for bodily pain and mental health.	Short duration. Ethics approval not stated. QS: 310
Franks et al (2006) UK	Cross sectional quantitative study NHP start, 24 and 48 weeks	n=95 Gender: 35 male Age: median age 76 years Venous, mixed, diabetic & multifactorial aetiology.	NHP to review longer term improvement in symptoms.	Improvements overall but esp. in pain, energy over 24 weeks. QoL improvement not maintained at 48 weeks. Pain & mobility improvement reduced compared baseline & 24 weeks. Positive effects of treatment on HRQoL may not be sustained over time.	Ethics approval stated. QS: 350
Furtado et al (2008) Portugal	Cross sectional quantitative study NHP, EQ & VAS at baseline & 12 weeks	98 at baseline / 68 FU at 12 weeks (37% male) Age: Mean age 71.9 (SD 10.6) Aetiology: ND	Examine impact of CVLU on HRQoL in Portugal.	Higher NHP scores for all compared AEN. Improved over 12 weeks both NHP & EQ. Treatment improves pain but not in other areas. Energy & social isolation improved in patients who healed.	Ethics approval not stated. QS: 320

Heinan et al (2006) Netherlands	Descriptive, cross-sectional quantitative study with interview & questionnaire.	n=141 Gender: 37% male Age: 29-92 years Venous 50%	To describe leg ulcer issues for patients.	Main issues identified were pain, outdoor mobility, footwear. No difference VLU & mixed aetiology.	Venous & mixed aetiology. Outpatient sample. Ethics approval stated. QS: 340
Jull et al (2004) NZ	Case control study on one occasion comparing SF-36 scores to AEN	n=465 Gender: 41% male Age: mean age 75 years Aetiology not defined	To quantify the effect of leg ulceration on HRQoL.	Leg ulcers reduce QoL comparably to other long term conditions in all 8 domains of SF36	NZ AEN used. Modest response rate. Ethics approval stated. QS: 330
Lindholm et al (1993) Sweden	Postal survey questionnaire using the NHP on one occasion	n=125 Gender: 51 male Age: range 36-93 years All aetiologies	To explore the impact of CVLU on QoL	Higher score demonstrating increased impact for men. Also shop workers & longer duration of ulceration.	No comparison to AEN. Gender comparisons made. Consent detailed but not ethical approval. QS: 240
Wissing et al (2002) Sweden	Quantitative study Philadelphia Geriatric Center Multilevel Assessment Instrument PGCMAL on one occasion	n=144 Gender: 44 Age: mean 79 years Aetiology not defined	To compare life situation of ulcer patients to those without.	CVLU patients had lower mean value in all domains of physical health, ADL, cognition, time use & social behaviour, personal adjustment & environmental quality than those without.	Questionable relevance due to location of study. New questionnaire. Ethics approval stated. QS: 230
Yamada, B. & de Gouveia Santos, V. (2005) Brazil	Correlational descriptive, exploratory, cross-sectional study Interviews using the generic version of Ferrans & Powers QoL Index (QLI) adapted for Brazilians on one occasion	n=89 Gender: 28 male Age: 25-84 years Venous: 100%	Analyse QoL of individuals with CVLU in Brazil.	Applied the QLI instrument. Patients with VLUs showed good levels of QoL mainly in family & psychological/spiritual subscales – contradicts other studies demonstrated scores indicative of good & very good QoL in VLU.	Transferability of results. Contradictory findings. Ethics approval not stated. QS: 170

3.6 Overview of articles in the final review.

Due to the different approaches adopted and the diversity of reporting approaches in the included studies, these have been split in respect of their methodology. This approach is common to ensure the clarity of synthesis (Booth et al, 2012).

3.6.1 Characteristics of qualitative studies.

Eleven qualitative studies, published between 1995 and 2010, were selected for inclusion within the review. One study was reported in two papers (Brown, 2005 a&b). These studies represented the views of 106 participants. Where gender was specified (8 studies containing 74 of the total study participants; Charles, 1995; Walshe, 1995; Bland, 1996; Hyde et al, 1999; Douglas, 2001; Ebbeskog & Ekman, 2001a; Rich & Lachlan, 2003; Hopkins, 2004), 53 of these (68%) were female. Study participants were aged between 43 - 94 years and were located across three continents; Europe, North America and Australia. Study sample sizes ranged from 4 – 15, with the median number of participants being eight. Quality scores for study reporting ranged from three studies rated as poor (Charles, 1995; Bland, 1996; Byrne & Kelly, 2010), one study rated as fair (Chase et al, 1997) and seven rated as of good quality (Walshe, 1995; Hyde at al, 1999; Douglas, 2001; Ebbeskog & Ekman, 2001a; Rich & McLachlan, 2003; Hopkins, 2004; Brown, 2005a & b) (Hawker et al, 2002).

3.6.2 Characteristics from quantitative studies.

Thirteen quantitative studies, published between 1993 and 2012, were retained for inclusion in the review. These represented the views of 2634 participants, of which approximately 1563 (59%) were female. Study participants were between 25 - 92 years of age and were located across four

continents: North America, South America, Europe and Australia. Study sample sizes ranged from 21 – 758, with the median number of participants being 141. Quality scores for study reporting ranged from one study rated as poor (Yamada & Gouveia Santos, 2005), five rated as fair (Lindholm et al, 1993; Chase et al, 2000; Wissing et al, 2002; Charles, 2004; Faria et al, 2011) and seven rated as of good quality (Franks & Moffatt, 1998 & 2001; Jull et al, 2004; Franks et al, 2003; Franks et al, 2006; Heenan et al, 2007; Furtado et al, 2008).

3.7 Methods of Synthesis.

The value of any review, according to Booth et al (2012), lies not only in the search and selection of studies but in the synthesis of the evidence that is extracted, leading to new explanations or to strengthen our understanding. For the purpose of this review, the qualitative and quantitative studies were synthesised separately in order to ensure clarity; a process that commenced with data extraction and the completion of the summary table (table 4; page 63 - 67) (Booth et al, 2012).

The synthesis of the qualitative studies involved a process of thematic synthesis (Thomas et al, 2004) whereby the findings of multiple studies were coded, integrated and then grouped into themes. As a result, consistency of review technique was maintained across the studies and themes that enhance our understanding of the quality of life and leg ulceration were identified and thoroughly explored (Briggs, 2009; Booth et al, 2012).

The synthesis of the quantitative studies has similarly involved a narrative thematic synthesis and a meta-analysis where heterogeneity allowed (page 81) (Booth et al, 2012). For clarity, studies have

been grouped according to the main QoL instrument that was applied (SF36, NHP, etc), thus enabling comparisons of the reported themes to be more clearly reported.

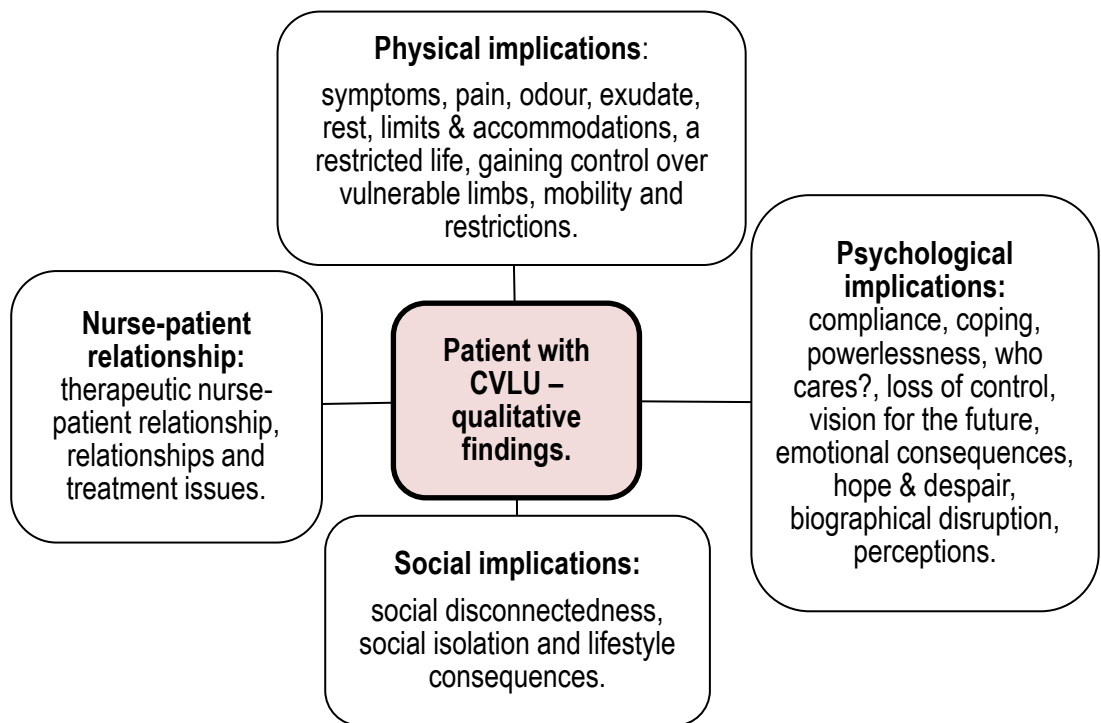
3.8 Results of qualitative studies.

The eleven qualitative studies reviewed combined their findings into a total of 41 subthemes. For the purpose of this narrative synthesis these 41 themes have been incorporated into the four overarching themes as a preliminary stage of the analysis using a process of thematic analysis (CRD, 2009). The four themes were:

- 1) The physical implications of CVLU;
- 2) The psychological implications of CVLU;
- 3) The social implications of CVLU;
- 4) The nurse-patient relationship.

Each of the themes also contained a number of related subthemes, which have been displayed in diagrammatic form in figure 6 below.

Figure 6: Thematic map of qualitative themes.



3.8.1 Physical Implications.

3.8.1.1 Pain.

Pain was the dominant theme reported consistently across all eleven of the qualitative studies. Pain was described as significant (Bland, 1996; Rich & McLachlan, 2003; Brown, 2005b); indeed, it was referred to as the worst symptom and the cause of enormous suffering. In Byrne and Kelly's (2010) study, one respondent commented on the severity of their pain, stating:

"Oh severe ache of a pain, as if you were jamming it with a knife all the time...." (Byrne & Kelly, 2010; p. 48)

Pain was overwhelming, continuous and unrelenting; it had profound effects, impacting on sleep, mobility and almost every other area of day-to-day functioning and was exacerbated by dressings and treatment regimens (Charles, 1995; Walshe, 1995; Hyde et al, 1999; Douglas, 2001). Pain, for some participants, was their 'constant companion', persistently reminding them of the unremitting nature of their ulceration (Walshe, 1995; Hopkins, 2004). Pain was central to the life of participants, it controlled their existence and made them sad, angry and 'to cry in despair' (Ebbeskog & Ekman, 2001; page 239).

The control of pain was also problematic and highlighted specifically in four of the studies (Walshe, 1995; Bland, 1996; Douglas, 2001; Byrne & Kelly, 2010); respondents disclosed that they often under-reported their pain and were reluctant to take analgesia which was often deemed to be ineffective against ulcer related pain. Pain management was felt to be an area of care that was frequently inadequately managed (Rich & McLachlan, 2003).

3.8.1.2 Exudate and Odour.

Eight of the eleven studies referred to issues with leakage from the wound and malodour (Walshe, 1995; Bland, 1996; Hyde et al, 1999; Douglas, 2001; Ebbeskog & Ekman, 2001a; Rich & McLachlan, 2003; Hopkins, 2004; Byrne & Kelly, 2010). Participants reported profuse exudate, which was unbearable and devastating (Rich & McLachlan, 2003). Dressings leaked regularly which caused distress and shame; exacerbated by the unpredictable nature of such episodes (Byrne & Kelly, 2010). There were reports of wet shoes, wet bedding and concerns of what people might think (Douglas, 2001). Where leakage was associated with malodour, the impact was even greater and the symptoms were often inadequately managed. These symptoms were of particular concern and

had an even greater impact when the patient was working (Hyde et al, 1999). Participants felt that mechanisms to manage exudate and odour were consistently inadequate, with the odour being described as the worst thing associated with ulceration (Walshe, 1995; Bland, 1996; Hopkins, 2004). For one study participant,

“It was an embarrassment. No matter where I went, people – you could see them moving away – because of the smell.” (Bland, 1996, p.13)

The leakage and odour resulted in limitations to social contacts, self-consciousness and a feeling that matters that should remain private had somehow become public with efforts to improve symptoms most often proving to be inadequate (Walshe, 1995; Chase et al, 1997).

3.8.1.3 Mobility and daily living.

Six of the studies referred to mobility issues (Walshe, 1995; Chase et al, 1997; Douglas, 2001; Ebbeskog & Ekman, 2001a; Brown, 2005b; Byrne & Kelly, 2010). For many respondents mobility was constrained, most often as a result of ulcer related pain, wound leakage and bandages (Walshe, 1995; Chase et al, 1997; Hyde et al, 1999; Douglas, 2001; Ebbeskog & Ekman, 2001a). Many were virtually housebound (Walshe, 1995), unable to work and to socialise; issues that were further limited by fears of falling and sustaining additional injuries (Brown, 2005b). These limitations were viewed with a sense of loss and resignation (Byrne & Kelly, 2010).

3.8.1.4 Sleep.

Sleep disturbances were a prevailing feature in six of the studies reviewed and was most often attributed to ulcer-related pain, which negatively impacted on well-being (Charles, 1995; Walshe,

1995; Douglas, 2001; Ebbeskog & Ekman, 2001a; Rich & McLachlan, 2003; Byrne & Kelly, 2010). Participants reported that it was rare to experience a full night of sleep, leading to daytime tiredness and a lack of strength and energy (Ebbeskog & Ekman, 2001b).

A number of other areas of physical functioning were restricted due to ulceration. There were difficulties in maintaining personal hygiene, raised in five of the studies, which further impacted on perceptions of well-being and contributed to social isolation (Walshe, 1995; Bland, 1996; Douglas, 2001; Ebbeskog & Ekman, 2001a; Rich & McLachlan, 2003). Respondents also reported not having their feet washed for long periods (Walshe, 1995; Bland, 1996; Chase et al, 1997; Ebbeskog & Ekman, 2001a), resulting in worries about odour that further exacerbated their social isolation.

Five of the studies explored issues relating to sourcing adequate, comfortable footwear and suitable clothing which would effectively conceal the dressings (Chase et al, 1997; Hyde et al, 1999; Ebbeskog & Ekman, 2001a; Rich & McLachlan, 2003; Hopkins, 2004). Hyde et al (1999), in their study of female participants, found respondents had to modify clothing to conceal their ulceration and referred to the limitations of choices of clothing as yet another restriction to their personal style and erosion to their femininity.

3.8.2 Social Implications.

All eleven studies made reference to the major impact CVLU has on social life, often as a result of wound leakage and any associated odour (Hyde et al, 1999; Ebbeskog & Ekman, 2001a; Hopkins, 2004). Some participants reflected on a desire not to subject those close to them to the effects of the

exude and voluntarily excluded themselves from engaging in social activity due to their fear of how people might react to them (Ebbeskog and Ekman, 2001a; Hopkins, 2004). Private things had been moved into the public domain was the response of participants (Hopkins, 2004) and, as a result of these concerns, sufferers reported that they would voluntarily exclude themselves from society, in an attempt to avoid the associated embarrassment (Rich & McLachlan, 2003).

Hyde et al (1999) reported a self-inflicted social isolation as an attempt to limit further damage to legs and to prevent ulcer recurrence. Patients spoke of looking forward to an end of ulceration so that they could initiate social interaction again; the time with ulcers was referred to as 'wasted days' (Walshe, 1994; Chase et al, 1997; Ebbeskog & Ekman, 2001a). Brown (2005b) referred to this social disconnectedness as being

"...on the inside, looking out" (Brown, 2005b; p. 986),

of being separate from everyday society, almost an introverted and closed life of social isolation (Hyde et al, 1999; Byrne & Kelly, 2010).

For some, their ulcers limited their ability to work (Charles, 1995; Bland, 1996); one gentleman reported having to finish working due to his ulcer, a situation he was resigned to, but felt that the ulcer had cost him his freedom and his livelihood (Chase et al, 1997). A gentleman in Bland's study (1996) reflected on concerns regarding job security due to extended and recurrent periods of sick time due to his ulceration.

3.8.3 Psychological Implications.

All eleven studies commented on the psychological implications of living with CVLU. Hopkins (2004) explains a concept of 'biographical disruption', whereby a clear distinction was perceived distinguishing life before and after ulceration, with a marked effect on their physical and social activity. Participants had feelings of loss but, despite this, many studies revealed that there was also hope for the future (Bland, 1996; Ebbeskog & Ekman, 2001a; Hopkins, 2004). This disparity between hope and expectations was seen as an important part of coping with the condition (Ebbeskog & Ekman, 2001a; Rich & McLachlan, 2003). Hyde et al (1999) reported an inner strength held by participants, a determination to cope, stoicism, resilience and hope for the future and healing.

Participants were preoccupied with their ulcers and constantly thought about them (Walshe, 1995). For some, in order to cope, there was an intentional normalisation of the ulcer, an attempt to bracket it off in an effort to live a normal life (Hopkins, 2004). Some had difficulties with self-image, feelings of disgust towards themselves and pessimism in relation to the likelihood of healing were reported (Walshe, 1995). Chase et al (1997) described the lengthy healing process as a 'forever healing', with the chronic nature of the wounds impacting on the sufferers daily living and making them want to hide their bodies. For many a role reversal had occurred, between the ulcer sufferer and their family, with those who had previously been the head of the family now being dependent on other members for help and support (Douglas, 2001).

3.8.4 Nurse-patient relationship.

Nine of the studies reported that the role of the DN was significant to the patient (Charles, 1995; Walshe, 1995; Bland, 1996; Chase et al, 1997; Douglas, 2001; Rich & McLachlan, 2003; Hopkins, 2004; Brown, 2005b; Byrne & Kelly, 2010) reflected on as one of the only positive aspects of CVLU, with reports of nurses going beyond the necessity of their visits and enjoying a 'laugh and a joke' (Walshe, 1995; Chase et al, 1997; Hopkins, 2004). Participants were confident in their nurses' ability. Some studies reported inconsistencies in and dissatisfaction with the care provided by nurses, especially temporary or agency nurses – the continuity of the nurse was paramount; some even complained of time wasted whilst they waited for nurse visits (Charles, 1995; Chase et al, 1997; Brown, 2005b; Byrne & Kelly, 2010). In spite of this, participants remained grateful and trusted in their nursing staff (Hyde et al, 1999; Douglas, 2001; Rich & McLachlan, 2003). Studies, however, revealed an overall lack of understanding of the underlying causes and treatment of ulceration, which served to exacerbate feelings of powerlessness and may have resulted in some compliance issues (Chase et al, 1997; Douglas, 2001). In spite of these factors, patients were grateful for the care provided, especially for the personal characteristics of the nurses.

3.9 Results of quantitative studies.

The thirteen quantitative studies reviewed combined a number of established generic HRQoL instruments. Five studies applied the Short Form 36 (Ware & Sherbourne, 1992) and five applied the Nottingham Health Profile (NHP) (Hunt et al, 1986), occasionally in combination with other instruments. The remaining three studies utilised a combination of other instruments including; the Sickness Impact Profile (de Bruin, 1996), Cantril's ladder of life (Cantril, 1965), the Barthel index (Mahoney & Barthell, 1965) and the subjective sleep quality scale (Cox, 1992; Heinen et al, 2007);

the Philadelphia geriatric center multilevel assessment (Wissing et al, 2002); Ferrans and Powers QoL index (1985) (Yamada & de Gouveia Santos, 2005) and Freiburg life quality assessment for wounds (Herberger et al, 2011). Meta-analysis has been undertaken where the heterogeneity of studies have allowed (page 85); otherwise synthesis has been purely narrative.

3.9.1 Studies using the SF-36

The Short Form – 36 is a generic health survey that provides QoL information and is designed for self-completion (Ware & Sherbourne, 1992). It is possibly the most widely evaluated tool and has proven validity and reliability (Garratt et al, 2002). Completion produces a range of scores across eight domains with lower scores indicating more limited functioning in that area; in contrast to the scoring range of the NHP. Five of the selected studies used the SF-36 in order to evaluate the QoL of their participants with CVLU (Charles, 1995; Chase et al, 2000; Franks et al, 2003; Jull et al, 2004; Faria et al, 2011). The studies range over a period of 16 years (1995 – 2011) and include a total sample size of 829 participants. Two studies (Franks et al, 2003; Jull et al, 2004) utilised a control group in order to demonstrate comparisons, whereas the remaining three studies used Age Equivalent Norms (AEN) of various origins (other studies, gender or country specific). A meta-analysis of three studies has been possible (Charles, 1995; Franks et al, 2003; Jull et al, 2004).

Scores are recorded in table 6 overleaf. The range of control and AEN scores show considerable variation but still serve to demonstrate the consistently lower scores, and hence compromised QoL, across all domains for the participants with CVLU. In some of the more recent studies composite scores were calculated to indicate overall physical and mental component scoring (PCS and MCS), however since these were not available for four of the selected studies they have not been utilised.

Two of the studies (Charles, 1995; Franks et al, 2003) recoded SF-36 scores at entry to the study and after 12 weeks in order to observe for improvements over time and with healing. The remaining three studies applied the SF-36 on a single occasion.

Table 6: SF-36 Mean domain scores.

	Charles (1995)			Chase et al (2000)		Franks et al (2003)			Jull et al (2004)		Faria et al (2011)	
SF-36 Domains	Entry	Exit	AEN	Study	AEN	Entry	Exit	Control	Study	Control	Study	Control
Physical function	44.3	45.1	59.0	56.2	84.2	29.1	31.1	50.7	49.5	75.7	48.68	80.06
Role-physical	35.4	38.5	54.0	67.9	81.0	41.8	40.3	63.0	43.2	72.7	22.5	75.31
Bodily pain	45.0	61.8	60.0	75.5	75.2	53.9	56.0	65.5	55.3	72.9	57.81	72.29
General Health	61.9	61.4	58.0	72.7	72.0	55.3	54.4	58.2	59.2	73.5	66.18	73.13
Vitality	44.8	49.4	60.0	50.0	69.9	45.9	45.9	48.7	53.2	67.6	59.37	70.75
Social functioning	49.7	59.8	76.0	83.9	83.3	57.3	55.6	78.6	69.9	87.6	56.25	81.60
Role-emotional	44.6	52.3	73.0	81.0	81.3	58.1	59.5	84.9	68.9	85.3	41.61	80.34
Mental health	62.5	68.1	68.0	80.0	74.1	69.1	67.5	73.2	76.2	82.2	64.9	71.94

Physical functioning explored limitations to performing physical activities such as washing and dressing and was limited across all five of the included studies, with mean scores being consistently below their comparators; this was also the case where scoring had been repeated at 12 weeks and even in the event of healing (Charles, 1995; Franks et al, 2003). The role-physical domain refers to problems working or with other daily activities due to physical health and was diminished across all

studies. Bodily pain refers to extremely debilitating pain and was significant for all participants across four of the five studies, with the exception of Chase et al (2000).

Where the study was conducted over 12 weeks, improvements in bodily pain were demonstrated irrespective of healing. General health was the least compromised of the eight health domains; indeed Charles (1995) and Chase et al (2000) demonstrated improved scores for their participants when compared with the AENs selected. General health was most compromised for the participants of Jull et al's (2004) study, which demonstrated a mean 14 points below their selected AEN. The vitality score represents energy levels for the respondents. Vitality was compromised for participants in all studies, to varying degrees, which reflects consistently reduced energy reserves for this client group.

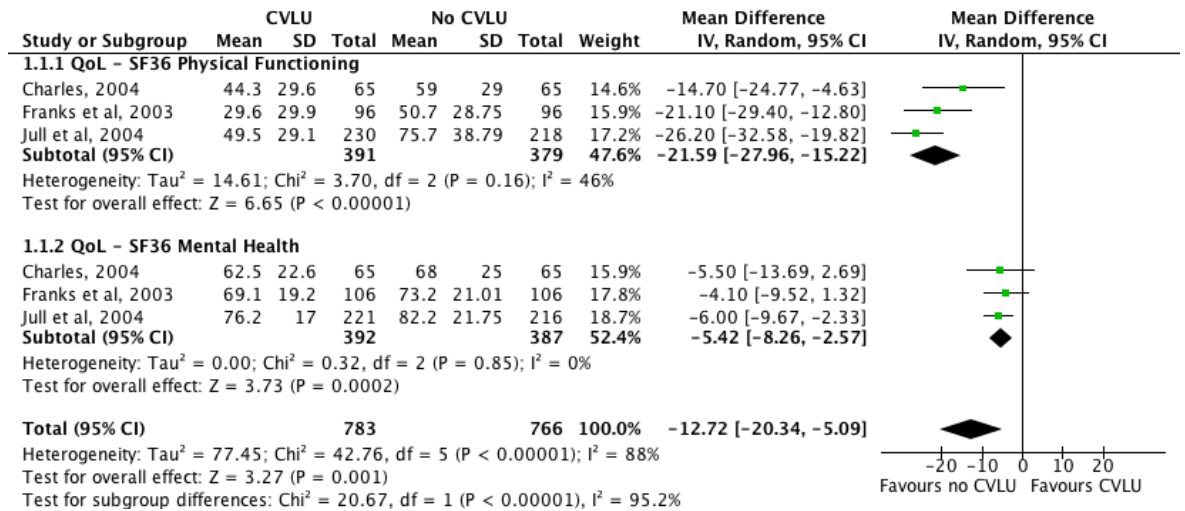
Social functioning reflects health interfering with the participant's ability to socialise as they would like and was reduced for the participants of four of the studies. Chase et al (2000) was the only study that demonstrated higher scores for their respondents in the social functioning domain than their AEN. Role-emotional scores explore limitations to daily physical functioning due to the emotional effects of their illness and were compromised for all; again with Chase et al (2000) demonstrating the least compromised compared to their AEN. The final domain, mental health, explores feelings of nervousness and depression and in four of the five studies was compromised, with Chase et al (2000) again being the exception. Charles (1995) demonstrated an improvement in mental health over the 12 weeks of her study with the final score being above her AEN. In contrast, Franks et al (2003) demonstrated a reduction in the mental health score indicating deteriorating function over the 12 weeks of their study.

Overall, all five studies demonstrate reduced functioning across all eight domains and thus compromised QoL for those patients with CVLU. Improved care delivery and even healing did not consistently improve functioning that reflects the recurring and debilitating nature of this condition. Jull et al (2004) proposed that CVLU compromised health states in all areas by approximately 10%, effectively reflecting their compromised health state with this condition (Faria et al, 2011).

3.9.1.1 Meta-analysis of SF-36 scores for physical functioning and mental health.

A meta-analysis refers to a statistical 'pooling' of data to allow for scores from a number of studies to be compared and contrasted in order to ascertain similarities or differences (Booth et al, 2012). In order for a meta-analysis to be undertaken, the studies need to be homogenous in terms of population, exposure, comparator and outcome (PECO) (NCCMT, 2012). For the quantitative studies reviewed here, only three demonstrated sufficient similarity in the reporting of data to be included in a meta-analysis (Charles, 1995; Franks et al, 2003; Jull et al, 2004). Review Manager 5.2, a computer package developed by the Cochrane Collaboration was utilised to undertake the meta-analysis (RevMan, 2012), with the output demonstrated in figure 7 overleaf.

Figure 7: Forest plot for SF36 Physical Functioning and Mental Health scores.



3.9.1.2 SF-36 QoL – Physical Functioning.

There were three studies in this analysis. The pooled mean difference for QoL physical functioning was -21.59 (95% CI: -27.96 to -15.22; $p < 0.00001$). Therefore, QoL physical functioning was 21.59 lower in people with CVLU than those without and this effect was statistically significant at the $p < 0.05$ level. There was moderate heterogeneity between the studies ($I^2 = 46\%$; $p = 0.16$). All three studies had a lower mean QoL physical functioning in the CVLU patients than in those without ulcers, but the magnitude of this effect varied between studies.

3.9.1.3 SF-36 QoL – Mental Health.

There were three studies in this analysis. The pooled mean difference for QoL mental health was -5.42 (95% CI: -8.26 to -2.57; $p = 0.0002$). Therefore, QoL mental health was 5.42 lower in people with CVLU than those without and this effect was statistically significant at the $p < 0.05$ level. There was

low heterogeneity between the studies ($I^2 = 0\%$; $p = 0.85$). All three studies had a lower mean QoL mental health in the CVLU patients than in those without ulcers, but the magnitude of this effect varied between studies.

3.9.1.4 Meta-analysis results overall.

Taking two outcomes for these three studies, demonstrated that the pooled mean difference for QoL in these areas was -12.72 (95% CI: -20.34 to -5.09; $p = 0.001$). Therefore, both QoL physical functioning and mental health was 12.72 lower in people with CVLU than those without and this effect was statistically significant at the $p < 0.05$ level. Overall, when these two outcomes were combined, there was high heterogeneity between the studies ($I^2 = 88\%$; $p < 0.000001$), however all three studies had lower mean QoL physical functioning and mental health scores in the CVLU patients than in those without ulcers, but the magnitude of this effect varied between studies.

This meta-analysis demonstrates a consistently lower mean score, and thus diminished QoL, for patients with CVLU when compared to those without ulceration on review of SF36 completion (Ware & Sherbourne, 1992) across these three studies (Charles, 1995; Franks et al, 2003; Jull et al, 2004). Such meta-analysis strengthens individual study results and represents the combined responses of 779 participants.

3.9.2 Studies using the Nottingham Health Profile.

The NHP (Hunt et al, 1986) is a generic quality of life survey that is used to evaluate subjective physical, emotional and social aspects of health of the respondent. It is designed for self-completion with higher scores over the six domains reflecting poorer levels of health and has proven levels reliability and validity (McDowell & Newell, 1996). Five of the fourteen quantitative studies used the NHP to determine the QoL of their participants with CVLU (Lindholm et al, 1993; Franks & Moffatt, 1998, 2001; Franks et al, 2006; Furtado et al, 2008). The studies range over a period of 15 years (1993 – 2008) and include a total sample size of 1459 participants. Two studies (Franks & Moffatt, 1998; Furtado et al, 2008) utilised AENs of various origins (age, gender or location specific) which provide a norm-referenced approach to facilitate the comparison of one individual with another (Hicks, 2004). Two recorded NHP scores at intervals throughout the study (Franks & Moffatt, 2001; Franks et al, 2006) and one of the earlier studies was only reported narratively (Lindholm et al, 1993), without the inclusion of scoring detail and thus scored only a fair quality score (240) (Hawker et al, 2002). This lack of consistency of reporting reflects considerable heterogeneity and has made comparisons difficult to draw, thus meta-analysis has not been possible and the studies have been reported narratively.

Lindholm et al (1993) concluded that CVLU presented a marked impact on subjectively assessed perceived health but failed to present the data on which this assumption was founded. Their analysis of NHP scores recorded on a single occasion was compared with age / sex adjusted norms and distinctions were made related to occupational / class status, although data was not included as evidence in the article. The narrative summary reported higher scores for men in the energy domain compared with the female respondents with CVLU and the general population. Higher pain scores were reported in both male and females participants. Emotion scores were similar for female

respondents compared to the general population but were higher for men. Sleep presented slightly higher scores for women but consistently higher for men. Social isolation was unchanged for the female respondents but the males demonstrated elevated scores. In the area of mobility, female respondents had slightly elevated scores whereas their male counterparts were significantly higher.

Franks and Moffatt (1998; 2001) and Franks et al (2006) conducted a number of studies exploring the QoL of patients with CVLU using the NHP. Only in the 1998 study (Franks & Moffatt, 1998) were scores compared to the general population according to gender, although data was collected on a single occasion. Both the 2001 and 2006 studies (Franks & Moffatt, 2001; Franks et al, 2006) were conducted over an extended period of 12 weeks and 48 weeks respectively. In addition Furtado et al (2008) applied the NHP (table 7 below).

Table 7: NHP Mean domain scores.

	Franks & Moffatt (1998)				Franks & Moffatt (2001)		Franks et al (2006)			Furtado et al (2008)		
NHP Domains	Male	Male AEN	Female	Female AEN	Entry	Week 12	Entry	Week 24	Week 48	Entry	Week 12	AEN
Energy	26.2	21.1	38.1	36.9	29.1	21.9	43.1	36.75	51.84	51.9	56.6	26.1
Bodily pain	28.5	9.5	32.5	21.6	30.8	18.0	31.3	21.7	25.32	61.3	50.8	27.7
Emotion	14.6	11.3	19.8	15.0	14.6	10.6	21.3	19.6	20.27	45.6	41.2	22.7
Sleep	23.8	17.9	31.3	35.2	29.6	20.8	34.3	32.56	28.44	47.3	43.0	33.7
Social isolation	12.0	7.2	14.6	10.6	11.7	8.9	18.9	19.23	19.02	35.4	29.9	21.2
Mobility	28.5	12.6	40.9	27.2	30.7	26.2	41.7	40.77	47.11	50.2	48.2	25.3

Three of the studies (Franks & Moffatt, 1998, 2001; Franks et al, 2006) revealed compromised QoL across all six domains at baseline of the study, with highest scores recorded for mobility, pain and energy. Franks and Moffatt (1998) demonstrated that participants scored considerably higher scores than the age/sex-matched scores available, which indicate poorer perceived health. Scores for women, when analysed, were higher than their male counterparts for energy, emotion, sleep and mobility. Scores were also higher in the younger patients, compared to their older equivalents in all domains.

Franks and Moffatt's (2001) study recorded NHP scores at baseline and after 12 weeks, allowing for analysis where a wound had healed. This analysis demonstrated that where ulcers healed, bodily pain and sleep improved most dramatically. Their later study in 2006 (Franks et al, 2006) recorded NHP scores at baseline, 24 weeks and 48 weeks providing greater scope for comparisons to be drawn. At 24 weeks, pain and energy had improved, irrespective of whether healing had occurred or not but social isolation had increased for all. However, such improvements were not sustained at 48 weeks (Franks et al, 2006) and in some domains scores returned to below those recorded at baseline in the latter stages of the study. Improvements in pain were reduced, energy levels and mobility declined below those recorded at baseline. These three studies (Franks & Moffatt, 1998, 2001; Franks et al, 2006) conclude that CVLU impacts on all areas of QoL when compared to the general population. There is some discrepancy in relation to age and gender effects but domains were limited for all, which implies reduced QoL and poorer functioning.

Furtado et al (2008) applied the NHP along with EuroQoL (EuroQoL Group, 1990) and Visual Analogue Scale (VAS) (Melzack, 1987) at entry to the study and after 12 weeks. The study was based in Portugal and scores were compared these to the Portuguese AEN. Higher scores were

seen for the study participants across all domains compared to the AEN at baseline and 12 weeks, although bodily pain was the only statistically significant result. Improvements were demonstrated over the 12 weeks of the study (Furtado et al, 2008). Where ulcer healing had occurred, improvements were seen in social isolation, sleep and energy when compared with their non-healed counterparts.

Overall, all five studies (Lindholm et al, 1993; Franks & Moffatt, 1998, 2001; Franks et al, 2006; Furtado et al, 2008) that applied the NHP demonstrate reduced functioning across the six domains and thus compromised QoL for those patients with CVLU. There is some variation in reporting in relation to age and gender but all studies conclude limitations attributable to CVLU and, significantly, Franks et al (2006) demonstrate that improvements recorded in the short term (12 week) were not sustained at 48 weeks.

3.9.3 Studies using other instruments.

The remaining three studies used a number of other generic instruments (Wissing et al, 2002; Yamada & de Gouveia Santos, 2005; Heinen et al, 2007) with two of the three similarly concluded that CVLU negatively impacts on QoL (Wissing et al, 2002; Heinen et al, 2007).

Wissing et al (2002) undertook a case control study in Sweden which compared 70 patients with leg ulceration with 74 elderly patients without leg ulceration, although recruitment was not randomised. The questionnaire used was the Philadelphia Geriatric Center Multilevel Assessment Instrument (PGCMAI) which assesses well-being and behavioural competence with low scores indicating

compromised functioning. Participants with CVLU demonstrated lower scores through all domains when compared to the control group. This revealed compromised functioning in physical health, activities of daily living, cognition, time management, social interaction, psychological well-being and environmental quality (Wissing et al, 2002).

Heinen et al (2007) undertook their study across seven hospitals in the Netherlands (n=141) with data collected using interviews, questionnaires and wound assessment. Sampling was not randomised but included all with an open venous or mixed aetiology ulcer who were able to understand the Dutch language. The questionnaires applied included the Sickness Impact Profile (de Bruin, 1996), Cantril's ladder of life (Cantril, 1965), the Barthel index (Mahoney & Barthell, 1965) and the subjective sleep quality scale (Cox, 1992). These were accompanied with interviews and wound observations. Results demonstrated a negative effect of ulcer related problems with pain, mobility and difficulties getting adequate footwear impacting significantly on QoL. Problems with sleep, wound care, daily activities and negative emotions were present as a result of CVLU (Heinen et al, 2007).

Yamada and de Gouveia Santos (2005) undertook their Brazilian study using the generic Ferrans and Powers Quality of Life Index (QLI) (1985) that had been specially translated and adapted for this client group. The study is described as a 'descriptive, exploratory and cross-sectional study' (Yamada & de Gouveia Santos, 2005; page 178) and accessed 89 patients across three public hospitals, although sampling was not randomised. This study was the first report of the application of the QLI to this population and provided results in four subscales; health/functioning, social/economic, psychological/spiritual and family. In complete opposition to other published studies, Yamada & de Gouveia Santos (2005) reported scores above 20 indicating positive QoL for those with CVLUs.

These results are hard to validate since the QLI has not been used either for this group of patients or translated for a Brazilian population prior to this study. This study achieved the only poor rating in terms of the quality score (180) (Hawker et al, 2002) and as such these results must be treated with caution.

3.10 Synthesis of study findings.

All but one of the studies included in this review (Yamada & de Gouveia Santos, 2005), whether qualitative or quantitative in their methodology, demonstrated a reduction in QoL caused by CVLU and the quality of the opposing study was poor. Each of the approaches adopted had inherent limitations but it is when the findings are synthesised that we can accurately assess the severe and wide ranging effects of the condition on the life of the sufferer.

Leg ulceration is a debilitating condition, characterised by long periods of ulceration, and where healing is achieved, a high incidence of recurrence exists (Heit et al, 2001). Significant, QoL limiting symptoms are the common theme across the research presented and the negative impact that the ulceration has on the psychological well-being of the sufferer is also an important feature; with feelings of low self-esteem, frustration and inadequacy being frequently reported. Self-imposed social isolation either to protect from further damage or to limit the exposure of others to the debilitating symptoms of ulceration was widespread and served to reduce the QoL of the participants.

3.11 Discussion.

3.11.1 Overall findings

For the purpose of this review, twenty five studies were identified, with a combined sample size of 2740 participants aged between 25 and 94 years. Qualitative studies provided rich data that revealed the very personal impact of CVLU on day-to-day functioning for the participant. The studies demonstrated that every area of life for the patient was restricted, with pain dominating the functioning of many (Bland, 1996; Rich & McLachlan, 2003; Brown, 2005b). Exudate and odour embarrassed participants which resulted in an often self-imposed social isolation, low mood and depression and poor self-esteem (Ebbeskog & Ekman, 2001a; Rich & McLachlan, 2003; Byrne & Kelly, 210). The ability of participants to maintain adequate standards of personal hygiene was restricted (Walshe, 1995; Bland, 1996; Rich & McLachlan, 2003) and choices in the selection of clothes and shoes were limited (Chase et al, 1997; Hopkins, 2004), factors which served to further limit self-esteem (Ebbeskog & Ekman, 2001a). Sleep was restricted due to pain and other symptoms and was a problem for many study participants (Douglas, 2001; Byrne & Kelly, 2010).

Quantitative studies similarly revealed poor QoL, demonstrating limitations across every area of functioning, whether physical, social or psychological (Franks & Moffatt, 1998; 2001; Jull et al, 2004). Scores were lower when compared to the AEN across the majority of studies and improvements as a result of healing were generally not sustained over studies of longer duration (Franks et al, 2006). All of the data presented supports the notion of CVLU as a long term condition, with sustained healing not likely to occur and widespread limitations in functioning for the sufferer – findings in line with similar reviews of literature (Persoon et al, 2004; Briggs & Flemming, 2007; Herber et al, 2007a; Gonzalez-Consuegra & Verdu, 2011).

3.12 Strengths and limitations of the review.

3.12.1 Strengths.

The strengths of this review are the application of robust and replicable systematic search strategy and the thorough peer reviewed process adopted for study selection. The application of a valid quality scoring tool (Hawker et al, 2002) to assess the quality of a range of areas of the reporting of each of the studies, in addition to the use of the CASP (CASP, 2010) approach to the critical appraisal of each article have also strengthened the review. A meta-analysis was undertaken on selected SF-36 data which reiterated the impact of CVLU on the lives of patients across the studies (Charles, 1995; Franks et al, 2003; Jull et al, 2004). This review was also subject to a double blind peer review prior to two publications in a popular nursing journal, although the search was updated for the final thesis; a factor which supports the rigour of the approach adopted (Green & Jester, 2009; 2010).

3.12.2 Limitations.

Studies not available in English were excluded from the study, as funding for translation services was not available which may have limited coverage. Studies that aimed to construct, validate or evaluate a QoL instrument were excluded, as mentioned previously, since their aim was instrument specific. The review was time limited as it formed part of an overall PhD study and was undertaken with only limited funding. Meta-analysis was not possible on all of the quantitative studies due to marked heterogeneity, especially in relation to the studies that applied the NHP (Lindholm et al, 1993; Franks & Moffatt, 1998, 2001; Franks et al, 2006; Furtado et al, 2008).

3.13 Conclusion and research implications.

This chapter has presented a review that has explored studies that have evaluated the impact of CVLU on the QoL of the patient. It supports the findings of earlier reviews (Persoon et al, 2004; Herber et al, 2007a) in demonstrating the wide-ranging nature of the effects of ulceration across every area of functioning. The consistently negative implications of CVLU reported in these studies that span over 16 years, clearly demonstrates a need to move away from studies that simply reiterate these negative effects, to more innovative research that explores potential solutions to these issues. The studies demonstrate a need to develop and evaluate interventions that may go some way to improving QoL for these patients and reiterate the research aims that form the basis for this study.

Chapter 4: Phase 1.

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Chapter 4 provides detail of the underlying methodological decisions made and the methods adopted during the first phase of the study, including an outline of the measures taken to ensure veracity and rigour (4.1). Subsequent results (4.2) are followed by a discussion of the significance of the findings in the light of the research presented in chapter 3 (page 50) (4.3).

4.1 Phase 1.

Phase 1 of this mixed methods study has been designed to answer the following research question:

What are the significant factors which impact on the day-to-day lives of people with chronic venous leg ulceration?

4.1.1 Phase 1 design and methodology.

A qualitative approach was adopted for phase 1, specifically phenomenology, in order to accurately establish the lived experience of patients with CVLU. The generic term qualitative research encompasses a range of methods of data collection and analysis characterised by the 'emic' perspective or 'insider's view' (Pike, 1954; Salmon, 2012); all aspire to uncover the participant's understanding of their world and experiences (Bowling & Ebrahim, 2005; Holloway & Wheeler, 2010; Smith et al, 2012). Qualitative research is inductive, providing opportunities to clarify the subjective interpretations which people place on their actions and encompasses a range of innovative

approaches which include ethnography, grounded theory and phenomenology (Atkinson et al, 2001; Meadows, 2003; Astin & Long, 2009). Phenomenological approaches aim to establish the meaning of a given phenomenon and to explore how an individual experiences it, often using first person narrative. Phenomenology endeavours to discover the uniqueness of human behaviour and to unveil and understand the everyday experiences of others without aiming to 'solve' the problem posed by the research question (Cresswell, 2007; Pratt, 2012; Salmon, 2012). Phenomenology is valuable, especially within nursing research, as it enlightens our understanding of the life experience and QoL of study participants (Pratt, 2012) and, as such, was seen as the ideal approach for phase 1 of this study which forms a preliminary basis for the subsequent phases.

A variety of research methods can be applied from a phenomenological perspective. Each of the potential methods have a similar focus on the

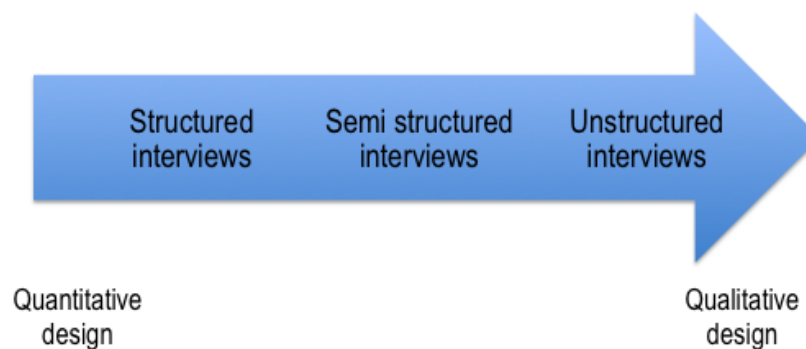
“...lived experience” (Husserl, 1970; p.240),

of the individual and include participant observation, focus groups, interviews and action research (Lester, 1999). Following consideration of a range of alternative methods, such as a patient focus group or a period of observation of patients with CVLU, interviews were selected as the most appropriate approach in order to effectively capture first person narrative from the study participants (Denscombe, 2007). Interviews are a versatile method, providing the researcher with ample opportunity to understand, explore and clarify the behaviour of participants by allowing their perceptions and views to be explored in their own words (Chung & Munroe, 2003; Kvale, 2004; Bowling & Ebrahim, 2005).

Interviews provide a structured encounter, with that level of 'structure' used to categorise them into three distinct types: structured, semi-structured and unstructured interviews (figure 8 below) (Green & Thorogood, 2004; Holloway and Wheeler, 2010). Structured interviews are likened to a

questionnaire that is administered face-to-face and are predominantly applied in quantitative research with pre-set questions and answers that are generally 'closed' in nature (Denscombe, 2007). Unstructured interviews are at the opposite extreme; entirely participant led allowing them to speak freely, with minimal intervention from the researcher (DiCicco-Bloom & Crabtree, 2006). Finally, semi-structured interviews fall somewhere between these two extremes, with the researcher able to set the agenda but the participant able to dictate the data produced (Hicks, 2004; Bowling & Ebrahim, 2005). In reality, semi-structured and unstructured interviews sit along a continuum and, within each interview, there is a seamless movement between these two 'approaches'; such flexibility ensures that the most comprehensive data is sourced (Grbich, 1999; Denscombe, 2007).

Figure 8: Interview continuum.



Since the aim of phase 1 was to gain a candid insight into the daily life of participants, an unstructured approach was felt to be most appropriate, whilst accepting that, on occasion, this approach might move along the interview continuum to a more semi-structured style (Denscombe, 2007). An unstructured approach is a powerful technique for gathering rich data and provides the participant with a 'voice', allowing them to tell their story with little direction or guidance from the

researcher (Meadows, 2003; DiCicco-Bloom & Crabtree, 2006). Each interview commenced with the researcher simply introducing the topic and asking the participant to

“....tell me about your leg ulceration?”

thus encouraging the participant to speak in a relaxed manner, free to develop their ideas and thoughts as they wished. In addition, a topic guide of potential questions and themes drawn from the literature review (chapter 3; page 50-92) was developed and available for use, if necessary, during the interviews (appendix 3). The availability of such a guide for such unstructured interviews is not uncommon (Ryan et al, 2009), simply providing a backup to ensure that important themes are not overlooked (Grbich, 1999). During this study, the topic guide was felt to be of particular importance since participants were generally older and the researcher was new to the process. Despite the preparation of the topic guide, it was not actually required during the phase 1 interviews and participants appeared comfortable to speak without prompting.

Interviewing is a skilled process that requires a rapport be built promptly between researcher and participant, thus encouraging the participant to speak openly about their thoughts and feelings within the ‘safety’ of the interview (Green & Thorogood, 2004). Interviewing is a skill, with the role of the researcher of central importance to the quality of the data produced; any lack of rapport and understanding would potentially constrain the quality of the data produced (Grbich, 1999; Meadows, 2003). Indeed, the interview process is founded on the premise that the events and feelings to be explored are of significance to both the researcher and the participant (Grbich, 1999). An important consideration for the phase 1 interviews was how the researcher should introduce themselves and their role to the participant, in order to optimise rapport and mutual understanding. The ‘role’ of the researcher is not without consequence; it assists the interviewer to gain access to the participant, but it also potentially affects the views and actions of both parties during the forthcoming interview

situation (O'Reilly, 2005). Following consideration, it was decided to make participants aware of the researcher's background as a DN since it was felt that participants may feel at ease when discussing their leg ulcer symptoms, confident in the knowledge that their condition would be fully understood. Such an approach is not without risk, since the perceived status difference between the interviewer and interviewee can give rise to 'expected' responses due to 'social desirability bias', with respondents responding in a manner that they feel is expected (Paulhus & Reid, 1991).

Despite the DN background, it was essential that each interview be approached from a position of equipoise, thus limiting the impact of the researcher on the data collected (Bowling & Ebrahim, 2005). To achieve this, the researcher was reflexive - actively reflecting on the process as a whole – in order to ensure the veracity and trustworthiness of the data produced (Kvale, 2004; Bowling & Ebrahim, 2005, Clarke, 2006). Such data is bound to the context from which it was drawn; thus it was essential that the researcher became immersed as an equal in order to truly establish, describe, analyse and understand the meanings and behaviour of the participant (Holloway & Wheeler, 2010).

Since the majority of care for patients with CVLU is delivered by DNs in the patient's own home (Callam et al, 1985; Nelzen et al, 1990; SIGN, 2010) and many such patients are elderly and physically limited (Ebbeskog & Ekman, 2001a), interviews were arranged at a time convenient to the participant at their own home, if the participant was agreeable to this. Interviewing the patient in his or her own environment, it was felt, might encourage them to feel comfortable and hasten the development of rapport between interviewer and interviewee (Green & Thorogood, 2004). If any patient had been uncomfortable being seen at their home and requested an alternate location, a clinic base was available; the location of interview, however, did not prove to be a problem.

4.1.2 Phase 1 sampling framework.

As outlined in chapter 1, following the completion of the phase 1 interviews, a period of non-participant observation of the nurse and patient participants was planned. As a result of this continued involvement of participants it was essential that both the nurse and patient participants were consistent across both phases, thus consent was gained for both phases at the start of the study. A purposive rather than a random approach to sampling was chosen for these phases since the selection of participants who were best able to provide quality information was deemed to be essential. Much qualitative research adopts such non-probability methods of sampling to ensure a 'good' informant (Patton, 1990; Coyne, 1997; Grbich, 1999; Bowling & Ebrahim, 2005; Saks & Allsop, 2007). This involves the intentional selection of the respondent, the study setting or both to ensure that specific characteristics of interest are captured in the research process and data quality is maximised (Greenhalgh, 1997; Bowling & Ebrahim, 2005).

For such qualitative studies such as this there is no universal agreement or calculation to indicate an optimal sample size. In view of this, interviews continued until data saturation was achieved, described as:

“...the point at which no new information or themes are observed in the data.”

(Guest et al, 2006; p. 74)

Guest et al (2006) cite a requirement of between four and 25 interviews for such 'theoretical saturation' to be attained, depending on the nature of the study, with the lower requirements ascribed to studies with greater participant homogeneity which is often the case when purposive sampling techniques are applied (Kuzel, 1992; Morse, 1994; Creswell, 1998; Guest et al, 2006). Since data during phase 1 was analysed simultaneously, as the interviews were undertaken, data saturation was achieved when no new themes emerged during the concurrent thematic analysis.

4.1.2.1 Inclusion and exclusion criteria.

In order to ensure data quality, meticulous consideration was given to the criteria for the sampling of both the nurse and the patient participants and the following inclusion / exclusion criteria were applied to sample selection (Hicks, 2004). These criteria were intended to be as inclusive as possible but it was acknowledged that hard to reach groups of patient participants, such as homeless clients, would be unlikely to be sampled since access to such groups are limited within mainstream district nursing.

Nurse participants:

Inclusion criteria for nurse participants:

- The nurse was registered with the Nursing and Midwifery Council.
- The nurse was a permanent team member rather than a temporary or bank member of staff.
- The nurse was willing to take part in the study.
- The nurse provided care for leg ulcer patients regularly.

Exclusion criteria for nurse participants:

- Unqualified staff.
- Agency / bank staff.
- Those who withheld consent.

Patient participants:

Inclusion criteria for patient participants:

- The patient suffers from leg ulceration of either venous or mixed aetiology (as diagnosed by Doppler Ankle Brachial Pressure Index (ABPI) ratio of between 0.5 - 1.2 and detailed history taking) (Vowden & Vowden, 2001).
- Ulceration had been present for in excess of six weeks.
- The patient was able to understand English.
- Visiting posed no risk to the patient or researcher.
- The patient was willing to take part in the study.

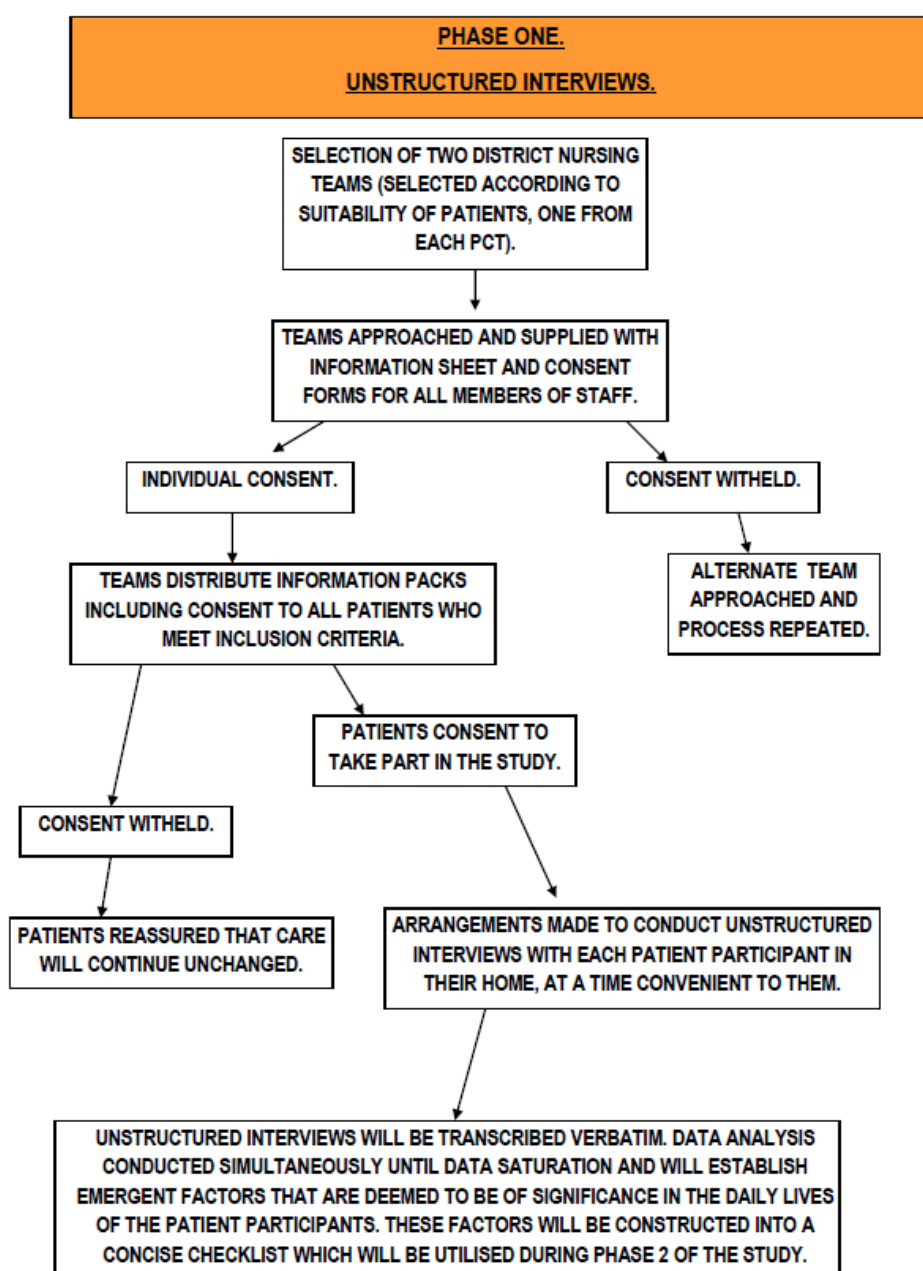
Exclusion criteria for patient participants:

- The patient does not fit all of the above inclusion criteria.
- The patient's leg ulceration, outlined under the first point of the inclusion criteria, is of arterial aetiology (as diagnosed by Doppler ABPI ratio of below 0.5 and detailed history taking) (Vowden & Vowden, 2001).

4.1.3 Phase 1 study procedure.

The study was undertaken across two, North Staffordshire Primary Care Trusts (PCT), one inner city and one rural in nature. A team was consented from each of the PCTs but, due to low patient participant recruitment levels, it was necessary to recruit a third team. The process of data collection for phase 1 is outlined in the following flow chart (figure 9, overleaf).

Figure 9: Phase 1 flow chart.



Managers nominated DN teams suitable for the study who were then contacted by the researcher to ascertain their interest in taking part. Study packs, including a letter of introduction, study information and a consent form, were distributed to staff (appendix 6). On receipt of their completed consent forms, a visit to each team was undertaken to provide study details and to explain the inclusion / exclusion criteria for the potential patient participants (detailed on page 98). Following this meeting and once the nurses felt comfortable, the distribution of the patient 'study packs' to those patients on their caseload who were deemed suitable to take part in the study commenced. Potential patient participants were encouraged to discuss study requirements with their relatives, carers and friends in order to support them in their decision to take part. Additional contact details were also provided if potential participants required any further information. Over the next three to four weeks the researcher received completed patient consent forms, these participants were then contacted and a convenient interview time and location arranged.

4.1.4 Phase 1 data collection.

With participant consent, interviews were digitally recorded to facilitate accurate transcription (Grbich, 1999). This ensured that the researcher could concentrate on what was said during the interview without needing to simultaneously take notes; which may have distracted the interviewee (Denscombe, 2007). Such recording is not without issue since many participants had a very strong local dialect; access to such a recording, however, allowed multiple attempts at transcription in order to ensure accuracy. Following transcription, each participant was offered an opportunity to review their interview transcripts prior to analysis, as is good practice, but, on this occasion, all refused (Ryan et al, 2009).

In order to ensure the veracity of the data collected, contextual notes and reflections on the interview, environment and post interview comments were recorded soon after completion of the interview and were reflected upon during the transcription process. Where notes were felt to provide important background information to the transcribed data, comments were added to the quotations in brackets, following the protocol outlined at the start of the thesis (page xxiv). In addition to these measures, an educational supervisor verified the accuracy of a sample of transcription from the original digital recordings. Both of these factors were designed to enhance the rigour of the data collection process (Seidman, 2005).

4.1.5 Phase 1 data analysis.

Analysis of the data from such interviews varies however, following consideration of alternatives (Colaizzi, 1978; Giorgi, 1985), a process of thematic analysis outlined by Braun and Clarke (2006) was adopted. This process provided a simple, structured step-by-step approach with an auditable decision trail which is ideal for a novice researcher (Braun & Clarke, 2006). Unclear reporting of thematic analysis has been criticised in the past (Colaizzi, 1978), with an emphasis on a need for clarity including clear reflection on the researcher's role in the analysis process, to minimise bias (Attride-Stirling, 2001). These features were all present in the Braun and Clarke framework (2006) displayed in table 8 below.

Table 8: The six phases of thematic analysis (Braun & Clarke, 2006).

Phase	Description of process
1. Familiarisation with the data.	Transcription of the data. Reading and re-reading with initial themes noted.
2. Generating initial codes.	Interesting features of the data are coded systematically across the entire data set. Data relevant to each code is collated.
3. Searching for themes.	Codes are collated into potential themes and all data relevant to each potential theme is collated.
4. Reviewing themes.	Checking if the themes work in relation to the coded extracts and the entire data set. Generating a thematic 'map' of the analysis.
5. Defining and naming themes.	On-going analysis to refine each theme and the overall story told by the data, generating clear definitions and names for each theme.
6. Producing the report.	The final analysis. Selecting compelling extracts and examples, relating the analysis back to the research question and producing a scholarly report of the analysis.

Thematic analysis commences with a close inspection of the key issues under investigation, which are gradually refined to provide a conceptual description of the phenomenon under review (Braun & Clarke, 2006). Holloway and Todres (2003) described this process as 'thematising', a skill they describe as generic in qualitative analysis which provides a rich and detailed account of the data by identifying, analysing and reporting themes (Braun & Clarke, 2006). The thematic analysis process initially provides a superficial reflection of the data but as the stages progress, the information beneath the surface of the data is unravelled and the focus is shifted from what was said and observed, to an investigation of what underlies this (Rapley, 2011). Miles and Huberman (1994) emphasise researcher engagement in this process of data reduction; the selecting, focussing, simplifying and transforming transcript data in order to draw out and verify conclusions. Immersion in the data is essential during this analysis process, especially when the researcher undertakes the analysis (Miles & Huberman, 1994).

Following verbatim transcription of each interview these were analysed using this six stage framework (Braun & Clarke, 2006). Initial immersion in the data was accompanied by 'repeated'

active reading to uncover meanings and patterns, a process aided by the coding of the early ideas. Once complete, more formal coding was undertaken and the data collated with themes formed. Themes were refined and the entire data revisited to ascertain whether these themes 'worked' in relation to the whole data set. A thematic map of the data was created to provide a description of the scope and content of the themes (appendix 7). Final analysis and formulation of a report to tell the complicated story completed the process (Braun & Clarke, 2006). To confirm the accuracy and to optimise rigour, an educational supervisor undertook an independent thematic analysis and consensus was achieved using a reflexive approach (Grbich, 1999; Todres, 2007).

4.1.6 Ethical considerations in phase 1.

Research ethics are fundamental to the research process, irrespective of design, and are underpinned by three central principles: respect for persons, beneficence and justice (Dimond, 2005). Participants have the right to an equitable recruitment process, informed consent and to be protected throughout the research process (Bowling, 2009). The UK process for ethical approval within health research is extremely robust in order to ensure that the rights, safety, dignity and well-being of all research participants – both staff and patients – is vigorously protected (RCN, 2011). The guide to consent provided by the DH (2001b) emphasises that all study participants are competent to provide consent and are provided with sufficient information to make an informed decision to take part. The guide to consent (DH, 2001b), along with the guidance relating to mental capacity (DH, 2007), were important considerations in view of the predominantly elderly nature of the patient participants for this study (Ebbeskog & Ekman, 2001a) and were considerations that were reflected in the inclusion / exclusion criteria for the study (page 100).

Specific considerations for patient participants were the location of interviews, undertaken in patients' own home by a lone researcher and a risk that participants may have unresolved questions or may become upset following completion of the interview. In order to address these considerations, the facility to undertake the interviews in a clinic location was an option if the patient participant so desired. The University 'lone working' policy was adopted to ensure the safety of the researcher and the information leaflet for patients included details of who to contact for support, should this have been necessary. For nurse participants, the challenges of their involvement included the provision of access to their caseload and the observation of their practice by the researcher in phase 2 which may have made them feel vulnerable. The nurse participants were made aware that if there were any issues about specific practice issues, these would be dealt with as recommended by the NMC (2008).

In February 2010 the Local Research Ethics Committee (LREC) granted their approval for phase 1 and 2 of the study to proceed (Ref: 10/H1203/13; appendix 4) and the local National Health Service (NHS) Research and Development Department (R&D) committee subsequently approved access to staff and patients in March 2010 (appendix 5). The process included stringent review and approval of potential nurse and patient participant information including letters of introduction, detailed consent forms and comprehensive written information to outline the study (appendix 6). The information included the requirements of respective study participants, arrangements for assuring the anonymity of participants, the maintenance of the confidentiality and information surrounding the withdrawal of consent in line with recommendations from the Research Ethics Service.

For the nurse participants, consent evidenced agreement to distribute research information to suitable patients on their caseload in preparation for the phase 1 interviews and also their agreement

for their wound care consultations to be observed during phase 2. The facility to withhold consent for the phase 2 observations was included in the consent form. If this were the case, arrangements would be made for that specific observation to be undertaken with another consenting member of staff. For patient participants, consent evidenced their agreement to be interviewed and to have their subsequent wound care consultations observed by the researcher. Consent forms also included the option for the digital recording of the interview and the inclusion of anonymous direct quotations in the final thesis. Consent from both nurse and patient participants was reaffirmed at every opportunity, at the start of each interview and prior to each of the observations, thus providing an additional opportunity for consent to be withdrawn if a participant so desired.

4.2 Phase 1 results.

Following the distribution of study packs, a total of 13 nurses across three teams consented to take part in the study. The nurses had worked within primary care for a median of five years (range 6 months – 20 years). Interviews were undertaken and continued, as discussed (page 99), until saturation, which provided a total of nine patient interviews all undertaken by the one researcher to ensure rigour (Guest et al, 2006). Table 9 (below) provides an outline of the demographic details of each of the patient participants and details the pseudonym assigned to each, to protect their confidentiality (NMC, 2010). The letter and number codes next to the name refer to the location of the patient (L1, L2 or L3) and number of the participant (P1 – P6). Four were male with a median age of 76 years (range 39–99 years).

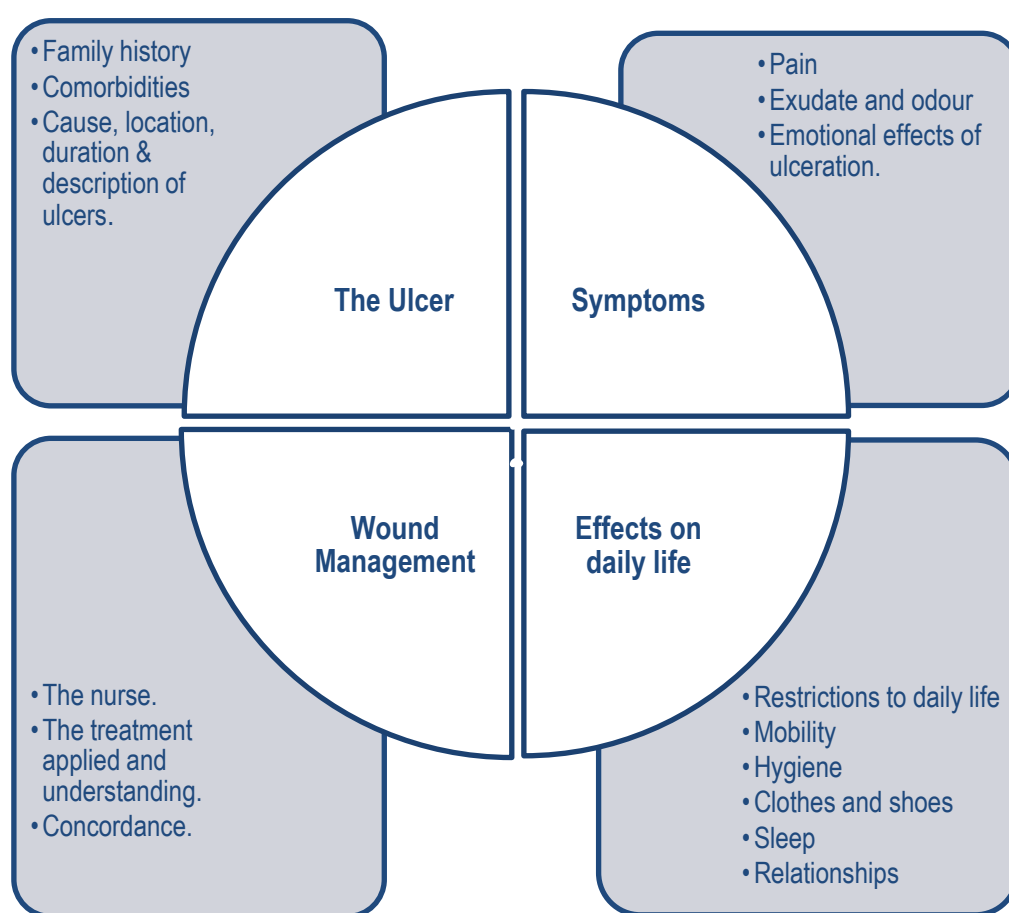
Table 9: Patient participant demographics.

<u>Participant pseudonym.</u>	<u>Age.</u>	<u>Gender.</u>	<u>Marital status.</u>	<u>Residential status.</u>	<u>Total duration of ulceration.</u>	<u>Number of episodes.</u>
Tom (L1,P1)	76	Male	Married	With wife, own adapted bungalow.	10 years	2-3
Mary (L1, P2)	72	Female	Married	With husband, own adapted bungalow.	30 years	>5
Evan (L1, P3)	76	Male	Single	Private Residential Home.	35 years	>5
May (L1, P4)	99	Female	Widow	Private Residential Home.	3 years	1
Pam (L1, P5)	78	Female	Married	With husband, own house.	30 years	3
Ellen (L1, P6)	80	Female	Widow	Private Residential Home.	2 years	1
Steve (L2, P1)	39	Male	Single	Alone, upstairs local authority flat.	14 years	1
Marg (L3, P1)	72	Female	Widow	With dog, upstairs local authority flat.	20 years	>5
Sam (L3, P2)	86	Male	Married	With wife, own house.	40 years	>5

4.2.1 Themes and subthemes.

The thematic analysis process identified four themes: the ulcer, symptoms, wound management and the effects on daily life and a number of subthemes significant in the lives of the patient participants. These are represented in the figure 10 below (Green et al, 2013a).

Figure 10: Themes and subthemes from the interviews (Green et al, 2013a).



Each theme and respective subthemes were summarised and illustrated with verbatim quotations, to add depth and enhance understanding and are presented under theme headings. Verbatim quotations that include the participant's local dialect are included but, to avoid any confusion, a

Standard English alternative is provided in brackets. At the end of each quotation, the pseudonym assigned to the participant (page 109) is provided.

4.2.2 Theme 1: The Ulcer.

Without exception, all study participants were keen to describe the 'journey' of their ulceration with the researcher. This generally included any associated family history, details of their co-morbidities and the cause, location and duration of their leg ulceration.

4.2.2.1 Family History.

Three participants reflected on the history of leg ulceration in their first order relatives. A family predisposition, for these participants, was significant and had led to them feeling susceptible to the development of leg ulcers throughout their life. When ulcers had subsequently developed they seemed to refer to them with almost resignation. Mary reflected:

'All my mother's sisters had it and me [my] mother...runs in my family it does with us.'

Mary

Marg similarly reflected on her family history and spoke of her mother's long-standing ulceration and them managing the ulcers at home for periods of time:

'My Mum had them and they've told me as [that] they can be hereditary.....have you heard that? She worked with hers (.....) the treatments that I've seen, they used to soak hers in this purple stuff, but they did seem to clear....you know, and she'd get another one (.....)

sometimes we've doctored them on our own because she'd seen how they'd done it them many times.' Marg

For the remaining participants (6), ulceration did not reflect a family predisposition.

4.2.2.2 Co-morbidities.

Co-morbidities were common. Three participants reported no co-morbidities, three had one and the remaining three had two or more. The co-morbidities were rheumatoid arthritis (RA) (2), osteoarthritis (OA) (3), cardiovascular disease (CVD) (1) and sight problems (2).

Where participants suffered from co-morbidities, their underlying conditions had a tendency to exacerbate their ulceration but despite this, having other conditions also appeared to make the participant more tolerant of the ulcer symptoms. Tom (76 years), who was extremely debilitated by his RA and had extremely severe bilateral ulceration, reflected on his ulcers as simply being a nuisance. In contrast, Marg, who other than her leg ulcer was in good health, was devastated by the impact of her leg ulcer symptoms on her daily life.

4.2.2.3 Cause, location, duration and description of ulcers.

All participants described the development of their ulcers; five were able to describe the actual incident which had caused the initial wound, which then progressed to become ulcerated. Ellen (80 years) reflected on two incidents which initiated an ulcer developing:

'I had a shower and I was getting out and I knocked my ankle (.....) I was going past this chair and there was something sticking out and I gashed all up me shin.' Ellen

For Steve (39 years), many years of intravenous (IV) drug abuse had culminated with him injecting heroin directly into his lower legs, as this was the only place he could gain access to his badly damaged venous system. This had resulted in him developing severe bilateral leg ulcers.

'When I was injecting under the skin, in little veins and I was going in capillaries as well (.....) just underneath the skin.....it's like acid just burning underneath my skin, that's how it all burned and fell into the big, deep holes.' Steve

The participants who were unable to describe the specific cause which led to their ulcer developing (4), reflected on their uncertainty about why they had started and a fear that they would recur as unexpectedly when they healed.

'Oh no, it must of [have] just come (....) I've got bad veins, I suppose that started it.'
Sam

Of the nine participants, six had a history of bilateral ulcers. Two reported ulcer recurrence in exactly the same location at each recurrence, whereas the remaining (7) reported ulceration recurring in a variety of different locations on their lower legs.

'It's always like this and always in the same place.' Marg

The patient participants disclosed a range of duration for their ulcers; most (7) had experienced at least one healed episode, although not all. For some, the healing was extremely slow and a very frustrating process. All participants reflected that long periods of their lives had been 'taken over' or defined by their ulceration.

Some participants reflected on periods when they were able to self-manage their ulcers, often when they initially occurred, before eventually having to accept that professional intervention was required as a result of the wound deteriorating or an infection developing. Steve spoke of periods when he completely avoided the required clinic visits, reflecting that he was 'non-compliant' when the situation just became too much for him:

'You just go through mad stages [...] I'd phone and say 'Sister, I don't need to come today me [my] bandages haven't leaked through'...are you sure cause we can change them or come to you?'.... I'd say 'no, you're alright, they haven't leaked through or nothing' but I'd done it myself, it was just a stage I went through with them, just trying not to have to go [...] three times a week, I mean, come on, it's tedious isn't it. They put them on on a Monday, you go up Monday afternoon, you've got Tuesday all day and I'm back there on Wednesday, so it's only a day and a half they're staying on and then they're being changed.' Steve

Most of the other participants had experienced some healed episodes (7). Steve, however, had never experienced healing and reflected on the time it was taking for the healing to take place:

'God, they've been doing it, this Christmas it'll be just over about 14 years. It's just been millimetres, millimetres all the time just going in, very, very slow. Cause I've not been anywhere, not done nothing for 12, 13, 14 years. All me [my] life's been is Doctors and hospitals and nurses and surgeons.... you know. It does get to you, you know, but I haven't let it get me down and I've stuck with it and, yes, I'm doing alright now like, I'm getting there, it's getting there.' Steve

Lack of healing or the slow nature of healing presented significant challenges for participants, with

their ulceration simply taking over their lives.

Recurrence of an ulcer following an episode of healing was seen as both frustrating and disheartening.

'Off and on, I must have had them at least a dozen times.'

Sam

'I think I've had about three or four, but the last two have been horrendous.'

Marg

The interviews revealed the very personal 'story' of leg ulceration. Comments were consistent and unprompted by the participants and provided a rich insight into the person behind the ulceration, the extent of the impact of CVLU on their daily life and provided the background to their personal journey.

4.2.3 Theme 2: Symptoms.

All participants reported a range of debilitating symptoms due to their ulceration which included pain, exudate and odour and the emotional impact of their ulcers.

4.2.3.1 Pain.

Pain dominated the lives of the participants and was at the heart of every interview. Descriptions of nature of the pain had many similarities, including its unceasing nature, severity and the timing of the pain. A number of subthemes emerged related to pain including the type of pain, the timing and duration, the cause and the use and effectiveness of pain relief.

All respondents described their pain as being significant and extremely debilitating. Steve's description was particularly disturbing:

'It was getting more painful, it was like one time it was like burning pain, then it was more like a stabbing pain, then (.....) now it's like real sore, like someone is just rubbing, rubbing, rubbing, all the time. Oh, the pain.....it's just unbearable.' Steve

Vivid descriptions of the pain associated with ulceration included its constant and persistent nature; which were often further complicated by intermittent episodes of a much more severe pain. Descriptions included:

'Sometimes you feel as though you're being cut' Ellen

Participants described the timing and duration of the pain, with a number of similarities in relation to its continuous nature and increasing severity, especially when legs were elevated, participants were in bed and throughout the night. Pain appeared to intensify during the night for many of the participants, leading to disturbed sleep and daytime tiredness.

'When you just lie down in bed, it's worse than any time all through the night and you just can't get any rest' Mary

Steve provided a comprehensive description of the unrelenting nature of the pain he experienced:

'It's just the same pain, 24/7, (...) I just have to put up with it; it's either that or kill myself or somat [something]. It's like the pain, I know I'll have pain but this pain and soreness, all the time' Steve

Steve's emotions as a result of his pain were quite extreme, but all participants reflected on the very depressing nature of their unrelenting discomfort.

Pain was attributed either to the actual ulcer or was exacerbated by the dressing procedure. Tom stated that when:

'It's been dressed...for a few hours it can be hell' Tom

Likewise Mary reflected on increased pain following her dressing change, a factor which was made worse as she attended her local wound care clinic a few miles away from her home:

'Sometimes I have a job to come home when it's just been dressed.' Mary

Many respondents reflected on the specific discomfort which they felt was caused by their compression bandages, a dressing technique undertaken as part of their wound management plan. Ellen stated:

'Ooohh, they hurt. They get you all across your instep, it gets that tight.... you know and then I'd say oh, I could just do with cutting this off' Ellen

Steve spoke of the severe pain he experienced when his dressings were changed and reflected that on one occasion he had to remove the outer bandages in an attempt to relieve the discomfort. He said:

'Last night I took the fourth layer off, cause it was that tight. They always tell me if you get anything like pain or that just whip off the fourth layer.' Steve

For Marg the severity of her pain did not appear to reflect the size of the wound. She reflected that her pain was very intense and was much greater than she had expected in view of the size of her wound:

'There's nothing to it, there's nothing to it now really; other than the pain.' Marg

Many of the participants (7) reflected on their reluctance to take any analgesia, either due to it not being effective or concerns that they might become dependent on it. Sam explained:

'I don't take them unless I have to, I'd rather not take painkillers.' Sam

Even when analgesia was taken, for many this did not relieve their pain and the analgesia was deemed to be ineffective. One respondent reflected:

'They don't really take the pain off though' Ellen

For those who reported co-morbidities (6), pain relief was often taken for their 'other' conditions. This was evident in a number of comments:

'With all that I take for my arthritis, I figured it was covered. No, I'm taking that damn many.' Tom

Even though participants had been encouraged to take additional analgesia, they appeared reluctant to increase or add to their current regime; even when this regime was ineffective.

Pain was the central issue and dominated every interview. It was vividly described in terms of its severity and its incapacitating nature by all of the patient participants.

4.2.3.2 Exudate and odour.

The impact of exudate and odour was also powerfully portrayed by all of the participants. These descriptions included reflections on the challenges that both exudate and odour posed in their daily lives. They also reflected on the absolutely devastating nature of these symptoms, which triggered embarrassment, shame and stress. A number of participants described the problems they experienced due to excessive exudate:

'When this started, more rubbish came out of it and it even came through three layers plus me socks.' Sam

'It varies, sometimes.... I can always tell because it comes through [looks at dressing].' Pam

Pam's solution to her excessive exudate had been to redress and clean her wound in between her scheduled dressing changes; an intervention which had made her relationship with her DN team particularly problematic. She stated:

'They're great with me on the whole [the nurses], but then they started getting cross that I washed me feet at night. Apart from showering I do wash me feet at night before bed anyway and they got a bit cross. I did leave it on, didn't I [to husband] for quite a long time, for a week or more in the past...but we had a bit of a set to last week [with the nurses]...they said 'You don't do what we say, you keep taking it off' and I said 'I don't keep taking it off'. But I said I do have a shower three times a week and if it's been weeping a lot then I do wash it as well, if it does come through and it looks like it's a mess then I take it off...cause I don't feel like I want to keep it on...seeping, it's seeping out. I'd say it was doing it a lot at one time (.....) you just have to take it off, I don't see there is anything to be gained by leaving it on.....' Pam

Pam strongly defended these actions saying:

'They get a bit cross [the nurses at clinic] because I do wash my legs but to me, 'cleanliness is next to Godliness'' Pam

Odour was often linked to an increase in exudate and was present, either occasionally or continuously, for most of the participants. All participants reflected that odour was both embarrassing and stressful. For some participants, the odour led them to restrict their contact with others which resulted in an almost self-imposed social isolation.

'Oh, and when you first have them, I wondered what the smell was.... oh, it's terrible the smell, it all comes out, a lot of rubbish.....when you went anywhere, you didn't get too close to people because I can smell it terrible (.....) you know.' Ellen

'They were really bad, once they'd been put on, the next day they were really stinky so.... so me, on the bus, paranoid, thinking people could smell it and everything.' Steve

For some participants, they interpreted their increased exudate and odour as an indication that their ulcer condition was deteriorating. This factor often resulted in a heightened monitoring of their exudate levels, in an attempt to assess whether healing was progressing satisfactorily or not. Steve explained:

'So when they were bad, they were bad, leaking and like I say, the smell and everything. If you were sitting here, what, eight years ago they'd be rank.....really bad (....) you know and wet, the smell, horrible.' Steve

Exudate and its associated odour had devastating effects on the lives of the participants, resulting in limited contact with family and friends and a self-imposed isolation. This was seen as preferable to the embarrassment which these symptoms caused.

4.2.3.3 Emotional effects of ulceration.

Participants reported a range of emotional effects due to their ulceration including depression, poor self-image and a fear of people's reactions. The interviews revealed a range of coping strategies adopted by participants. Some described themselves as striving to maintain the level of 'normal' functioning which they had prior to their ulceration. Others explained how they suffered from severe anxiety and depression, with one respondent disclosing that he even had suicidal thoughts on occasions. Steve reflected on the disheartening nature of his condition and stated:

'It's just depressing really, if you think about it, (...) I am on antidepressants; I just have to put up with it. It's either that or kill myself.' Steve

But despite the obvious anguish that Steve expressed, he also spoke of his hope for healing:

'But I haven't let it get me down and I've stuck with it and, yes, I'm doing alright now like, I'm getting there, it's getting there...if it was like falling back and oh God, nothing's working and they were on about me having one off (...) I'd be proper depressed you know. But luckily it is getting there, yes....' Steve

Steve was not alone in his feelings of depression. Marg reflected:

'It's the lowness...very, very depressing.' Marg

'Yes well, they've got me down, especially the pain..... the pain gets me down.' Sam

Participants also disclosed their fears which included a fear of sustaining any further injury to their legs, which might exacerbate the condition of their ulcers. One participant reflected that she consciously protected the leg at all time and another felt her bandages gave her some protection:

'When I went up the hospital, I went and knocked it on there again and well (.....) it made it worse. You have got be very careful, I said, when they're better and I've got these bandages off, I shall have to have a bell 'Please mind my legs'.' Ellen

'I'm frightened in the supermarket; I am frightened when I'm out. When I have been at the supermarket cause some people, they do push their trolleys everywhere, so it means that you're on your guard all the time.' Marg

Participants reflected that they always needed to be on their guard, always conscious of any risks to their legs. Some even consciously avoided potentially 'risky' situations in order to escape any further injury.

Other participants feared what people thought of them, a factor that was particularly problematic when ulcers were judged to be self-inflicted, such as in Steve's case:

'And all this with me legs, would I tell people and I think probably no I wouldn't. I'd say I was in a bad fire or something or make something up as some people just don't take to saying you were on drugs and something like that' Steve

Finally, Steve spoke of his fears for the future:

'It's been hard, like I say, but it's something I've had to do or else, legs off you know what I mean? I didn't want to lose my legs.' Steve

In contrast, despite the profound impact that Marg's ulceration had on her daily life, she described how she endeavoured to continue with her activities as she had before her ulceration:

'I could cry (....) but I tell you, you have to shake yourself, shake your feathers and when you go out you have to put your outside face on, you just have to.' Marg

These symptoms that presented as three debilitating subthemes, were common to all interview participants and were vividly described.

4.2.4 Theme 3: Wound Management.

Themes surrounding wound management were also raised in all of the interviews. A number of subthemes were identified which include issues surrounding the role of nurse, the treatment applied, the participants' understanding of their regime and their concordance.

4.2.4.1 The nurse.

Each nurse was highly valued by the participants; they were seen as very knowledgeable and experts in the management of leg ulcers. Tom reflected on a recent visit to his GP to review his wounds and being re-directed to the nurse for further advice and management:

'Doctors (...) say go to the nurses, they know more about ulcers than we ever know.'

Tom

Despite the nurses being deemed the 'expert' in their management of leg ulcers, some participants reflected on times when their dressing change resulted in increased discomfort, either due to some inconsistency in the dressing technique or the application of a dressing by a less experienced nurse. Some respondents reflected on such inconsistency despite still positively evaluated their relationship with the nurses. Tom stated:

'At times they can get it just wrong...'

Tom

Another remarked:

'I think they're tightened up too much....'

Marg

One participant remembered an occasion when he had to correct the nurse's dressing technique during a consultation at the wound care clinic:

'I've seen loads of different nurses come and go (...) if they're talking and putting something on and I'm talking to them and they've put something on wrong.... I'll consciously just say 'that doesn't go on there like that' and after that they'll say 'Oh, I'm ever so sorry like' '

Steve

The consistency of the nurses, whether in clinic or at home, was seen as an extremely important factor to all of the participants:

'With the consistency of a team, much better. They did once send another from another surgery out of.....it wasn't the same, when you're seeing someone only once, it isn't the same. Nothing wrong with her...did the job just the same, fine, but I wasn't used to her.'

Tom

Marg also commented:

'Last year when I had this other one, you'd go and there would be girls there and you'd perhaps see them twice and then you wouldn't see them again. So, you'd get somebody else, so somebody else has a different way of doing it. So you didn't know where you were (...) now the nurse I see, it seems to me that she's like a bit in charge there, she's there for three months.' Marg

For most participants the relationship with their nurse was special and something they valued. The nurses were seen as friends with close bonds made over the course of many visits. and a number of participants revealed what their nurse meant to them:

'Some lovely nurses, they've been brilliant' Mary

'I can have a joke with them, I torment them!' Tom

In contrast, Pam reflected on having a rather tense and difficult relationship with her nurses due, she felt, to her being perceived by them as non-compliant with her treatment regime. Pam felt the nurses had reprimanded her for removing her dressing in between clinic visits and reflected:

'As I say, they're great with me on the whole [nurses], but then they started getting cross that I washed me feet at night. Errr..... apart from showering I do wash me feet at night before I go to bed anyway, and they got a bit cross [nurses].' Pam

For one participant waiting for the nurses to arrive to dress his wound had been an issue for him and at times had caused him to miss out on activities or trips at the residential home where he lived. Evan reflected:

'Sometimes when the nurses were late (...) I'd have to wait' Evan

Other participants (2) had made a conscious decision to attend the local wound care clinic rather than have dressings renewed at home. This enabled them to get out and also avoided the risk of

them being tied up waiting for the nurses to visit. Sam felt clinic attendance encouraged him to be active and, as a result, he felt it also had a therapeutic benefit.

'Well, they just asked me which would I prefer....you know, when I first went they said which would you prefer? Do you want to come here or do you want us to come to your house? (....) I just said that I'd come up to Clinic. I just thought moving about a bit would be better (....) might do me better than just sitting about.' Sam

Some participants had needed a referral to the local hospital for a Tissue Viability Nurse (TVN) or Vascular Consultant review of their wound. When this happened, the participants reflected that such a specialist assessment provided them with new advice and was a welcome opportunity for some 'expert' feedback about the progress of their wound. Such visits were often eagerly anticipated. Steve said:

'I went see me surgeon up the hospital (....) I saw him about three months ago (...) when he looked at it (...) he said carry on with this treatment. He tells the nurses what and then they write the letter for my District Nurses for [to] carry on, what to put on my legs and that And they measure them and that every time I go up.' Steve

Pam, who felt resented by her nurses as they felt she was 'non-compliant', had also been referred to a local specialist clinic for a review of her wound. In contrast, Pam felt that there was an ulterior motive for this referral:

'Next week I'm going to the general clinic cause they're going to see whether they think I (...) I can accept the (...) compression bandages.' Pam

She felt this clinic visit would be an opportunity for the nurses to impose their advice on her and encourage her to be more compliant with the dressing regime for leg ulcer. She did not feel that this was a battle which she would lose, reflecting that:

'Oh, they give up!!' Pam

4.2.4.2 The treatment applied and patient understanding.

Participants spoke of the requirement for 'tight' compression bandages in order to bring about healing of their wounds.

'That's how tight the bandages are and that's how they've got to be because they're compression bandages.' Steve

May, a 99 year old lady in a local residential home, spoke of the bandages stating:

'It's got to be tight...to send the fluid back up.' May

Of the participants interviewed, eight had experienced periods of requiring compression bandages applying. Some reflected that they were fully able to tolerate this technique:

'I can tolerate tight bandages (...) you know it doesn't matter, I've had them on a lot (...) and it doesn't bother me one bit (...) I feel comfortable in them because (...) it doesn't hurt me with them on.' Mary

Whereas others felt that the dressings were uncomfortable and, at times, they were unable to tolerate them:

'I was in four layer and the nurse wrapped round the fourth layer, really tight. I got up for to walk and I couldn't.... arrrgh, I was like a robot! I said are they supposed to be like this? She said 'yes, they've got be tight' (...) me [my] legs were really bad you know, holes in em [them] and that.... I was saying 'they're killing me' and 'they're hurting me (...).' She said, 'Well yes, but that's how it is.' Steve

Another reflected on the tightness, which often resulted in the nurses being re-called for unscheduled visits to reapply or readjust the bandages:

'That's what does it (...) they hurt; they get all across your instep...it gets that tight, you know. And then I'd say 'oh.... I could just do with this cutting off.' Ellen

All participants reflected on having had a variety of wound care products applied to their ulcers. They were knowledgeable about the products available and had a good understanding of how they worked. They spoke of their 'partnership' with the nurse, jointly trying to heal the ulcer. Steve stated:

'You name it, all the different patches with stuff in and creams. (...) The patches come out with the silver in and we went through every one of them. Errr...I've gone through loads of different stuff. They've put.... I've had trials of different stuffs put on and some have worked and some hasn't.' Steve

Many were able to name the various dressing products they had experienced over the course of many dressing changes.

'Yes, they tried all sorts you know. I think I've had iodine.... and different sorts of things.'

Ellen

'But I've had loads of different dressings on before that. I've had a lot of different things – silver, honey....' Sam

Patients' experiences of the effectiveness of these products, however, varied. A number of participants spoke of having honey preparations applied to their wounds with varying responses.

Sam reflected:

'Yes, I've never had honey on it before and even some of the girls there said they hadn't heard of honey being used much (...) honey had definitely done this good, just a small piece, just enough to cover the ulcer itself, just cut accordingly.' Sam

Another participant had not been able to tolerate the honey at all and had found:

'They put honey on it. Oh dear, I wished it'd worked, cause people said to me honey is ever so good. But it drew and drew and, well that pain.... it felt as if it was knocking your hat off.'

Marg

4.2.4.3 Concordance.

Participant concordance with the advice, treatment regimens and dressing procedures was also raised during the interviews. As has been confirmed, compliance with the dressing regime was problematic for Pam as a result of her regular removal of the dressing:

'You don't do what we say, you keep taking it off' (...) I said 'I don't keep taking it off', but I said I do have a shower three times a week.... and if it's been weeping a lot then I do wash it as well.' Pam

She attributed the need to remove the dressing solely to the hygiene issues she was experiencing, stating:

'If it looks like it's a mess then I do, I take it off cause I don't feel like I want to keep it on, seeping. It's seeping out. I'd say it was doing it a lot at one time (...) and you just have to take it off. I don't see there is anything to be gained by leaving it on.... and it stops it smelling.' Pam

Steve, who had endured many years of ulceration, also alluded to concordance issues. He felt that at times he electively avoided scheduled clinic attendance as a way of regaining some control over his life; a feature which was often short lived as his wounds deteriorated and he had to return to clinic.

4.2.5 Theme 4: Effects on daily life.

All participants raised issues around the impact of their ulceration on daily life. These comments were grouped into the several subthemes including restrictions to daily life, limited mobility, issues when working, maintenance of personal hygiene, limited choices with clothes and shoes, sleep and the effect on relationships.

4.2.5.1 Restrictions to daily life.

For some participants the impact of their ulcers on day-to-day functioning was significant and something they were unable to limit:

'Well, they stop you from going anywhere...really, you know, you can't get about, not the same.' Ellen

Steve forcefully summed up the effects on his life:

'I couldn't get about (...) if I had to go somewhere I'd either get a lift off me [my] Dad or go on the bus but it'd only be healthcare, either the Doctors, the hospital, or the dentist. It was all to do with health, you know what I mean. That's all me life's been since I've had the holes in me [my] legs.' Steve

But despite his despair, he still had hope and looked forward to a time when his ulcers had fully healed and he could plan for his future:

'I'll just go away (...) not to get in the sun like but just to get out of England (.....) cause I've not been anywhere.' Steve

Marg spoke of the limiting effects of her current ulcer, stating:

'It is this [points to leg]; it keeps me as a prisoner. On top of the pain (...) I've always been one who's done me [my] housework, I can't seem to get it done because I can stand for so long and then I think, I've got to sit down cause it starts to hurt.' Marg

Finally, Sam reflected that he usually acted as a carer for his wife who was partially sighted but found that he was struggling to fulfil this role due to his current episode of ulceration.

'When you find you can't do the things you normally do, and when I'm in pain.... they soon starting aching now if I stand on them for long (.....) for any length of time. This time has been much worse, I haven't been able to go round the supermarket, I just haven't been able to manage it. I'd have to sit down and my wife would struggle round.' Sam

For others, their daily activities were not too constrained by their ulceration and they had managed to carry on just as they had before their ulcers.

'Yes, mine never stopped me doing anything. They've never, I can't say that they've ever interfered with anything I've wanted to do.' Mary

'I don't let anything restrict my life.' Pam

Ellen reflected that despite not feeling up to it at times, she felt it important to make an effort to get involved with people and clubs:

'You've not got to let that bother you. I go to the Blind Club once a month and I go to Old Age Pensioners.' Ellen

One participant reflected on needing to ask her neighbours to help her, to provide assistance with her shopping and lifts to clinic appointments:

'Yesterday the young man from along the way, he took me to the clinic. It's a good job that he's out of work else I don't know what I'd have done, I don't honestly. And he took me to the supermarket and I haven't been since way before Christmas...he took me then. I mean you're alright cause you've got the trolley, you can hold onto the trolley (...) he took me and then he came and dropped the shopping off and he came and fetched me (...) but I want things for myself, personal things but I can't go. I just feel like... I know I'm getting older but I don't feel old.... this has made me depressed [points to left leg].' Marg

Again, the youngest participant Steve summed up the extreme effects of his ulceration on his ability to engage with life:

'Social life? 'Errrr, I haven't got one [long pause] I just don't bother cause I know I've gotta [got to] get myself better.' Steve

Steve described times when he totally avoided any contact with others and spoke of the feelings of shame related to his ulceration.

Only one of the interview participants was of working age and he had been unable to work throughout the 15 year duration of his ulceration. He claimed sickness benefits for financial support; a factor which caused him considerable concern:

'When I come to renew it again, I get a bit worried (...) you think with your legs, have you got the nurses on board. I know I've got the Doctor on me [my] side but you don't really need the nurses it's just what the Doctor writes down, you know...but I have got a good Doctor'
Steve

Other participants remembered difficulties working during episodes of active ulceration and reflected on these:

'I carried on at work. I worked in a school kitchen...it never stopped me from working'
Mary

Marg remembered having problems with needing her dressing changes during work time but reflected that she had an understanding employer:

'For the last six years of my life I worked at a local factory (...) you were on your feet a lot. (...) the boss used to take me twice a week to the clinic'
Marg

For others, ulceration started after they had retired so had not influenced their ability to work:

'I've been retired twenty five years (...) I don't think I had 'em [them] until I finished...but I've had them quite a lot since I've left work.'
Sam

4.2.5.2 Mobility.

Mobility problems were common for participants, although for some the problems were also complicated by the impact of their co-morbidities. A number of respondents reported that pain was worse when walking, but revealed that they persevered despite this discomfort:

'Oh I can walk with my frame (...) no they've never stopped me doing things. I could walk better really before I had them. I've always walked alright with them until recently.'

May

One respondent actually felt that her mobility was limited, not as a result of the ulcers themselves, but as a result of their bandages:

'You can't walk well cause I got these compression bandages on.' Ellen

Many of the participants were afraid of falling and sustaining further injury. Marg revealed her fears about falling stating:

'I'm scared of falling; I am so scared of falling. I mean last Christmas (...) I fell, and it had been snowing a little bit and that's when I did this ulcer on this leg [indicates right leg]...it must have been when they tried for pick me up and scraped it (...) so I'm scared of falling.'

Marg

Marg felt that the risk of falling was made worse by her ill-fitting prescription shoes which caused her to walk differently:

'Cause you still throw your foot out (...) I put my foot out [indicates with left hand] (...) It's because it isn't a size as such, you know, it's just a general size (...) you'd be in it if you took 3's, 4's or 5's.' Marg

Steve spoke of more severe and life-limiting effects on his mobility:

'I felt as if I wasn't walking right, wasn't walking as far...before that I'd walk everywhere (...) you know I'd say to me [my] mate, 'Wait for us, what's up with you.... I can't walk, I got to slow down' (...) it was like me [my] veins and everything were tightening up back of me [my] carves and everything.' Steve

4.2.5.3 Hygiene.

Some respondents raised the topic of difficulties maintaining effective hygiene levels, especially their ability to shower. Others referred to having their legs washed in between dressing changes. Steve, the youngest respondent, possibly had the most to say on this area:

'It's bathing, things like that. I do whip them off and have, not a shower.... I could do with a shower. I whip them off and jump in the bath, wash them sometimes, about 15 minutes before I'm due up there [clinic] and then the compression isn't really lost.' Steve

Pam, who removed her dressing regularly, spoke of her need to be clean. She said:

'But, every night I wash me [my] (...) leg and foot.... especially the foot to get all that white stuff off and put a fresh one [dressing] on.' Pam

Ellen spoke of the dressing process undertaken by the nurses' when they visited. She stated that they often did not wash her legs properly:

'No, they cut it all off (...) and then she just puts a bit of cream on.... and that's it, another bandage on.' Ellen

One participant talked positively about a new aid which the nurses had prescribed for her. She explained that it was a waterproof boot; a 'Seal Tight' (Stang, 2010) and using it had enabled her to have a bath:

'You slide your foot to the point and then this at top seals around your leg like that [demonstrates]. Yes, it's great, I wash my leg down to there [indicates right knee] before I get in the bath and then I sponge me [my] feet to there [indicates the start of the bandages].'
Sam

For Pam showering had recently become problematic and, as a result, her husband had had to start to assist her. She reflected:

'He's me [my] husband, fair enough, he's seen more of me these last few months that he's seen for years [laughs]. Well I said, I can put that leg in the shower and wash that leg up to about here [indicates knee] and that's it. But then I've got to wash all the front of me. He's got to wash all the back and do me [my] hair because I can't do it on my own.' Pam

4.2.5.4 Clothes and shoes.

The selection of and the suitability of clothing and shoes was another frequently reported feature throughout the interviews. Steve said:

'I just have to undo the laces and untie them (...) so if I do go for a pair of trainers like, it's hard, I have to get a pair a size bigger cause of all these bandages (...) I take a 9's, these are 10's and I went to buy a pair the other day and they were 11's. They just looked like that [indicates length] and I thought I can't wear them they look like boats.' Steve

Difficulties selecting footwear which would fit over the bandage was problematic for a number of participants. Ellen had to make her own adaptations to her shoes to enable them to fasten but they now appeared to be quite dangerous:

'I took the laces out because with these bandages I couldn't get them on.' Ellen

In terms of clothing, Steve reflected:

'I've just lived in tracksuits, cause it's the only thing I can get on (...) I can't wear jeans or anything (...) at least I can get them up, unzip them so the nurses can get at the dressings. I've tried trousers, canvas trousers, jeans.... I just conna [can't] get them on at all....' Steve

Similarly, the female respondents had made choices regarding their clothes, electing to wear items which would conceal their dressings but also allow easy access for the dressing procedures:

'I wear trousers all the time now.' Mary

Marg was frustrated by her inability to wear the many attractive clothes which she owned:

'It's horrible.... you can't dress as you want to. I've got nice fine skirts (...) printed skirts for the summer, ever so nice.' Marg

4.2.5.5 Sleep.

Sleep was an issue which was raised by most respondents and was often attributed to the presence of uncontrolled pain. Marg reflected that she would get up rather than be uncomfortable in bed:

'Some nights...last Thursday (...) I had no sleep with it all night (...) it was going like this [indicates clenching motion] every few minutes and you're there trying to find somewhere to put your leg (...) it's awful, so I'd get up and hobble in here [lounge] and get myself a drink and some Paracetamol.' Marg

Some participants attributed their night time discomfort to their compression bandages. For some analgesia relieved the problem and made it easier to sleep. Sam reflected:

'They've got me down, especially the pain...the pain gets me down (.....) when I went into bed, I tried to take the tablets, these co-codamols, I had to just so as I could get off to sleep.'
Sam

4.2.5.6 Relationships.

Many of the participants spoke of the effects of ulceration on their relationships - whether with friends, family members or more intimate relationships. Pam reflected on the need for her husband to assist her in day-to-day activities. Sam similarly reflected on being unable to provide his wife with the support she needed.

Steve differed slightly from the other participants, as he felt ashamed of his wounds feeling that he had inflicted them on himself. He found it difficult to reveal the true nature of his condition to his friends. He stated:

'I have got a few other people I can go and see them and talk to them (...) because they're bad in their own ways you see (.....) I've got other mates as well who don't know anything about [points to legs], they can't see them and I just keep me [my] mouth shut.' Steve.

Steve also reflected on the effects of his ulcers on forming more intimate relationships. His ulcers had developed when he was 24 years old and reflected on the decision he had made to avoid such relationships, something he had almost put on hold until a time when his wounds had healed. He reflected:

'But relationship wise.... erm, no chance...I couldn't. Once these have healed then, obviously yes...but it's just, you know, with these on me legs all the time you know. I can't get in bed with me tracky [tracksuit] bottoms on can I [laughs] (...) there was one girl and I tried. She said 'what's all that on your legs?' and I tried make out that I'd been in a fire and I'd burned myself but, with the smelling and that, it didn't last and I've just sort of put it off.'

Steve

4.3 Phase 1 discussion.

The findings of phase 1 of this study poignantly establish the persistent and profound impact of CVLUs on the daily lives of participants; indeed, the impact on physical, psychological, social functioning and, QoL overall, was devastating. Despite the overwhelming nature of their ulceration, participants demonstrated a range of responses. Some participants saw CVLUs as a challenge and, despite their associated difficulties, did all they could to maintain their usual functioning. In contrast, others withdrew from their normal activities, limiting their contact with others until a time when their condition would improve. This range of personal responses could be attributed to the theories discussed in chapter 2 (page 39 - 48) and is explored further on page 148-149.

This study reinforces the findings of the other qualitative studies reviewed (Charles, 1995; Walshe, 1995; Bland, 1996; Chase et al, 1997; Hyde et al, 1999; Douglas, 2001; Ebbeskog & Ekman, 2001; Rich & McLachlan, 2003; Hopkins, 2004; Brown, 2005 a & b; Byrne & Kelly, 2010; page 68 onwards) and also serves to extend our understanding of the impact of CVLUs with a number of findings contributing to new knowledge in this area (page 156).

4.3.1 Sample demographics.

A review of the demographic details of the patient participants for phases 1 and 2 (table 9; page 109), when compared with known characteristics for those with CVLU, demonstrate that the sample participants were fairly typical. The study sample demonstrated a median age of 76 years and CVLU prevalence is known to increase in frequency with age in both genders (Nelzen et al, 1991; Beebe-Dimmer et al, 2004). CVLUs are also known to be slightly more prevalent in women (1:1.4) (Nelzen et al, 1991), again reflected in a 4:5 male to female ratio for the study sample. Obesity (Moffatt, 1998; Gattringer et al, 2010) and leg injuries (Moffatt, 1998) are also known to predispose to the

condition but in terms of the sample only one participant appeared to be significantly overweight however five had sustained leg injuries that had caused their initial ulceration (page 111). Other predictors highlighted in the research include deep vein thrombosis (DVT), pulmonary embolism (PE) (Scott et al, 1995; Bérard et al, 2002) and increased multiparity (Elder & Greer, 1995; Bérard et al, 2001) but these were not demonstrated in the sample.

The one outlier in terms of this profile was Steve who, at 39 years of age, was by far the youngest study participant. Steve was an ex-IV drug abuser who revealed, during his interview, that he had frequently injected into the vessels in his lower legs which had resulted in his ulceration. IV drug abusers such as Steve represent a significant sub-group of CVLU patients who have the condition as a result of the irreversible damage caused by their drug addiction (Sudhindran, 1997; Finnie & Nicolson, 2002; Pieper & Hopper, 2005; Palfreyman, 2007b). Steve had suffered from severe ulceration for many years and provided a lengthy narrative about the impact of the condition on his life but, interestingly, the themes and subthemes were the same as those from the 'traditional' patients with CVLU but, at times, the impact was more profound (page 116).

4.3.2 Theme discussion.

4.3.2.1 The Ulcer.

Each of the interview participants provided a narrative of their leg ulcer journey, without prompting from the researcher. The value of such patient stories is increasingly being recognised as significant in evaluating the effectiveness of healthcare delivery, especially in the care of patients with a range of LTC. Personal stories are also used to investigate the meanings people attribute to their health and illness and, as part of the consultation, are seen as an integral part of the therapeutic relationship between the patient and their HCP (Winterbottom et al, 2012). During the interviews, the

participants took the opportunity to put their illness into context and to describe their journey to the interviewer; almost, as described in Antonovsky's (1987) theory of salutogenesis, trying to develop a sense of coherence surrounding their illness (page 46).

4.3.2.1.1 Family history.

Three of the phase 1 participants reflected on what they described as a family predisposition to ulceration. Predictors for the development of CVLUs, to date, have mainly been extrapolated from data relating heredity and the development of varicose veins (Scott et al, 1995; Beebe-Dimmer et al, 2004) however, evidence to support a link between heredity and subsequent CVLU development has been not only limited but also conflicting (Scott et al, 1995; Berard et al, 2002). One study demonstrated no association between heredity and either varicose veins or CVLU when estimates were adjusted for age, gender, obesity, previous thrombophlebitis and leg injury (Scott et al, 1995). In contrast, Bérard et al (2002) identified a number of new predictors for the development of CVLUs, which included a family history of maternal venous insufficiency. In relation to the study sample, the three participants who cited what they termed a 'family predisposition' were all evident on their maternal side.

4.3.2.1.2 Co-morbidities.

Six of the phase 1 participants suffered from co-morbidities which complicated their daily lives and also limited their QoL. Two participants suffered from extensive rheumatoid arthritis (RA), a condition known to predispose the sufferer to the development of CVLUs (Thurtle & Cawley, 1983); with a reported prevalence of between 9% (McRorie, 2000) and 38% (Nishikawa, 1983) compared to a 1% prevalence in the general adult population (McRorie et al, 2000). Three participants reported that

they suffered from quite extensive osteoarthritis (OA), present in up to 25% patients who present with a CVLU (Margolis et al, 2003). In both RA and OA, research demonstrates a link between the condition and calf pump dysfunction, which may result in the development of CVLU (Browse et al, 1988; Margolis et al, 2003). Two of the participants reported sight problems, with one reporting that she was registered as blind; both attributed their ulcers to injuries they had sustained to their lower legs potentially as a result of their reduced vision.

Of the six participants with co-morbidities, there was a preoccupation with these conditions during their interviews which appeared to almost diminish the impact of their CVLU, almost serving as a distraction (Tom, Ellen & Sam; page 110). In contrast, where ulceration occurred in isolation, symptoms seemed to overwhelm the participant and almost defined their existence (Marg; page 121). This may well reflect the individual personal characteristics discussed in chapter 2 (page 39 - 48) such as locus of control (Rotter, 1954; page 44), self efficacy (Bandura, 1977; page 45) and learned helplessness (Seligman, 1975; page 45) which identified that certain characteristics improved an individual's ability to cope with the threats posed by illness.

Indeed, Charles (1995) investigated whether her study participants with CVLU demonstrated either an internal or external locus of control and concluded that those with an internal locus assumed an active approach to their ulcer management and often appeared to cope better, believing that they had control over events. In contrast, those participants with demonstrated an external locus tended to believe that they are under the control of others and failed to cope as well with the impact of their CVLU (Rotter, 1954). Further research into the impact of the personal characteristics discussed in chapter 2 (page 39 - 48) and coping with LTCs including CVLU, would be useful and may enable nurses to motivate and empower their patients by tailoring their approaches to disease management in a more appropriate way for their patients.

4.3.2.1.3

Cause, location, duration and description of ulcers.

All participants reflected on the cause, location, duration and recurrence of their venous ulceration but no overall pattern was demonstrated. Six participants identified an injury that caused their ulcer whereas three could identify no precursor and felt that their ulcers simply appeared 'out of the blue'. Six participants suffered extensive bilateral ulcers, whereas three reported only unilateral ulceration. Two suffered recurrence at exactly the same site on each occasion, which they both, interestingly, attributed to an area where all of their shoes rubbed and they had both experienced periods of healing, despite wearing the same shoes. The duration of ulceration demonstrated by participants ranged between three and fourteen years.

Recurrence of CVLU is known to be common, with ulcers generally proving to be difficult to heal and demonstrating a high tendency to recur (Callam et al, 1985; Moffat et al, 1992; Nelzen et al, 1997). This was alluded to earlier (page 9), with Heit et al (2001) reporting an estimated annual recurrence of such ulcers as between 33-42%, similar to the results of an earlier UK study by Franks et al (1995) which reported recurrence of 26% after one year and 31% after 18 months. A more recent study by Etufugh and Phillips in 2007 estimated CVLU recurrence rates to be at an alarmingly high level of between a 54 and 78%. Recurrence is demoralising for both the patient and the providers of care (Bérard et al, 2002; Barwell et al, 2004) however, most participants appeared to be resigned to this pattern of ulceration, healing and re-ulceration.

The longevity of the healing process was a challenge to many of the participants who reflected on the time wasted either whilst waiting for healing to take place or waiting for the nurse to visit. This was a distressing feature and echoed the findings of Chase (1997) whose participants reflected on wasted days. Some participants had made a conscious decision to get out and about and to attend their local clinic for their wound care. This seemed to have had positive benefits in terms of their

outlook and coping strategies but may well have been influenced by their underlying personal characteristics, as discussed in chapter 2 (page 23 - 49). This may well prove to be a key feature of future research (Lindsay, 2000).

4.3.2.2 Symptoms

Table 10 below provides a summary of the themes and subthemes from the interviews related to the participants symptoms.

Table 10: Symptoms – summary of themes and subthemes from phase 1 interviews.

Subthemes:		Key findings – Symptoms.
Pain:		<ul style="list-style-type: none"> • The theme of pain dominated all of the interviews.
	Descriptions of type of pain:	<ul style="list-style-type: none"> • Background pain reported to always be present. • Intermittent episodes of more severe pain.
	Timing & duration of pain:	<ul style="list-style-type: none"> • Continuous nature of pain reported. • Pain worse at night resulting in disturbed sleep.
	Causes of pain:	<ul style="list-style-type: none"> • Described as constant pain, made worse by dressing procedure or the dressings applied. • Pain not directly related to wound size.
	Use & effectiveness of pain relief:	<ul style="list-style-type: none"> • Some were reluctant to take analgesia due to side effects, a stoical approach or too much medication taken already. • Effectiveness was poor when taken.
Exudate and odour:		<ul style="list-style-type: none"> • Management of excessive exudate was problematic which occasionally led to non-compliance. • Odour was embarrassing, leading to self-imposed social isolation.
Emotional impact of ulceration:		<ul style="list-style-type: none"> • Where present along with multiple co-morbidities, accepted with stoicism. • Result in depression, even suicidal thoughts. • Some participants made a conscious effort to engage with daily activities despite ulceration. • Despite despair, all spoke of hope and optimism surrounding healing and were looking to the future. • Fears of further injury, of making a mess, of what other people think and of what the future holds.

4.3.2.2.1

Pain.

Pain overwhelmingly dominated the lives of all participants and impacted on every aspect of the participant's functioning. Pain interrupted sleep, limited their mobility, lowered mood and was often ineffectively managed. Pain was described as continuous, unbearable and was a constant reminder of their ulceration; findings similar to other studies reviewed (Walshe, 1995; Chase, 1997; Hyde, 1999; Rich & McLachlan, 2003; Hopkins, 2004). Ebbeskog and Ekman (2001a) likewise reflected that pain was central to their participants' lives, which made their participants 'cry in despair' (Ebbeskog & Ekman, 2001a; page 69), and analgesia was deemed to be ineffectual against their ulcer related pain.

Tornvell and Wilhelmsson (2010) also reported inadequacies in pain management for patients with CVLU in their satisfaction study (page 12). The enduring nature of the pain experienced by patients with CVLU and the inadequacy of the analgesic options available to the study participants were themes which dominated the interviews and highlight the need for urgent research into the successful management of pain for this patient group (Douglas, 2001; Ebbeskog & Ekman, 2001b).

4.3.2.2.2

Exudate and odour.

Difficulties managing wound exudate and odour were again evident for all and had a distressing impact. The humiliation of the odour and its impact on self-image, the resultant self-imposed isolation in order to prevent others from being exposed to this embarrassing symptom, were key findings of this study. Odour and leakage have been acknowledged in other studies (Douglas, 2001; Ebbeskog & Ekman, 2001b; Persoon, 2004; Briggs & Fleming, 2007) but the daily effects of these symptoms on the social and psychological functioning of participants in this study provides an original insight and serves to highlight the need for more effective wound management strategies for these

distressing symptoms. The devastating impact of exudate and odour on the participant group is reminiscent of the work of Price (1995) on body image, albeit in a different condition, which similarly resulted in feelings of loss of control and a fear of the reaction of others to the effects of their condition.

The combination of pain, exudate and odour severely limited social functioning and lowered the mood of study participants; even prompting thoughts of suicide for Steve. But despite the devastating limitations of these symptoms, the participants, on the whole, strived to maintain their functioning and some even attempted to engage as they had before their ulceration. The theme of hope, especially hope for healing, was evident for all participants and may again reflect their underlying personal characteristics (chapter 2; page 39 - 48) and is a theme that echoes the work of Walshe (1995).

4.3.2.2.3 Emotional effects of ulceration

The impact of CVLU on the psychological functioning of the study participants was also consistently reported and also reflected the findings of the studies reviewed (Rich & McLachlan, 2003; Byrne & Kelly, 2010). Feelings of depression, low mood and poor self image were common and impacted on the daily lives of participants. The psychological impact of the condition was evident in the fears disclosed by participants; fears about whether their ulcer would heal, of what people thought (Price, 1999) and fears of further injury. The ability of participants to cope with these stressors may, again, be facilitated by their personal coping strategies (Antonovsky, 1987; Lazarus, 1993) and may be an area for future research.

Such psychological effects of ulceration were common to the research presented in chapter 3 (page 50 - 92) and, when combined with the physical effects of ulceration, seem to intensify the impact on the participant's functioning (Hopkins, 2004). But, again, despite such feelings of loss the participants also had hope for the future, which echoes the findings of Hyde et al (1999) whose participants had an inner strength, a determination to cope, stoicism, resilience and hope for the future. Again, outlooks that may be explained, in part, by the theories discussed in chapter 2 (page 39 - 48) such as locus of control (Rotter, 1954; page 44), self efficacy (Bandura, 1977; page 45) and learned helplessness (Seligman, 1975; page 45).

4.3.2.3 Wound Management

Table 11 below summarises the wound management themes from the phase 1 interviews.

Table 11: Wound management – summary of themes and subthemes from phase 1 interviews.

Subthemes:	Key findings – Wound Management:
The Nurse:	<ul style="list-style-type: none"> • An expert in the care of ulcers. • The nurse-patient relationship was valued. • Consistency of team was important. • Variations in dressing technique noted. • One reflected on a problematic nurse-patient relationship. • The location and timing of dressing was important, especially when chosen rather than imposed. • Specialist support was valued.
Treatment applied and patient understanding:	<ul style="list-style-type: none"> • Compression proved difficult for some and well tolerated by others. • The variety of dressing products was discussed; with some products tolerated better than others. • Patients demonstrated an excellent understanding of their care, the products applied and their management.

Most of the phase 1 participants (n=8) reflected positively about the expertise and support offered by their nurses with many commenting on their preference for the same nurses, claiming that this was a key factor in improving the personal nature and the effectiveness of the care they received. This is a finding echoed in a number of other studies (Chase et al, 1997; Tornvist et al, 2000; Hopkins, 2004; Tornvell & Wilhelmsson, 2010) and may have important implications in the organisation of future care delivery. As confirmed by earlier studies, consistent care (Chase et al, 1997; Hopkins, 2004), the competence of the nurse in dressing selection and application (Chase et al, 1997; Douglas, 2001) and the provision of regular feedback on the progress of the wound to the patient (Charles, 1995; Brown, 2005b) were considered key factors in the quality of the care delivered, elements that were important to the patient and are encapsulated by the theory of patient centred care (page 23 - 37).

For many, where the healing process was prolonged and their ulcer recurrence felt to be almost inevitable, the focus of care on healing as the sole outcome of care has to be questioned. Briggs and Flemming (2007) recommend the adoption of a new approach to leg ulcer management where care is delivered in line with other chronic, long term conditions. They suggested that the focus on healing may actually intensify the 'hopelessness' felt by the patient, almost fostering a 'learned helplessness' as described by Seligman (1975; page 45) by the patient (Briggs & Flemming, 2007). Briggs and Flemming (2007) recommend a renewed focus in wound care and propose that it may improve the patients coping strategies (page 43), enhance the patient focus of the consultations (page 24 - 37) and encourage the nurse to move away from a focus solely on the wound (page 2) (Persoon et al, 2004).

For just one participant in this study, Pam, the nurse-patient relationship had become problematic; a finding supported by other studies which highlighted potential negative nurse-patient relationships

(Chase et al, 1997; Hyde, 1999). Such problems were often attributed to a perceived non-concordance to treatment recommendations by the nurse (Chase et al, 1997; Hyde, 1999) which may, in part, be due to issues relating to power in the HCP-patient relationship (Hewison, 1995; page 43) and ineffective communication (Ley, 1988; page 24-37). The promotion of an open, concordant relationship between the patient and their HCP is essential to the fostering of the best quality of care and is key to a patient centred approach, where the patient is listened to and care delivered in accordance with their preferences (Stewart et al, 2004; page 10).

Participants reflected that they had experienced a wide variety of wound care products over time and were knowledgeable about the wound management strategy adopted by their nursing team; often seeing themselves in partnership with their nurse against the ulceration. Other studies highlight similar positive effects of the nurse-patient relationship (Ebbeskog & Ekman, 2001a; Brown, 2005a & b).

4.3.2.4 Effects on daily life.

Table 12 below summarises the effects on daily life subthemes for the phase 1 interviews.

Table 12: Effects on daily life - summary of themes and subthemes from phase 1 interviews.

Subthemes:	Key findings – Effects on daily life.
Restrictions to daily life:	<ul style="list-style-type: none">• Some reflected on being a 'prisoner'.• Inability to provide care for loved ones.• Reflections on loss of independence.• Missed opportunities.• Some reflected on having little social life.• Optimism for the future.• Efforts to get out despite ulceration.
Mobility:	<ul style="list-style-type: none">• Poor mobility due to the ulcer, the dressing or due to age.• Fear of falling.
Hygiene:	<ul style="list-style-type: none">• Difficulties staying clean.• Led to non-compliance for one participant.• New aid was improving personal hygiene.
Clothes & shoes:	<ul style="list-style-type: none">• Restricted choices of clothes & shoes.• Attempts were made to conceal dressings.
Sleep:	<ul style="list-style-type: none">• Pain caused issues with sleep.• Many reflected on getting up in the night.
Relationships:	<ul style="list-style-type: none">• Reliance on family for support.• The need to provide care was problematic.• Profound effects of severity of ulcers on family members.• Avoidance of intimate relationships.• Avoidance of telling friends about the ulceration.

For many studies, as with this, the physical effects of CVLUs dictated the reflections of the participant. Daily living proved a challenge for all with getting out and about, limited mobility and difficulties maintaining personal hygiene due to the wound, the dressing or both; as were choices in what to wear. Sleep was regularly disturbed, most often by pain and relationships were altered, with carers becoming cared for and intimacy avoided; factors echoed in the findings of Bland (1996); Brown (2005b), Rich and McLachlan (2003) and Byrne and Kelly (2010).

Ulceration affected every area of functioning over long periods of time. Other studies have similarly presented a dominance of physical effects due to ulceration but have claimed, where this is the case, often the psychological and social issues are diluted (Brown, 2005 a & b); this did not appear to be the case during this study. Participants spoke at length about the impact on their psychological functioning, describing the effect on their mood, their motivation and their ability to engage in activities. When combined with the physical symptoms of ulceration, these two areas served to severely limit their social functioning.

4.3.3 Strengths and weaknesses of phase 1.

4.3.3.1 Strengths.

The phase 1 interviews were conducted by a single researcher, which ensured that a consistent approach was maintained for each of the interviews. The researcher was a practicing DN, which may have enhanced disclosure by the participant who appeared happy to discuss the details of their condition, confident in the knowledge that these factors would be understood by the interviewer. This potentially served to enhance the flow of the interviews, as symptoms did not need to be explained or clarified.

The researcher undertook the thematic analysis which ensured immersion in the data, recommended for the process of thematic analysis (Hicks, 2004). In addition, an educational supervisor undertook an independent analysis and achieved consensus with the researcher using a reflexive approach. Additionally, the findings from Phase 1 have undergone double blind peer review prior to publication (Green et al, 2013a), both factors that have confirmed the veracity and rigour of the process.

4.3.3.2 Weaknesses.

On occasion, what appears to be a strength, could potentially become a weakness. The role of the researcher as a DN, which following deliberation with educational supervisors was disclosed to the patient participants (page 97), was felt to have facilitated a more open discussion but in reality, such knowledge may have led the participant to embellish factors relating to their ulceration due to the influence of social desirability bias discussed on page 98 (Paulhus & Reid, 1991).

During every interview the researcher has an effect, the influence of which cannot be accounted for (Hicks, 2004). Approaching the interview in position of equipoise (Bowling & Ebrahim, 2005) and reflexivity throughout the process (Kvale, 2004) aims to limit this effect and were factors applied to the data collection, analysis and reporting of the study findings.

4.3.4 Contribution to new knowledge.

This phase of the study aimed to build on the body of knowledge presented by the reviewed studies (Charles, 1995; Walshe, 1995; Bland, 1996; Chase et al, 1997; Hyde et al, 1999; Douglas, 2001; Ebbeskog & Ekman, 2001; Rich & McLachlan, 2003; Hopkins, 2004; Brown, 2005 a & b; Byrne & Kelly, 2010; page 68). In addition, it is felt that there are a number of findings that have enhanced our understanding or are, indeed, new. These include:

- The dominance and constancy of pain, reported as always being present for all participants, has not been reported as consistently by participants in other studies (page 116-119).
- The presence of inadequate strategies to manage pain was a theme that was stressed by all participants, and again is alluded to by other studies but the prevalence in this study was greater (page 116-119)

- The presence of hope for all participants, despite them all reflecting on their poor QoL, was again more consistently reported (page 122-124).
- The patient's preference for a consistent nursing team was reflected on by all participants and may be significant in the organisation of future care delivery (page 125-129).
- Poor symptom management, especially in relation to exudate and odour, was revealed (page 119-121).
- The impact of exudate and odour on both psychological and social functioning was identified (page 119-121).

4.3.5 Further research.

The evidence surrounding the impact of personal characteristics on the patients' ability to cope with their long term conditions appears to be relevant to patients with CVLU (page 39-48). Further research that explores this relationship and encompasses this knowledge in the development and 'personalisation' of the consultation may have the potential to effectively enhance PCC.

Fostering of a therapeutic relationship between the patient and the nurse that is really patient centred; where the patient feels valued, supported and listened to and where the chronicity of their ulceration is understood, is vital and may result in improved healing rates and reduced ulcer recurrence (Briggs & Flemming, 2007). Further research is needed to determine whether this is so.

In this current climate of modernisation of community care (DH, 2013) priorities need to focus on the importance of the patient in the consultation and the delivery of holistic care. The importance of the nurse-patient relationship and the need for consistent care provision highlighted by this study is an area that is of central importance.

Where patients had engaged and attended a clinic for their wound care, they reflected on a renewed positivity, an enhanced outlook and improved coping strategies, feeling in control of their care, rather than controlled by it (page 127-128). Research that builds on that of Lindsay (2000) in relation to wound care clinics and promotes patient choice in the location of care delivery would be beneficial.

Reflection on personal narratives during the consultation may well serve to enhance patient understanding of their condition and enable them to develop effective coping strategies (Lazarus, 1993) and a sense of coherence (Antonovsky, 1987). Consultation based research that facilitates a focus on such discussion may prove to be effective.

4.3.6 Conclusion.

This phase has effectively demonstrated that the QoL of patients with CVLUs is impaired in physical, social and psychological domains. The impact of ulceration was vividly described together with the life changing, debilitating symptoms which were often inadequately managed; combined these had an enervating effect on every aspects of daily living. Understanding the 'lived experience', listening to the patient and providing effective symptom management for this chronic condition during wound care consultations is crucial to the improvement of QoL for this patient group. Subsequent phases of this study build on these findings.

Chapter 5: Phase 2.

Chapter 5: Phase 2.

Chapter 5 provides detail of the underlying methodological decisions, the methods used, the research procedure undertaken during phase 2 (5.1), the subsequent results (5.2) followed by a discussion of the significance of the findings in the light of the research (5.3).

5.1 Phase 2.

Phase 2 of this mixed methods study was designed to answer the following research question:

To what extent are the significant factors highlighted in the phase 1 interviews, elicited and addressed during the patients' consultations?

As with phase 1, qualitative methods of enquiry were applied during phase 2 of the study to determine the extent to which the themes and subthemes disclosed during the phase 1 interviews were addressed during the subsequent consultations for the same participants. Following consideration of other potential designs for phase 2, such as holding a focus group for nursing staff to discuss the nature of their consultations or the distribution of questionnaires to patients following their consultations, it was decided that to explore consultations as they happen, a period of non-participant observation would be the optimal approach. Observation would facilitate the study of interactions between the nurse and the patient in real time and provide the researcher with an insight

into what actually happens during the consultations and nurse-patient interactions as they take place in reality (Spradley, 1979; Hicks, 2004; Denscombe, 2007).

5.1.1 Phase 2 design and methodology.

As discussed (page 94), qualitative research encompasses a range of approaches and associated data collection methods to enable the researcher to gain a true-life perspective (Salmon, 2012). Observation itself is an important research technique which aims to provide a systematic description of people's way of life and often affords a unique insight into the social context (Strauss and Corbin, 1998; Barfield & Thomas, 2001). Observation provides an understanding of interactions and their context, whilst providing additional information regarding the physical environment; factors inextricably bound to the research process (Polgar & Thomas, 1991; Mulhall, 2003).

Such research can be either overt in nature, with the purpose of the research known to participants, or covert; with participants unaware that the research is taking place. Each approach has inherent advantages and disadvantages in terms of the quality of the data produced and the ethical acceptability of the research (Denscombe, 2007). Phase 2 was designed to be overt which is often the case in healthcare research to comply with the stringent ethical processes with which it is governed. Thus, during phase 2, both the purpose and the process of the observations was fully explained to both nurse and patient participants, prior to their consent being gained but it was felt to be likely that the participants would 'forget' that they were the subjects of observation and, as a result, may act normally; a situation reported in other similar observational studies (O'Reilly, 2005).

The technique of observation is particularly important within the practice-based professions such as nursing, since it facilitates the study of participants' behaviour and provides an opportunity to understand the actions and reactions of participants (Lofland & Lofland, 1971; Parahoo, 1997). In nursing the goal of 'observation-type' research is often to improve practice and it provides an excellent opportunity to describe and interpret behaviour, including interactions between patients and their HCPs (LeCompte & Preissle, 1993; Kennedy, 1999; Holloway & Wheeler, 2010; Fetterman, 2010). Savage (2000) emphasises the importance of such research to understand the patients' and clinicians' worlds, from their own perspective and stresses that health researchers have a distinct advantage in such research situations as they are insiders and, as such, are able to ask questions and legitimately stay in the 'field'; factors which may go some way to reducing any observer effect (Holloway & Wheeler, 2010). Despite this, the influence of the observer must always be taken into account, as all such data is influenced by the participation of the observer in the field (Borbasi et al, 2005).

Gold (1958) and Junker (1960) identified four types of observation and developed the typology displayed in figure 11. Observation approaches range on a continuum from the complete participant, where the true identity and purpose of the research is not known to those observed; participant-as-observer, where both the researcher and the participants are aware that they have a field relationship; observer-as-participant with the observer participating simply by being in the location rather than actually working there and, finally, the complete observer, with the researcher completely removed from any social interaction with the informants and simply observes.

Figure 11: Typology of observation (Gold, 1958; Junker, 1960).



This typology (Gold, 1958; Junker, 1960) places the observer on a continuum of participation, moving between these levels of involvement; a principle upheld by many subsequent researchers (Pretzlik, 1994; Hammersley & Atkinson, 1995). Indeed Pretzlik (1994) suggests that in advance of the observation taking place, it is actually impossible to plan the intended 'type' of observation, as this alters along the continuum during the period of fieldwork (Gold, 1958; Wolcott, 1994; Hammersley & Atkinson, 1995; Pope & May, 1995). These shifts may well be beneficial since they may limit the influence of the observer on the data produced (Hammersley & Atkinson, 1995; Holloway & Wheeler, 2010).

The intended approach to the observations in phase 2 was initially anticipated to be non-participant in nature, however, reflecting on the above typology (figure 11) and the need for a flexible response to the requirements of the participants and the environment, movement along the observation continuum was experienced (Gold, 1958; Junker, 1960). At times the researcher was a complete observer and at others a participant-as-observer; a role that was further complicated as the

researcher was now known to the participants, having previously undertaken the phase 1 interviews. On occasion this did lead to comments from the participants and openings for conversation directed to the observer but these were minimised by the researcher responding politely but closing the questioning or diverting attention back to the nurse participant.

The success of any observational research relies on gaining access to the environment to be studied which is often controlled by 'gatekeepers' who restrict access to protect either the environment, the potential participants or both (Hammersley & Atkinson, 1995; Pope & May, 1995). The gatekeepers for phase 2, as for phase 1, were the DNs but, having already assisted with access to the patient sample in phase 1, no problems were experienced gaining access to the sample during phase 2. Access issues often heighten the need for the researcher to consider their identity, as with interviewing (page 98), in order to assure gatekeepers that the research is non-threatening; a factor made easier when research is overt in nature such as this (Waddington, 1994; O'Reilly, 2005).

Despite meticulous preparations prior to accessing the research environment, the presence of a researcher in the field invariably stimulates some sort of response from those 'observed' (Lincoln and Guba, 1985). The Hawthorne Effect (Roethlisberger & Dickson, 1939), where behaviour is altered as a direct result of the observation, cannot ever be completely eliminated and its effects can only be estimated (Alder & Alder, 1987), however, strategies can be employed to attempt to minimise this effect, including extending the duration or frequency of the observations. The phase 2 observations were repeated on four occasions for each of the patient participants, a strategy intended to minimise both the Hawthorne Effect (Roethlisberger & Dickson, 1939) and any researcher effect (Denscombe, 2007). This approach appeared to be effective.

Field notes are said to be a vital element of observational research and depend on the quality of the observation skills of the researcher but also on their methods of recording the observations (Pope & Mays, 1995; Mulhall, 2003; Polit & Tatano Beck, 2004). Pretzlik (1994) advocates the use of a predetermined observation schedule completed during the observation to ensure an accurate recording of the detail and also to allow for quantitative data to be generated from the process (Denscombe, 1998; Bowling, 2009; Fetterman, 2010). For phase 2, an observation consultation checklist (appendix 9) was developed, in conjunction with an educational supervisor, based on the themes and subthemes extrapolated from the phase 1 interview data to facilitate accurate recording of observation detail and to minimise disruption during the observations (Denscombe, 1998; Bowling, 2009; Fetterman, 2010). The development of the observation checklist utilised the thematic map constructed during the phase 1 thematic analysis (appendix 7) to map potential checklist items to the themes (appendix 8), which resulted in 28 items, each independently selected by the researcher and an educational supervisor, thus ensuring rigour. As a result of the comprehensive development, the observation checklist successfully encompassed all of the phase 1 themes and subthemes (appendix 9). Table 13 below demonstrates the alignment of interview themes and subthemes with the checklist items.

Table 13: Phase 1 themes / subthemes with phase 2 checklist items.

Phase 1 themes:	Phase 1 subthemes.	Phase 2 checklist items.
The ulcer:		
	Family history.	
	Co-morbidities.	
	The cause, location and duration of ulcers.	
Symptoms:		
	Pain – description of the type of pain.	Pain:
	- timing and duration of pain.	Presence of pain.
	- causes of pain.	Cause of pain.
	- use and effectiveness of pain relief.	Type of pain.
		Timing and duration of pain.
		Use & effectiveness of analgesia.
		Advice regarding pain management.
		Has the dressing been comfortable?
		Discomfort during the procedure.
		Advice regarding pain management.
	Exudate and odour.	Exudate
		Odour
	Emotional effects of ulceration.	Depression
		Fears and concerns
		Self-image
		Fear of people's reactions
		Fear of recurrence.
Wound management:		
	The nurse.	Nurse advice.
	The treatment applied and patient understanding.	Wound management:
	Patient compliance.	Has the dressing been comfortable?
		Discomfort during the procedure.
		Update on condition of the wound.
		Objective measurement.
		Knowledge and understanding of dressings.
Effects on daily life:		
	Restrictions with everyday activities.	Isolation.
	Mobility.	Restrictions to mobility.
	Working.	Opportunities for work and leisure.
		Financial issues.
	Maintenance of hygiene.	Personal hygiene.
	Clothes and shoes.	Limitations to choice of clothes and shoes.
	Sleep.	Sleep problems.
	Relationships.	Relationships: carers, partners, etc.
	Fears.	Fears and concerns
		Fear of people's reactions
		Fear of recurrence.

The checklist (appendix 9) included tick, comment and 'scoring' boxes for each of the items to ensure ease of completion and minimal distraction for the researcher, nurse and patient participants. The template also included the facility to indicate whether it was the patient participant or the nurse who raised a theme or subtheme, an important consideration since patient participants raised themes and subthemes without prompting during their interviews. A 'scoring' tool was also included, based on tools used in similar observational studies (Henbest & Stewart, 1989). The scoring tool facilitated the rapid assessment of the depth to which themes were explored during the consultation (table 14).

Table 14: Scoring tool for checklist themes.

0	Theme not raised by nurse or patient.
1	Nurse did not identify cue.
2	Nurse picked up cue only.
3	Nurse identified patient cue and asked about the issue.
4	Nurse picked up cue and partially dealt with it.
5	Nurse picked up cue and dealt with it fully.

5.1.2 Phase 2 sampling framework.

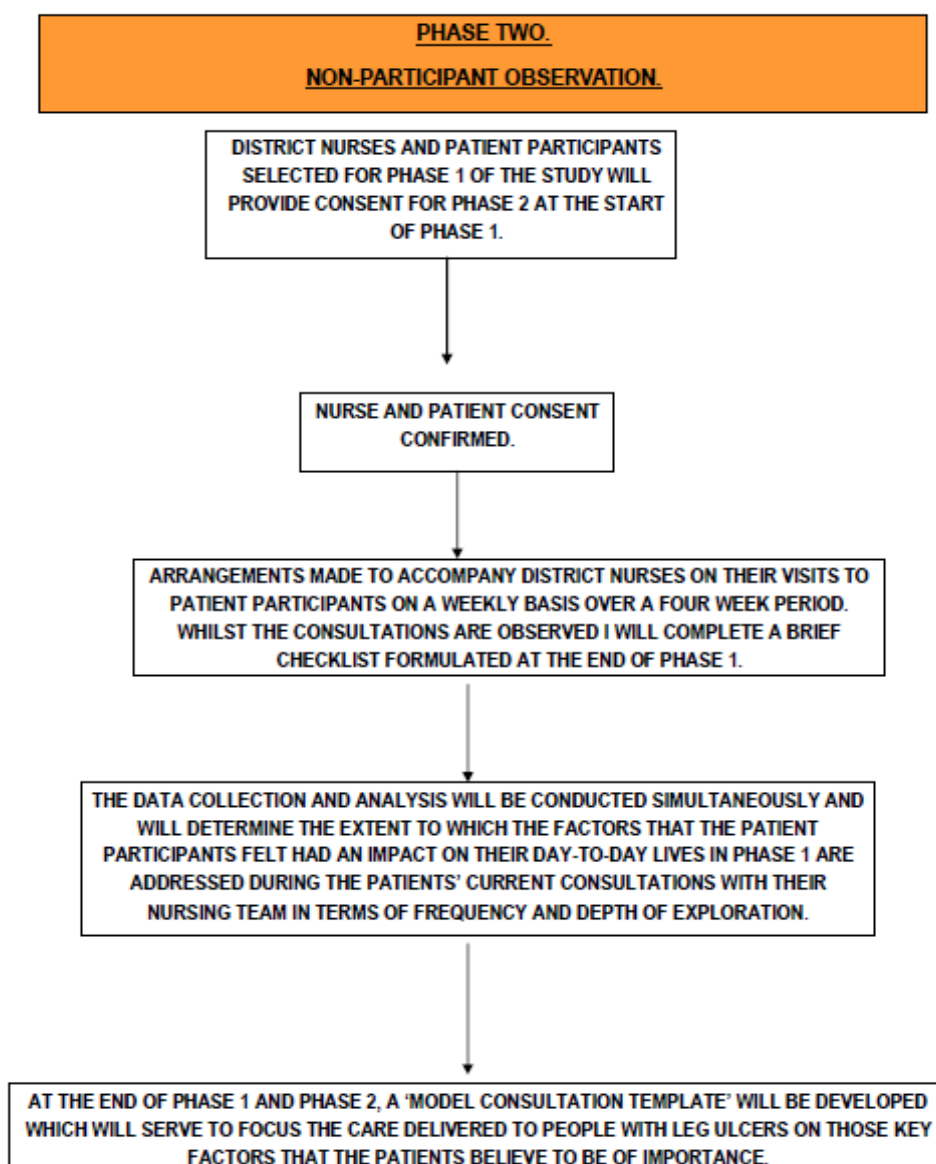
The key to the success of phases 1 and 2 of the study was access to the same patient participants, a factor that would facilitate the tracking and linkage of the phase 1 data with the observation data. As a result, phase 2 utilised the same nurse and patient sample as phase 1 with the sampling framework, inclusion and exclusion criteria and sample size, as detailed for phase 1 of the study (pages 99 - 101).

5.1.3 Phase 2 study procedure.

Once the consultation checklist had been developed on completion of phase 1; phase 2 commenced and is outlined in the following flow chart (figure 12). Nurse participants were accompanied during their routine wound care consultations with the phase 1 patient participants and the patients each had their consultations observed on four occasions, most often undertaken over four consecutive weeks. This 'repetition' designed to allow for a variety of staff members to be observed and also to minimise the Hawthorne Effect (Roethlisberger & Dickson, 1939) as discussed (page 164). Such repeated observations are said to provide the best opportunity to observe interactions as they take place in reality (Denscombe, 2007). In view of the time lapse between phases, prior to each observation opportunities were provided to reaffirm consent and to provide opportunity for consent to be withdrawn if any of the participants so desired.

Each observation lasted for between 20 and 30 minutes, during which time the researcher, whilst remaining as unobtrusive as possible, completed the consultation checklist. Field notes were recorded promptly following each observation and referred to the context, interactions and relevant information about the environment. An example of such case notes is provided in appendix 10. Since only minimal time had elapsed since the interviews, and in view of the nature of CVLU, it was felt that the issues raised as significant during phase 1, would still be similarly problematic for the participants during phase 2.

Figure 12: Phase 2 flow chart.



5.1.4 Phase 2 data collection.

The researcher completed the checklist during each observation, which provided a structured format for recording data and also serving to enhance the researchers' objectivity during the observations (table 14, page 167). Reflexivity was enhanced by prompt completion of field notes following the observation adding to the veracity of the procedure (Miles & Huberman, 1994) (appendix 10). During each observation the researcher documented a score for each item on the checklist. A score of 0 was allocated if either the patient or the nurse did not raise a theme, during the consultation. A score of 1 if the patient mentioned the theme, thus providing the nurse with a cue, but the nurse failed to acknowledge it, for whatever reason. A score of 2 was allocated if the patient gave a cue, the cue was acknowledged by the nurse but there was no further discussion relating to the theme. A score of 3 allocated if there was some general discussion surrounding the theme. A score of 4 was attributed if the nurse offered a partial solution to the issues raised and, finally, a score of 5 was allocated if the nurse explored and fully dealt with the theme.

5.1.5 Phase 2 data analysis.

Data collection and analysis were simultaneous during phase 2, with analysis undertaken after each observation. The completed templates were analysed using descriptive statistics which provided ordinal data to illustrate both the frequency and depth to which the phase 1 themes and subthemes were raised and explored. Such quantitative analysis of qualitative data is not uncommon and serves to allow for the reporting of summary results in numeric terms to summarise the large quantity of qualitative data accumulated (Young, 1981; Abeyasekera & Lawson-McDowall, 2000).

5.1.6 Ethical considerations.

In order to facilitate the consistency of the participants, ethical approval was gained for both study phases at the start, thereby ensuring that the nurses and patients were consistent across the phases. Consideration of ethical issues relating to phases 1 and 2 were presented from page 99 onwards. LREC NHS and R&D approval were applied for jointly for the two phases and were approved at the same time (REF: 10/H1203/13, appendix 4 & 5). The patient and nurse participant study packs and consent forms (appendix 6) included the details of both phases of the study and were completed at the start of phase 1. Nurse and patient participants were contacted at the start of phase 2 to confirm their consent and allow the researcher to make arrangements to accompany the nurses on their scheduled visits to participants whilst they delivered their usual wound care.

It was acknowledged that phase 2 required a more extensive level of involvement from nurse participants since their consultations were now to be observed by a RN, which some may perceive as daunting. In view of this, the nurse participants were provided with the facility to withhold consent for the observation element of the study on their consent form. If this was case, arrangements were put in place for an alternate, consenting member of staff to conduct the consultation for the scheduled observation. Nurse participants were aware that if any issues surrounding their practice were of concern during the consultation, these would be dealt with as recommended by the NMC (2008). Specific issues in relation to phase 2 for the patient participant were the repeated nature and location of the observations, offered either at a clinic base or the patients' own home.

5.2 Phase 2 results.

5.2.1 Introduction.

Of the nine patient participants recruited at the start of phase 1, five (three male) remained involved in phase 2 of the study. Of those unable to take part, the ulcer of two had healed (Evan; Marg), one was in hospital following a fall (May) and one had been discharged (Pam). The patients involved in phase 2 had a median age of 76 years (range 39 - 86 years) (additional detail on page 109). As in phase 1, thirteen experienced nurses remained involved and were observed during phase 2. The nurses had a median of five years of experience in primary care (range 6 months – 20 years).

5.2.2 Checklist items.

During each of the observations, the checklist was completed for each participant. Results are displayed overall in summary table below (table 15 overleaf). In the summary table, each of the boxes has a corresponding score based on the scoring tool (table 14; page 167). Where scoring boxes are also highlighted in yellow, this indicates that the theme or subtheme was specifically emphasised as being of particular importance to the participant during their phase 1 interview. This 'highlighting' facilitated the tracking of known items across from the interview phase to the observation phase of the study and it is these statistics which constitute the reported results and was made possible by recruiting the same sample for both phases (page 99). In order to ensure the usefulness of the results, if a theme was not emphasised as being important to a participant, the score has been excluded. As discussed in the data analysis section (page 170), each theme and subtheme has been reported using descriptive statistics in the form of percentages.

Table 15: Summary table of checklist items.

THEMES																												
	Name & visit number	Presence of pain	Cause of pain	Type of pain	Timing & duration	Use/ effect of analgesia	Advice on pain management	Comfort of dressing	Discomfort during dressing	Exudate	Odour	Depression	Fears & concerns	Self-image	Fear of people's reactions	Isolation	Fear of recurrence	Update on wound	Wound Measurement	Nurse advice	Patient knowledge & understanding of dressings	Sleep	Hygiene	Legs washed?	Mobility	Clothes & shoes	Opportunities for work & leisure	Relationships – carers, partners, etc.
Tom: 01		5	5	5	5	3	3	3	3	5	0	3	3	0	0	3	0	4	0	5	5	3	4	3	3	5	0	3
Tom: 02		3	3	3	3	1	0	5	5	0	0	3	0	0	0	0	0	3	0	0	0	3	0	0	0	3	3	3
Tom: 03		5	5	0	0	0	0	0	4	0	0	0	0	0	0	0	0	5	0	5	3	3	0	0	0	5	1	3
Tom: 04		5	0	4	0	3	3	3	0	5	0	0	0	0	0	0	0	3	0	3	5	0	0	3	0	3	3	3
Mary: 01		0	0	0	0	0	0	4	0	4	0	0	0	0	0	0	3	5	0	5	0	0	0	0	0	0	0	0
Mary: 02		0	0	0	5	0	5	0	0	3	0	0	0	0	0	0	0	0	0	5	0	0	0	0	3	3	3	0
Mary: 03		3	5	0	0	0	0	5	0	5	0	0	0	0	0	0	0	5	0	5	0	0	0	0	0	3	3	0
Mary: 04		0	0	0	3	3	5	3	0	5	0	0	0	0	0	0	0	5	3	3	0	0	0	0	3	3	3	0
Ellen: 01		4	0	0	4	5	5	3	4	5	0	4	3	0	5	3	0	5	0	5	3	3	5	0	3	3	0	0
Ellen: 02		3	3	3	3	5	5	3	0	3	0	3	0	0	0	0	0	3	0	5	0	4	5	0	3	3	3	0
Ellen: 03		3	5	3	0	4	5	3	0	5	0	3	0	0	0	3	0	3	0	5	3	0	5	5	3	3	3	0
Ellen: 04		3	3	0	0	3	0	5	3	5	0	0	3	0	0	0	0	4	5	3	3	0	0	0	3	3	3	0
Steve: 01		4	4	3	0	0	0	5	3	5	0	5	0	0	3	0	0	5	3	4	4	0	4	3	5	4	0	0
Steve: 02		3	0	3	0	0	0	5	0	0	1	3	3	0	2	0	0	4	3	5	5	0	1	0	3	0	0	3
Steve: 03		0	0	0	0	0	0	3	0	5	2	0	1	0	0	1	1	4	0	3	5	0	0	0	0	0	0	0
Steve: 04		1	0	0	0	1	0	0	0	5	5	0	3	0	0	0	0	0	0	4	0	0	2	0	0	0	0	5
Sam: 01		3	0	0	3	0	0	3	3	5	0	0	0	0	0	0	3	5	0	3	3	0	5	0	3	3	3	3
Sam: 02		1	3	2	0	1	0	5	5	3	0	1	0	1	0	0	3	3	0	4	3	0	3	0	1	1	1	3
Sam: 03		3	5	3	3	0	0	3	3	5	0	3	5	0	0	0	1	5	0	5	3	0	5	0	1	3	3	1
Sam: 04		3	1	1	1	1	1	0	1	3	3	1	3	0	0	0	0	3	0	3	2	0	3	0	1	3	1	3

NON-PARTICIPANT OBSERVATION RATING SCALE.

0	Theme not raised by nurse or patient.
1	Nurse did not identify cue.
2	Nurse picked up cue only.
3	Nurse identified patient cue and asked about the issue.
4	Nurse picked up cue and partially dealt with it.
5	Nurse picked up cue and dealt with it fully.

Symptoms

Wound Management

Effects on daily life

Highlighted as important in phase 1

5.2.3 Themes and subthemes.

This section is presented in theme order in line with the reporting of phase 1. Each theme is presented individually, with overall scores in table form for each theme and subtheme. Individual scoring, displayed in pie charts, for each of the important subthemes has been included as an appendix (appendix 11). Overall results for the themes are summarised in the table below (table 16).

Table 16: Summary scores for the main themes from the phase 2 analysis.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Pain (132)	55 (42%)	9 (7%)	1 (1%)	36 (27%)	9 (7%)	22 (16%)
Exudate & odour (28)	9 (32%)	1 (4%)	1 (4%)	5 (18%)	1 (4%)	11 (38%)
Emotional effects (28)	16 (56%)	2 (7%)	1 (4%)	8 (29%)	0 (0%)	1 (4%)
Wound management (32)	3 (9%)	0 (0%)	1 (3%)	9 (28%)	4 (13%)	15 (47%)
Effects on daily life (84)	32 (38%)	8 (10%)	1 (1%)	33 (39%)	3 (4%)	7 (8%)
Total (304)	115 (38%)	20 (7%)	5 (1%)	91 (30%)	17 (6%)	56 (18%)

There was an opportunity to assess each of the 28 themes and subthemes within the checklist on 20 occasions (four observations each for the five participants), which provided a total of 560 checklist items for assessment. As described, scores were only reported where the patient had stressed that the issue was important to them during their interviews, thus, of these 560 assessment opportunities,

304 of these items were highlighted as important to the patient participants and included in these results.

Of these 304 themes of known importance, 189 (62%) were a feature of the consultation whereas 115 (38%) items were not raised during the observed consultation. On 20 occasions (7%), the patient provided a cue about the theme but this was overlooked or not noticed by the nurse. On 5 (1%) occasions the cue was acknowledged by the nurse but was not explored further. On 91 (30%) of occasions the nurse acknowledged the theme and proceeded to have a discussion with the patient about the issue. On 17 (6%) of occasions there was a partial solution offered and on 56 (18%) occasions the issue was fully dealt with.

5.2.3.1 Theme 1: The ulcer results.

During each of the interviews, the 'ulcer' theme encompassed the patients' story of their ulcer journey and was used by the patient to set the scene, often including their family history, co-morbidities and wound history. During each of the observed consultations, discussion about the ulcer featured, providing the patient with an opportunity to put their ulceration into context. This theme did not require a specific response or intervention by the consulting nurse and, as a result, was not directly included within the consultation checklist. Where relevant, field notes recorded any significant disclosure which may have influenced the care delivered.

5.2.3.2 Theme 2: Symptoms results.

5.2.3.2.1 Results for pain.

Eight subthemes - the presence, cause, type, timing and duration of pain, the use and effectiveness of analgesia, advice regarding pain management, the comfort of the dressing and any discomfort during the procedure – encapsulated issues surrounding pain for participants. Each was assessed on 20 occasions (as discussed on page 174). Thus pain related items provided 160 opportunities in total to assess pain, but only 132 were stressed by participants as being significant during their phase 1 interview.

Of these 132 occasions which were now 'known' to be significant, the items were not raised (score of 0) on 55 occasions (42%); the cue was overlooked (score of 1) on 9 (7%) occasions and the theme was acknowledged but not explored further (score of 2) on 1 (1%) of the 132 occasions possible. The theme was discussed (score of 3) on 36 occasions (27%); partially dealt with (score of 4) on 9 occasions (7%) and fully dealt with (score of 5) on 22 of the occasions (16%). These scores are displayed in table 17 below.

Table 17: Overall scores for pain.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Pain (132)	55 (42%)	9 (7%)	1 (1%)	36 (27%)	9 (7%)	22 (16%)

The subthemes related to pain - the presence, cause, type, timing and duration of pain, the use and effectiveness of analgesia, advice provided regarding pain management, the comfort of the dressing

and discomfort during the dressing procedure - were also analysed individually. Table 18 below shows the overall scores for each of the subthemes in the pain category.

Table 18: Scores for pain subthemes.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Presence of pain (20)	4 (20%)	2 (10%)	0 (0%)	9 (45%)	2 (10%)	3 (15%)
Cause of pain (20).	9 (45%)	1 (5%)	0 (0%)	4 (20%)	1 (5%)	5 (25%)
Type of pain (16).	8 (50%)	1 (6.25%)	1 (6.25%)	4 (25%)	1 (6.25%)	1 (6.25%)
Timing & duration of pain (20).	11 (55%)	1 (5%)	0 (0%)	5 (25%)	1 (5%)	2 (10%)
Use & effectiveness of analgesia (20).	9 (45%)	4 (20%)	0 (0%)	4 (20%)	1 (5%)	2 (10%)
Advice regarding pain management (12).	5 (42%)	0 (0%)	0 (0%)	2 (16%)	0 (0%)	5 (42%)
Comfort of the dressing (12).	2 (17%)	0 (0%)	0 (0%)	6 (50%)	1 (8%)	3 (25%)
Discomfort: dressing procedure (12).	7 (58%)	0 (0%)	0 (0%)	2 (17%)	2 (17%)	1 (8%)
Total (132)	55 (42%)	9 (7%)	1 (1%)	36 (27%)	9 (7%)	22 (16%)

5.2.3.2.2

Exudate and odour.

Two items within the checklist related to exudate and odour which provided 40 total opportunities for assessment of which 28 were highlighted as important to participants. Of these 28 occasions to address known exudate and odour issues, the items were not raised (score of 0) on 9 occasions (32%); the cue was overlooked (score of 1) on 1 (4%) occasion and the theme was acknowledged but not explored further (score of 2) on 1 (4%) of the 28 occasions possible. The theme was discussed (score of 3) on 5 occasions (18%); partially dealt with (score of 4) on 1 occasion (4%) and fully dealt with (score of 5) on 11 occasions (38%). These scores are displayed in table 19 below.

Table 19 – Overall scores for exudate and odour.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Exudate & odour (28)	9 (32%)	1 (4%)	1 (4%)	5 (18%)	1 (4%)	11 (38%)

5.2.3.2.3

Emotional effects.

A number of items within the checklist related to the emotional effects of ulceration and included depression, fears and concerns, self-image, fear of people's reactions, isolation and the fear of ulcer recurrence. These six subthemes provided 120 opportunities to assess this subtheme which were highlighted to be significant to participants on 28 occasions. Of the 28 occasions to address known emotional effects, the items were not raised (score of 0) on 16 occasions (56%); the cue was

overlooked (score of 1) on 2 (7%) of occasions and the theme was acknowledged but not explored further (score of 2) on 1 (4%) of the 28 occasions possible. The theme was discussed (score of 3) on 8 occasions (29%) and fully dealt with (score of 5) on 1 of the occasions possible (4%). These scores are displayed in table 20 below.

Table 20 – Scores for emotional effects theme.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Emotional effects (28)	16 (56%)	2 (7%)	1 (4%)	8 (29%)	0 (0%)	1 (4%)

Each of the subthemes were also analysed individually and table 21 below shows the overall scores for each of the subthemes in the emotional effects category.

Table 21: Scores for emotional effects subthemes.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Depression (8).	4 (50%)	0 (0%)	0 (0%)	3 (38%)	0 (0%)	1 (12%)
Fears and concerns (4).	2 (50%)	0 (0%)	0 (0%)	2 (50%)	0 (0%)	0 (0%)
Self-image (4).	4 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Fear of people's reactions (4)	2 (50%)	0 (0%)	1 (25%)	1 (25%)	0 (0%)	0 (0%)
Isolation (4)	3 (75%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Fear of recurrence (4)	1 (25%)	1 (25%)	0 (0%)	2 (50%)	0 (0%)	0 (0%)
Total (28)	16 (56%)	2 (7%)	1 (4%)	8 (29%)	0 (0%)	1 (4%)

5.2.3.3 Theme 2: Wound management results.

A number of items within the checklist related to wound management included an update on the wound, nurse advice and patient knowledge and understanding of their dressings. These items provided a total of 80 opportunities overall of which 32 were deemed to be important by phase 1 participants. Of these 32 occasions to address wound management issues, the items were not raised (score of 0) on 3 occasions (9%) and acknowledged but not explored further (score of 2) on 1 (3%) of occasions. A score of 1 was not attributed to this theme. The theme was discussed (score of 3) on 4 occasions (13%); partially dealt with (score of 4) on 4 occasions (13%) and fully dealt with (score of 5) on 15 occasions (47%). These scores are displayed in table 22 below.

Table 22 – Scores for wound management issues.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Wound management (32)	3 (9%)	0 (0%)	1 (3%)	9 (28%)	4 (13%)	15 (47%)

The subthemes of the wound update, advice from the nurse and patient knowledge were also analysed individually and table 23 below shows the overall scores for each of the subthemes in the wound management category.

Table 23: Scores for wound management subthemes.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Wound update (4)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (75%)
Advice from the nurse (20).	1 (5%)	0 (0%)	0 (0%)	6 (30%)	3 (15%)	10 (50%)
Patient knowledge (8).	1 (12.5%)	0 (0%)	1 (12.5%)	3 (37.5%)	1 (12.5%)	2 (25%)
Total (32)	3 (9%)	0 (0%)	1 (3%)	9 (28%)	4 (13%)	15 (47%)

5.2.3.4 Effects on daily life.

Items related to the effect of ulceration on daily life included work and leisure; sleep; personal hygiene; mobility; choices of clothes and shoes; impact on work and the impact on relationships. These seven items provided a total of 140 opportunities to be evaluated of which 84 were deemed to be important by phase 1 participants. Of these 84 occasions to address known themes items were not raised (score of 0) on 32 occasions (38%); the cue was overlooked (score of 1) on 8 (10%) of occasions and the theme acknowledged but not explored further (score of 3) on 1 (1%) of the occasions possible. The theme was discussed (score of 3) on 33 occasions (39%); partially dealt with (score of 4) on 3 occasions (4%) and fully dealt with (score of 5) on 7 occasions (8%). These scores are displayed in table 24 below.

Table 24 – Scores for effects on daily life.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Effects on daily life (84)	32 (38%)	8 (10%)	1 (1%)	33 (39%)	3 (4%)	7 (8%)

The subthemes were also analysed individually and are displayed in table 25 below.

Table 25: Scores for effects on daily life subthemes.

Issue (total number of potential occurrences of each issue)						
	Not raised (score = 0)	Cue not identified (score = 1)	Cue blocked (score = 2)	Discussed (score = 3)	Partially dealt with (score = 4)	Fully dealt with (score = 5)
Work & leisure (8)	1 (12.5%)	2 (25%)	0 (0%)	5 (62.5%)	0 (0%)	0 (0%)
Mobility (12)	2 (17%)	3 (25%)	0 (0%)	6 (50%)	0 (0%)	1 (8%)
Hygiene (12)	2 (17%)	1 (8%)	1 (8%)	2 (17%)	1 (8%)	5 (42%)
Legs washed? (8)	7 (87.5%)	0 (0%)	0 (0%)	1 (12.5%)	0 (0%)	0 (0%)
Clothes & shoes (16).	4 (25%)	1 (6.25%)	0 (0%)	10 (62.5%)	1 (6.25%)	0 (0%)
Sleep (16)	14 (87.5%)	0 (0%)	0 (0%)	1 (6.25%)	1 (6.25%)	0 (0%)
Relationships (12).	2 (17%)	1 (8%)	0 (0%)	8 (67%)	0 (0%)	1 (8%)
Total (84)	32 (38%)	8 (10%)	1 (1%)	33 (39%)	3 (4%)	7 (8%)

5.3 Phase 2 discussion

Phase 1 clearly established the profound effect of CVLUs across all areas of the daily lives of the participants. Where these issues were emphasised as being important to participants during their interviews, they were highlighted and specifically observed in terms of the frequency and depth to which they were disclosed and addressed during the phase 2 observations.

5.3.1 Discussion of results in theme category.

5.3.1.1 Symptoms.

Table 10 (page 148) provided a summary of the interview findings for the theme of symptoms. As demonstrated in the phase 1 analysis, patient symptoms dominated the interviews but were subsequently infrequently disclosed during the observed consultations (table 16; page 174).

Despite pain dominating all of the interviews, patients seemed to be reluctant to raise this topic with the consulting nurse and, complete solutions with the provision of an effective pain management strategy were only achieved on 22 (16%) of occasions. The patient did not raise the issue during their consultation on 55 (42%) occasions, despite having highlighted its importance during their interview. On 10 (8%) occasions the nurse either overlooked or intentionally 'blocked' the topic, thus preventing any further exploration or the delivery of any advice to alleviate this symptom, which is a concern. These findings echo studies where pain has similarly been overlooked or ineffectually managed (Walshe, 1995; Rich & McLachlan, 2003). Indeed, Tornvall and Wilhelmson's (2010) review of satisfaction with the care for CVLU patients specifically raised their overall dissatisfaction with the management of their pain (page 11).

Exudate and odour were managed more effectively than pain issues during observed consultations but this could have been attributed to the overt nature of this symptom which would have removed the need for the patient to raise the issue and the opportunity for the nurse to overlook it. These issues were not raised on 9 (32%) occasions however, a complete solution was offered on 11 (38%) of occasions. Generally in the literature, exudate and odour were not managed well with participants experiencing regular episodes of leakage and the reports of embarrassing odours (Walshe, 1995; Bland, 1996; Hopkins, 2004; Byrne & Kelly, 2010). Ineffectual management of exudate and odour may be as a result of a knowledge deficit on the part of the consulting nurse or may be due to a lack of effective products to manage this distressing symptom; both areas requiring further investment and research.

Where patient concerns focussed on the emotional effects of ulceration, these were raised even less frequently on only 16 (56%) occasions and a complete solution was only offered on 1 (4%) occasion. This demonstrates a heightened reluctance by patients to raise issues relating to their psychological status with their nurses which may be due to the range of issues raised in Bugge et al's (2006) study (page 32) and supported by other studies (Henderson, 2003). Further research would be useful to ascertain the reasons for such non-disclosure.

5.3.1.2 Wound Management.

Table 11 (page 151) provided a summary of the interview findings in the theme of wound management which was an area that patients raised more frequently than others. Only on 3 (9%) occasions did the patient fail to raise an issue which had been emphasised at interview; when it was raised, on 1 (3%) occasion the nurse blocked a cue, on 9 (28%) occasions there was some discussion, a partial solution was offered on 4 (13%) and a complete solution was offered on 15

(47%) occasions. These results demonstrate that the nurses provided wound care updates, advice and updated patient knowledge, at least at the level of discussion, on 28 (88%) of occasions; by far the best result of all of the themes and highlighting wound management as an area where both patients and nurses felt comfortable both disclosing and discussing issues.

5.3.1.3 Effects on daily life.

Table 12 (page 154) provided a summary of the interview findings in the theme of effects on daily life, however during the observations, the impact on daily life was only completely dealt with on 8% of occasions and patients failed to raise known issues on 32 (38%) occasions. When reviewed by subthemes, hygiene issues were most effectively addressed during the consultations being fully tackled on 5 (42%) occasions. Patients raised themes but most often a discussion of the issues ensued on 33 (39%) occasions with nurses failing to actually offer effective solutions.

5.3.2 Discussion

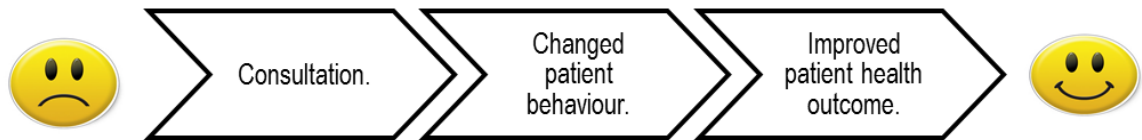
The findings of this phase overall demonstrate a reluctance by the patient participants to raise the issues during their wound care consultation that directly impacted on their daily lives, despite such issues being disclosed without prompting during their earlier interviews. Indeed, of the 304 opportunities overall to disclose these known issues, they were not disclosed on 115 (38%) of occasions and when issues were raised, a complete solution was provided in only a minority of cases (18%), with discussion being the most common action of the consulting nurse on 91 (30%) of the possible 304 occasions.

A similar lack of patient disclosure was alluded to in Bugge et al's (2006) study who postulated a number of reasons for this which included an unsuitable environment, a non-receptive HCP or the patient not feeling that the information was relevant. Other studies have also alluded to similar issues (Henderson, 2003; Pendleton, 2003; Swenson et al, 2004; Thorne, 2005). Such factors may have been apparent during the phase 2 observations but this cannot be quantified; further research where the patient was also interviewed following the observation would be useful to triangulate such results.

Where known issues were raised across all themes and subthemes, a discussion most often ensued (30% of occasions) and only on a minority of occasions was a partial (6% of occasions) or complete solution offered (18% of occasions). This result is important and may indicate a reluctance of consulting nurses to move the consultation to a stage where they problem solve, preferring to simply engage in discussion; as such this is an area worthy of further research. Such a response may be due to organisational matters and time constraints but this lack of a patient focus to consultations requires further investigation (Henderson, 2003; Bugge et al, 2006).

As discussed in chapter 2 (page 23 - 37), the clinical consultation is the central focus of PCC (Dieppe et al, 2002) with its effectiveness relying not only on the consulting skills of the HCP, although these are important (EPOC, 2008), but also on the willingness of the patient to disclose their concerns. Phase 2 has demonstrated an overall reluctance for disclosure on the part of the patient (38% of occasions). Stewart (2004), in her research into the clinical consultation, proposed a mechanism as to how the consultation could be utilised to improve health outcomes largely through its impact on patient behaviour (figure 13 overleaf).

Figure 13: The effects of patient centred care (Stewart, 2004).



The combination of PCC and shared decision making (SDM), when applied, serve to facilitate a greater level of agreement between the patient and HCP and, as a result, the potential for increased concordance with an agreed management plan (page 10). Ideally, such increased concordance would result in enhanced behaviour change, improved health outcomes and an increased likelihood of improvements in patients' functional status, self-care and satisfaction (Ekman et al, 2011). Although Stewart's (2004) hypothesis appears to be relatively straightforward, evidence from a number of earlier studies outlined in chapter 2 (page 23 - 49) demonstrated that HCPs continue to fail to elicit patient concerns or share decision making within the consultation (Ley et al, 1976; Griffin et al, 2004; Wong & van der Worst, 2010). This reluctance may be due to inadequacies on the part of the HCP, but are also hampered by a lack of disclosure by the patient during their consultation (Bugge et al, 2006).

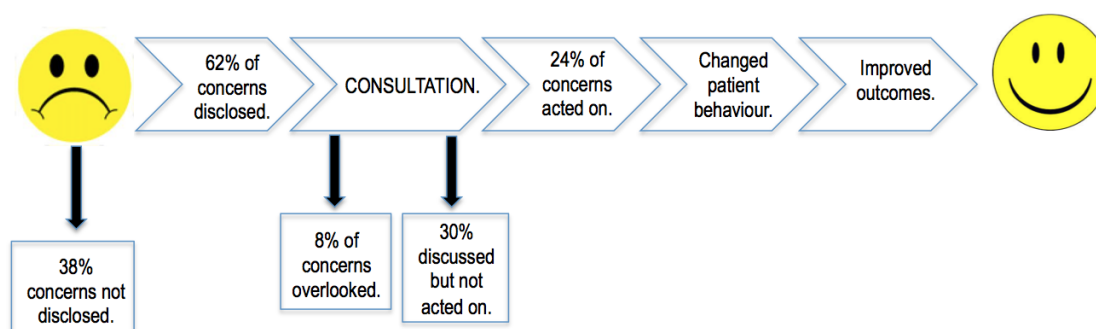
Phase 2 has explored patient disclosure, which has been aided by utilising the same study participants across the two phases; an innovative design that has facilitated previously highlighted factors, known to be impacting on daily lives, to be monitored. Disclosure by the patient of their concerns is of similar importance to the abilities of the HCP in ensuring that the consultation is effective but if the patient, for whatever reason, does not share their concerns with the HCP, opportunities for PCC and SDM are thus severely limited (Bugge et al, 2006). As demonstrated,

during the phase 2 observations, the patient participants did not raise 38% of their concerns within the consultation and of the 62% that were raised, 8% were either missed or ignored by nurse participants, 30% were discussed but not managed leaving 24% that were at least partially managed (table 16; page 174).

Wound management concerns were more likely to be acknowledged, with 60% being partially or completely managed, whilst emotional effects of the ulcer were the least likely to be acknowledged, with only 4% being managed effectively. On many occasions themes were discussed, most often without solutions being suggested (30% of occasions). Thus only 24% of patients' concerns, overall, were addressed to some degree during the consultation. For every concern not picked up by the nurse (38% of occasions) the patient did not raise their concerns on a further 38% of occasions.

If the results of phase 2 are developed into a figure based on Stewart's (2004) earlier consultation hypothesis, where optimised PCC and SDM within the consultation could result in changed patient behaviour and improved patient health outcomes, the effects of this non-disclosure by the patient is demonstrated (figure 14 below).

Figure14: Phase 2 results flow chart.



These results echo those of Stewart et al's (1979) study of GP consultations where 54% of patient problems were not elicited or acted upon during the consultation, discussed on page 27, although Stewart et al's (1979) study failed to identify the proportion of concerns that the patient failed to disclose. Phase 2 of this study has enabled this data to be unpicked to reveal that patients failed to raise 38% of their concerns during their consultations. Since the effectiveness of the consultation relies on the SDM behaviour of both the patient and the practitioner (LeBlanc et al, 2009), successful interventions require enhancement of patient disclosure as well as improved clinician training.

Patient-practitioner communication has long been a subject of research (McKenzie, 2002) with barriers to effective communication being attributed to the mentioned 'asymmetry of the physician-patient relationship' (p. 32) (Jordan, 1997). Work to date has tended to focus on practitioner developments (Langewitz et al, 1998; Légare et al, 2009; Lewin et al, 2009) with minimal attention paid as to why the patient may not express their concerns (Bugge et al, 2006). This second phase serves to quantify these facets that for every issue disclosed by a patient and not dealt with by a nurse (38%), another issue was not disclosed by the patient (38%). The focus of research into patient-practitioner communication in the future needs to be widened to include the patient and their role in the consultation. Unless patients are enabled to articulate their concerns, many will remain unacknowledged and, therefore unmanaged, thus urgent future work is needed to determine how HCPs can more effectively enable their patients to share their concerns, so that together they can be addressed and health outcomes subsequently improved. This provides the rationale for the remaining phases of the study.

5.3.2.1 Strengths and weaknesses of phase 2.

5.3.2.1.1 Strengths.

Each of the 20 observations in phase 2 was undertaken by the same researcher, a consistency which may have served to reduce the observer effect (page 164). With repeated observations and a single researcher, the participants had an opportunity to become accustomed to the same person observing on a number of occasions. Double blind peer review also confirmed the rigour of phase 2, prior to publication (Green et al, 2013b).

The development and application of the consultation checklist during the observations enhanced the rigour and subsequent data collection, as this formed a pre-determined schedule (Pretzlik, 1994). The checklist proved to be simple, quick to apply and to provide the facility to provide summary numeric results from a large amount of data (Abeyasekera & Lason-McDowall, 2000; page 165). The scoring tool, adapted from earlier research by Henbest and Stewart (1989) again added to the robustness of the item assessment.

The inclusion of the same sample for phase 1 and 2 was an innovative design, which facilitated the assessment of known issues in phase 2. Such a design would be useful in similar studies, especially with the addition of phases to triangulate the results.

5.3.2.1.2 Weaknesses.

As with phase 1 (page 93 – 158), despite the repeated nature of the observations which enabled the patient and nurse participants to adjust to the presence of the observer, the observer still has an effect on the data collected, although the degree of this influence is unknown (Lincoln & Guba, 1985).

This phase demonstrated that patient participants failed to disclose known items of importance during their wound care consultations but the reasons for this were not ascertained during the study and highlight a future research need.

5.3.2.2 Contribution to new knowledge.

This novel phase of research has provided a number of elements of new knowledge.

- When themes were reviewed overall, nurses had a discussion with their patient (30% of cases) more often than moving the consultation to offer a partial or complete problem solving approach (23%).
- Despite pain being overwhelming for the patient participants, this was not disclosed to the consulting nurse on 42% of the possible occasions.
- The data produced from phase 2 serves to define the data from Stewart et al's (1979) study where 54% of patient problems were not elicited or acted upon. In phase 2, 38% were not disclosed, 8% were overlooked and a discussion ensued on 30% of opportunities (page 174).

5.3.2.3 Further research.

As a result of phase 2, there are a number of areas that would benefit from further research. Exploring the reasons that result in the lack of patient disclosure would be informative and may well enhance developments to improve the patient centredness of future consultations. Also, exploring why nurse participants demonstrated a reluctance to move to either partial or complete problem solving, preferring to simply discuss issues with the patient, may provide a basis to improve future training in relation to consultation skills.

5.4 Summary

The discussion of the phase 2 findings has established that many of the issues which were of known importance to participants were often not raised during the consultation and, when raised, were often inadequately addressed. In view of this and to support the development of an appropriate PCC based intervention a literature review of potential nurse-led interventions was undertaken, in order to assist in the development of the new consultation template.

Chapter 6: Literature review of patient centred interventions.

Chapter 6: Literature review of patient centred interventions.

This chapter provides a review of the literature that explores the effectiveness of nurse-led interventions to enhance the patient centredness of consultations. This review was undertaken to inform the design of the final phase of the research project which involved the development and pilot of a consultation template to enhance the patient focus of wound care consultations.

6.1. Introduction.

As explored in chapter 2 (page 23 - 34), PCC represents a move from purely seeing patient care in terms of disease or pathology towards thinking of the patient and their problems and is recognised as a measure of the quality of health care (Ballint, 1955; Henbest & Stewart, 1989; WHO, 2005; Lewin et al, 2009; Timmins & Astin, 2009). This involves the patient, as a person, being central to the consultation and includes SDM between the patient and HCP regarding the patient's health problems (Lewin, 2009).

In chapter 2 the approaches to enhance PCC were discussed (page 23 - 34). A number of studies have explored either HCP training, interventions to enhance patient activation in order to improve PCC or a combination of these approaches (Lewin et al, 2009; Fischer & Ereaut, 2011) which have demonstrated an impact on patient satisfaction and the quality of care. However, there is minimal evidence of a consistent improvement in patient outcomes due to enhanced patient centredness (Henbest & Stewart, 1989; McLean, & Armstrong, 2004).

6.2 Aim.

The aim of this review was to explore nurse-led interventions within primary care consultations that aimed to enhance patient centredness, with effectiveness evaluated in terms of an improvement in patient outcomes.

6.3 Research question.

In order to generate the question for this review, the PICO approach (Richardson et al, 1995; detailed on page 6) was applied. In this case, in order to develop a question that could be answered by the review, the acronym stood for:

- the population (P): adult patients within primary care;
- the intervention (I): nurse led interventions to enhance PCC;
- the comparison (C): defined by the study;
- the outcome (O): patient outcomes, again defined by the study;
- the study (s): any study design.

As a result the following review question was developed:

Does a nurse-led intervention to improve patient centredness within a primary care consultation improve patient outcomes?

6.4 Methods.

A systematic search of articles was undertaken using the Health Databases Advanced Search (HDAS) engine to facilitate access to a range of bibliographic databases, which were each searched individually as specified in chapter 3 (page 53).

6.4.1 Literature databases.

A range of resources were accessed in order to undertake this review including MEDLINE, AMED, BNI, CINAHL, Health Business Elite, HMIC (NHS), PsycINFO, the Cochrane Collaboration database and EMBASE (1991-2012). Further detail of these databases was provided in chapter 3 (page 53). As with the initial review, additional studies were identified via Google Scholar, reference list, author and citation searching and the hand searching of relevant journals.

6.4.2 Article inclusion criteria.

In order for a study to be selected for review a range of criteria was applied (table 26 overleaf). Only study participants over the age of 18 years were included, since the care for those prior to 18 years often has a family focus, which may make the interventions of less relevance to an adult population. Only studies undertaken within primary care were selected, as face to face consultations between a patient and their HCP are most often undertaken within this environment. This review specifically has a nursing focus, thus only reviews where nursing participants were involved were suitable for inclusion; studies were still included if nurses were involved in addition to other HCPs. Face to face interventions between the patient and their HCP were included where the outcome was patient

rather than solely HCP focused. Again, only articles available in English were sourced due to funding constraints and no date restrictions imposed.

Table 26: Criteria for inclusion in the review:

Inclusion Criteria.

Available in English
Adult patients.
Primary care.
Nursing based intervention.
Face to face interventions.
Focus on improving patient outcomes.

6.4.3 Article exclusion criteria.

Studies were excluded (table 27 below) if the participants were 17 years of age or under, were based within secondary care, outpatient departments or within residential care; or if there was no nursing involvement in the study. Telephone and Internet interventions were also excluded as the study focus was on the actual face to face consultation rather than more 'distant' interventions.

Table 27: Criteria for exclusion in the review:

Exclusion Criteria.

Paediatric patients.
Secondary, Out Patient Dept. & Residential care.
No nursing involvement.
Telephone & internet interventions.
No patient outcome evaluation.

6.4.4 Search strategy.

This systematic search accessed eight databases individually, the Cochrane Collection and Google Scholar and are detailed in appendix 12. In order to focus on the area of choice a series of comprehensive search terms were systematically applied (table 28 below).

Table 28: Search terms applied for this PCC review.

1	consult*
2	intervent*
3	1 AND 2
4	patient centre*
5	3 AND 4
6	nurs*
7	5 AND 6.

6.4.5 Screening, selection and quality assessment of articles.

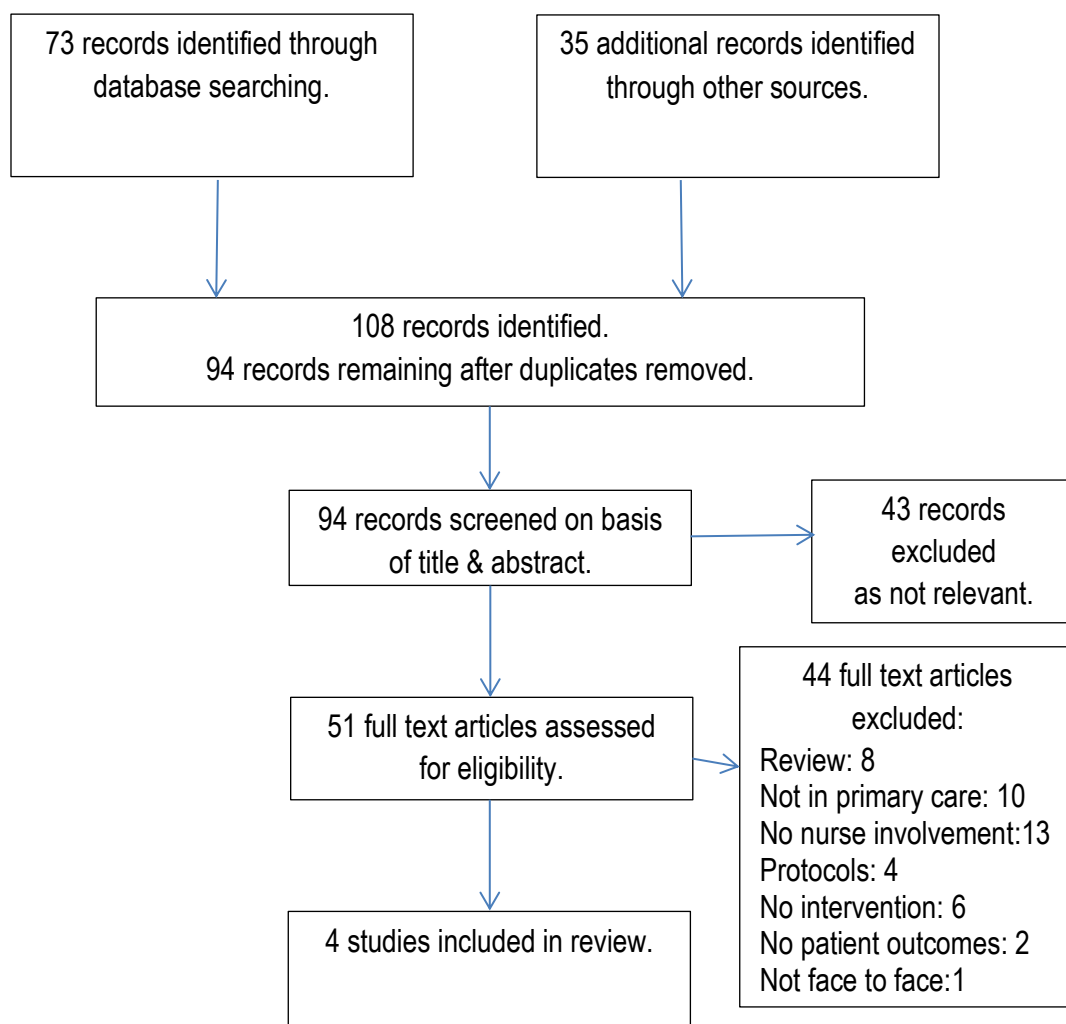
As with the first review of literature, title, abstract and full text were assessed against the eligibility criteria by the researcher, with duplicates and unsuitable articles being removed at this point. Independent assessment of the rejected articles was undertaken by an educational supervisor to verify the decisions made. The researcher and educational supervisor independently reviewed the remaining studies and consensus was reached for final inclusion.

6.5 PCC search results.

The search overall resulted in a total of 108 articles. Following removal of duplicates, 94 articles remained. Of these, on review of the title and abstract, 43 were deemed to be unsuitable which left

51 for full text review. The researcher and an educational supervisor independently reviewed the full text articles which resulted in the exclusion of 44 articles and the retention of four research studies within seven articles being retained for full synthesis. This process is demonstrated in a flow diagram (figure 15).

Figure 15: Stages of article selection.



6.5.1 Data extraction.

For each study, data was extracted and summarised on data extraction sheets (table 30 below) by the researcher and reviewed by an educational supervisor for accuracy. The information of interest included the author, year and location of the study; study design; participant characteristics; outcome measures and results. In addition a note was made of any limitations, whether the appropriate ethical approval was recorded and the quality score (QS) (Hawker et al, 2002).

6.5.2 Quality assessment.

Studies were again assessed for quality using the comprehensive tool applied in chapter 3 (page 70) (Hawker et al, 2002). Nine areas of each study were assessed with scoring range between 90 -360. Full details of the assessment are detailed in appendix 13 but the studies included in the review ranged, using the Hawker et al (2002) scale (detailed on page 61), from none of very poor or poor quality, three of fair quality and one of good quality and are displayed alphabetically in table 29 below.

Table 29: Quality appraisal scores for the PCC review.

Author & year (alphabetical order)	Total Score (Range: 90-360)
Holmstrom et al (2004)	220 (F)
Kinmonth et al (1998)	300 (G)
Ogden & Hoppe (1997)	250 (F)
Pill et al (1998)	250 (F)

Table 30: Data extraction chart for the PCC review (4 studies).

Author, year & location	Design of study	Participant characteristics	Outcome measures	Results	Limitations & ethical approval.
Holmstrom, Larsson, Lindberg & Rosenqvist (2004) Sweden	Mixed method study to investigate whether an intervention focussed on HCP's understanding of the diabetes-patient encounter could improve PCC. Interviews, videos of consultations & patient comments. Videos of 18 encounters reviewed by HCP & patients.	Purposeful 4 HCPs (2 GPs & 2 Diabetes Nurses). 18 patients. Type 2 diabetes.	Verona-MICS/Dr analysis of video recordings. Categories dichotomised for PCC or doctor-centred. Assessed whether consultations were prescriptive (medical facts), reflective (patients' experiences) or combined model. Patient comment 4 categories: 1.satisfied & reached new understanding; 2. satisfied; 3. neutral & 4. non-satisfied.	Overall PCC of consultations did not improve (2 better/2 worse). Reflection for all 4 staff improved & use of patient-involving transitions. New patient understanding occurred only in reflective encounters. Patients felt combined consultations were good enough but reflective model explores & influences patient understanding. Consultation skills of practitioner changed as early as the 2 nd consultation.	Small scale study. HCPs were a selected sample who wanted to develop way of encountering patients which may have caused bias. Ethical approval was gained. Consent of participants is mentioned. QS: 220
Kinmonth, Woodcock, Griffin, Spiegel, Campbell (1998) UK	A pragmatic parallel group study with randomisation between practice teams to assess the effect of additional training of PNs & GPs in PCC on lifestyle & physiological status with new Type 2 diabetes patients. Additional training for HCPs of 1.5 days introducing evidence for & skills of PCC & patient held booklet encouraging questions.	All new Type 2 diabetic patients between 30-70 years over 12 months were recruited [250 patients] in 41 practices (21 intervention / 20 comparator).	Self-report by patients on satisfaction & communication of practitioners. QoL, wellbeing, HbA1C, lipids, Bp, BMI. Analysis at 1 year. Baseline & 12 months.	Patients in intervention group reported better communication with HCPs, greater treatment satisfaction & well-being. BMI was slightly higher & lipids & knowledge scores were lower. Lifestyle & glycaemic scores unchanged. First study to show training in PCC can significantly improve communication, wellbeing & satisfaction amongst newly diagnosed diabetics.	No improvement on hypothesised HCP and patient agreement on concerns, knowledge of diabetes & knowledge of care. Underpowered study. Ethical approval stated & consent. QS: 300

Author, year & location	Design of study	Participant characteristics	Outcome measures	Results	Limitations & ethical approval.
Ogden & Hoppe (1997) UK.	RCT to investigate impact of 2 styles of educational package on PNs management of obesity. PNs allocated to 3 groups – learner centred (leaflet & seminar), expert (leaflet) & control. At 1 month, PNs gave 5 patients a questionnaire re. content & type of consultation. At 6 months, PN & patients sent questionnaire about consultation style & weight loss respectively.	240 PNs in total – 80 to each of 3 groups. 179 patient questionnaires returned at 1 month; 35 returned after 6 months. Leaflet to 2 groups and learner centred seminar for 1 of those group.	Responders & non-responders compared over 6 months. Data collection from questionnaires at baseline, 1 month & 6 months.	No change in PN beliefs about obesity. Learner group spent longer on the consultation & were more PC. Their patients rated themselves as more satisfied & were offered calorie controlled diets less often. PNs in the expert group reported giving weight loss advice more often & being less PCC. Their patients were more confident about weight loss but felt more likely to be offered traditional interventions. No effects on weight.	Long questionnaire initially reduced FU questionnaire response rate. Attendance at seminar was poor. Ethical approval not mentioned. QS: 250
Pill, Stott, Rollnick & Rees (1998) UK	RCT with before & after design for measures of patient outcome to evaluate the effect of training in a PCC intervention for GPs & PNs on patient outcomes in Type2 diabetes. Experimental group: training at surgery to improve patient participation – at least 2 3hr sessions plus on-going support.	29 practices recruited [15 experimental [190 [1] - 165 [2] patients with NIDDM over 6 months.	Glycosated haemoglobin, patient satisfaction, SF36 & professional ability. Start & 18 months. Audiotaped consultations at 9 months after training.	Limited change in biochemical or functional improvements. More improvement in control group satisfaction than experimental. Control group improved in physical functioning. Failed to find significant clinical improvements in experimental group. Competence in intervention was minimal after 9 months.	2 year study only 19% applying method at 2 years despite enthusiastic start. All practices self-selected & committed to improve diabetic care. Change was not sustained. Ethical approval included. QS: 250

6.6 Overview of PCC studies for final review.

6.6.1 Characteristics of the studies.

One mixed method study and three quantitative studies, published between 1997 and 2004 were retained for inclusion in this review. These studies accessed 809 patients in total and 230 primary care practices in the UK and Sweden. Three explored consultation based interventions within Type 2 diabetes care and the other the care of patients requiring weight loss advice. Study sample sizes ranged from 4 - 240 HCPs and between 18 - 250 patients. Studies were heterogeneous and used complex, multifaceted interventions and a range of outcome measures.

6.6.2 Results from the mixed method study.

Holmstrom et al (2004) applied a mixed methods approach with 4 HCPS and 18 patient participants to investigate whether an intervention to enhance the HCPs management of consultations with diabetic patients would facilitate enhanced patient centredness in future encounters. Four HCPs, two GPs and two Practice Nurses (PNs), were purposefully recruited for the 12 month intervention. The study included interviews, videos of patient-practitioner encounters and patient comments relating to that encounter. Videos of consultations were analysed using the Verona Medical Interview Classification System (VR-MICS) using 22 mutually exclusive categories that were classified as patient-centred or doctor-centred.

Assessment of the approach to the consultation was recorded, whether prescriptive, reflective or combined. A prescriptive consultation was based on medical facts; reflective on the patients' life experiences and combined, the combination of both approaches was used. Patients' comments

following the consultation were also reviewed in terms of whether they had received the help they required, whether they understood their illness and treatment with a range of responses from satisfied with new understanding; satisfied, neutral or non-satisfied. The results indicated a significant increase in two of the 'patient-centred' outcomes, facilitations and reassurance, over the study period but, whilst two HCPs changed their educational model, the approach of the remaining two HCPs was unchanged. Staff were reported to reflect on their practice and patient encounters, however the results were limited. Patients who had experienced the 'reflective' type of encounter with their HCP were the only participants to cite new understanding whereas difficulties in changing established consultation patterns for even willing HCPs were highlighted. The patient participants expressed high levels of satisfaction with the consultation but this seemed to reflect low expectations rather than the quality of the 'improved' consultation, although this was a small-scale study that involved a total of 18 patient participants.

6.6.3 Results from the quantitative studies.

Three studies, published between 1997 and 1998, adopted randomised approaches to evaluate changes in patient outcomes as a result of enhanced consultations. These studies were heterogeneous and applied a variety of interventions and a range of patient outcome measures. Two studies related to the care of patients with Type 2 diabetes in general practice (Kinmonth et al, 1998 Pill et al, 1998) and one (Ogden & Hoppe, 1997), the management of the obese patient in relation to weight loss advice, again in general practice. The diabetes studies involved interventions to both the GP and the PN consultation techniques whereas the obesity study solely manipulated the PN approach.

Kinmonth et al (1998) adopted a pragmatic parallel RCT with 41 practices of which 21 undertook the intervention, routine care with additional training on PCC including active listening, negotiation and eliciting behavioural change and 20 practices delivered routine care. Over the 12 month recruitment period, 250 people with newly diagnosed diabetes were recruited to the study with outcomes recorded at baseline and one year; to include a range of clinical and lifestyle data, patient rating of HCP communication, satisfaction with treatment and style of care, agreement with the HCP on their main concerns over the last 12 months and an evaluation of patient knowledge. For the intervention group, the study demonstrated improved communication between patient and HCP, greater satisfaction with treatment and improved well-being but also raised body mass index (BMI), raised triglycerides and lower knowledge scores. Other outcomes were not deemed to be significant. The study concluded that the intervention had resulted in greater attention to the consultation by the HCP but, as a result, preventative care no longer received the same level of attention, which may have resulted in the reported changes to BMI, and knowledge of their condition. This PCC intervention appeared to have positive outcomes, but such a focus should ideally not be at the expense of accurate disease management (Kinmonth et al, 1998).

Pill et al (1998) similarly adopted an RCT approach at practice level with a before and after design for their three year study. In total 29 practices were recruited with 190 patients completing the first questionnaire (165 completed the second). Each practice was required to recruit 12 patients with established Type 2 diabetes over a six month period. The intervention practices received training for HCPs to encourage active patient participation including encouraging the patient to voice their concerns and to set targets; whilst the control practices delivered routine care. Patient data was collected by a blinded evaluation team at baseline and after 18 months to include physical measures, the SF 36 and validated diabetic specific measures to record well-being and satisfaction with treatment (Pill et al, 1998).

Results from Pill et al's (1998) study demonstrated improved patient satisfaction with their recent consultations and the treatment they had received in the intervention arm of the study, although these outcomes also improved for the control arm over the period of the study. The study revealed that, despite enthusiasm from the HCPs involved in the study, after two years only 19% continued to apply the PCC approach systematically which is a concern since all practices involved already demonstrated an enhanced interest in diabetes care prior to recruitment to the study.

Finally, Ogden and Hoppe (1997) undertook an RCT to investigate the impact of two styles of educational package on the management of obesity by PNs. The consented PNs were allocated randomly to three groups; the learner centred, who provided a leaflet but also underwent a learner centred seminar; the expert group, who provided a leaflet for the patient in addition to routine care and the control group who provided routine care. After a month, the PNs gave questionnaires to their five patients; this questionnaire related to the content and type of consultation that they had experienced. In addition, after 6 months, both the PN and the patients completed questionnaires about consultation style and weight loss respectively (Ogden & Hoppe, 1997).

The study (Ogden & Hoppe, 1997) demonstrated that there was no change in PN beliefs about obesity, however the PNs allocated to the learner centred group provided longer consultations and were more PC; their patients rated themselves as more satisfied and reflected that they were simply offered calorie controlled diets less often. PNs in the expert group, providing a leaflet only, reported giving weight loss advice more often and being less PC in their consultation; their patients were confident about weight loss but felt that they were more likely to be offered traditional interventions. The study demonstrated no effects on weight overall. Ogden and Hoppe's (1997) concluded that both PN and patient behaviour and the style of consultation could be altered by either training or access to educational resources.

6.7 Amalgamation of the study findings.

All studies reflected some positive patient outcomes as a result of manipulation of the consultation. The improved outcomes tended to relate to the satisfaction of the patient participant with their consultation and the approach to their disease management, rather than any direct improvement in the actual management of their condition. Both Pill et al (1998) and Holmstrom et al (2004) reflected on the difficulties associated with changing the consultation behaviour of HCPs and, indeed, sustaining such change for the HCPs involved, despite their prior enthusiasm for that area of disease management (Pill et al, 1998). Results are summarised in table 31 below.

Table 31: Summary of results from PCC studies.

Author & year.	Results
Ogden & Hoppe (1997)	<ul style="list-style-type: none">- No change in PN beliefs about obesity.- Learner group spent longer on the consultation & were more PC, patients were more satisfied & were offered calorie controlled diets less often.- PNs in the expert group reported giving weight loss advice more often & being less PCC.
Kinmonth et al (1998)	<ul style="list-style-type: none">- Patients in intervention group reported better communication with HCPs, greater treatment satisfaction & well-being.- First study to show training in PCC can significantly improve communication, wellbeing & satisfaction amongst newly diagnosed diabetics.
Pill et al (1998)	<ul style="list-style-type: none">- More improvement in control group with satisfaction & physical functioning.- Failed to find significant clinical improvements in experimental group.- Compliance with intervention was minimal after 9 months.
Holmstrom et al (2004)	<ul style="list-style-type: none">- Overall PCC of consultations did not improve - 2 better/2 worse. Staff reflected on improvements with involvement of the patient.- New patient understanding occurred only in reflective encounters.- Consultation skills of practitioner changed as early as the 2nd consultation.

6.8 Discussion.

Despite a systematic search to evaluate nurse-led interventions that aimed to enhance the PC of consultations, a paucity of such studies was available, with only four studies retained for inclusion in the review. Three studies were relatively dated and were reported on between 1997-1998 and despite the final study being published in 2004, data was collected between 1997-1998. There were no more recent studies that fitted the criteria, which itself highlights a need for further and more up to date research in this area. All studies implemented a relatively robust randomised approach but some adopted extremely complex interventions that unduly lengthened the consultation beyond a sustainable level (Holmstrom et al, 2004); even to the point that HCP participants' understanding of the study diminished over time (Pill et al, 1998).

Enhanced satisfaction with the intervention consultation was revealed across all four studies, which demonstrates that a PCC approach improves patient experience. The ability to sustain such changes, even when the HCPs had a particular interest in the area of disease management, was demonstrated to be poor (Pill et al, 1998) but this could have reflected the complexity of the study design rather than the dedication of the HCPs. There was a comparable lack of change in physical outcomes across the studies as a result of the interventions described and an actual deterioration in knowledge and biomedical indices demonstrated by Kinmonth et al (2004), which may have been attributed to a shift of focus to PCC at the expense of disease management.

6.9 Strengths and limitations.

6.9.1 Strengths

The strength of this review is the application of a replicable search strategy and the peer review process for study selection. As in chapter 3 (page 61), the application of the quality scoring tool

(Hawker et al, 2002) and the use of the CASP (CASP, 2010) approach to the critical appraisal of each article has enhanced the robustness of the review.

6.9.2 Limitations.

As with the review documented in chapter 3 (page 55), studies not available in English were excluded from the study, as there was no funding available for translation. Studies undertaken with participants under the age of 17 years were excluded which may have limited the breadth of the search, but since these generally demonstrated a family centred approach any relevancy with an adult population is uncertain.

6.10 Conclusions and research implications.

This chapter has presented a review of nurse-led interventions which aimed to enhance the PC of consultations in primary care, and to evaluate the effect on patient focused outcomes. Simplicity of the intervention appears to have been the key to its sustainability over the duration of the study and subsequent satisfaction of the patient with their consultation and treatment, the principal outcome measure to be improved by such interventions. These findings have directed and influenced the design of the consultation-based intervention, to enhance the patient focus in CVLU care. The simplicity of the tool, the duration of the study and the application of patient satisfaction as a primary outcome measure were all implemented as a result.

Chapter 7: Development of the consultation template.

Chapter 7: Development of the consultation template.

Chapter 7 presents provides detail of the underlying methodological decisions, the methods used, the procedure undertaken (7.1) and the template produced (results) (7.2), followed by a discussion of the process and output in the light of the research reviewed (7.3).

7.1 The nominal group.

The nominal group stage of this mixed methods study was designed to answer the following research question:

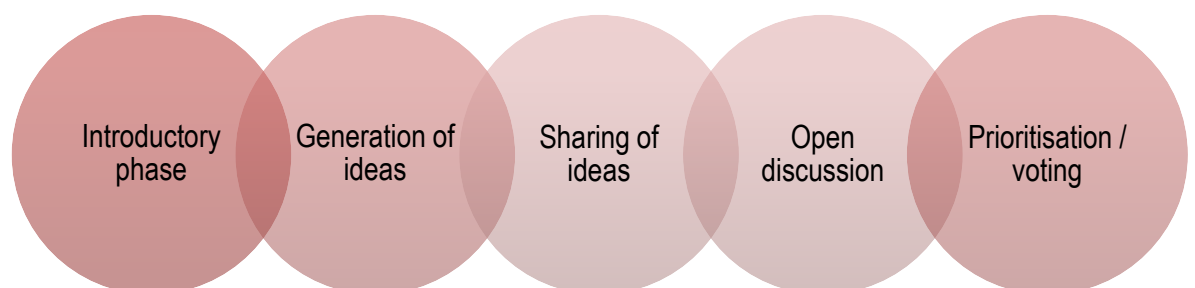
Can expert and patient consensus create a model consultation template for patients with chronic venous leg ulceration?

7.1.1 Nominal group design and methodology.

Qualitative methods of enquiry were applied to facilitate the development of the new consultation template to focus wound care consultations on patient concern. Phase 1 (page 93 - 158) and 2 (page 159 - 193) of the study established that CVLUs impact on every area of patient functioning however the participants appeared reluctant to disclose these issues during their subsequent consultations with their DN. Following consideration of other methods with which to effectively construct the planned consultation template, such as the Delphi technique or a traditional focus group, the nominal group technique (NGT) was selected.

The advantage of the NGT is the requirement for a single, face-to-face meeting of approximately two hours thus providing a cost effective and efficient method and minimal preparation by group participants (Carney et al, 1996; Vella et al, 2000; Potter et al, 2004). In addition, the NGT has the potential to facilitate both qualitative and quantitative data since items for inclusion in the meeting are prioritised during group discussion (Carney et al, 1996). The structured nature of the meeting minimises researcher bias as they take the role of facilitator rather than leader and ensures that members efficiently generate ideas (Potter et al, 2004). Immediate feedback is provided to group members by the researcher and, due to its democratic style, problems due to dominant group members, who may distort group functioning are minimised (Carney et al, 1996; Vella et al, 2000; Potter et al, 2004). Studies that have applied the technique have demonstrated that it effectively provides views representative of the wider community from which group members are drawn, despite the actual group itself being relatively small (Vella et al, 2000; Lancaster et al, 2002; Kadam et al, 2006). The structured approach of the meeting comprises five clear stages (Carney et al, 1996) (figure16).

Figure 16: Nominal Group stages (Carney et al, 1996).



7.1.2. Sampling framework for the nominal group.

The acceptable range of participants for a NG ranges from five and nine participants to include a combination of nurse and patient participants (Potter et al, 2004). Participants were drawn from the two North Staffordshire PCTs, as with phase 1 and 2, and were purposively sampled to ensure the relevancy and validity of the subsequent template (Bowling & Ebrahim, 2005; Denscombe, 2007). In order to ensure the quality of the template, it was felt that nurse participants should be experienced in the care of patients with leg ulceration or knowledgeable about the development of such consultation templates. Patient participants involved in phase 1 and 2 were approached to be involved. The following inclusion and exclusion criteria for nurse and patient participants were applied.

7.1.2.1 Inclusion and exclusion criteria.

Nurse participants:

Inclusion criteria for nurse participants:

- The nurse was registered with the Nursing and Midwifery Council.
- The nurse was experienced in the care of patients with CVLU OR was experienced in the development of tools to enhance the PC of the consultation.
- The nurse was willing to take part in the study.

Exclusion criteria for nurse participants:

- Unqualified staff.
- Those who withhold consent.

Patient participants:

Inclusion criteria for patient participants:

- The patient had previously been involved in phase 1 and 2 of the study.

7.1.3 Nominal group study procedure.

As with phase 1 and 2 of the study, this phase was undertaken across the two local PCTs. Nurse managers were asked to nominate potential nurse participants for the NG based on their knowledge and experience in Tissue Viability. Once potential members were nominated, they were contacted directly to discuss the requirements of the NG, including a brief overview of the process and provided with written study information (appendix 15). Once participant consent forms were received, a venue, date and time for the NG was arranged in an easily accessible area with free parking; major considerations for the nurse participants who were allowed, by their managers, to attend within their scheduled working day. The patient participants consented to be part of the study but requested that their opportunity to comment on the template was after the 'experts' had developed the template during the NG. Despite this not being an ideal situation, in order to respect their views, this was arranged and further communication with group members was undertaken by email.

7.1.4 Nominal group data collection.

Prior to the meeting a small amount of pre-reading was circulated to prepare members for the topic and ensure prompt engagement in the meeting. The actual meeting started with an opening statement by the group facilitator, which summarised and described the task to be undertaken during the meeting and outlines the expected contribution from the group members and the NG process, summarising how the output or results will be utilised. The stages of the meeting were outlined and group 'ground rules' established and agreed (Carney et al, 1996); this 'housekeeping' section of the meeting settles group members and ensures all are aware of their role (Vella et al, 2000).

Following the introductory phase, ten minutes were allocated for the 'silent generation of ideas'; providing group members with time to focus their thoughts on the task ahead. When members had collected their thoughts on the topic, each participant was provided with an opportunity to share their ideas in turn which were recorded by the scribe on a flipchart, providing a record of the ideas and comments generated (Vella et al, 2000). Each participant, individually and without interruption, has the opportunity to contribute their ideas to encourage participation, even from quieter group members. The systematic recording of ideas serves to de-personalise contributions, making ideas 'group' rather than the individual ideas (Carney et al, 1996).

Once all members had a chance to contribute, there was an opportunity for open discussion and for the recorded ideas to be clarified. To conclude the NG meeting, group members have an opportunity to prioritise or rate the ideas that have been generated. Participants 'voted' for item inclusion in order to achieve this prioritisation, which provided some quantitative data (Carney et al, 1996). The meeting concluded when no new ideas were generated, which indicates that data saturation was achieved (Basch, 1987; Krueger, 1994).

7.1.5 Nominal group data analysis.

The NGT represents a consensus technique, where all members discuss, debate, compromise but ultimately agree about the work undertaken within the timespan of the meeting (Vella et al, 2000). The output of the NG meeting, in this case, was the new consultation template, based on the phase 1 and 2 findings. Both nurse and patient participants agreed items for inclusion in the template, using a voting technique. During the nominal group, the scribe made notes of the proceedings and the discussions that were undertaken (appendix 16) and, in addition, key concepts for inclusion were recorded on a flip chart. Notes were recorded on the prioritisation of factors for inclusion in the

template, thus ensuring the rigour of the process. Any further changes were communicated with all members via email for their agreement. Records of these emails were retained, again to ensure the integrity of the process.

7.1.6 Ethical considerations for the nominal group.

As discussed in chapter 4 (page 106), the ethical principles governing this research project were stringently adhered to and were informed by the guide to consent (DH, 2001b) and mental capacity guidance (DH, 2007). Ethical approval had been gained for phases 1 and 2 of the study (page 106). At the time of the original submission to LREC detail of the design of the study beyond the initial two phases was not finalised and the application merely stated that:

'The model consultation template, once developed, will be verified by experts in the field of tissue viability to ensure content validity' (A13, p.18, Ethical approval: 10/H1203/13).

As the study progressed and the NG phase was finalised, a minor amendment to the original LREC application was submitted detailing the formal NG design to develop the consultation template at the end of phase 2. After due consideration of the application and the accompanying documentation, LREC granted permission to proceed (LREC No: 10/H1203/13; AM01; appendix 14 & 15).

Informed consent was sought from both nurse and patient participants for the NG and all potential participants were provided with a copy of their appropriate 'study pack' including the requirements of participant involvement in the study, arrangements for assuring the anonymity and confidentiality of information and withdrawal from the study, should this be necessary. For the nurse and patient participants completion of the consent forms evidenced their agreement to attend the NG for no more than 2 hours and undertake a small amount of pre-reading. Once consent was received, this

was reaffirmed at the start of the NG and in all correspondence or meetings; thus providing ample opportunity for consent to be withdrawn if any of the participants so desired.

7.2 Nominal group results.

7.2.1 Introduction.

Five nurse and three patient participants consented to take part in the NG. The patient participants were all previously involved in phase 1 and 2. Three specialist nurses, two representing Tissue Viability (TVNs), an academic nurse who was experienced in research surrounding the efficacy of nurse consultations and two experienced community nurses consented to be involved in the NG. The facilitator (the researcher) and a scribe made up the NG meeting membership (table 32 below). Three patients also provided review of the template during the development stages during one to one meetings with the researcher, details are provided in table 33 overleaf.

Table 32: The nominal group nurse members.

	Background.	Gender	Experience
1	Tissue Viability Specialist Nurse	F	12 years
2	Tissue Viability Specialist from industry.	F	10 years
3	Academic specialist in consultation design.	F	20 years
4	District Nursing Sister.	F	25 years
5	District Nursing Sister.	F	20 years
6	Scribe.	F	Student Nurse (Yr 3)
7	Facilitator.	F	25 years

Table 33: Patient nominal group participants.

	Name	Gender	Duration of ulceration
1	Tom	M	10 years
2	Mary	F	30 years
3	Sam	M	40 years

7.2.2 General group discussion.

On completion of the NG and once all members had made their suggestions and no new ideas were being generated, the charted ideas were discussed by the group as a whole, including individually with the patient participants, and were recorded in the meeting minutes (appendix 15). Some initial decisions regarding template layout were made at the start of the discussion period with all members agreeing that the template needed to be brief and should be printed back to back on a single A4 sheet. It was felt that this length would facilitate speedy completion and avoid undue lengthening of the duration of the wound care visits. Group members also agreed on the inclusion of some brief explanatory guidance to ensure that the nurses completing the template would include appropriate topics in their discussions with their patients. This section would be constructed in question order for ease of use (figure 17).

Figure 17: Assessment guidance (excerpt from the template).

Template assessment guidance.	
<p>Assessment of mobility & ability to get out & about:</p> <ul style="list-style-type: none"> • Are leg ulcers restricting mobility? Are you able to recommend anything to assist with mobility? • Is your patient able to enjoy the activities that they did prior to having an ulcer? Is there anything you can recommend to improve this? <p>Assessment of sleep, nutrition and pain:</p> <ul style="list-style-type: none"> • Does the ulcer interfere with sleep? What advice have you given? eg. the timing of analgesia, positioning, etc. Where are they sleeping? Is this suitable? • Is dietary intake sufficient? Is a full nutritional assessment necessary? Have suitable supplements been prescribed? • Assess your patient's pain and ascertain whether this is improving or deteriorating? Is it intermittent or continuous? What makes the pain better or worse? • What analgesia is currently being taken and is this effective? Does the medication need reviewing? What advice have you given in relation to non-pharmacological methods of pain relief such as positioning of the limb, timing of the visit, etc.? <p>Assessment of personal hygiene, clothes & shoes:</p> <ul style="list-style-type: none"> • Is your patient able to maintain their personal hygiene? Can you make any recommendations to improve this? Is it possible for legs to be washed or for any aids and appliances to be recommended? • Is your patient struggling to wear clothes and shoes that they would like to? Is their footwear safe? Review any advice given. 	<p>Assessment of emotional effects, relationships & fears:</p> <ul style="list-style-type: none"> • How is your patient feeling today and how is their ulceration impacting on their daily life? Is there anything you can offer to support your patient? • Does your patient confide in friends and family about their ulcers and do they feel well supported? <p>Assessment of wound management:</p> <ul style="list-style-type: none"> • Complete a full assessment of the wound and document the details in the patients' notes. • Assess exudate and odour – are the dressing product suitable and the frequency of visits appropriate? How are these symptoms impacting on your patient? • Does your patient understand their management plan and do they agree with this? Are they able to follow the advice given? <p>Problem solving / comments:</p> <ul style="list-style-type: none"> • This box is provided to record any problems that you have solved during your visit today. This may have been by making a referral to another service, undertaking a reassessment, giving advice or making a recommendation or by making a change to treatment in response to a problem that you have assessed. Discuss and agree your actions and the plan of care with your patient and document here. <p>Review the assessments you make, the advice you give and the interventions you recommend at each visit.</p>

In order to facilitate speedy completion of the template and to avoid lengthening consultation time, members suggested that 'yes / no' tick boxes in response to the questions posed and additional space for any relevant comments accompanied by a larger 'comments and problem solving' section, included at the end of the template (figure 18).

Comments and problem solving:

Completed by.....Signed (nurse).....Signed (patient).....

Members agreed that a signature, where possible, from both the patient and the consulting nurse on completion of the form would potentially promote 'ownership' of the areas discussed and the actions agreed. It was accepted that for some patients this might not be possible. Self-completion prior to a DN visit by the patient and their carer was also discussed and felt to be something that could be encouraged by the DNs.

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7.2.2.1 The Ulcer.

In order for the template to be concise and relatively quick to complete during time-limited wound care consultations, the theme of the ulcer was not included in the final template. It was felt by group members to represent an opportunity for patients to reflect on their ulcer history but not something that needed to be recorded or necessarily explored during every consultation. New detail or relevant comments would be recorded in the comments and problem solving section if necessary.

7.2.2.2 Symptoms.

As discussed (page 116-124), during the phase 1 interviews all participants reported a range of debilitating symptoms as a result of their ulceration. These included pain, exudate and odour and emotional effects of their ulceration.

Pain was a priority for all patient participants in phase 1 and was deemed an essential inclusion in the new template by NG members. There was some debate on the need for the inclusion of a pain scale within the template, but it was agreed that this was not necessary since it was included within the current nurse assessment documentation. All members agreed that, rather than merely gaining a pain score, it was actually important to ascertain the trend of the patients' pain, whether this was improving or deteriorating, in order for the nurse to take any necessary action.

The use and effectiveness of analgesia was again felt to be important and an area that required specific assessment and action. It was agreed that this should include a note of current medication and an opportunity for the nurse to indicate the effectiveness of the current regime. The comments box was included to allow alternate suggestions to be recorded and a record made of any advice given (figure 19 overleaf).

Figure 19: Pain and analgesia (excerpt from the template).

Is your pain better or worse since your last visit?		
Better: <input type="checkbox"/>	Worse: <input type="checkbox"/>	Comments: <input type="text"/>
What pain killers are you taking? Do you take these regularly?		
Medication dose & frequency taken: <input type="text"/>		
Are they effective?		
Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	Comments: <input type="text"/>

Group members unanimously agreed that the subthemes of exudate and odour should be included in the template. It was felt that by including a 'yes / no' tick box for whether the patient's legs were wet and a comments section for whether odour was present would encourage the consulting nurse to apply their problem solving skills in this area. The exudate and odour section is demonstrated in Figure 20.

Figure 20: Exudate and odour (excerpt from the template).

Are your patient's legs wet? Is there any odour?		
Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	Comments: <input type="text"/>

Phase 1 of the study revealed that there were many emotional effects of leg ulceration that impacted on patients' quality of life. All NG members agreed that psychological and social factors needed to be given a high priority within the template, especially since these issues were frequently overlooked during consultations. It was felt to be appropriate to ask whether the ulceration resulted in low mood and the following question was approved for inclusion: Do your ulcers get you down? Followed by the question: How are you feeling today? A 'yes / no' tick box and a comments section, aimed to

allow the nurse to record any discussions or recommendations made, followed these two questions (figure 21).

Figure 21: The emotional impact (excerpt from the template).

Do your ulcers get you down? How are you feeling today?		
Yes:	<input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input type="text"/>
Do you have friends or family members who support you?		
Comments:	<input type="text"/>	
Do you have any concerns about your ulcer?		
Comments:	<input type="text"/>	

7.2.2.3 Wound management.

All members of the NG group were keen to avoid duplication of information that was also required elsewhere, thus ensuring that the resulting template was not a burden to the consulting nurse. Since there is a requirement that the details of the physical care provided to patients be recorded in detail in the patient's notes, with a carbon copy removed to place in the patients' clinic notes; it was felt to be important that this information was not duplicated. In view of this, a brief wound management section was developed to include alongside the earlier mentioned exudate and odour question. This allowed the nurse to complete brief notes to document advice and treatment given, a record of the dressing applied and finally, a note that the patient has been made aware of their wound care and management plan (figure 22).

Figure 22: Wound management (excerpt from the template).

Have you documented your patient's treatment and the advice you have given to them in their notes?		
Yes:	<input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input type="text"/>
Are your patient's legs wet? Is there any odour?		
Yes:	<input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input type="text"/>
Have you made your patient aware of their wound assessment and their management plan?		
Yes:	<input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input type="text"/>

7.2.2.4 Effects on daily life.

Many of the phase 1 participants had reflected on their inability to get out and about as a result of their ulceration and reflected on the impact that this had on their lives. All NG members supported the inclusion of a question relating to this, along with a comparison to what the patient could achieve prior to their ulceration; thus providing the consulting nurse with an overall impression of any deterioration in function in this area (figure 23).

Figure 23: Ability to get out and about (excerpt from the template).

Are you able to get out and about and socialise as you did?		
Yes:	<input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input type="text"/>

The group also decided that a question relating to the dietary intake, although this was not cited in the phase 1 findings, of the patient was important as this may reveal areas where the nurse could potentially organise additional support, advice or further interventions. The question: Are you eating

a normal diet? If not, why? was agreed for inclusion with a 'yes / no' tick box and a short comments section to detail what this may include (figure 24).

Figure 24: Diet (excerpt from the template).

Are you eating a normal diet? If not, why?		
Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	Comments: <input type="text"/>

Mobility and the limitations imposed both by the presence of ulcers and the dressings applied were felt to be important and were included at the start of the template. Mobility was seen by all NG members as a defining symptom and often an issue that limited the patient's ability to engage with daily activities as they once did. As a result, the template started with the question: Are you able to mobilise as you did prior to having an ulcer? Again, a 'yes / no' tick box and a short comments section were included. This was then followed by the question relating to the patient's ability to get out and socialise (figure 25).

Figure 25: Mobility (excerpt from the template)-

Are you able to mobilise as you did prior to having an ulcer?		
Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	If not, what stops you? <input type="text"/>
Are you able to get out and about and socialise as you did?		
Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	Comments: <input type="text"/>

Maintenance of personal hygiene was agreed as being an important area to include in the template. For many of the study participants, hygiene posed complex problems, as many were unable to wash due to their ulcer, their bandages or both. It was recognised by NG members that a number of new

aids and adaptations were available to make bathing / showering achievable so a question was included: Are you managing to shower or bathe? With a 'yes / no' tick box and a comments section (figure 26).

Figure 26: Hygiene (excerpt from the template).

Are you managing to shower or bathe?		
Yes:	<input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input type="text"/>

Participants reflected on their limited choices of both clothes and shoes during their interviews. It was felt by all NG members that this was an area to be addressed by the consulting nurse. Again, the group agreed that there was a need to establish whether this had become an issue since having an ulcer so the question: 'Are you able to wear the clothes and shoes that you did prior to having an ulcer?' was included along with a 'yes / no' tick box and a comments section.

It was acknowledged that many patients modified previous clothing and shoes to fit over their bandages, etc. so all agreed to include a longer comments section and the questions: If not, what are you wearing? Is this suitable? It was felt that nurses would then be able to record what was being used and any advice that had been given (figure 27).

Figure 27: Clothes and shoes (excerpt from the template).

Are you able to wear the clothes and shoes that you did prior to having an ulcer?		
Yes:	<input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input type="text"/>
If not, what are you wearing? Is this suitable?		
Comments:	<input type="text"/>	

Sleep was an issue for many during the phase 1 interviews and was unanimously supported by the NG members for inclusion in the template. It was suggested that the location for sleeping was also an important issue. Two questions were included relating to sleeping. The first: 'Where are you sleeping?' with tick boxes for bed and chair and a short comments section; followed by: 'Do you sleep well? If not, what stops you from sleeping?' followed by a 'yes / no' tick box and a comments section (figure 28).

Figure 28: Sleep (excerpt from the template).

Where are you sleeping?		
Bed: <input type="checkbox"/>	Chair: <input type="checkbox"/>	Comments: <input type="text"/>
Do you sleep well? If not, what stops you from sleeping?		
Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	Comments: <input type="text"/>

Relationships were seen to reflect the level of social support received by the patient and all NG members felt that it was important for the consulting nurse to explore this area. The following question was included in the template: 'Do you have friends or family members who support you?' followed by a comments box (figure 29).

Figure 29: Relationships (excerpt from the template).

Do you have friends or family members who support you?	
Comments:	<input type="text"/>

7.2.3 Final editorial considerations.

For ease of application, NG members decided that themes and subthemes should be grouped together with similar items, thus allowing the nurse to explore similar areas at the same time. This led to the following groupings: (i) mobility, ability to get out and to socialise; (ii) sleep, diet and pain; (iii) personal hygiene and issues with clothes and shoes; (iv) emotional effects of ulceration, relationships and fears; (v) documentation of care provided, exudate and odour, type of dressings and information given to the patient. This arrangement reflects the activities of daily living expounded by Roper, Logan and Tierney (2000).

At the end of the NG consensus had been reached about the themes and subthemes to be included in the template. On completion of the meeting and a review of the meeting notes, a draft template was developed and circulated by email to the NG members. Brief comments were received from NG members regarding any typographical errors and the need for order changes. These were amended, version numbers changed and the template re-circulated for additional comments.

7.2.4 Patient comments.

Once there were no further comments from the nurse NG members, version 3 of the template was taken to three of the patient participants from phases 1 and 2 of the study (Tom, Mary and Sam). These pre-arranged visits, for which the patients had consented, provided an opportunity for them to individually comment on the new template.

Tom suggested having a run through of the template with him as if it was being applied during a consultation. As a result of this process amendments were made to the wording of four of the questions to make them more easily understood. Also as a result of these comments, the

comments/problem solving section was increased in size. Mary also made some supportive suggestions for these alterations.

Following the above amendments, a visit was made to Sam where it was confirmed that these simple wording adaptations were effective and made the template much easier to understand. Sam felt that the template did focus on relevant issues but made no further suggestions for further amendments. Finally, following the patient review, version 4 of the template was circulated to all NG members for final approval. Agreement was received from all members and the template was deemed ready for submission to the ethics committee in preparation to be piloted in phase 3 (template in full in appendix 17).

7.3 The development of the consultation template: discussion.

The NGT represents a novel research method which aims to achieve consensus between members, HCPs and patients in this case, and is often used to bring about change to policy or to develop educational interventions (Vella et al, 2000). Unfortunately all three patient participants, whilst wanting to be involved in the template development, refused to attend the formal NG group which would have provided an opportunity to integrate their comments and communicate with other group members. Patient participants revealed that they would be unlikely to contribute effectively at such a meeting due to the presence of 'experts' at the meeting; which further reflects that the HCP-patient relationship is not necessarily one of equals (Beck, 1997; Henderson, 2003; page 27). This lack of a cohesive NG limited the formation of the template.

The new consultations template, with its focus on a range of issues that cross physical, social and psychological functioning, would encourage the adoption of a more holistic approach to wound care (Beresford, 2010), more effective communication (Ley, 1988; page 26) and aims to equalise power within the HCP-patient relationship (Hewison, 1995). Many of the personal characteristics presented in chapter 2 (page 39 - 48) attempt to explain why patients are willing to relinquish the control of their wound to their consulting nurse and do not appear to cope with the threat it poses (Rotter, 1954; Antonovsky, 1987); almost simply accepting their condition (Seligman, 1975). The intention for this template was to encourage the consulting nurse to activate the patient to engage in their care (Stewart et al, 2000), to make sense of their condition (Antonovsky, 1987; Lazarus, 1993) and to build a concordant relationship with their HCP (Rotter, 1954; Seligman, 1975; Morden et al, 2012).

Research surrounding PCC, although scarce, purports positive benefits for the patient including optimised participation in care, enhanced satisfaction and improvements in QoL (Mead & Bower,

2000; Stewart et al, 2000; Stewart, 2001; de Haes, 2006). HCPs are shown to benefit from PCC as well (Thorne, 2005; Brown et al, 2006). The effectiveness of the new consultation template would therefore be evaluated in terms of its impact on patient satisfaction and QoL, since both of these patient outcomes are said to be responsive to PCC interventions (Mead & Bowers, 2000; Stewart et al, 2000).

7.3.1 Strengths and weaknesses.

7.3.1.1 Strengths.

The NG meeting encompassed a range of experts, experienced in both CVLU care and the development of consultation aids which served to ensure that the resultant template was robust and suitable for this client group. Such expert knowledge underpinned the design which was then verified by patient participants as explained on page 215.

7.3.1.2 Weaknesses.

As explained, the patient participants declined to attend the actual group, preferring to provide individual comments with the researcher (page 215). The lack of patient involvement in the actual NG was a weakness to this phase since providing comment from outside of the meeting, although such comments were conveyed to other members via email, this was not as effective.

In retrospect, if a future NG was planned, the need for the researcher to retain some editorial control would be a factor that would require consideration. Prior to the meeting, a few sketched templates had been considered but the output from the NG was very different from anything that had previously been considered. Had something been developed that was really not fit for purpose, introducing

editorial change after the meeting was held may have been extremely challenging. Dominant group members are a threat to any meeting structure which is minimised by the NGT structure since all members have an opportunity to contribute but, despite this, where grades of staff are mixed some appeared reluctant to comment (Paulhus & Reid, 1991).

7.3.2 Contribution to new knowledge.

- A range of physical assessment tools for patients with CVLU are readily available (SIGN, 2010) but this new consultation template represents the first template to focus in detail on known QoL issues that impact on the day-to-day functioning for patients with CVLU.

7.3.3 Further research.

This consultation template aims to focus the consulting nurse on issues that are known to impact on the daily lives of patients with CVLU. Manipulating practitioner behaviour in order to facilitate PCC is a known approach (Kinnersley et al, 2007; EPOC, 2008; O'Connor, 2009); alternatively, activating the patient to become more involved in the consultation and to disclose their concerns could be used. Use of the consultation template for self-completion by the patient prior to their consultation may prove to be beneficial and serve to activate the patient.

7.4 Conclusion.

In conclusion, the NG process resulted in a concise, easy to complete template that promptly directs the consulting nurse to potential QoL issues for the patient as a result of their CVLU. The template developed was attractive and included a range of nurse responses from tick boxes, to additional

comments. The final box that encouraged 'comments and problem solving', it was anticipated, would encourage the nurse to detail goals, developed jointly with the patient, for consideration at the next consultation. Patient comment and recommendations confirmed the suitability of the template in preparation for the pilot which is detailed in chapter 8.

Chapter 8: Phase 3.

Chapter 8: Phase 3.

This chapter presents the pilot of the consultation template and provides an outline of the methodology and the methods adopted (8.1), the results (8.2) and, finally, a discussion of these findings in the light of current research (8.3).

8.1 Phase 3.

This final phase of the study comprises a pilot designed to answer the following research question:

Is a future full randomised controlled trial (RCT) of the new model consultation template feasible (Phase 3)?

A future full RCT, if feasible, would investigate the following hypotheses however, since pilot studies do not support such hypothesis testing (Leon et al, 2011), these have simply been used to guide the design of the phase 3 pilot.

H₁ Patients with chronic venous leg ulceration will demonstrate improvements in satisfaction with their care as a result of a patient centred consultation when compared to their usual consultation.

- H₀ Patients with chronic venous leg ulceration will not demonstrate improvements in satisfaction with their care as a result of a patient centred consultation when compared to their usual consultation.
- H₁ Patients with chronic venous leg ulceration will demonstrate improvements in their quality of life as a result of a patient centred consultation when compared to their usual consultation.
- H₀ Patients with chronic venous leg ulceration will not demonstrate improvements in their quality of life as a result of a patient centred consultation when compared to their usual consultation.

8.1.1 Phase 3 design and methodology.

RCTs are a rigorous quantitative method which explore the relationship between a treatment or intervention and an outcome (Denscombe, 2007). Such quantitative methods involve the application of statistical formulae, testing of hypotheses and enumeration of data and are often accompanied by complex randomisation procedures underpinned by a pre-specified, deductive approach which is theory driven (Meadows, 2003; Denscombe, 2007). Such approaches, to date, have formed the cornerstone of health research (Meadows, 2003). Large quantitative studies can be extremely costly and time consuming so, prior to their commencement, their viability needs to be ensured; a process most often achieved by a pilot or feasibility study (Lancaster et al, 2004; Thabane et al, 2010).

The terms pilot study or feasibility study, Morin (2013) highlights, have often been applied interchangeably (Arian et al, 2010) but more recent distinctions have been made between what constitutes a pilot study and what falls under the remit of a 'feasibility' study (Lancaster et al, 2010; Arain et al, 2010). The preferred definition is provided by NETSCC (2014)

(www.netscc.ac.uk/glossary) and is agreed by the National Institute of Health Research (www.nihr.ac.uk), developed to reduce the any current confusion between the two terms (Arain et al, 2010). The NETSCC (2014) glossary outlines that feasibility studies are undertaken prior to a main study in order to establish parameters required in the design of the full study and to answer the question “Can this study be done?” whereas a pilot study is a miniature of a full study and tests whether components of the full study can work together focusing on “recruitment, randomisation, treatment, and follow-up assessments” (Arain et al, 2010; NETSCC, 2014). These distinctions demonstrate that well designed feasibility or pilot studies provide differing but vital information in the planning, design and justification of the definitive study (Polit et al, 2001; Lancaster et al, 2004; Thabane et al, 2010; Leon et al, 2011). For both approaches, the samples are not based on formal power calculations so subsequent analysis of data should be descriptive and findings treated as preliminary rather than conclusive (van Teijlingen et al, 2001; Lancaster et al, 2004; Altman & Simera, 2010).

In order to establish the viability of a full scale study, it is essential that a feasibility or pilot study has clearly defined and appropriate aims. There are five *a priori* aims for this phase of the study, which is described here as a pilot study, however taking into account the NETSCC definitions (2014), the first four most closely meet the feasibility remit and the final one that of a pilot study (Arain et al, 2010; NETSCC, 2014):

- To test the recruitment procedure and to confirm the recruitment rates for nurse and patient participants to the study;
- To test the utility or usefulness of the consultation template for the patient and the nurse;
- To determine the most appropriate measures to assess the primary and secondary outcomes for a future full study;

- To determine the feasibility of a future randomised controlled trial;
- To provide an initial indication of effect size in order to inform a power calculation.

Of similar importance are the criteria adopted to establish the success of such a study for which there are four potential recommendations on completion: that a future study should not proceed; that modifications are required; that the study may proceed with close monitoring or that the study can proceed unchanged (Thabane et al, 2010). Any of these outcomes are acceptable and indicate that the pilot / feasibility study has been successful potentially preventing an expensive but ineffective study from proceeding (Thabane et al, 2010).

A feasibility study can adopt a variety of designs which may or may not reflect the proposed design of the future full study, however a pilot study should ideally mirror the full study design (Meadows, 2003; Arian et al, 2010; NETSCC, 2014). For phase 3, however, following consideration of other potential designs such as a RCT, a within-subjects design was selected as most appropriate (Seltman, 2010). The main advantage of this design is that the sample size requirements are minimised with participants acting as both control and subject to the intervention (Seltman, 2010) (table 34 below). This approach facilitates the evaluation of outcomes for all participants at a number of time intervals in order to evaluate change over time and, as a result, unsystematic variance is minimised since subjects act as their own control and thus the power of the experiment is increased (Hicks, 2004; Field, 2006; Seltman, 2010).

Table 34: Within subject outcome measure intervals.

SUBJECT 1	PRETEST Measurement (M) 1	CONTROL (6 weeks)	TEST M 2	TEMPLATE APPLIED (6 weeks)	TEST M 3	TEMPLATE APPLIED (6 weeks)	POST TEST M 4
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8.1.2 Phase 3 outcome measures.

Following a review the literature surrounding PCC (chapter 2; page 23-37) and nurse-led consultation interventions (chapter 6; page 194-210) the outcomes to be explored within the pilot were defined. Patient satisfaction, an important indicator of the quality of care and responsive to PCC interventions, was selected as the primary outcome measure (Donabedian, 1980; Mead & Bower, 2000; Bowling, 2005; Moore & Cowman, 2009). The QoL of participants, useful in evaluating the impact of chronic illness, was selected as the secondary outcome measure (Walters et al, 1999; Fayers & Machin, 2000; Franks & Moffatt, 2001; Asadi-Lari et al, 2004; Charles, 2004; van Korlaar et al, 2004; Bowling, 2005).

Over the 18 week study these patient outcomes were assessed at four intervals utilising a total of four instruments. A number of other instruments were considered but dismissed for a variety of reasons: some instruments were condition specific and were therefore not relevant to CVLU (Vileikyte et al, 2003); others related to secondary or intermediate care (Wilson et al, 2006); others were excessively long and would thus increase the burden on patients (Ware & Sherbourne, 1992) and, finally, the validity of others was not, as yet, established (Asadi-Lari et al; 2004). The tools that were ultimately selected to assess the primary and secondary outcome measures were: Poulton's

(1996) adapted Consultation Satisfaction Questionnaire (CSQ); the Medical Short Form 12 (SF-12) (Ware et al, 1996), the EuroQol 5D (EQ 5D) (EuroQol Group, 1990) and the Cardiff Wound Impact Scale (CWIS) (Price and Harding, 2004). These tools required patient participants to complete 67 questions on each of the four occasions and, whilst it was accepted that this would pose a considerable burden to participants, their inclusion served to highlight their suitability for a future full study.

8.1.2.1 Consultation Satisfaction Questionnaire (CSQ) (Baker, 1990, 1993; Poulton, 1996).

The CSQ (Poulton, 1996) (appendix 18) is a patient satisfaction tool used extensively within primary care, originally to measure patient satisfaction with recent GP consultations (Baker, 1990), but subsequently modified by Poulton (1996) to optimise utility for nurse consultations. It was the modified version which was utilised in phase 3. The CSQ has 18 questions over four scales: general satisfaction (CSQ-GS), professional care (CSQ-PC), depth of relationship (CSQ-DR) and length of consultation (CSQ-PT). Individual scores and an overall score for each scale are calculated (0-100), with high scores indicating a positive rating. Answers take the form of a 5-point scale from strongly agree to strongly disagree with statements varied with positive and negative framing, in order to increase the validity of the instrument (Baker, 1990). Reliability and validity have been extensively evaluated (Cronbach's $\alpha=0.81$; Poulton, 1996), test-retest reliability was 0.92 over 3 weeks (Baker and Whitfield, 1992) and sensitivity to changes of care delivery have been demonstrated (Baker, 1990).

8.1.2.2 Short Form 12 v2 (SF-12) (Ware et al, 1996).

The SF-12 (Ware et al, 1996) (appendix 19) is a multi-purpose, generic, short survey developed in 1994 as an efficient and cost effective alternative to the then widely used SF-36 (Ware & Sherbourne, 1992). The 12 items ask the respondent to reflect on their experience over the last four weeks (a one week version is also available), with the updated version 2, used here, including improved wording. Each response assesses physical and mental functioning with scores amalgamated to provide two scales: physical health composite score (PCS) and mental health composite score (MCS). These are computed using the 12 question scores between 0-100, with 100 indicating the highest level of health. Reliability of the SF-12 is represented by a Cronbach's alpha of 0.87 for PCS-12 and 0.84 for MCS-12 scales, both indicating a good level of internal consistency (de Smedt et al, 2012). The SF-12 has assured validity and is simple and quick to complete whilst providing reliable data (Ware et al, 1996).

8.1.2.3 EuroQol 5D 5L (EQ-5D) (EuroQol, 1990).

The EQ-5D (EuroQol, 1990) (appendix 20) is a brief, reliable, generic measure of health status for both clinical and economic evaluation. The EQ-5D consists of a descriptive system where the respondent indicates their health status in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression and, in addition, a EQ visual analogue score (VAS) allows the respondent to self-rate their health 'today' on a vertical scale from 'worst imaginable health state' to 'best imaginable health state'; representing a quantitative measure of health. The EQ-5D-5 level (5L) version was introduced in 2005 to reduce ceiling effects reported from the 3L version, with responses for each of the 5 dimensions increased to include; no problems, slight problems, some problems, severe problems and extreme problems. Scoring provides a descriptive profile of the

respondents' health status using the single digit score for each of the 5 dimensions, with a total of 3125 possible health states (EuroQol, 1990). The 5 digit 'score', in the future, will be converted to a country specific single index value once full data is available but currently a 'crosswalk' score, a response mapping undertaken by EQ-5D with the established general population EQ-5D-3L scores is available, thus linking the 3L and 5L scores (Euroqol, 2012) (EQ5D Crosswalk). In addition, the EQ-5D provides a single index value from the VAS score (EQ5D VAS). Reliability of the EQ-5D is demonstrated with an overall Cronbach's alpha of 0.73, indicating an acceptable level of internal consistency (de Smedt et al, 2012). The EQ-5D also facilitates economic costing of interventions (Euroqol, 2012).

8.1.2.4 Cardiff Wound Impact Schedule (CWIS) (Price and Harding, 2004).

The CWIS (Price & Harding, 2004) (appendix 21) is a validated questionnaire designed to measure the impact of chronic wounds on the QoL of the patient. The questionnaire contains 28-items over three scales: physical symptoms and everyday living (12 items) (CWIS PS), social life (7 items) (CWIS SL) and well-being (7 items) (CWIS WB). Each item is scored on a 5-point scale with patients reflecting on their experiences over the past week. Both physical symptoms and social life require the patient to also reflect on how stressful the experiences have been. All scales are transformed onto a 0-100 scale, with high scores indicating a positive rating. Finally, respondents are asked to rate their QoL (0-10) (CWIS QoL) and their satisfaction with their QoL (0-10) using a visual analogue scale (CWIS Satis). Questionnaire development was based on focus groups and semi-structured interviews for item generation and reliability and validity are acceptable with a Cronbach's alpha of 0.75 across the three scales; test-retest reliability 0.9 over 5-7 days and sensitivity to changes as a result of healing were demonstrated (Price and Harding, 2004).

8.1.3 Phase 3 sampling framework.

Pilot study findings, via their calculated effect size, inform a sample size calculation for the full study. Thus the size of the sample recruited to the pilot is also an important consideration to minimise bias and optimise the accuracy of the calculation (Ross-McGill et al, 2000; Lancaster et al, 2004; Leon et al, 2011). Browne (1995) and Lancaster et al (2004) recommend a pilot sample of 30 or more patients in order to accurately estimate the parameter; however, more recently Sim and Lewis (2011) have recommended sample sizes of at least 55 for a pilot. In view of this, the recruitment procedure for this pilot aimed to recruit between 30-55 patient participants and to achieve this it aimed to recruit two DN teams and suitable patients. The following inclusion criteria were applied for nurse and patient participants selection.

8.1.3.1 Inclusion and exclusion criteria.

Nurse participants:

Inclusion criteria for nurse participants:

- The teams' staff has experience in the care of patients with CVLU.
- The team has sufficient suitable patients on their caseload.
- Staff were willing to take part in the study and to apply the consultation template.
- The teams had not been involved in earlier phases of this study.

Exclusion criteria for nurse participants:

- Where the team were undergoing widespread staff changes.
- Staff were unwilling to take part.

Patient participants:

Inclusion criteria for patient participants:

- The patient has leg ulceration of either venous or mixed aetiology (as diagnosed by Doppler Ankle Brachial Pressure Index (ABPI) ratio of between 0.5 – 1.2 and detailed history taking) (Vowden & Vowden, 2001).
- Ulceration has been present for in excess of 6 weeks.
- The patient was able to understand English.
- Visiting posed no risk to the patient or researcher.
- The patient was willing to take part in the study.
- The patient had not been involved in earlier phases of this study.

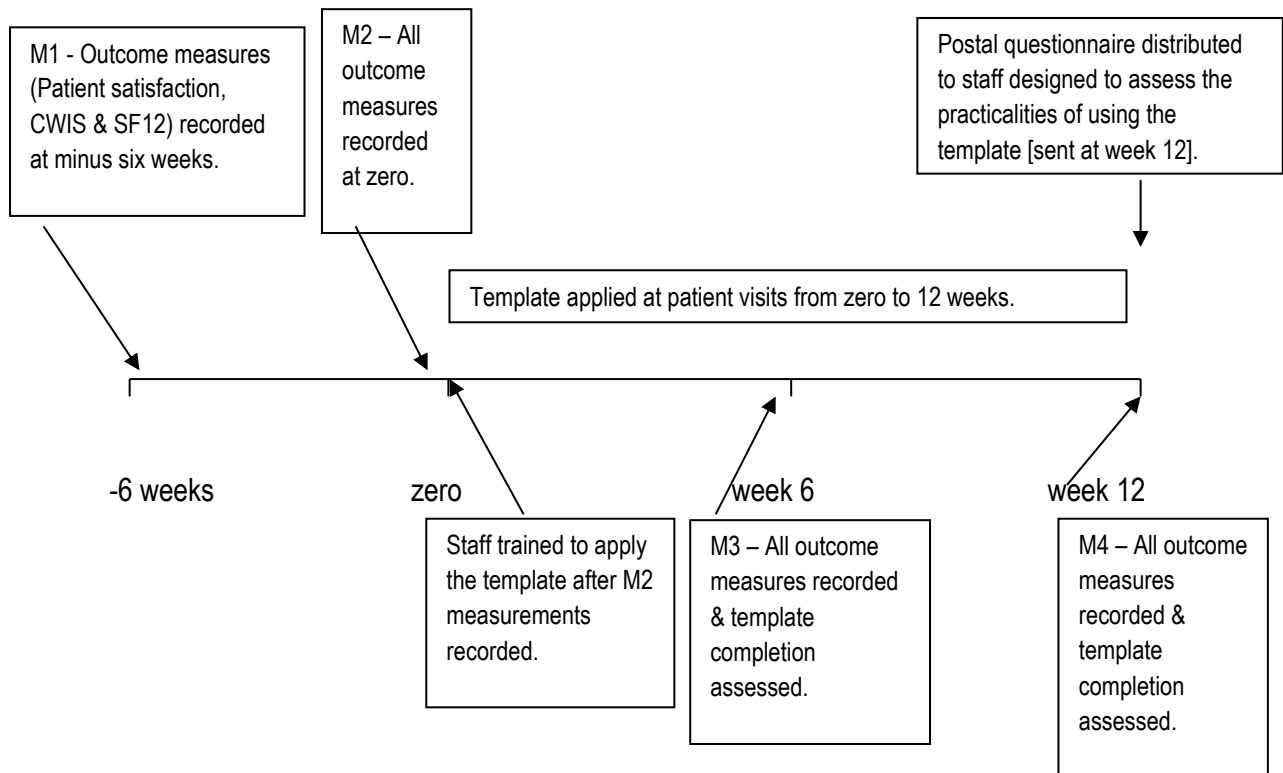
Exclusion criteria for patient participants:

- The patient does not fit the above inclusion criteria.
- The patient's leg ulceration, outlined under the first point of the inclusion criteria, is of arterial aetiology (as diagnosed by Doppler Ankle Brachial Pressure Index (ABPI) ratio of between 0.5 – 1.2 and detailed history taking) (Vowden & Vowden, 2001).

8.1.4 Phase 3 study procedure.

The final phase of the study was undertaken across the same two areas as earlier phases but this had now merged to form one large Primary Care Trust (PCT). The phase 3 timeline is depicted in figure 30 below.

Figure 30: Phase 3 timeline.



Managers were requested to suggest appropriate DN teams who provided regular care for CVLU patients and where staffing appeared to be stable for the duration of the study. It was also a requirement that staff had not been involved in earlier phases of this study, in order to avoid any bias that this could potentially introduce with participants aware of earlier study phases (Hicks, 2004). Once managers had nominated teams, the researcher made contact with the respective team leader to discuss study requirements and to provide a brief overview of the study. Arrangements were then

made to post out study packs, including a letter of introduction, a detailed consent form and comprehensive written information describing the study (appendix 23). Informed consent from nurse participants would be established prior to the study commencing.

Between January 2012 and June 2012, as a result of a frequent contact with managers and team staff, a total of four DN teams had been put forward and fully consented to take part in phase 3; but the first two withdrew their consent due to staffing changes prior to the start of their involvement. Once study packs had been dispatched and consent received, the two remaining teams were ready to start phase 3. Each team distributed study packs (appendix 23) to the patients on their caseload who met the inclusion criteria (page 246) and, once consent from patient participants had been received, the pilot study commenced. Throughout the 18 week study, patient participants continued to attend their routine, scheduled wound care consultations with the nurse participants (see figure 30; page 245). During the first 6 weeks care was unchanged and during this time the outcome measurement tools (page 242-245) were completed with the patient participants at the start of the study (baseline: M1) and after 6 weeks (M2). This provided 2 sets of scores at the start and end of the control period (M1 and M2) for which a mean was calculated providing one data point. Since these results were derived from the same participant, it was assumed that these would remain roughly similar during this period (Field, 2006). After the control period, the experimental period of the study commenced with the two DN teams trained to apply the new consultation template, which the nurse participants applied weekly during their routine wound care consultations with each of the patient participants. During this 12 week period, the outcome measures were again recorded every six weeks (M3 and M4).

8.1.5 Phase 3 data collection.

For this 18 week study, a six week control period of 'normal' care was followed by a 12 week period when the nurse participant applied the consultation template during each patient visit, thus optimising the response rate and ensuring a consistent approach to data collection (Pallant, 2007). At six weekly intervals patient participants, supported by the researcher, undertook the four outcome measurement tools (page 242-245). This provided four data collection points in total but since the control period reflected unchanged care, the first two scores were averaged to providing three data points overall. In addition, at the end of the study, a brief, basic questionnaire developed by the researcher and approved by the ethics committee (LREC 10/H1203/13) (appendix 27) was circulated to the DN team members allowing them an opportunity to provide anonymous feedback and to evaluate the utility of the consultation template.

8.1.6 Phase 3 data analysis.

Data analysis for the pilot focused on the five *a priori* aims detailed on page 238 and, although analysis was mainly descriptive (Lancaster et al, 2004; Thabane et al, 2010; Leon et al, 2011), a limited amount of additional *a posteriori* exploratory analysis was undertaken on the data collected (appendix 26). Extreme caution has been applied to the interpretation of such ad hoc data analysis, the results of which have simply been used to provide suggestions for future research design.

Studies adopting a within subject design provide the researcher with 'paired data' which, when statistically analysed, in this case using the Statistical Package for the Social Sciences v. 19 (SPSS) (IBM, 2010), can indicate change in outcome measures over time. Since preliminary analyses of the data using the Shapiro-Wilk Test of Normality demonstrated violation of normality and since outcome

scales were ordinal, non-parametric testing was deemed to be most appropriate for this pilot (Hicks, 2004; Pallant, 2007) (appendix 23). In view of this the Wilcoxon Signed Rank Test, a test specifically designed for such paired data, was applied. The Wilcoxon Test converts the scores at each of the time interval to ranks (Z) and compares them. From this Z value it is then possible to calculate an effect size, an objective and standardised measure of the magnitude of an observed effect, which can then be used to estimate the required sample for a future full study (Lancaster et al, 2004; Thabane et al, 2010; Leon et al, 2011). Here effect size is represented by the notation r (Pallant, 2007) and the scale, an adaptation of Cohen's d (Cohen, 1988), of 0 to 1; $r=0.1$ (small effect), $r=0.3$ (medium effect) and $r=0.5$ (large effect) has been applied (Pallant, 2007).

8.1.7 Ethical considerations in phase 3.

As with phases 1 and 2 of the study, to ensure that the rights, safety, dignity and well-being of all research participants were maintained (Dimond, 2005), the principles expounded in the guide to consent (DH, 2001b) and guidance related to mental capacity (DH, 2007) were followed. Ethical approval was applied for and granted by the Local Research Ethics Committee (LREC 10/H1203/13) (appendix 21) and agreement to proceed was confirmed by the National Health Service (NHS) Research and Development (R&D) Department in March 2012 (appendix 22).

Specific ethical considerations relating to phase 3 included the location of meetings between the patient participant and the researcher and both the quantity and repeated nature of the recording of the outcome measures for the patient participants. Both of these were explained in the patient information leaflets to ensure that potential participants were fully aware of the level of commitment required (Appendix 23) and consent was reaffirmed at the start of every meeting; thus providing

opportunity for withdrawal from the study if necessary. Patients were reassured that their care would continue unchanged should this occur.

8.2 Phase 3 results.

As stated, two DN teams consented to be involved in phase 3 of the study. These were described as L4 (Location 4) and L5 (Location 5) and each had quite different characteristics. L4 was a busy, modern clinic in an inner city area serving a number of GP practices with patient referral made by DNs if the patients were mobile and willing to attend. A single nurse, trained in wound care, provided the care with clinics delivered every day. Each appointment provided a 20-minute slot, with double slots booked by the patient when clinically indicated. Whereas L5 was a busy DN team providing domiciliary visits to 'housebound' patients and, in addition, conducted clinics daily between 2-3pm for more mobile patients. The team consisted of six registered nurses and a Health Care Support Worker (HCSW). Patient visits were allocated to staff each day, with each lasting for varying periods of time, depending both on clinical need and the staff involved. Patients were informed of the day and approximate time period of their next visit by their nurse. For those able, clinic appointments were available at the surgery, at clinics staffed by any nurse from the team.

Following distribution of study packs to potential patient participants, nine patients were recruited across the two teams: L4 provided 5 patients (L4, P1 – 5) all of whom were mobile and physically able to attend clinic and L5 provided four patients (L5, P1-4), three seen during domiciliary visits and one attending clinic. Seven participants were male and the median age was 68 years (range of 34 to 87 years) (table 35 below). Demographic details were recorded during the first meeting with the participant to provide an additional insight into sample characteristics.

Table 35: Phase 3 patient participant details.

<u>Participant pseudonym.</u>	<u>Age.</u>	<u>Gender.</u>	<u>Marital status.</u>	<u>Residential status.</u>	<u>Total duration of ulceration.</u>	<u>Number of episodes.</u>
Eric (L4)	85	Male	Widower	Lives alone in a ground floor flat	10 years	2-3
Dave (L4)	54	Male	Divorced	Lives with son in terraced house.	30 years	over 5
Peter (L4)	72	Male	Single	Lives alone in a house	10 years	over 3
Paul (L4)	34	Male	Single	Lives alone in a ground floor flat	8 years	1
Stuart(L4)	52	Male	Single	Lives alone in a house	30 years	1
Mick (L5)	68	Male	Single	Lives alone in a house	10 years	1
Elsie (L5)	87	Female	Widow	Lives alone in a house	14 years	over 3
Ian (L5)	72	Male	Married	Lives with wife in a house	2 years	1
Cath (L5)	45	Female	Married	Lives with family in a house	5 years	1

8.2.1 The control period.

Scores recorded at M1 and M2 (control period) were averaged to provide a mean baseline score to reflect the control period for each participant for each of the outcome measures (appendix 26); thus providing a baseline score and to enable further analysis to take place (table 36 below).

Table 36: Mean baseline scores for all outcomes.

	Consultation Satisfaction Questionnaire				SF-12		EuroQoL 5D		Cardiff Wound Impact Schedule				
	CSQ GS	CSQ PC	CSQ DR	CSQ PT	PCS	MCS	EQ5 D	EQ VAS	CWIS QoL	CWIS Satis	CWIS WB	CWIS PS	CWIS SL
L4P1	95.84	97.5	100	100	34.65	53.14	0.53	70	6.5	7.5	53.57	79.69	92.85
L4P2	100	100	97.5	100	24.5	69.24	0.73	52.5	7	7	56.64	89.59	95.54
L4P3	100	100	100	100	38.31	62.99	0.78	70	7	7	57.14	92.71	95.54
L4P4	100	100	100	100	22.65	42.04	0.26	50	5	4.5	26.79	32.81	52.68
L4P5	100	100	100	95.84	42.49	39.16	0.6	72.5	4.5	4.5	24.96	57.3	83.93
L5P1	54.17	82.14	80	91.66	26.46	48.53	0.36	50	6	5	64.29	58.34	74.11
L5P2	37.5	83.93	77.5	37.5	40.42	21.44	0.57	57.5	6.5	6.5	41.07	38.02	29.47
L5P3	36.31	69.65	55	75	35.32	60.69	0.59	67.5	7	4	39.29	90.1	100
L5P4	66.66	71.43	70	37.5	24.86	29.2	0.04	5	1.5	0	10.71	20.31	11.61

8.2.2 Outcome data.

8.2.2.1 The Wilcoxon Signed Rank Test.

8.2.2.1.1 Time 1 (Mean M1 and M2) to Time 2 (M3).

The difference between outcome scores between Time 1 and Time 2 was tested for significance using the Wilcoxon Signed Rank Test (table 37 below). This test provides a Z value and associated significance level (*p* value) along with a median score at Time 1 (*Pre Md*) and Time 2 (*Post Md*). From these results an effect size, *r* value, was calculated (Z value divided by the square root of N (N = total number of observations over the two time points) (Pallant, 2007).

Table 37: Wilcoxon Signed Rank Test between Time 1 (mean M1 and M2) and Time 2 (M3).

		Outcome (median)		Wilcoxon		Effect size
		Time 1 (mean of M1 and M2)	Time 2 (M3)	Z value	p value	r
Consultation Satisfaction Questionnaire	CSQ GS	95.83	100	0.14	0.89	0.03
	CSQ PC	97.5	100	0.41	0.69	0.08
	CSQ DR	97.5	100	0.67	0.5	0.13
	CSQ PT	95.83	100	1.21	0.23	0.24
SF-12	PCS	34.65	29.33	1.01	0.31	0.2
	MCS	48.53	55.27	0.42	0.68	0.08
EuroQoL 5D	EQ5D	0.57	0.64	0.3	0.77	0.06
	EQ VAS	57.5	70	0.28	0.79	0.06
Cardiff Wound Impact Schedule	CWIS QoL	6.5	7.0	1.02	0.31	0.2
	CWIS Satis	5.0	7.0	1.06	0.29	0.21
	CWIS WB	41.07	50	1.96	0.05	0.38
	CWIS PS	58.33	75	0.42	0.68	0.08
	CWIS SL	83.92	85.71	0.28	0.79	0.06

As displayed above (table 37), all outcome scores, apart from the PCS, increased over the period Time 1 to Time 2, however, only one result was of significance ($p < 0.05$), with an increase in the CWIS WB (well-being) score following the application of the consultation template over this six week period ($z = 1.96$, $p < 0.05$) demonstrating a medium effect size ($r = 0.38$). Effect sizes for all outcomes were calculated (r) (table 37) however, as is usual, the effect size for the primary outcome measure (patient satisfaction) was used for the sample size calculation. For the primary outcome (CSQ scores) effect sizes were within the range of $r = 0.03$ to 0.24 ; thus demonstrating a small effect size.

8.2.2.1.2 Time 1 (Mean M1 and M2) to Time 3 (M4).

The Wilcoxon Signed Rank Test from Time 1 (mean of M1 and M2) to Time 3 (M4) (table 38 below) was also calculated.

Table 38: Wilcoxon Signed Rank Test between Time 1 (mean M1 and M2) and Time 3 (M4).

		Outcome (median)		Wilcoxon		Effect size
		Time 1 (mean of M1 and M2)	Time 3 (M4)	Z value	p value	r
Consultation Satisfaction Questionnaire	CSQ GS	95.83	100	0.95	0.34	0.19
	CSQ PC	97.5	100	0.14	0.89	0.03
	CSQ DR	97.5	100	0.21	0.83	0.04
	CSQ PT	95.83	100	0.00	0.74	0.0
SF-12	PCS	34.65	34.85	0.3	0.77	0.06
	MCS	48.53	45.07	1.36	0.17	0.27
EuroQoL 5D	EQ5D	0.57	0.57	1.36	0.17	0.27
	EQ VAS	57.5	60	0.28	0.78	0.06
Cardiff Wound Impact Schedule	CWIS QoL	6.5	7.0	0.94	0.35	0.18
	CWIS Satis	5.0	7.0	0.84	0.4	0.16
	CWIS WB	41.07	50	1.01	0.31	0.2
	CWIS PS	58.33	71.88	0.65	0.52	0.13
	CWIS SL	83.92	96.42	0.42	0.67	0.08

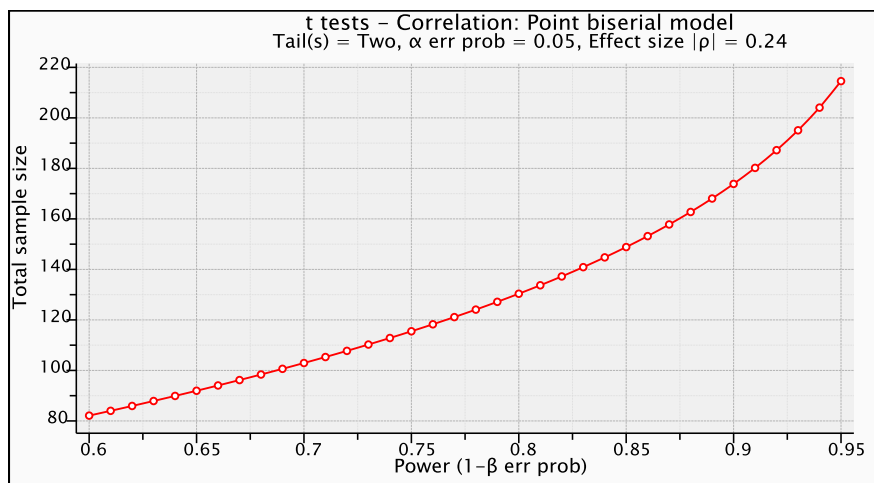
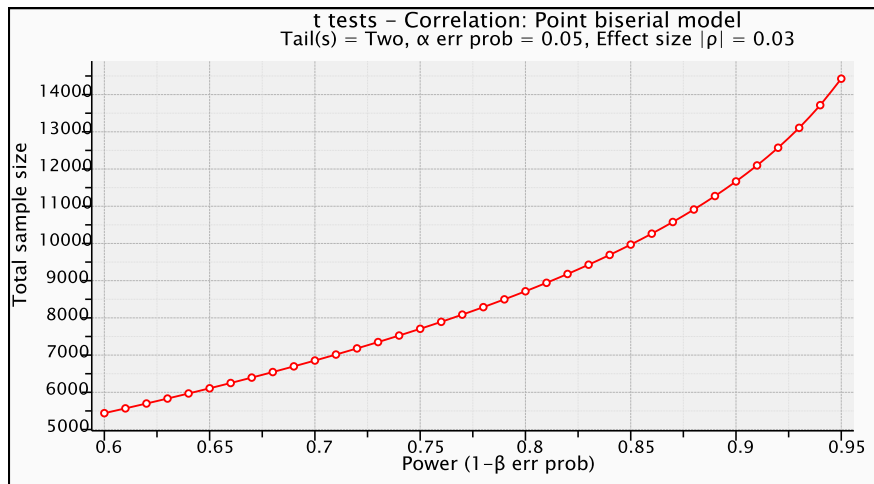
Scores here revealed that while all outcome scores, other than the MCS and the EQ-5D Index score, may have increased following the control period, but that none of the changes were significant. Again

effect sizes (r) for all outcomes were calculated but only the effect sizes for the primary outcome measure (patient satisfaction) were used for the sample size calculation. CSQ outcomes were in the range $r = 0.03$ to 0.19 and again demonstrated a small effect size.

8.2.3 Sample size calculation.

In order to accurately calculate the sample that would be required for a future RCT based on the data from this pilot study the effect size of the Wilcoxon Signed Rank Tests for the primary outcome measures were used (Hicks, 2004; Pallant, 2007; Field, 2006; McCrum-Gardner, 2010; Leon et al, 2011). The range of effects sizes (r) values (0.03 to 0.24) for the two data points Time 1-2 and Time 1-3 demonstrate an overall small effect (Pallant, 2007). Using a reputable sample size calculation programme entitled 'G*Power' (Faul et al, 2009) the above effect size range was utilised to estimate the required sample size for a future full RCT: If the future RCT were to have the desired statistical power level of 0.8 and a probability level of less than or equal to 0.05 ; for a two tailed design, an overall sample of between 8716 ($r = 0.03$) and 131 ($r = 0.24$) patient participants would be required (Field, 2006; Pallant, 2007) (figure 31).

Figure 31: G*Power (Faul et al, 2007) output for the sample size calculation range 0.03 – 0.24.



In view of the non-parametric nature of the data, accurate sample size calculation is known to be more difficult (Pallant, 2007), thus in such a case Lehmann (1998) recommends that, providing the intended sample is quite large and that distribution is not excessively unusual, an additional 15% should be added to the sample size, giving a total future RCT sample size of between 151 – 10, 024.

8.2.3 *A posteriori* findings.

Although further statistical analysis was not planned at the start of the study due to the pilot study issues discussed (Field, 2006), a small amount of *a posteriori* exploratory analysis has been included in appendix 26. Such ad hoc analysis provided some additional information which, when cautiously considered, provides suggestions for a number areas for future research. The data for the nine participants indicated:

- QoL scores were extremely variable during the control period which may indicate that, for this client group, QoL is not a suitable primary outcome measure (appendix 25).
- The satisfaction scores (CSG) (Baker, 1990) indicated that patients in L4 who attended a clinic and saw the same nurse appeared to be more satisfied than both population scores (Shum et al, 2001) and the L5 participants who were seen at home by a variety of nurses.
- Study patients reported lower QoL scores than the general population with the exception of the L4 patients who reported improved mental health functioning.

8.2.4 Nurse evaluation of the template.

After phase 3 was completed, the nurses had the opportunity to comment on the utility of the template and its usefulness in their day-to-day care. A brief questionnaire, developed by the researcher and approved by the ethics committee (LREC 10/H1203/13) (appendix 27), was distributed to both teams, L4 and L5, but was completed by only one of the teams involved. L5 returned a single, jointly completed questionnaire which included a comment that they felt that the template was simple and quick to apply but that patients did not feel that the full consultation template was required at each consultation. L5 felt that the impact of the template was positive overall stating that:

“Some patients did not appreciate more questions and tick boxes and the nurses completing more paper work than normal. Other patients enjoyed the opportunity to discuss their worries in depth.”

8.3 Phase 3 discussion.

Discussion of the phase 3 results is initially presented in response to the five initial aims for the pilot / feasibility study presented on page 239. The first four aims reflect the feasibility aspects whilst the final aim the pilot study remit.

8.3.1 To test the recruitment procedure and to confirm the recruitment rates for nurses and patients to the study.

Arain et al (2010) asserts that feasibility studies provide important information in relation to the 'willingness of clinicians to recruit participants' and the ability to recruit sufficient 'number of eligible patients, carers or other appropriate participants.' The procedure for phase 3 of the study aimed to recruit two DN teams across a now single PCT in order to access sufficient patient participants. Recruitment was problematic. Two teams, despite indicating that they would be keen to be involved, decided not to consent. Both appeared to be working under considerable pressure and had staffing shortages due to organisational changes and staff sickness. This process of engagement and withdrawal took in excess of three months of the study time. Once it was established that these initial teams were not proceeding, recruitment restarted and was successful with two new teams fully consented to take part in the study.

Once these new DN teams were consented, they were requested to distribute study packs to their patients who met the study inclusion criteria (detailed on page 244). Twelve weeks were allocated for patient participant recruitment and eventually nine patient participants in total were recruited, many fewer than the target of 30-55 required for an effective pilot study (Browne, 1995; Lancaster et al, 2004; Sim & Lewis, 2011). Despite encouragement, this could not be improved. Despite the inadequacy of the sample, it was decided to proceed with the pilot study but to treat any results with

caution. Positive elements of the recruitment process demonstrated that both the consented nurses and patients remained in the study and completed the required intervention or measurements throughout the 18 week duration.

It was felt that the difficulties with recruitment were influenced by the extensive changes that local primary care delivery was undergoing during the period of the study. These changes appeared to severely limit potential recruitment and, despite a relatively straightforward process to recruit via the manager, then the DN and then the patient, this proved to be ineffective. Experiences with phase 3 in relation to this feasibility aim indicate that the process of recruitment was not fit for purpose and the ability to recruit both the teams of nurses required and the patient participants for this type of community based study was extremely problematic, which indicates that a larger study of this design would not be possible.

8.3.2 To test the utility or usefulness of the consultation template.

Once the six week control period of the study had been undertaken, each DN team was trained in the application of the new consultation template. These training sessions lasted for between 10 - 20 minutes and were designed to introduce the nursing staff in the application of the template. In terms of the initial utility of the template, the brevity of the required training indicated that training issues for this type of intervention were minimal. There were some concerns from nurses that they already had to complete considerable paper work but they were reassured when they reviewed the template, since having been developed with the input of local Tissue Viability experts, duplication of information had been minimised. Nurses appreciated the format of the template and reflected on the usefulness of tick boxes, with additional comment boxes if needed.

Evaluation by nurses at the end of phase 3 was minimal, with only one team completed questionnaire returned. This questionnaire indicated that some patients felt they had to repeat information when the template was completed during consecutive visits. This may indicate that less frequent completion would provide the required PC focus or that patient completion of the template prior to the DN consultation may well be as or more effective. This constitutes an area where further research might be beneficial. In terms of feasibility, this outcome may indicate the need to change the design of any future study to reflect less frequent application of the template.

8.3.3 To determine the most appropriate measure to assess the primary outcome for a future full study.

NETSCC (2014) criteria for a feasibility study describes the facility to explore the characteristics of the proposed outcome measure (Arain et al, 2010). It was acknowledged (page 240) that the application of the four measurement tools repeated at the four time intervals may potentially have presented a considerable burden to the patient participants of phase 3 of the study. However, it was felt that this was acceptable in order to establish the appropriate outcome measures for a future full study.

Following the additional analysis of the data (appendix 26), although the sample size was small and the data was treated as exploratory, the considerable differences in scores for patient satisfaction between participants suggest that patient satisfaction would be the most suitable primary outcome measure for a future full study. This is in line with the outcome measures applied in the nurse based studies reviewed in chapter 6 (page 194 - 210) and an area where there is a need for more UK research.

8.3.4 To determine the feasibility of a future randomised controlled trial.

As highlighted in the points above, the difficulties that the pilot study revealed in terms of recruitment combined with the need for such a large sample size, indicate that a full study with an RCT design of this intervention would not be feasible. This does not, however, preclude a further study that adopts an alternate design where the requirements of sample size are not as great.

8.3.5 To provide an initial indication of effect sizes in order to inform a power calculation.

The majority of outcome scores demonstrated a positive trend at each of the data collection points, which indicates that template application may be of some clinical benefit (page 253 - 255). These scores demonstrate that the intervention may have had a small effect on both the satisfaction and QoL of the patient participants.

Sample size calculations for definitive trials from pilot data are imprecise (Leon et al, 2011). To improve the precision of such estimates, it is recommended that 30 plus participants are included in pilot studies (Sim and Lewis, 2011). Any sample size calculation based on these data (which were obtained from only nine participants) must therefore be treated cautiously. Furthermore, the effect sizes vary from 0.03 to 0.24 for satisfaction (the primary outcome measure) and thus a definitive trial would need 151 to 10,024 participants, accounting for allowances for the non parametric nature of the data (Lehman, 1998).

The clinical significance of the template, however, is based on the effectiveness, suitability and utility of the newly developed template in clinical practice. An improving trend of outcome scores during the experimental period of the pilot, although minimal, may indicate further exploration of template

acceptability and utility using an alternative method would be appropriate to determine its clinical significance.

8.4 Overview

Currently the only available template in relation to CVLU for use by nurses during their consultations is a physical assessment tool and includes the minutiae of wound assessment (SIGN, 2010). Such templates present a very medicalised approach to CVLU care and almost direct the nurse away from seeing the patient holistically (Beresford, 2010; page 39). Since consultations between the nurse and patient in CVLU care are known to overlook these important QoL issues (Persoon et al, 2004; page 2), this template was designed to re-dress this balance and to focus the nurse on issues and concerns that impact on the day-to-day lives of such patients.

8.4.1 *A posteriori* findings.

As said, the ad hoc, *a posteriori* analyses of the outcome measurement scores (appendix 26) provide some areas for future research.

- The variability of QoL during the control period was unexpected and may indicate that QoL is a variable outcome measure for this client group (Franks & Moffatt, 1998, 2001; Franks et al, 2006). Since many studies that seek to enumerate the impact of CVLU apply such QoL tools, this raises some doubts about the suitability of QoL as a primary outcome measure. Further study to explore the suitability of QoL for this client group would be informative.

- The overall reduced physical functioning represented by the SF-12 scores (Ware et al, 1996) echoes the findings of a number of other studies (Rich & McLachlan, 2003; Briggs & Flemming, 2007) and supports the severe physical impact of this condition on the life of the patient. Studies to implement and evaluate interventions that aim to improve physical functioning would be welcomed by patients and nurses alike and would constitute particularly useful research.
- Whilst treating these results with caution (Leon et al, 2011), the differences identified between L4 and L5 may present interesting hypotheses for future research. L4 patients were unusual in that the same nurse provided their care, at each consultation, in a clinic location. Whether higher satisfaction with care is due to either the location of that care or continuity of the nurse delivering the care, a factor of importance alluded to by participants in phase 1 of the study (chapter 4; page 93 - 158) is worthy of further research.
- Those patients in the L4 group who attended clinic, whilst being as physically compromised as their L5 counterparts (appendix 26), demonstrated a higher mental health (SF-12 MCS score; Ware et al, 1996) which indicates improved mental health functioning. This may be explained by the personal characteristic theories outlined in chapter 2 (page 23 - 49) and may reflect locus of control (Rotter, 1954; page 44), self efficacy (Bandura, 1977; page 45) or self management (Morden et al, 2012; page 45) theories. This would present an interesting area for future research.
- Although CVLU predominantly affects those of increasing age (Posnett & Franks, 2007), the results suggest that those aged under 45 years may be more compromised using scores from both the SF-12 (Ware et al, 1996) and EQ-5D (EuroQol, 1990). Again, an important area for future research.

8.5 Strengths and weakness.

8.5.1 Strengths.

- The phase 3 pilot adopted a robust within-subjects design. This reduced the sample size required compared to a pilot that mirrored an RCT design (Seltman, 2010).
- All outcome measures were recorded during face to face meetings between the researcher and the patient participants, thus ensuring consistency in the recording the responses and improving the response rate, often the case with more direct methods of contact with participants (Hicks, 2004).

8.5.2 Weaknesses.

- Despite every effort to optimise recruitment, the sample size for this pilot was much smaller than anticipated. The study was undertaken during an extended period of regional NHS reorganisation within both primary and secondary care and this appeared to have impacted greatly on the willingness of nurses to engage with the study. Once the nurses had been consented to take part in the study, patient recruitment remained unsatisfactory: whether due to a lack of enthusiasm by nurses to recruit to the study, patients on their caseload being unsuitable or patients refusing to take part. This ultimately resulted in a sample of only nine patients. Despite poor recruitment proving to be a weakness, it served to inform the first aim of the study, that recruitment to such a full RCT would not be feasible and thus ruled out a future full RCT.
- A lack of individual nurse response to the post study questionnaire was disappointing and limits understanding of the nurse perspective of the usefulness of the consultation template.

8.5.3 Contribution to new knowledge.

- The consultation template itself represents new knowledge as it is the first template for use during a nurse-patient wound care consultation which addresses QoL issues which are known to impact on patients with CVLU.
- The variability of QoL as an outcome measure in patients with CVLU may indicate its unsuitability for use as a primary outcome measure (caution as based on a *posteriori* analysis) and highlights the need for cautiousness when QoL outcome scores are reported.
- Higher levels of satisfaction from patients receiving care from a single nurse in a clinic location (caution as based on an *a posteriori* analysis).

8.5.4 Further research.

The findings of this pilot study suggest a number of areas that are worthy of further research, including the evaluation of the efficacy of the consultation template using an alternative approach. Since the study did reveal small improvements in the patient outcomes across the duration of the pilot study (although the effect size was small $r = 0.03$ to 0.24), further exploration using a different approach such as observation as in phase 2 of the template application or using the template as a patient activation tool, may prove to be more successful. Since patients reflected on some repetition when the template was applied during every visit, further research into template efficacy with less frequent application or patient self-completion may prove beneficial.

Some of the additional analysis included in appendix 26, indicated that there may have been higher satisfaction in clinic attendees and/or when care was delivered by the same nurse, although these results are treated with caution and may have been the result of a number of factors (Pallant, 2007). Phase 1 highlighted the importance of the continuity of the nurse to patients with CVLU (chapter 4;

page 93 - 156), thus further research to investigate the impact of the location of care and nurse consistency may prove worthwhile and serve to inform the design of future care delivery.

Patient participants demonstrated variable psychological effects (MCS; Ware et al, 1996), with L4, the clinic attenders with a single nurse, functioning very well whereas L5, mainly receiving domiciliary visits, performed poorly in this area (appendix 26). These findings may reflect either patient participant personal characteristics (Rotter, 1954; Bandura, 1977; Morden et al, 2012) or their coping mechanisms (Antonovsky, 1987; Lazarus, 1993) or simply the effect of getting the patient out of the house. These would both provide interesting areas for future research.

Younger patients with CVLU demonstrated more compromised SF-12 (Ware et al, 1996) and EQ-5D (EuroQol, 1990) scores (appendix 26). Although CVLU is not as prevalent in this age range, the impact on all areas of functioning appears greater and is an area that would also benefit from further study.

8.6 Conclusion.

This pilot has demonstrated that in the context of current nursing care delivery, recruitment of nursing teams for the necessary sample size for a future full RCT would not be possible. The small effect size demonstrated across the pilot study indicates that such a study would require an inordinately large sample, which further confounds the feasibility of such an undertaking. Further research into template utility with a different design may provide an insight into potential usefulness and also would determine whether, despite this small effect, template application could be of clinical significance. The template was designed in response to a lack of disclosure of QoL issues that were

impacting on their lives by patients during their consultations, thus there remains a real area of need and further research is necessary.

Chapter 9: Overall discussion, conclusions and recommendations.

Chapter 9: Overall discussion, conclusions and recommendations.

9.1 Introduction.

Research has demonstrated that wound care consultations are frequently of poor quality, with patient concerns about daily life often overlooked by nurses who specifically focus on the wound and its associated care (Callam et al, 1985; McGuckin et al, 2000; Persoon et al, 2004). In response to this lack of PCC, and as a result of personal experience, this study was designed to clarify the concerns of patients with CVLU (chapter 4; page 93 - 158) and to establish whether these were disclosed and addressed during their current wound care consultations (chapter 5; page 159 - 193). Phase 1 effectively demonstrated the negative impact of CVLU on the participants' QoL and phase 2 indicated that, despite this compromised QoL, 38% of patients did not disclose their concerns to the consulting nurse and, even when concerns were disclosed, on 38% of occasions they were not fully addressed leaving only 24% of concerns partially or completely tackled by the nurse. In response to these findings and following a review of nurse-led primary care interventions to improve PCC (chapter 6; page 194 - 210), a consultation template with a focus on known QoL issues was developed using a consensus technique (chapter 7; page 211 - 234). Finally, a pilot study of the new template was undertaken to explore recruitment and effect size (chapter 8; page 236 - 269) which demonstrated that a future study using an RCT design would not be feasible.

9.2 Synthesis of the research findings.

The findings in phase 1 clarified the devastating consequences of CVLU for the patient; across physical, psychological and social functioning (Chase et al, 1997; Hyde et al, 1999; Douglas, 2001; Ebbeskog & Ekman, 2001; Rich & McLachlan, 2003; Hopkins, 2004). These findings were similarly corroborated by the low baseline QoL scores for patient participants in the phase 3 pilot study that

included SF-12 (Ware et al, 1996) and EQ-5D (EuroQol, 1990). When compared to population values (Gandek et al, 1998) these measures were significantly compromised (appendix 26). Indeed, Steve, the youngest participant, spoke at length about the devastating impact of his intractable ulcers and provided a very personal insight into the condition.

'It's just the same pain, 24/7, (...) I just have to put up with it; it's either that or kill myself...'

Phase 3 similarly demonstrated that younger participants (five under the age of 60 years) were more significantly compromised across all domains than their older counterparts; a finding not clearly alluded to previously but which could potentially be explained by the impact of CVLU on their body image (Price, 1999; page 42).

A preference for seeing 'their' nurse for consultations was a prevailing theme within the narratives of the phase 1 participants (chapter 4; page 125) however, participants acknowledged that this care probably did not differ in quality, but their relationship with 'their' nurse and the continuity were important to them. This finding may be supported by the pilot analysis which demonstrated that those whose care was provided by a single nurse (L4) may be more satisfied with their care (appendix 26); themes also evident in a number of earlier studies (Charles, 1995; Chase et al, 1997; Brown, 2005b; Byrne & Kelly, 2010). Key features of PCC include the patient focus, partnership and SDM, all elements which are reliant on the continuity of the relationship between the HCP and the patient (Stewart et al, 2000).

Literature demonstrated that some patients with CVLU lacked a clear understanding of the underlying causes and treatment of their ulceration, which exacerbated their feelings of powerlessness and may have resulted in some compliance issues (Chase et al, 1997; Douglas,

2001). In contrast to this evidence, phase 1 participants demonstrated an in-depth knowledge of the dressings used and the condition of their wound, they appeared to see themselves as partners with their consulting nurse, working together to heal the ulcer. Indeed, this was supported in phase 2 with the issues surrounding wound management being explored and addressed most effectively, with 47% of concerns being fully dealt with by the nurses, effectively serving to maintain this level of patient insight. This sharing of information is essential to a PCC approach to care (Henderson, 2003) and serves to equalise the balance of power within the HCP-patient relationship (DH, 2001c).

Despite the overwhelming psychological effects of CVLU (Bland, 1996; Hyde et al, 1999; Hopkins, 2004), phase 1 similarly revealed that participants continued to have hope and an inner strength, which served to improve their ability to cope. Aspects potentially influenced by the personal characteristics reviewed in chapter 2 (page 39 - 48). Those able to draw on this 'inner strength' or internal locus of control (Rotter, 1954) or 'sense of coherence' (Antonovsky, 1987) seemed more able to cope with the daily impact of their CVLU. Interestingly, *ad hoc* analysis of phase 3 indicated that those patients who attended clinic (L4), despite being as physically compromised as their home visit counterparts, exhibited improved mental health functioning, as demonstrated by their SF-12 MCS score (Ware et al, 1996), although if this is a generalisable finding is unknown. It would be interesting to explore whether their improved mental health functioning led these patients to engage with clinic attendance or whether clinic attendance actually led to their enhanced their mental health functioning. Similar considerations have led to a number of leg ulcer clinic developments (Lindsay, 2000), although attendance at such clinics by those with such compromised physical functioning is not always possible. Research into this area may well inform future service design.

As outlined in Chapter 4 (page 116 - 119), pain dominated the interviews and often analgesia proved to be ineffective; a theme supported by the literature (Bland, 1996; Rich & McLachlan, 2003; Brown, 2005b). Patient participants throughout the study were all severely physically compromised as a result of their CVLU but, nevertheless, pain was not raised during 42% of the observed consultations.

During many of the consultations observed in phase 2 nurses exhibited a preference for discussion rather than adopting a problem solving approach, especially in the area of the effects of CVLU on daily life where 39% of concerns led to a discussion (page 174). Patients attend their consultation with many concerns, hopeful that they may be offered a solution and, if only a discussion with the nurse is provided the patient may well not raise these concerns during their future consultations. Nurses need to be trained to be more problem focused in their consultations, indeed the inclusion of a 'comments and problem solving' box within the new consultation template was designed in an attempt to encourage nurses to adopt this approach (page 222). Such a problem focused approach needs further exploration and evaluation to see if patient outcomes improve as a result.

The lack of disclosure of established themes by patients during phase 2 was significant and provides an added insight into the findings of the study by Stewart et al (1979) where 45% of patient concerns were either not elicited or disclosed by the patient during GP-patient consultations. In this nurse-patient study, 38% of concerns were not disclosed and, when raised, a further 38% were only either acknowledged or discussed; leaving the remaining 24% to be either partially or completely addressed (chapter 5; page 174). Data from this study serves to clarify earlier data from Stewart et al (1979) and provides worrying reading regarding the effectiveness of current consultation skills. Whilst this is unlikely to be sufficient on its own, patient activation may serve to increase the level of

disclosure and thus optimise the response of the HCP thereby enhancing PCC. All areas that require further investigation.

9.3 Overall contribution to new knowledge.

Across a number of areas this study has revealed new knowledge or extended previous knowledge.

- Some findings suggest that consultations for those with CVLU lack of a PC focus.
- Some participants reflected that their physical symptoms; pain, exudate and odour, were poorly managed and served to diminish their QoL.
- For some, hope, despite the overwhelming impact of their CVLU, continued to be present.
- Some participants reflected on the importance of having a consistent nursing team.
- Observations of consultations suggested that nurses may prefer a discussion with their patient rather than a problem solving approach during consultations.
- Some of the observations suggested that the disclosure of known concerns by patients was poor, most notably issues relating to pain.
- The consultation template is the first template for use during a nurse-patient wound care consultation to address QoL issues which are known to impact on patients with CVLU.
- The study suggests that both the location of and continuity of care has an impact on the patients' satisfaction with their care.
- Data suggests that QoL is a variable outcome measure for patients who suffer from CVLU and, for this feasibility study, patient satisfaction appeared to be more appropriate as a primary outcome for a future study.

9.4 Strengths and weaknesses.

9.4.1 Strengths.

This study demonstrated a number of overall strengths. The comprehensive systematic review of the impact of CVLU on the QoL of the patient was robustly conducted (chapter 3; page 50 - 92), using the most up to date guidelines (CRD, 2009; Higgins & Green, 2011) and served to corroborate our understanding of the effects of CVLU on all areas of functioning for the patient.

This study demonstrates a novel approach across phases 1 and 2 to establishing the concerns of patients with CVLU and then tracking these into an observation phase, in order to establish whether they are appropriately explored. Such an approach has revealed a noteworthy insight into the nature of consultations and has exposed a lack of disclosure by patients and a deficiency of problem solving by nurses. Results have provided interesting data that provides a further dimension to key research by Stewart et al (1979). Similarly, the adoption of a consensus technique for the development of the consultation template ensured that a robust tool, validated by patient participants, was produced and subsequently piloted.

This study has applied a wide-ranging mixed methods approach over a four year period which was robustly designed and conscientiously undertaken and, in its undertaking, has provided the opportunity for extensive and thorough research training for the researcher. This has also been accompanied by numerous opportunities to present findings to both national and international audiences (appendix 29) and the publication of a number of creditable articles (Green & Jester, 2009; 2010; Green et al, 2013a & b) (appendix 30), which has further enhanced the value of this research training.

9.4.2 Weaknesses.

For the duration of this study there have been major issues with recruitment. At a time when the NHS is undergoing considerable and relentless reorganisation (DH, 2013), undertaking research within primary care has proved to be extremely challenging. This, however, does not detract from the value of such research. Consultations in primary care (GP and nurse) in England are predicted to rise from 300 million to 433 million between 2008 and 2035 (King's Fund, 2013) and, if this is the case, research that endeavours to put the patient at the heart of the consultation may well improve the quality of the care delivered and the satisfaction of patients.

9.5 Further research.

This study has provided a novel insight into the experiences of patients with CVLU. In so doing it has highlighted a number of areas worthy of further research:

- In this current climate of modernisation of community care (DH, 2013) priorities need to focus on the importance of the patient in the consultation and the delivery of holistic care. The importance of the nurse-patient relationship and the need for consistent care provision highlighted by this study is an area that is of central importance. Indeed, further research into the location of care and the consistency of the consulting nurse would be beneficial and would establish which of these factors had the greatest impact. Indeed, an exploration of whether engineering improved nurse-patient continuity would continue to enhance satisfaction may well serve to inform future service design.
- An exploration of the reasons that result in the lack of patient disclosure would be informative and may well enhance developments to improve the patient centredness of future consultations.

- In addition, exploring why nurse participants demonstrated a reluctance to move to either partial or complete problem solving, preferring to simply discuss issues with the patient, may provide a basis to improve future training in relation to consultation skills.
- The consultation template aims to focus the consulting nurse on issues that are known to impact on the daily lives of patients with CVLU. Manipulating practitioner behaviour in order to facilitate PCC is a known approach (Kinnersley et al, 2007; EPOC, 2008; O'Connor, 2009); alternatively, activating the patient to become more involved in the consultation and to disclose their concerns could be used. Further research, using the consultation template, for patient self-completion prior to their consultation may prove to be beneficial and may serve to activate the patient.
- The evidence surrounding the impact of personal characteristics on the patient's ability to cope with their long term conditions appears to be relevant to patients with CVLU (page 38). Further research that explores this relationship, encompassing this knowledge to develop a 'personalised' consultation may have the potential to enhance PCC.
- Younger patients with CVLU seemed to be more compromised by the condition. Further research to determine this may inform approaches to care that are more effective for this client group.
- The patients who attended a clinic for their wound care, reported a renewed positivity, an enhanced outlook and improved coping strategies, feeling that they were in control of their care, rather than controlled by it (page 122-124). Research that builds on that of Lindsay (2000) in relation to wound care clinics and aims to promote patient choice in the location of care delivery would be beneficial.
- Reflection on personal narratives during the consultation is said to enhance patient understanding of their condition and enable them to develop effective coping strategies

(Lazarus, 1993) and a sense of coherence (Antonovsky, 1987). Consultation based research that facilitates a focus on such narratives may prove to be effective.

- Triangulation of the phase 2 results would have enhanced the quality of this study. An opportunity to interview both patient and nurse participants following the consultation observations would provide detail regarding the underlying reasons for the deficits exposed. In retrospect, such a phase would have provided useful information and may be something that can be incorporated into a future study.

9.6 Recommendations for practice.

In addition to the contribution that this study has made to new knowledge and the recommendations made for future research, a number of simple recommendations for practice are highlighted.

- Holistic assessment of patients and the delivery of care that addresses poorly managed symptoms such as pain, exudate, odour and depression.
- The development and evaluation of interventions that improve the consulting skills of HCPs and activate the patient to express their concerns across a range of locations of care and conditions.
- For a shift in focus in the delivery of chronic wound care from a blinkered approach with healing as the only goal to an approach that supports the patient and their carers, addresses the range of quality of life issues that such conditions inevitably bring and responds effectively to patient need.

9.7 Conclusion.

This study was primarily designed to establish the impact of CVLU on QoL, to examine whether this was explored during current consultations and to design a tool to improve a patient focus. The study was rigorously designed but demonstrated that a future full RCT would not be feasible. A number of factors contributed to this, including considerable change within the NHS and difficulties with recruitment. Demands on the DN service are increasing year on year, patients have a more acute profile and staff numbers are diminishing (QNI, 2013), both serving to increase the demands on the service. This study has demonstrated that patient centred care is not at the forefront of care delivery and, combined with these increasing pressures, may be an approach that becomes less achievable in the future unless action is taken now.

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Appendices

Appendix 1

Database search results (HDAS).

Appendix 1: Database search results (HDAS).

Search Term	MEDLINE	CINAHL	BNI	EMBASE	PsycINFO	AMED	Health Business Elite	HMIC	Google Scholar	Total
1. venous ulcer*	4574	6393	507	6904	288	65	1092	54	0	19877
2. chronic venous insufficiency	2096	253	21	3248	78	26	11	2	0	5735
3. varicose ulcer*	2008	514	13	563	13	33	170	14	0	3328
4. stasis ulcer*	435	893	7	677	30	10	239	1	0	2292
5. leg ulcer*	5505	7389	1594	9438	354	116	2007	170	0	26573
6. chronic wound*	9956	15437	501	12444	3876	175	4680	38	0	47107
7. MeSH leg ulcer	10223	3244	1542	28951	0	0	0	71	0	44031
8. OR all of above	17041	21619	1914	35095	4325	309	6860	212	0	87375
9. quality of life	188718	160576	5862	296108	158722	10367	187888	6143	0	1014384
10. "quality of life"	168082	97687	5855	263270	94581	9418	39318	4978	0	683189
11. health related quality of life	33230	82317	779	46419	71995	2294	52900	771	0	290705
12. "health related quality of life"	18222	12557	779	25048	22967	1675	1584	433	0	83265
13. MeSH quality of life	103170	35861	4569	211195	22785	6478	3350	2303	0	389711
14. OR 9-13	188594	160576	5862	296108	158722	10367	187888	6143	0	1014260
15. combine 9 AND 14	741	7689	112	1713	1347	29	1890	17	0	13538
Total for Review:	741	7689	112	1713	1347	29	1890	17	22	13560
Studies retained following electronic screening stage.	105	143	50	108	14	9	3	10	11	453
Studies retained following abstract screening stage.	6	35	37	21	0	6	0	0	9	114

Appendix 2

Quality appraisal of the literature.

Appendix 2: Quality appraisal of the literature (Hawker et al, 2002).

Total Score: <90 - Very Poor.

90-180 – Poor.

180-270 – Fair.

270-360 – Good.

Author, year & location	Abstract & title	Introduction & aims	Method & data	Sampling	Data analysis	Ethics & bias	Findings / results	Transferability /generalisability	Implications & usefulness	Total Score (Range: 90-360)
Bland, M. (1996)	10	10	10	20	20	10	20	20	10	130 (P)
Brown, A. (2005 a, b)	20	30	30	40	30	40	40	30	30	290 (G)
Byrne, O. & Kelly, M. (2010)	10	20	20	20	20	10	20	20	20	160 (P)
Charles, H. (1995)	20	20	20	20	20	20	20	20	10	170 (P)
Charles, H. (2004)	40	30	30	30	20	20	20	20	20	230 (F)
Chase et al (1997)	30	30	30	30	30	20	30	30	20	240 (F)
Chase et al (2000)	20	30	30	30	30	20	30	20	20	230 (F)
Douglas, V. (2001)	30	30	40	30	30	20	30	30	30	270 (G)
Ebbeskog, B. & Ekman, S. (2001)	30	30	40	40	40	30	40	40	30	320 (G)
Faria, E. et al (2011)	30	20	30	30	30	30	30	30	20	250 (F)
Franks, P.J. & Moffatt, C. (1998)	40	30	30	40	40	30	40	30	30	310 (G)
Franks, P.J. & Moffatt, C. (2001)	40	40	40	40	40	30	40	30	30	330 (G)

Franks,P, McCullagh, L. & Moffatt, C.(2003)	40	40	40	40	40	20	40	30	20	310 (G)
Franks et al (2006)	40	40	40	40	40	40	40	30	40	350 (G)
Furtado et al (2008)	40	40	40	40	40	20	40	30	30	320 (G)
Heinan et al (2006)	40	40	40	40	40	40	40	30	30	340 (G)
Hopkins, A. (2004)	20	30	40	30	30	40	30	30	20	270 (G)
Hyde et al (1999)	30	30	40	30	40	20	40	30	20	280 (G)
Jull et al (2004)	40	40	40	40	40	40	30	30	30	330 (G)
Lindholm et al (1993)	40	30	40	10	30	30	10	30	30	240 (F)
Rich, A. & McLachlan, L. (2003)	40	40	40	40	40	40	40	30	30	340 (G)
Walshe, C. (1995)	30	40	40	40	40	40	40	30	30	330 (G)
Wissing et al (2002)	30	10	20	20	30	30	30	30	30	230 (F)
Yamada, B.& Santos, V. (2005)	30	20	20	20	20	10	20	10	10	180 (P)

Appendix 3

Phase 1 topic guide.

Appendix 3: CHRONIC VENOUS LEG ULCERATION – TOPIC GUIDE.

AT THE START OF THE INTERVIEW:

Explain the purpose of the study.

Reassure the participant about confidentiality.

Gain consent.

HEALTH NARRATIVE:

- Establish what health was like prior to leg ulceration.
- Explore memories of the start of the leg ulceration.
- Explore what life is like with leg ulceration?
- Talk about interactions with the participants' Doctor.
- Talk about interactions with the participants' Nurses.
 - What does your Nurse do?
 - What do you discuss?
 - What advice is given?
 - What arrangements do you make?
 - Is the information consistent?
- Explore the impact of leg ulceration on family and friends?
- Explore compliance with the advised treatment regimes.
- Explore the impact on ulceration on ability to work.

AT THE END OF THE INTERVIEW:

Ask if there are any questions.

Reaffirm consent and confidentiality.

Thank the participant for taking part and explain what will happen next.

Appendix 4

Ethical approval phase 1 and 2.

South Staffordshire Local Research Ethics Committee

Medical Institute
Hartshill Road
Hartshill
Stoke-on-Trent
Staffordshire
ST4 7NY

Telephone: 01782 714980
Facsimile: 01782 714975

11 March 2010

Mrs Julie Green
Lecturer in Nursing
Keele University
School of Nursing and Midwifery
Clinical Education Centre,
UHNS,
Stoke-on-Trent
ST4 6QG

Dear Mrs Green

Study Title:	Does a patient focus to consultations in chronic venous leg ulcer care improve patient satisfaction and health related quality of life? (v2)
REC reference number:	10/H1203/13
Protocol number:	6

The Research Ethics Committee reviewed the above application at the meeting held on 03 March 2010. Thank you for attending to discuss the study. The coordinator explained that the Committee did not need to see you.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research (“R&D approval”) should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

Other conditions specified by the REC

The Committee was content to give a favourable opinion of phases one and two of the application with the following condition/s:

1. The reference to training in the information sheet for the district nurses should be removed as it relates to phase three
2. In the information sheets participants are asked three times to “please complete the enclosed consent form and return in the prepaid envelope provided within seven days”. The phrase is also included in the letters of invitation. Such repetition is unnecessary and should be taken out.

The Committee decided that phases one and two follow on naturally but phase three will require a separate application as, until phases one and two have been completed, there is insufficient detail relating to phase three to enable a decision to be made.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
Covering Letter		10 February 2010	
REC application		10 February 2010	
Protocol	6	25 January 2010	
Investigator CV		24 November 2009	
Participant Information Sheet: Phase 1 & 2	2	14 January 2010	
Participant Information Sheet: Phase 1 & 2 District Nurse	2	14 January 2010	
Participant Information Sheet: Phase 3	2	14 January 2010	
Participant Information Sheet: Phase 3 District Nurse	2	14 January 2010	
Participant Consent Form: Phase 1 & 2	3	14 January 2010	
Participant Consent Form: Phase 1 & 2 District Nurse	3	14 January 2010	
Participant Consent Form: Phase 3	3	14 January 2010	
Participant Consent Form: Phase 1 & 2 District Nurse	3	14 January 2010	
Evidence of insurance or indemnity		24 July 2009	
Letter from Sponsor		30 November 2009	
Referees or other scientific critique report		23 October 2009	

Questionnaire: Community Nurse Satisfaction			
Questionnaire: Medical Outcome short form			
Questionnaire: Cardiff Wound Impact Schedule			
CV Professor Jester		18 November 2009	
Letter of Invitation Phase 1 & 2	3	14 January 2010	
Letter of Invitation Phase 1 & 2 District Nurse	3	14 January 2010	
Letter of Invitation Phase 3	3	14 January 2010	
Interview Schedules/Topic Guides	2	25 January 2010	
Letter of Invitation Phase 3 District Nurse	3	14 January 2010	
Full Study Flow Chart	5	10 February 2010	
Phase 1 Flow Chart	2	10 February 2010	
Phase 2 Flow Chart	2	10 February 2010	
Phase 3 Flow Chart	4	10 February 2010	
Unfavourable Opinion Letter		12 January 2010	

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H1203/13

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Professor Tim Reynolds
Chair

Email: Janet.Clarke@uhns.nhs.uk

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"*

Copy to: Nicola Leighton, Research and Enterprise Services, Keele University
Nemonie Marriot, Research and Development, North Staffordshire and Stoke-on-Trent PCT
Professor R Jester, School of Nursing, Keele University, Clinical Education Centre, UHNS, Stoke-on-Trent, ST4 6QG

South Staffordshire Local Research Ethics Committee

Attendance at Committee meeting on 03 March 2010

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>	
Mrs Sandra Chambers	Head Teacher (Retired)	Yes		
Mr Robert Edgar	Engineer (Retired)	Yes		
Dr Nitin Gupta	Consultant Psychiatrist	Yes		
Dr Brian Hynam	Retired Director of Pharmacy Services	Yes		
Dr Kathryn Kinmond	Senior Lecturer	Yes		
Dr Arabinda Kundu	Head of Contraceptive & Sexual Health Service	Yes		
Dr Diarmuid Mulherin	Consultant Rheumatologist	Yes		
Dr Laofe Oladele Ogundipe	Consultant Psychiatrist	Yes		
Professor Tim Reynolds	Consultant Chemical Pathologist	Yes		
Dr Sandie Sandbrook	Senior Lecturer	Yes		
Mr Victor Scofield	Legal Advisor, Banking (Retired)	Yes		

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>	
Mrs Barbara Cannings	Coordinator	

Appendix 5

R&D approval.

Ref: 10/H1203/13

30th April 2010

Julie Green
Lecturer in Nursing
Keele University
School of Nursing and Midwifery
Keele
Staffordshire
ST5 5BG

Dear Julie Green

RE: Chronic Venous Leg Ulceration and Health Related Quality of Life (V2)

I can confirm that the above project has been approved by the NHS Stoke on Trent/ NHS North Staffordshire Research & Development Department and the details entered on to the R&D database.

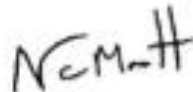
I note that this research project has been approved by South Staffordshire Local Research Ethics Committee (10/H1203/13)

In line with the requirements of the Research Governance Framework may I draw your attention to the need for you to provide the following documentation/notifications to the R&D Department throughout the course of the study:-

- ❖ Annual Progress Report Form (sent to you by this department)
- ❖ End of Study Declaration Form (available on NRES website)
- ❖ Changes to study start and end dates
- ❖ Changes in study personnel
- ❖ Participation in dissemination activities as requested

I would like to take this opportunity to wish you well with your research. If you need any further advice or guidance please do not hesitate to contact us.

Yours sincerely



Nemonie Marriott
Research Development Manager

Appendix 6

Participant letters, consent & information leaflets: phase 1 & 2.



K E E L E
U N I V E R S I T Y

Version 3, Date: 14/01/2010.
LREC Number: 10/H1203/13

Keele University School of Nursing and Midwifery,
Clinical Education Centre,
University Hospital of North Staffordshire NHS Trust,
City General Site,
Newcastle Road,
Stoke-on-Trent.
ST4 6QG.
Tel: 01782 556605.

Dear Sir or Madam,

I am currently studying for a PhD. The research I am undertaking explores chronic venous leg ulceration and the impact on the patients' quality of life. I have enclosed an information leaflet for you to read which outlines the study in more depth and also what will be required of you if you agree to take part.

If you have any queries about the study, please do not hesitate to contact me on the above telephone number. If you do agree to take part then I would be very grateful if you could complete the enclosed consent form and contact details and return, in the prepaid, addressed envelope within seven days.

I am very grateful for your time and for the help that you can provide to this research project.

Yours sincerely,

Julie Green
Lecturer in Nursing.



K E E L E
U N I V E R S I T Y

Version 3, Date: 14/01/2010.
LREC Number: 10/H1203/13

Keele University School of Nursing and Midwifery,
Clinical Education Centre,
University Hospital of North Staffordshire NHS Trust,
City General Site,
Newcastle Road,
Stoke-on-Trent.
ST4 6QG.
Tel: 01782 556605.

Dear District Nurse,

I am currently studying for a PhD. The research I am undertaking explores chronic venous leg ulceration and the impact on the patients' quality of life. Phase 1 of the study will involve interviewing some of your patients who suffer from leg ulceration. Once these interviews have been analysed, Phase 2 will involve observing your consultations with the same patients to explore the extent to which the factors they highlight as being important in Phase 1 are addressed. Your District Nursing team has been selected to take part in this research.

I enclose an information leaflet to provide full details of the study and a consent form for each District Nurse who agrees to be involved in the study. Please complete these and return in the stamped addressed envelope provided, ideally within seven days. If you have any queries about the study, please do not hesitate to contact me on the above telephone number.

I am very grateful for your time and for the help that you can provide to this research project.
Yours sincerely,

Julie Green
Lecturer in Nursing.



KEELE UNIVERSITY

Patient Information Leaflet.

Version 2, Date: 14/01/10.

LREC Number: 10/H1203/13.

Study Title:

Chronic venous leg ulceration and health related quality of life.

You are invited to take part in a research study.

Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and your District Nurse if you wish.

If there is anything that is not clear or if you would like more information, please feel free to contact Julie Green at the School of Nursing and Midwifery, Keele University on 01782 556605.

What is the purpose of the study?

Many people in the UK suffer from leg ulcers. This research will explore the day-to-day effects of having a leg ulcer.

Why have I been chosen?

You have been invited to take part because you are currently receiving care from a District Nurse for your leg ulcer.

Do I have to take part?

You are free to decide if you wish to take part or not.

If you do decide to take part, please complete the enclosed consent form and return it in the prepaid envelope provided within seven days.

If you do decide to take part, you can withdraw at any time and without having to give a reason. This will not affect your treatment or the care for your leg ulcer.

If you do not wish to take part, please simply destroy the enclosed literature and be assured that your care will not be affected.

What will happen if I take part?

If you agree to take part in the study, I will contact you to arrange a convenient time to conduct an interview. When I visit, I will ask you to tell me about your experiences of having a leg ulcer.

If you agree, I will record the interview on a small tape recorder. This will allow me to write down what is said after the interview, so that nothing is overlooked.

The interview will take between 60 and 90 minutes.

Following your interview, I will arrange to accompany your District Nurse on a number of visits to provide care for your leg ulceration. During these visits, I will simply observe the visit and complete a brief checklist.

What do I have to do?

Simply complete and return the enclosed consent form and I will then contact you to arrange a visit to conduct the interview.

What are the benefits of taking part?

It is hoped that the information gathered during this study will provide an understanding of the day-to-day lives of people with leg ulceration and may help to shape the care that is delivered in the future.

What are the possible disadvantages or risks of taking part?

There are no expected disadvantages or risks associated with taking part in this study.

What if something goes wrong?

I do not expect any problems to arise during this study.

If you have a concern about any aspect of the study, you should speak to me, Julie Green, and I will do my best to answer your questions. I can be contacted on 01782 556605.

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:- Nicola Leighton, Research Governance Officer, Research & Enterprise Services, Dorothy Hodgkin Building, Keele University, ST5 5BG.

Will my taking part be kept confidential?

All of the information collected during this study will be kept strictly confidential.

Your name and address will be removed from all documents and any other identifying information, including the consent form, will be kept in a locked drawer in a lockable office. Some information may be stored on a computer, but this will be protected by a password known only to myself.

What will happen to the results of the research study?

This research will form part of a PhD study. No one will be identifiable in the completed thesis.

Who is organising and funding this research?

This research is a student project for a PhD. It has no funding available from any organisations or drug companies. Most of the work will be done in my own time.

Thank you for your time in reading this information sheet.

If you agree to take part in this study, please complete the enclosed consent form.

Many thanks,

Julie Green



K E E L E
U N I V E R S I T Y
District Nurse Information Leaflet.

Version 2, Date: 14/01/2010.

LREC Number: 10/H1203/13

Study Title:

Chronic venous leg ulceration and health related quality of life.

You are being invited to take part in a research study.

Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with your colleagues.

If there is anything that is not clear or if you would like more information, please feel free to contact Julie Green at the School of Nursing and Midwifery, Keele University on 01782 556605.

What is the purpose of the study?

Leg ulceration affects many thousands of people in the UK. Dressing products and techniques are frequently reviewed but the impact of the ulceration on the day-to-day life of the sufferer is often overlooked. This research aims to explore the lived experience of a number of patients who suffer from leg ulcers.

Why has my team been chosen?

The research involves interviewing a number of patients from your caseload, with their consent, who suffer from chronic leg ulceration. Following the interview, again with their consent, these patients will have their visits from the nurse observed over a four week period. This will involve me accompanying the District Nurses as they provide leg ulcer care during their domiciliary visits. Your team has been selected due to the suitability of the patients that you see.

Do I have to take part?

You are free to decide if you wish to take part.

If you do decide to take part, please complete the enclosed consent form and return it in the prepaid envelope provided within seven days.

If you do not wish to take part, please simply destroy the enclosed literature.

What will happen if I take part?

If you do decide to take part in the study, I will ask that you distribute a pack containing a letter of invitation, an information leaflet, a consent form and a stamped addressed envelope to all of the patients registered on your caseload who meet the study inclusion criteria.

Once patient consent has been received, I will arrange to conduct interviews on a one to one basis in the patient's home, at a time convenient to them. These interviews will be unstructured and will explore the lived experience of patients with chronic venous leg ulceration. If the patient agrees, the interview will be recorded on a small tape recorder to enable the researcher to write down what was said, so that nothing is overlooked. These interviews will then be analysed to identify key factors that the patients' feel affect their quality of life. These factors will be used to construct an observation checklist.

Once this is completed, I will arrange the period of observation. I will accompany you on a number of occasions and observe your consultations with the same patient participants. During these visits I will be as unobtrusive as possible. I will complete the brief checklist based on the factors elicited from the interview phase of the study. These accompanied visits will take place over a period of approximately four weeks.

In the unlikely event of me observing poor practice, in accordance with the requirements of the Code of Conduct (NMC, 2009), I will be duty bound to report this.

What do I have to do?

If you decide to take part in the study, please complete and return the enclosed consent form in the prepaid envelope provided within seven days.

I will then contact you to arrange to visit to provide an overview of the study.

What are the benefits of taking part?

It is the aim that the information gathered from this study will give an insight into the day-to-day lives of people suffering from venous leg ulceration and, as a result, may be used to make recommendations about future care that is delivered. This, however, is not a guaranteed outcome.

What are the possible disadvantages or risks of taking part?

There are no expected disadvantages or risks associated with taking part in this study.

What if something goes wrong?

I do not expect any problems to arise during this study.

If you have a concern about any aspect of the study, you should speak to me, Julie Green, and I will do my best to answer your questions. I can be contacted on 01782 556605.

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:- Nicola Leighton, Research Governance Officer, Research & Enterprise Services, Dorothy Hodgkin Building, Keele University, ST5 5BG.

Will my taking part be kept confidential?

All of the information collected during this study will be kept strictly confidential.

Your name and address will be removed from all documents and any other identifying information, including the consent form, will be kept in a locked drawer in a lockable office. Some information may be stored on a computer, but this will be protected by a password known only to myself.

What will happen to the results of the research study?

This research will form part of a PhD study. No one will be identifiable in this piece of work.

Who is organising and funding this research?

This research is a student project for a PhD. It has no funding available from any organisations or drug companies. Most of the work will be done in my own time.

Thank you for your time in reading this information sheet.

If you agree to take part in this study, please complete the enclosed consent form and return in the prepaid envelope provided within seven days.

Many thanks,
Julie Green



K E E L E
U N I V E R S I T Y

Patient Consent Form.

Version 3, Date: 14/01/2010.

LREC Number: 10/H1203/13

Title of Project: Does a patient focus to consultations in chronic venous leg ulcer care improve patient satisfaction and health related quality of life?

Name of Researcher: Julie Green.

Please Tick.

1. I confirm that I have read and understood the information leaflet and have had the opportunity to ask questions.....

☐

2. I understand that my participation is voluntary, that I can refuse to answer a question, or withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.....

☐

3. I understand that the interview will be taped and transcribed, and that tapes will be stored in a secure location, but will bear no personal identifying information. I understand that the tapes and transcripts will be kept for up to 10 years and after this time they will be destroyed.....

☐

4. I understand that quotations from the interview may be included in reports or publications from this study, but that these will be anonymous and I will not be identifiable.....

☐

I want to see all quotations obtained during my interview before publication.....

☐

5. I agree to take part in the above study.....

☐

6. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is

☐

relevant to my taking part in this research. I give permission to these individuals to have access to my records.....

Please sign and date on the line below:

-----	-----	-----
Name of Patient	Date	Signature

-----	-----	-----
Name of Researcher	Date	Signature

Please provide me with your contact details below:

Your full name, address and telephone number.

Name:.....

Address:.....

.....

.....

.....

Telephone number:.....

Thank you for your help with this research study.

If you have any further questions about this study



K E E L E
U N I V E R S I T Y

District Nurse Consent Form.

Version 3, Date: 14/01/2010.

LREC Number: 10/H1203/13

Title of Project: Does a patient focus to consultations in chronic venous leg ulcer care improve patient satisfaction and health related quality of life?

Name of Researcher: Julie Green.

Please Tick.

1. I confirm that I have read and understood the information leaflet and have had the opportunity to ask questions.....

☐

2. I understand that my participation is voluntary, that I can refuse to answer a question, or withdraw at any time, without giving a reason.....

☐

3. I agree to take part in the study and to have my patient consultations observed.....

☐

4. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records.....

☐

Name of District Nurse

Date

Signature

Name of Researcher

Date

Signature

Please provide me with your work contact details below:

Your full name, work address and telephone number.

Name:.....

Work Address:.....

.....

.....

.....

Work Telephone number:.....

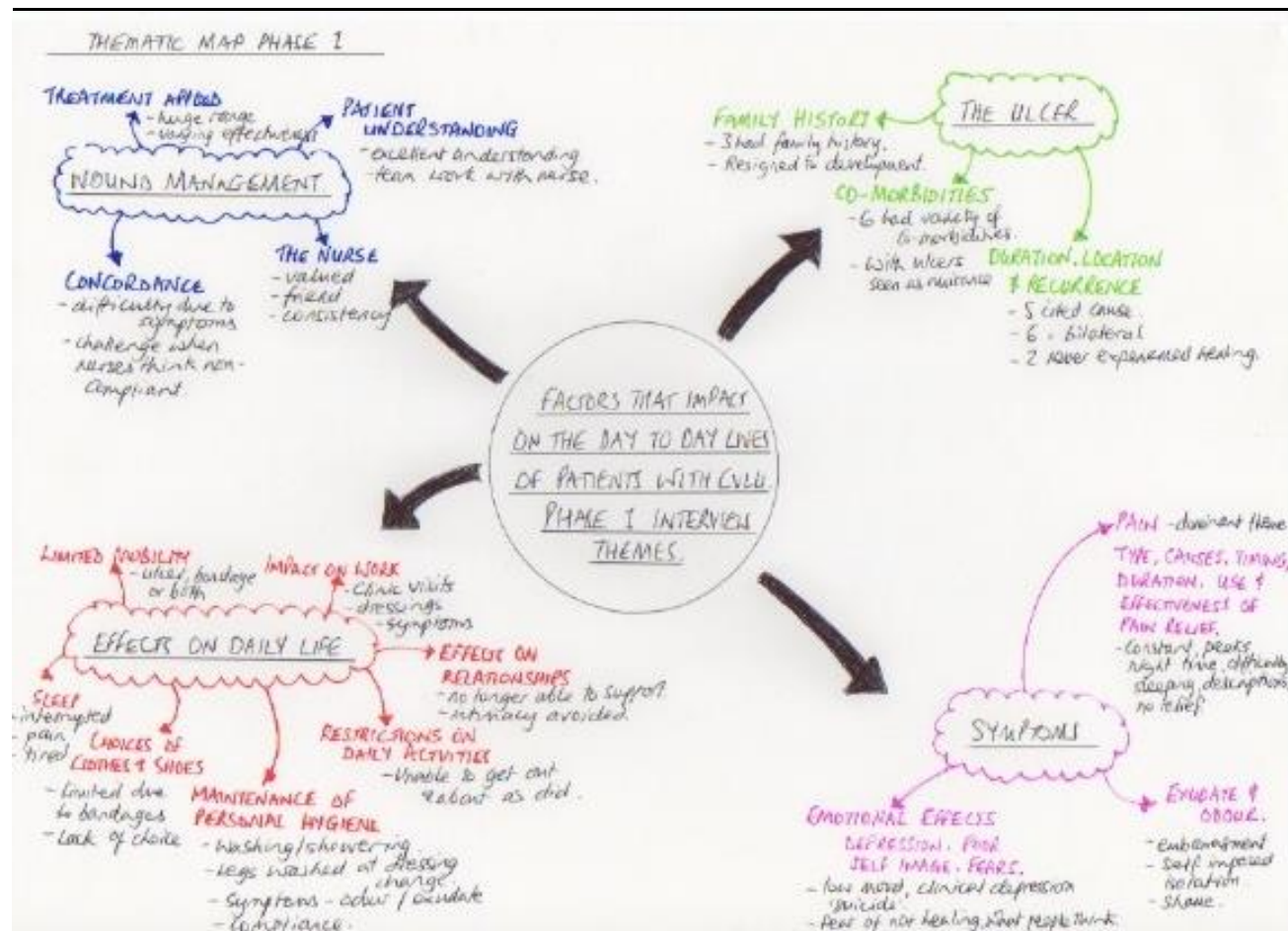
Thank you for your help with this research study.

If you have any further questions about this study, you can telephone me, Julie Green, on 01782 556605.

Appendix 7

Thematic map phase 1.

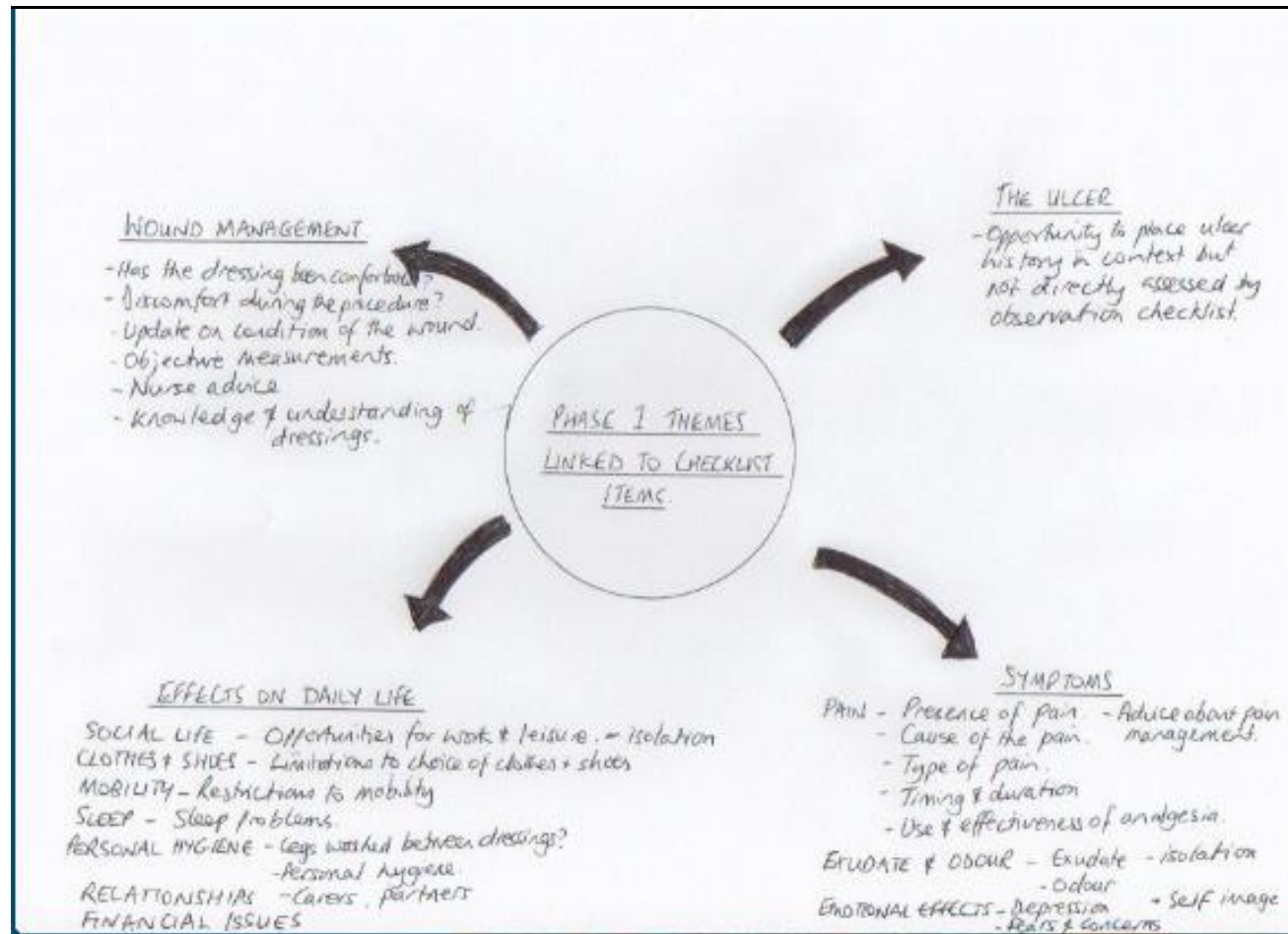
Appendix 7: Thematic map phase 1.



Appendix 8

Checklist items linked to thematic map.

Appendix 8: Checklist items linked to thematic map.



Appendix 9

Observation checklist from phase 2.

Observation checklist from phase 2:

NON-PARTICIPANT OBSERVATION CHECKLIST.

THEME.	THEME IDENTIFIED BY:		RATING (0-5)
	PATIENT	NURSE	
PAIN			
• PRESENCE OF PAIN.			
• CAUSE OF THE PAIN.			
• TYPE OF PAIN.			
• TIMING AND DURATION OF PAIN.			
• USE & EFFECTIVENESS OF ANALGESIA.			
SLEEP PROBLEMS.			
EXUDATE.			
ODOUR.			
PERSONAL HYGIENE.			
RESTRICTIONS TO MOBILITY			
LIMITATIONS TO CHOICE OF CLOTHES & SHOES.			
WOUND MANAGEMENT			
• HAS THE DRESSING BEEN COMFORTABLE?			
• DISCOMFORT DURING PROCEDURE?			
• ADVICE REGARDING PAIN MANAGEMENT.			
• UPDATE ON CONDITION OF WOUND.			
• OBJECTIVE MEASUREMENTS.			
• LEGS WASHED BETWEEN DRESSINGS?			
MOOD			
• DEPRESSION.			
• FEARS & CONCERNS.			
• SELF IMAGE.			
• FEAR OF PEOPLE'S REACTIONS.			
• FEAR OF RECURRENCE			
SOCIAL LIFE			
• OPPORTUNITIES FOR WORK & LEISURE.			
• ISOLATION.			
RELATIONSHIPS: CARERS, PARTNERS.			
FINANCIAL ISSUES			
NURSE ADVICE			
KNOWLEDGE & UNDERSTANDING OF DRESSINGS			

NON-PARTICIPANT OBSERVATION RATING SCALE.

0	Theme not raised by nurse or patient.
1	Nurse did not identify cue.
2	Nurse picked up cue only.
3	Nurse identified patient cue and asked about the issue.
4	Nurse picked up cue and partially dealt with it.
5	Nurse picked up cue and dealt with it fully.

Appendix 10

Example field notes from phase 2

Example field notes from phase 2:

L1, P1 – Consultation Observations.

O1 – Wednesday 12th January 2011.

Over to Moorland Medical centre at Leek for 8.50am to accompany Sr. (S2) to visit 3 of the 6 patients interviewed. (P4 in hospital with fractured femur, P3 healed and P5 attending clinic – need to liaise directly with her).

S2 rang P2 to take P1's dressing down in preparation for our visit in 15 minutes time. Travelled over.

P1 sat in wheelchair in bedroom. Left trouser leg up to knee, dressing off and leg resting on sterile field. P2 noted that leg less wet but S2 and P1 discussed P1's longstanding sweating problem. Felt legs were more of a deteriorating issue than simple leg ulceration. P1 had been on Myocrisin and Methotrexate for many years. Leg reddened and skin thickened to knee and toes raw and discharging, break to inner and outer malleolus. Redressed by S2.

P1 discussed his pain – constant but tolerable. Takes too many tablets for other conditions and felt that the pain is not the type that analgesia is effective on. Is now less severe than previously – worse after the dressing and when in bed resulting in disturbed sleep. Not able to elevate legs due to knee difficulties and has to side lie whilst in bed, which results in some sleep issues. S2 did discuss timing and effectiveness of analgesia. Commented and discussed the improvement in exudate and currently no odour present. Legs padded well until next visit. Due to rural nature of visit, S2 felt this was a contingency plan in case visits need to be cancelled due to snow.

S2 discussed P1's lack of bathing / showering – P1 seemed very resistant to any suggestions. Transfers on a board so felt bath would not work and reluctant to have any adaptations made to shower – S2 encouraged stating she felt it would be helpful to his legs. P1 said he would think about this. Not able to elevate his legs at all due to knee issues. Immobile and non-weight bearing – only able to transfer.

Soft boots only worn due to the size of the dressings, etc. – not able to wear 'normal' shoes. Complained of discomfort initially after the dressing change and during the procedure. P1 given an update on the condition of his wounds but no measurements taken. Legs not washed today but arrangements made for the next visit – too time consuming to wash at every visit.

P1 positive, cheerful and accepting – feels legs will never get better but are improving – currently redressed three times a week. Isolation mentioned – not been out for three months due to the weather, etc. so quite isolated due to co-morbidities. Joking with the nurses – lots of banter and sarcasm but a nice supportive relationship. P1 had commented in his interview that he values this relationship. S2 gave some advice regarding analgesia, personal hygiene, etc. but P1 quite resistive to change. P1 dictated level of compression – not tolerating at correct tightness. Fully aware of application and process.

O2 – Wednesday 26th January 2011.

Over to Leek for 8.45. S2 out seeing diabetic patients. Student on placement today. Out with S2 and student. Travelled over to Rudyard following a phone call to request P2 to soak P1s legs.

P1 had dressings removed and had soaked legs prior to timed visit. Very jovial and jokey on arrival. Student undertook the dressing procedure with teaching from S2. P1 complained of discomfort in legs which is worse overnight once legs are elevated, in addition to pain due to arthritis. Difficulties positioning comfortably in bed. Unable to tolerate correct level of compression so quite anxious whilst lymphoedema (Actico) bandages were applied. Analgesia not discussed ? because P1 is on such a range of other medication. Long term Gold patient, now on Methotrexate for over 10 years. Night time highlighted as a time with problems due to discomfort.

No odour or exudate evident. Personal hygiene managed by P2 and a carer, legs soaked but solutions to bathing / showering refused. Wheelchair user – had been to GPs for bloods on Monday and had had to transfer 12 times which had made him really uncomfortable. S2 offered that in the future bloods could be done at home. Difficulties with the procedure due to tightness of trousers at the knee – S2 requested that he remove his trousers prior to the next visit. Soft orthopaedic shoes worn but modified by P1 as uncomfortable. Patient manages level of compression – adhered to by nurses.

Wounds progressing well and nurse provided this feedback but no objective measurements taken. Itching recognised as problematic. Betnovate prescribed and applied, especially around dressing margin. P1 appeared to be brighter although tired due to trip to GP. Felt weather improving with increased possibilities to get out – had been for a ride to the Roaches on Monday and visitors yesterday. Reflected on feeling tired.

Very jovial and cheerful with the student but very much the 'expert' patient who dictated dressing procedure.

O3 – Wednesday 2nd February 2011.

Over to Leek and out with S2 again. Over to P1 following a phone call to prepare legs. P1 was quite cheerful, sat on the side of his bed without his trousers on, as requested by S2. As she had commented how difficult it was to get his dressing and cream high enough up with trousers on. Legs not washed. S2 commented that the left leg seemed to not be as wet which was confirmed by P1. P1 requested right leg to be redressed as well and for Betnovate rather than Betnovate RD to be applied (Betnovate RD had been recommended by the Dermatology Specialist nurse) as he felt that this was ineffective.

Leg redressed, creamed with Trimovate, non-adherent between toes following cleaning, 50/50 to legs, N/A and padding, K soft & Actico Lymphoedema bandaging. Again commented and requested that these were not applied too tightly. No comments about pain, etc., continuing to take a wide range of medication for Rheumatoid Arthritis. Had been out for a ride in the car yesterday and seemed tired and less talkative. Itching to legs less of a problem so Benovate omitted.

04 – Wednesday 9th February 2011.

Over to Moorland Medical Centre. Out with S2 and a student. S2 rang ahead to P2 to ask her to soak P1's legs in Potassium Permanganate. Arrived after they had been soaked for 20 minutes. Both in the bedroom. P1 sat on the side of the bed with left leg soaking. Right not due to be redressed today. Both appeared to be cheerful and welcoming.

John complained of some redness to left knee where stoma bag insitu – S2 will arrange for ? new stoma bags. Complained of the same areas of itching around the margin of the bandaging and new wet area to lateral malleolus. Leg dried and redressed. P1 advised student on the dressing procedure throughout: which creams were to be applied where, how much padding and in what order and the tightness of application of the bandage. Continuing on 3 times weekly visits each lasting 60 minutes.

P1 chatted light heartedly throughout the procedure. Commented on having been out yesterday and of looking forward to spring coming. Had had different nurses on Monday due his usual nurses being busy but reflected that it had been OK. Happy with the leg dressing.

Appendix 11

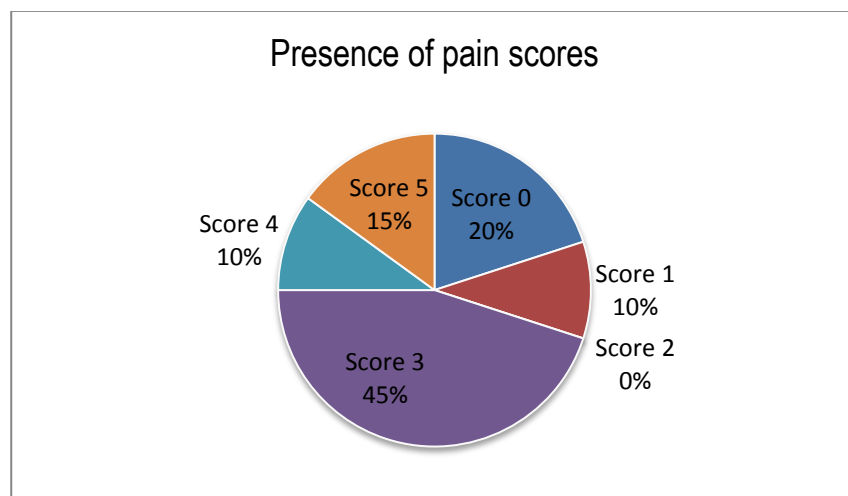
Phase 2 pie chart subtheme results

Appendix 11 – Phase 2 pie chart subtheme results.

11.1 The presence of pain.

The checklist item entitled the 'presence of pain' was emphasised as being of importance by all observation participants. Results are summarised in the pie chart below (Chart 1).

Chart 1: The presence of pain.

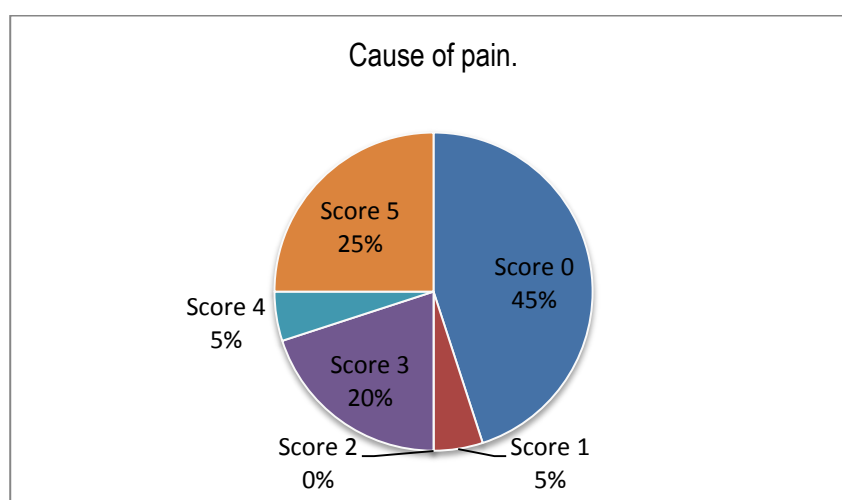


Scoring for the presence of pain indicated that, although it was a subtheme of known importance to all participants, a discussion was the dominant result within the consultation. The nurse only moved to a partial or complete solution on 25% of occasions possible.

11.2 The cause of pain.

All phase 2 participants again raised the cause of pain as significant. Results are summarised in the pie chart below (Chart 2).

Chart 2: The cause of pain.

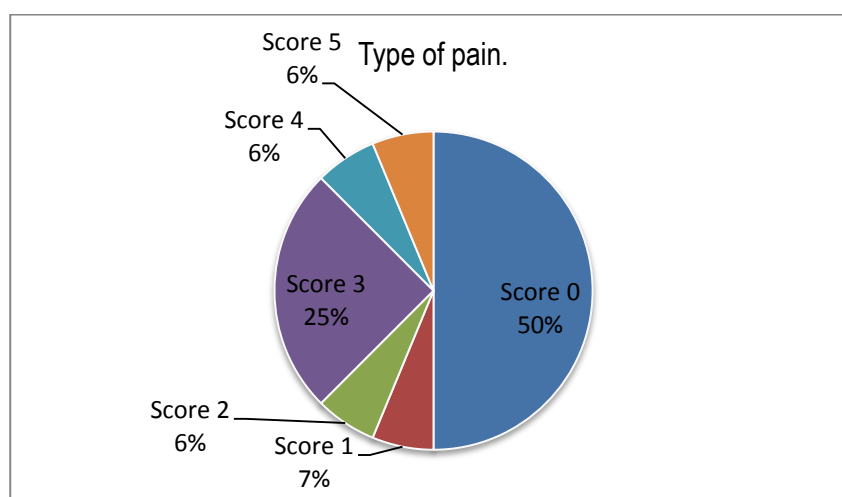


Scoring for the cause of the participants' pain, again a subtheme of known importance to all participants, indicated that the theme was most often not raised during the consultation. Where it was raised, the consulting nurse offered a solution on 30% of opportunities

11.3 Type of pain.

Four of the five phase 2 participants raised their type of pain during their phase 1 interview. Results are summarised in the pie chart below (Chart 3).

Chart 3: Type of pain.

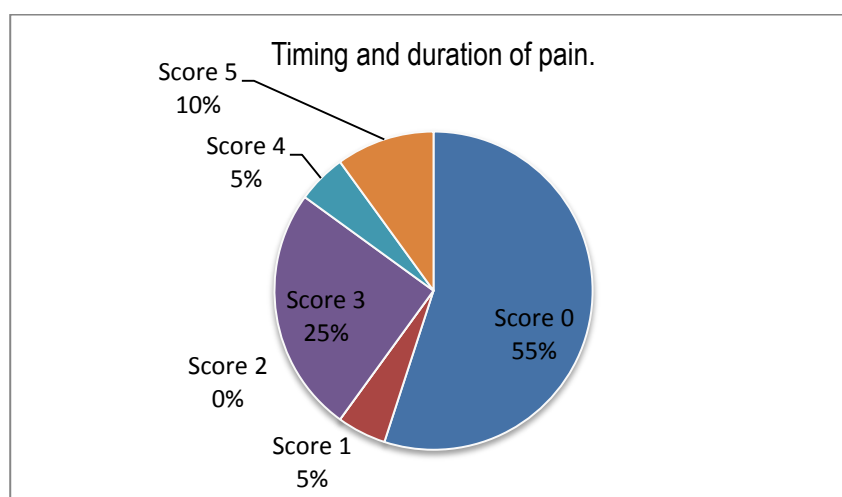


Scoring for the type of pain described by the participant indicated that the theme was most often not raised during the consultation. When the theme was raised a discussion ensued on 25% of occasions and a solution, whether partial or complete, was found on only 12% of the possible opportunities.

11.4 Timing and duration of pain.

All phase 2 participants again raised the timing and duration of their pain as significant during the phase 1 interviews. The results are summarised in the pie chart below (Chart 4).

Chart 4: Timing and duration of pain.

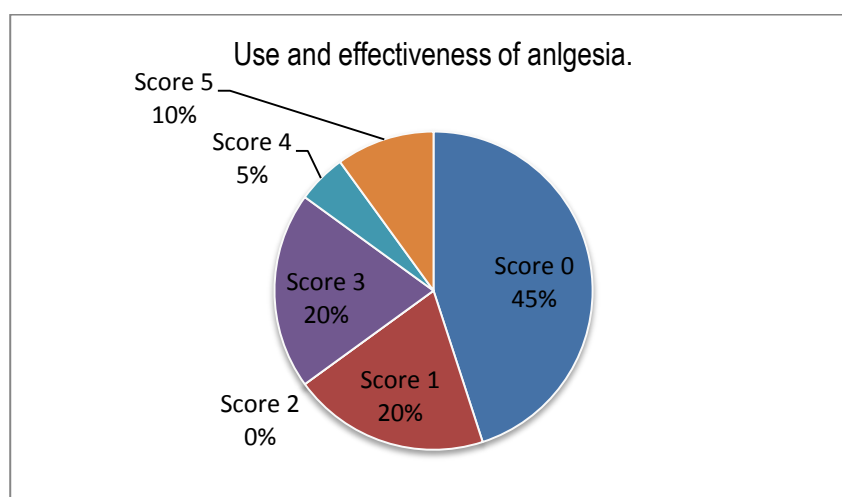


Scoring for the timing and duration of pain, again a subtheme of known importance to all participants, indicated that the theme was most often not raised during the consultation. Where it was raised, the consulting nurse offered a solution of some form on 15% of opportunities.

11.5 Use and effectiveness of analgesia.

All phase 2 participants raised the use and effectiveness of analgesia as significant during the phase 1 interviews. The results are summarised in the pie chart below (Chart 5).

Chart 5: Use and effectiveness of analgesia.

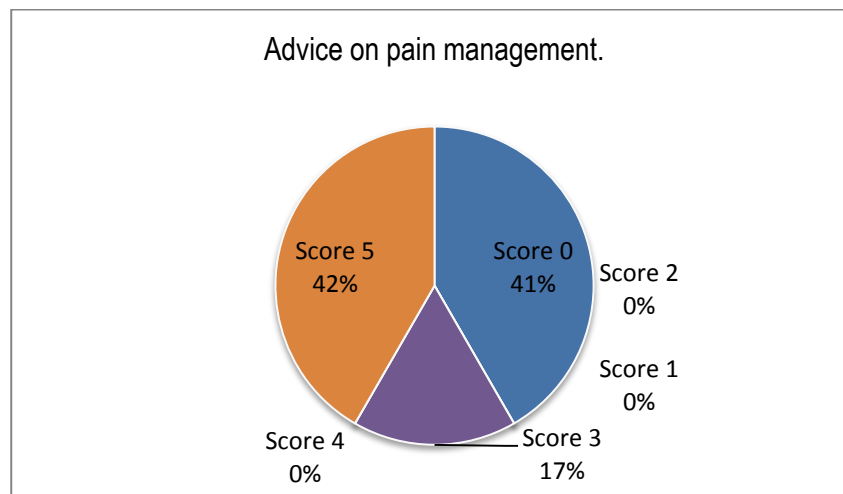


Scoring for the use and effectiveness of analgesia, again a subtheme of known importance to all participants indicated that the theme was most often not raised during the consultation. Where it was raised, the consulting nurse offered a solution of some form on 15% of opportunities.

11.6 Advice on pain management.

Three of the five phase 2 participants raised advice on pain management during their phase 1 interview. The results are summarised in the pie chart below (Chart 6).

Chart 6: Advice on pain management.

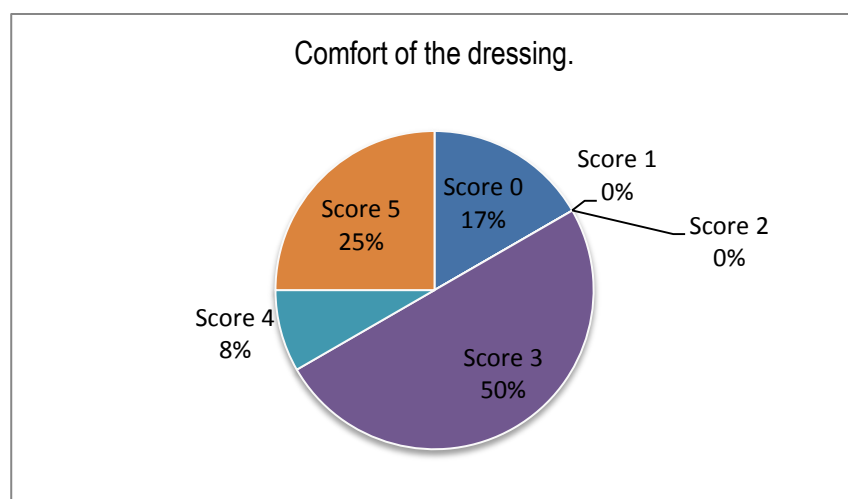


Scoring for advice on pain management during the consultation, of known importance to three of the participants, indicated that the theme was frequently not raised during the consultation. Where it was raised, the consulting nurse offered a complete solution on 42% of opportunities.

11.7 Comfort of the dressing.

Again, three of the five phase 2 participants stressed the importance of their dressing being comfortable during their phase 1 interview. The results are summarised in the pie chart below (Chart 7).

Chart 7: Comfort of the dressing.

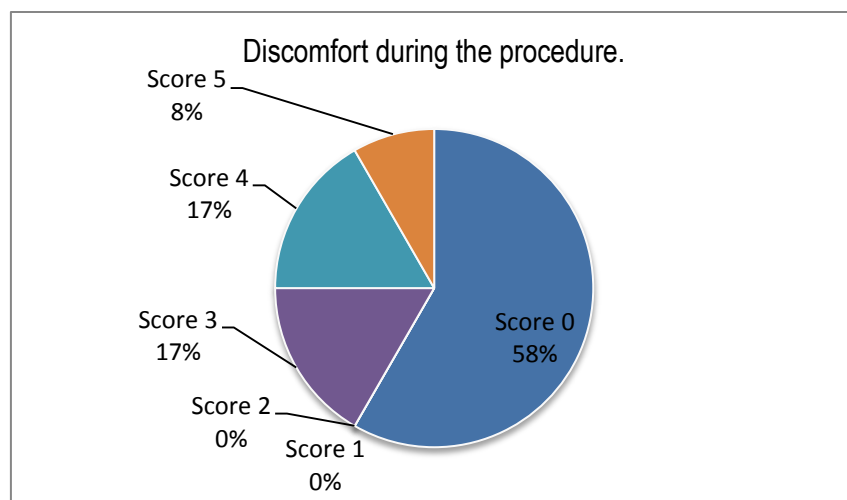


Scoring for the comfort of the dressing indicated that the theme was most often discussed during the consultation. Where it was raised, the consulting nurse offered a solution of some form on 33% of opportunities.

11.8 Discomfort during the procedure.

The final subtheme of pain referred to discomfort during the dressing procedure and was stressed as important by three participants during their phase 1 interview. The results are summarised in the pie chart below (Chart 8).

Chart 8: Discomfort during the procedure.

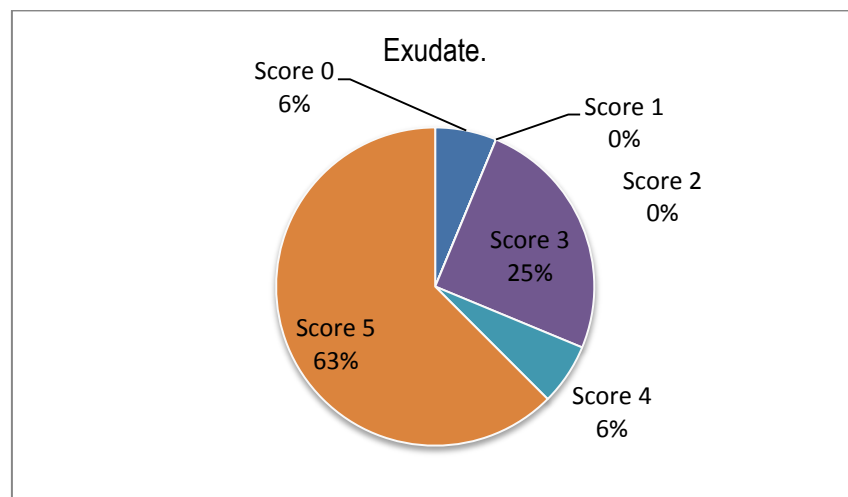


Scoring for discomfort during the dressing procedure indicated that the theme was most often not raised during the consultation. Where it was raised, the consulting nurse offered a solution of some form on 25% of opportunities.

11.9 Exudate.

Four of the five phase 2 participants raised exudate during their phase 1 interview. Results are summarised in the pie chart below (Chart 9).

Chart 9: Exudate.

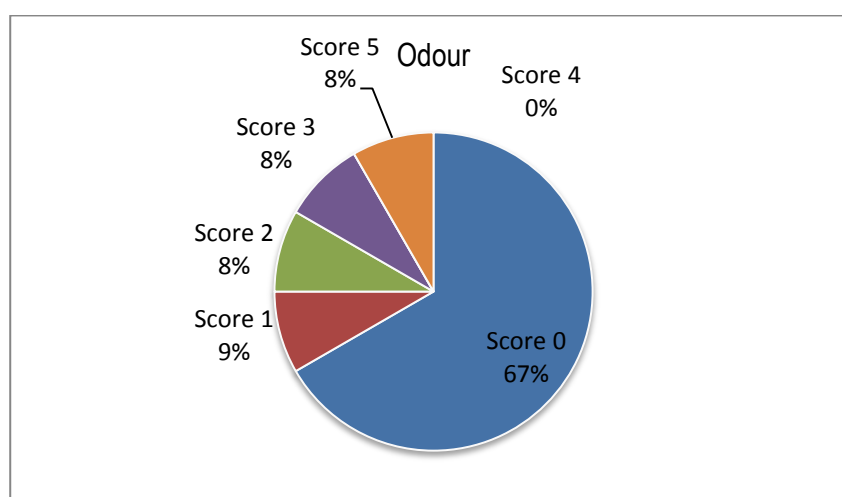


Scoring for the subtheme of exudate, of importance to four of the five participants, indicated that the theme was most often fully addressed and was rarely not raised.

11.91 Odour.

Three of the five phase 2 participants raised odour during their phase 1 interview. Results are summarised in the pie chart below (Chart 10).

Chart 10: Odour.

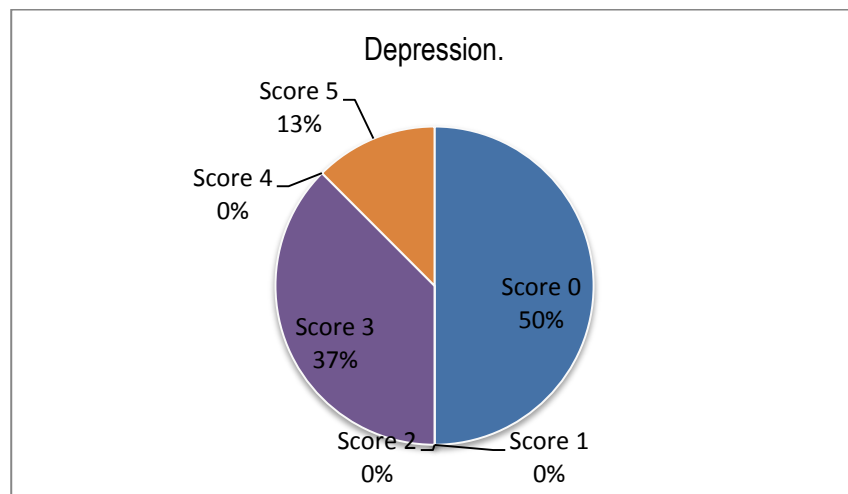


Scoring for odour indicated that the theme was most often not raised during the consultation. Where it was raised, the consulting nurse offered a partial solution on 8% of opportunities. A complete solution was not offered.

11.92 Depression.

Two of the five phase 2 participants raised depression during their phase 1 interview. The results are summarised in the pie chart below (Chart 11).

Chart 11: Depression.



Scoring for depression, a subtheme of known importance to two of the participants, indicated that the theme was most often not raised during the consultation. Where it was raised, the consulting nurse most often discussed the issues rather than offering a solution.

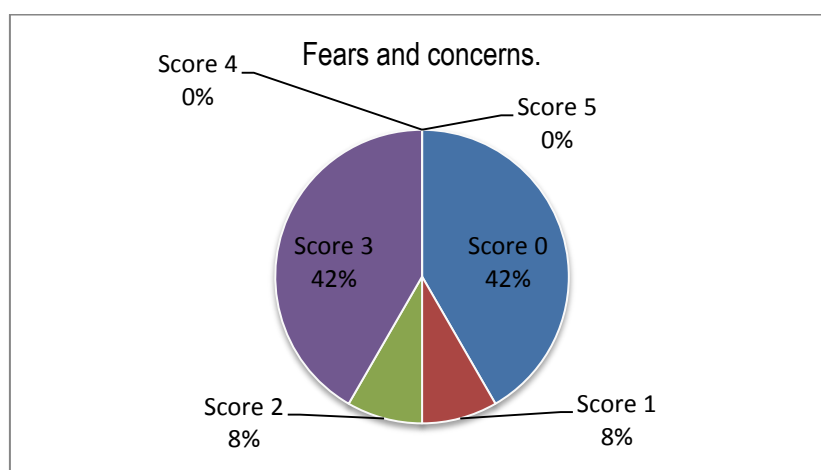
11.93 Self-image.

One of the five phase 2 participants raised self-image issues during their phase 1 interview. Results are summarised in the pie chart below.

11.94 Fears and concerns.

Three patients in raised fears during their phase 1 interview. Fears included the fears and concerns, fear of recurrence and fears of people's reactions. Results are summarised in the pie chart below (Chart 12).

Chart 12: Fears and concerns.

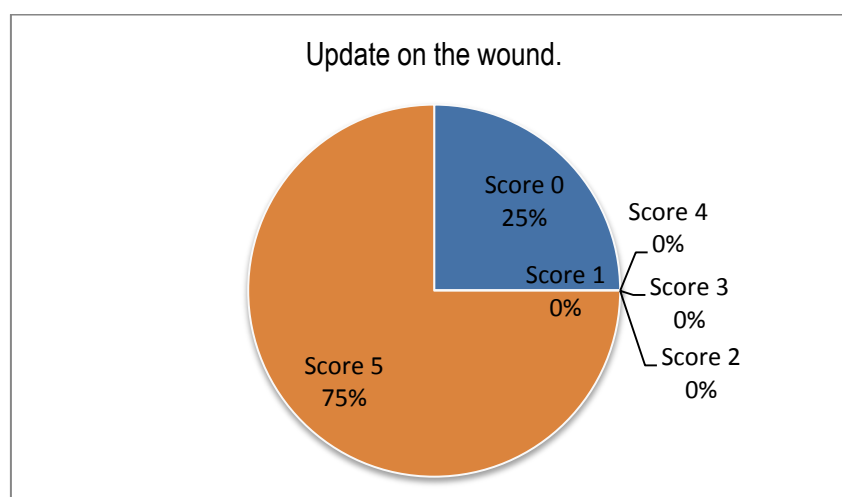


Scoring for fears and concerns that the theme was often not raised during the consultation. Where it was raised, the consulting nurse discussed the issues on 42% of occasions. A solution, whether partial or complete, was never offered.

11.95 Update on the wound.

One of the five phase 2 participants raised having an update on the progress of their wound during their phase 1 interview. Results are summarised in the pie chart below (Chart 13).

Chart 13: Update on the wound.

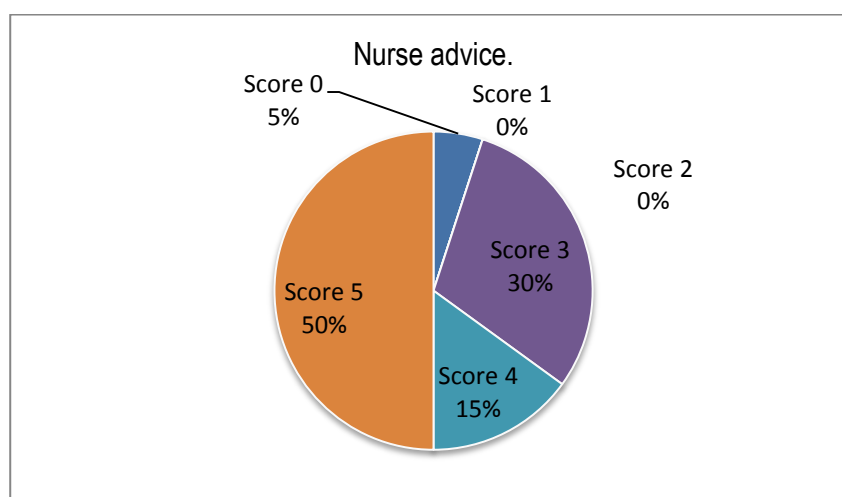


Scoring for a wound update indicated that a full solution was offered on 75% of the opportunities presented.

11.97 Nurse advice.

All five of the phase 2 participants emphasised the need for advice from the nurse during their phase 1 interview. Results are summarised in the pie chart below (Chart 144).

Chart 14: Nurse advice.

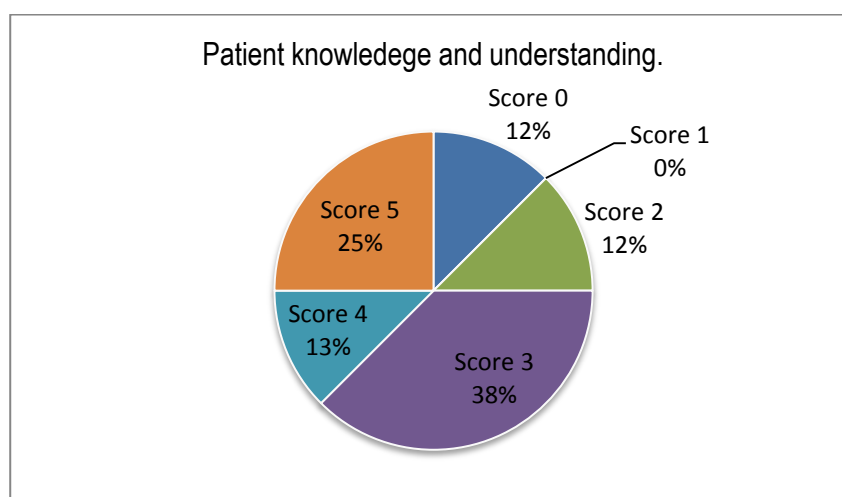


Scoring for nurse advice, again a subtheme of known importance to all participants, indicated that the theme was always raised and a solution was offered on 65% of occasions.

11.98 Patient knowledge and understanding.

Two of the phase 2 participants emphasised the importance of understanding their treatment during their phase 1 interviews. These results are summarised in the pie chart below (Chart 15).

Chart 15: Patient knowledge and understanding.

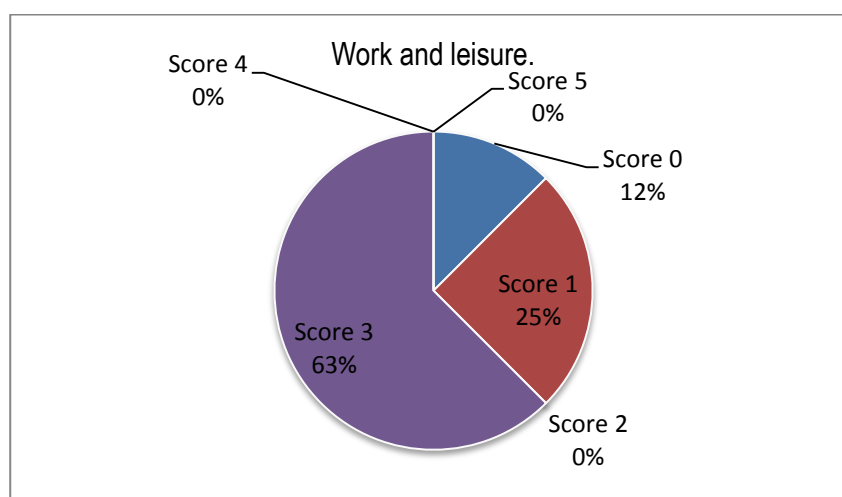


Scoring for patient knowledge and understanding indicated that the theme was discussed most often during the consultation. Where it was raised, the consulting nurse offered a solution of some form on 38% of opportunities.

11.99 Opportunities for work and leisure.

Two of the phase 2 participants emphasised the importance of work and leisure during their phase 1 interview). These results are summarised in the pie chart below (Chart 16).

Chart 16: Opportunities for work and leisure.

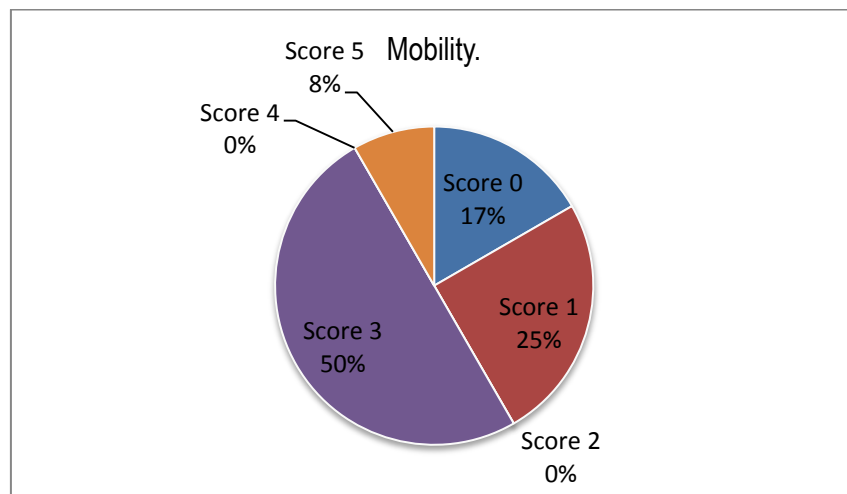


Scoring for issues surrounding work and leisure indicated that the theme was most often discussed during the consultation. Solutions to the issues raised were not offered. A cue was overlooked by the nurse during a quarter of consultations.

11.991 Mobility.

Three of the phase 2 participants emphasised the importance of their mobility during their phase 1 interview. These results are summarised in the pie chart below (Chart 17).

Chart 17: Mobility.

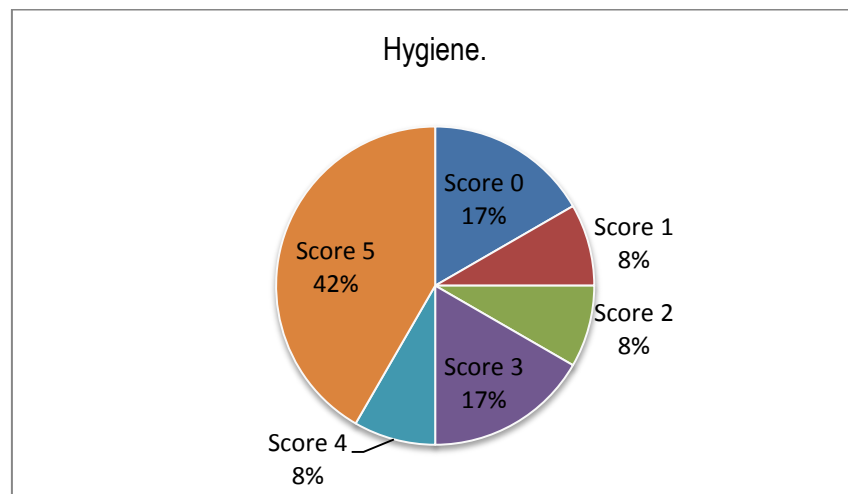


Scoring for issues relating to mobility indicated that the theme was most discussed with a solution only offered on 8% of occasions. Again, a cue was overlooked during 25% of consultations.

11.992 Hygiene.

Three of the phase 2 participants emphasised the importance of personal hygiene during their phase 1 interview. These results are summarised in the pie chart below (Chart 18).

Chart 18: Hygiene.

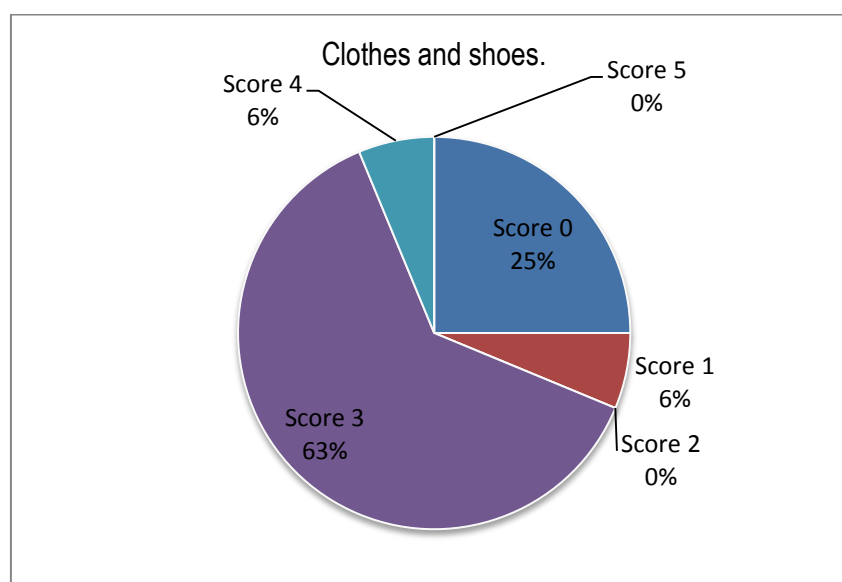


Scoring for hygiene subtheme indicated a full solution to the issues raised was provided on 42% of opportunities. The theme was overlooked or not explored on 16% of occasions.

11.993 Clothes and shoes.

Four of the phase 2 participants emphasised the importance of their choices with clothes and shoes during their phase 1 interview. These results are summarised in the pie chart below (Chart 19).

Chart 19: Clothes and shoes.



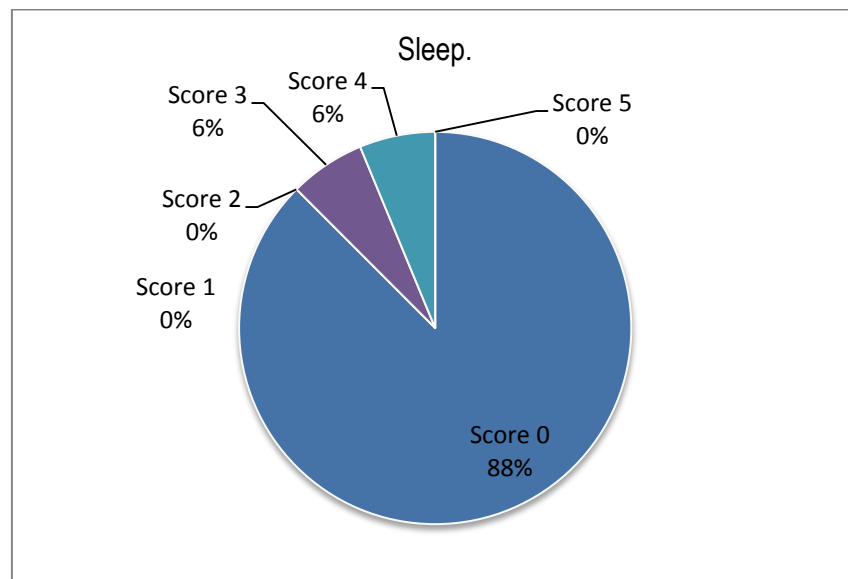
Scoring for problems with clothes and shoes indicated that the theme was most often discussed during the consultation.

11.994 Sleep.

Four of the phase 2 participants emphasised the importance of sleep during their phase 1 interview.

These results are summarised in the pie chart below (Chart 20).

Chart 20: Sleep.

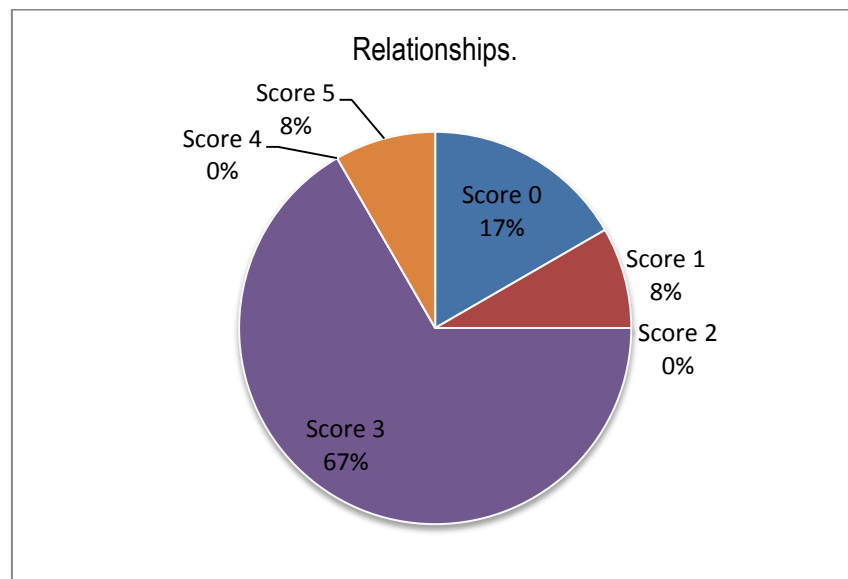


Scoring sleep issues, a subtheme of known importance to four of the participants, indicated that the theme was most often not raised during the consultation. Where it was raised, the consulting nurse discussed or offered a partial solution during 12% of opportunities.

11.995 Relationships.

Three of the phase 2 participants emphasised the importance of relationships during their phase 1 interview. These results are summarised in the pie chart below (Chart 21).

Chart 21: Relationships.



Scoring for the subtheme of relationships indicated that it was most often discussed during the consultation.

Appendix 12

Search results: Patient intervention literature review.

Search results: Patient intervention literature review.

Search Term	AMED (NHS)	BNI (NHS)	CINAHL (NHS)	EMBASE (NHS)	Health Business Elite (NHS)	HMIC (NHS)	MEDLINE (NHS)	Psyc INFO (NHS)	All Health (Keele)	RCN search	Google Scholar	Total
1. consult*	2048	2048	21040	95893	44385	14101	71477	33888	240590	-	-	-
2. intervent*	18560	6802	128587	582959	12183	14312	465556	19284 4	878921	-	-	-
3. 1 AND 2	339	68	2330	9854	211	763	7033	5187	24466	-	-	-
4. patient centre*	666	621	4055	31913	889	2881	19800	2101	7504	-	-	-
5. 3 AND 4	6	3	50	287	1	45	177	0	91	-	-	-
6. nurs*	7394	61049	307810	331739	29832	35589	309851	60639	1326623	-	-	-
7. 5 AND 6	0	0	18	71	0	0	0	0	30	15	45	-
Items selected:	1	2	10	13	0	9	20	0	18	5	30	108

Appendix 13

Quality appraisal of the literature chapter 6.

Appendix 13: Quality appraisal of the literature (Hawker et al, 2002).

Total Score: <90 - Very Poor.

90-180 – Poor.

180-270 – Fair.

270-360 – Good.

Author, year & location	Abstract & title	Introduction & aims	Method & data	Sampling	Data analysis	Ethics & bias	Findings / results	Transferability /generalisability	Implications & usefulness	Total Score (Range: 90-360)
Holmstrom, Larsson, Lindberg & Rosenqvist (2004)	30	20	30	20	20	20	30	20	30	220 (F)
Ogden & Hoppe (1997)	40	30	30	30	20	20	30	30	20	250 (F)
Pill, Stott, Rollnick & Rees (1998)	40	20	20	40	30	20	30	30	20	250 (F)
Kinmonth, Woodcock, Griffin, Spiegel, Campbell (1998)	40	30	40	30	40	30	30	30	30	300 (G)

Appendix 14

Ethical approval nominal group.



Staffordshire Research Ethics Committee

Prospect House
Fishing Lane Road
Redditch
Worcestershire
B97 6DW

Tel: 01527 562535

03 May 2011

Mrs Julie Green
Lecturer in Nursing
Keele University
School of Nursing and Midwifery
Clinical Education Centre,
UHNS, Stoke-on-Trent
ST4 6QD

Dear Mrs Green

Study title: Does a patient focus to consultations in chronic venous leg ulcer care improve patient satisfaction and health related quality of life? (v2)
REC reference: 10/H1203/13
Amendment number: (Our ref AM01)
Amendment date: 23 March 2011

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Nominal Group letter of invitation	V1	14 March 2011
Letter of invitation to participant	V1	01 March 2011
Participant Consent Form: District Nurse Consent Form	V1	14 March 2011
Participant Consent Form: Patient Consent Form	V1	14 January 2010
Participant Information Sheet: Nominal Group Information Leaflet	V1	14 March 2011
Participant Information Sheet: Patient Information Sheet	V1	01 March 2011
Protocol	V7	14 March 2011
Notice of Substantial Amendment (non-CTIMPs)	AMS1	23 March 2011
Covering Letter		23 March 2011

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H1203/13:

Please quote this number on all correspondence

Yours sincerely



Jenny Tyers (Mrs) for and on behalf of
Dr Kathryn Kinmond
Chair

E-mail: jenny.tyers@westmidlands.nhs.uk

Enclosures:

List of names and professions of members who took part in the review

Copy to:

Ms Nicole Leighton
Keele University
School of Nursing and Midwifery
Clinical Education Centre,
UHNS, Stoke-on-Trent
ST4 6QG

Appendix 15

Patient letters, information leaflets & consent: nominal group meeting.



K E E L E
U N I V E R S I T Y

LREC Number: 10/H1203/13 Amendment number one

Keele University School of Nursing and Midwifery,
Clinical Education Centre,
University Hospital of North Staffordshire NHS Trust,
City General Site,
Newcastle Road,
Stoke-on-Trent.
ST4 6QG.
Tel: 01782 556605.

Dear Sir or Madam,

I am currently studying for a PhD and you have kindly taken part in my research that explores chronic venous leg ulceration and the impact that this condition has on quality of life. I now wish to invite you to comment on the completed consultation template. I have enclosed an information leaflet for you to read which outlines the study in more depth and also what will be required of you if you agree to take part.

If you have any queries about the study, please do not hesitate to contact me on the above telephone number. If you do agree to take part then I would be very grateful if you could complete the enclosed consent form and return in the prepaid, addressed envelope within seven days.

I am very grateful for your time and for the help that you can provide to this research project.

Yours sincerely,

Julie Green

Lecturer in Nursing.



K E E L E
U N I V E R S I T Y

Version , Date: 14/03/20110.
LREC Number: 10/H1203/13 Amendment number one

Keele University School of Nursing and Midwifery,
Clinical Education Centre,
University Hospital of North Staffordshire NHS Trust,
City General Site,
Newcastle Road,
Stoke-on-Trent.
ST4 6QG.
Tel: 01782 556605.

Dear Sir or Madam,

I am currently studying for a PhD. The research I am undertaking explores chronic venous leg ulceration and the impact on the patients' quality of life. I have complete two phases of my research so far which has included interviewing patients who suffer from leg ulceration and observation of their consultations to explore the extent to which the factors they highlight as being important are addressed.

I now wish to use the information gained, along with the literature available in this area, to formulate a new consultation template. I wish to invite you to be part of such a focus group, known as a nominal group. I enclose an information leaflet to provide full details of the study and a consent form for you to return if you wish to take part. Please complete these and return in the stamped addressed envelope provided, ideally within seven days. If you have any queries about the study, please do not hesitate to contact me on the above telephone number.

I am very grateful for your time and for the help that you can provide to this research project.
Yours sincerely,

Julie Green
Lecturer in Nursing.



KEELE UNIVERSITY

Patient Information Leaflet.

LREC Number: 10/H1203/13 Amendment number one

Study Title:

Chronic venous leg ulceration and health related quality of life.

You are invited to take part in a research study.

Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and your District Nurse if you wish.

If there is anything that is not clear or if you would like more information, please feel free to contact Julie Green at the School of Nursing and Midwifery, Keele University on 01782 556605.

What is the purpose of the study?

Many people in the UK suffer from leg ulcers. This research will explore the day-to-day effects of having a leg ulcer.

Why have I been chosen?

You have been invited to take part because you are currently receiving care from a District Nurse for your leg ulcer.

Do I have to take part?

You are free to decide if you wish to take part or not.

If you do decide to take part, please complete the enclosed consent form and return it in the prepaid envelope provided within seven days.

If you do decide to take part, you can withdraw at any time and without having to give a reason. This will not affect your treatment or the care for your leg ulcer.

If you do not wish to take part, please simply destroy the enclosed literature and be assured that your care will not be affected.

What will happen if I take part?

If you agree to take part in the study, I will contact you to arrange a convenient time to meet with you to discuss the newly developed consultation template. This has been developed based on the patient interviews and observations that you were part of. By giving your input you will help to confirm that the new template accurately reflects the issues that are important to the patients with chronic venous leg ulcers.

What do I have to do?

Simply complete and return the enclosed consent form and I will then contact you to arrange a visit to conduct the interview.

What are the benefits of taking part?

It is hoped that the information gathered during this study will provide an understanding of the day-to-day lives of people with leg ulceration and may help to shape the care that is delivered in the future.

What are the possible disadvantages or risks of taking part?

There are no expected disadvantages or risks associated with taking part in this study.

What if something goes wrong?

I do not expect any problems to arise during this study.

If you have a concern about any aspect of the study, you should speak to me, Julie Green, and I will do my best to answer your questions. I can be contacted on 01782 556605.

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:- Nicola Leighton, Research Governance Officer, Research & Enterprise Services, Dorothy Hodgkin Building, Keele University, ST5 5BG.

Will my taking part be kept confidential?

All of the information collected during this study will be kept strictly confidential.

Your name and address will be removed from all documents and any other identifying information, including the consent form, will be kept in a locked drawer in a lockable office. Some information may be stored on a computer, but this will be protected by a password known only to myself.

What will happen to the results of the research study?

This research will form part of a PhD study. No one will be identifiable in the completed thesis.

Who is organising and funding this research?

This research is a student project for a PhD. It has no funding available from any organisations or drug companies. Most of the work will be done in my own time.

Thank you for your time in reading this information sheet.

If you agree to take part in this study, please complete the enclosed consent form.

Many thanks,

Julie Green



K E E L E
U N I V E R S I T Y
Nominal Group Information Leaflet.

Version 1, Date: 14/03/2011.

LREC Number: 10/H1203/13 Amendment number one

Study Title:

Chronic venous leg ulceration and health related quality of life.

You are being invited to take part in a research study.

Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with your colleagues.

If there is anything that is not clear or if you would like more information, please feel free to contact Julie Green at the School of Nursing and Midwifery, Keele University on 01782 556605.

What is the purpose of the study?

Leg ulceration affects many thousands of people in the UK. Dressing products and techniques are frequently reviewed but the impact of the ulceration on the day-to-day life of the sufferer is often overlooked. This research aims to explore the lived experience of a number of patients who suffer from leg ulcers.

Why have I been chosen?

The research has involved interviewing a number of patients who have chronic venous leg ulcers and observing their care over a four week period. This information, along with themes from the literature, will now be developed into a new consultation template. You have been asked to take part in a short focus group, known as a nominal group, to aid in the development of this template.

Do I have to take part?

You are free to decide if you wish to take part.

If you do decide to take part, please complete the enclosed consent form and return it in the prepaid envelope provided within seven days.

If you do not wish to take part, please simply destroy the enclosed literature.

What will happen if I take part?

If you do decide to take part in the study, I will ask that you to attend a short nominal group lasting approximately 90 minutes at the School of Nursing and Midwifery at Keele University, where I will present the findings from the project to date, both interviews and observations, along with themes from the literature.

During this group, a number of nurses with experience in this area of wound care, will discuss and come to some consensus as to the content of a new consultation template for chronic venous leg ulceration. Following this meeting, two patients who have been involved in the study will have the opportunity to review the template. Should this result in any recommendations for the template to be amended, this will be communicated to you via email for further comment. The finalised template will then be piloted in the next phase of my project.

What do I have to do?

If you decide to take part in the study, please complete and return the enclosed consent form in the prepaid envelope provided within seven days.

I will then contact you to arrange to visit to provide an overview of the study.

What are the benefits of taking part?

It is the aim that the information gathered from this study will give an insight into the day-to-day lives of people suffering from venous leg ulceration and, as a result, may be used to make recommendations about future care that is delivered. This, however, is not a guaranteed outcome.

What are the possible disadvantages or risks of taking part?

There are no expected disadvantages or risks associated with taking part in this study.

What if something goes wrong?

I do not expect any problems to arise during this study.

If you have a concern about any aspect of the study, you should speak to me, Julie Green, and I will do my best to answer your questions. I can be contacted on 01782 556605.

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:- Nicola Leighton, Research Governance Officer, Research & Enterprise Services, Dorothy Hodgkin Building, Keele University, ST5 5BG.

Will my taking part be kept confidential?

All of the information collected during this study will be kept strictly confidential.

Your name and address will be removed from all documents and any other identifying information, including the consent form, will be kept in a locked drawer in a lockable office. Some information may be stored on a computer, but this will be protected by a password known only to myself.

What will happen to the results of the research study?

This research will form part of a PhD study. No one will be identifiable in this piece of work.

Who is organising and funding this research?

This research is a student project for a PhD. It has no funding available from any organisations or drug companies. Most of the work will be done in my own time.

Thank you for your time in reading this information sheet.

If you agree to take part in this study, please complete the enclosed consent form and return in the prepaid envelope provided within seven days.

Many thanks,
Julie Green



K E E L E
U N I V E R S I T Y

Patient Consent Form.

Version 1, Date: 14/01/2010.

LREC Number: 10/H1203/13 Amendment one.

Title of Project: Does a patient focus to consultations in chronic venous leg ulcer care
improve patient satisfaction and health related quality of life?

Name of Researcher: Julie Green.

Please Tick.

1. I confirm that I have read and understood the information leaflet and have
had the opportunity to ask questions.....

☐

2. I understand that my participation is voluntary, that I can refuse to answer
a question, or withdraw at any time, without giving a reason, and without my
medical care or legal rights being affected.....

☐

3. I agree to review and comment on the newly developed consultation template
.....

☐

4. I understand that data collected during the study may be looked at by
individuals from regulatory authorities or from the NHS Trust, where it is
relevant to my taking part in this research. I give permission to these
individuals to have access to my records.....

☐

Please sign and date on the line below:

Name of Patient

Date

Signature

Name of Researcher

Date

Signature

Please provide me with your contact details below:

Your full name, address and telephone number.

Name:.....

Address:.....

.....

.....

.....

Telephone number:.....

Thank you for your help with this research study.

If you have any further questions about this study, you can me, Julie Green, on 01782 556605.



K E E L E
U N I V E R S I T Y

District Nurse Consent Form.

Version 1, Date: 14/03/2011.

LREC Number: 10/H1203/13 : Amendment One.

Title of Project: Does a patient focus to consultations in chronic venous leg ulcer care
improve patient satisfaction and health related quality of life?

Name of Researcher: Julie Green.

Please Tick.

1. I confirm that I have read and understood the information leaflet and have
had the opportunity to ask questions.....

☐

2. I understand that my participation is voluntary, that I can refuse to answer
a question, or withdraw at any time, without giving a reason.....

☐

3. I agree to take part in the nominal group to develop the new consultation
template.....

☐

4. I am aware that notes will be taken during this meeting.....

☐

5. I agree to being contacted by email should any recommendations be made
following patient review of the new template.....

☐

6. I understand that data collected during the study may be looked at by
individuals from regulatory authorities or from the NHS Trust, where it is
relevant to my taking part in this research. I give permission to these
individuals to have access to my records.....

☐

Name of District Nurse Date Signature

Name of Researcher Date Signature

Please provide me with your work contact details below:

Your full name, work address and telephone number.

Name:.....

Work Address:.....

.....

.....

.....

Work Telephone number:.....

Thank you for your help with this research study.

If you have any further questions about this study, you can telephone me, Julie Green, on 01782 556605.

Appendix 16

Nominal group minutes.

Appendix 16: Nominal group minutes.

What are the factors that impact on the day-to-day lives of people with leg ulcers and do we address these during patient consultations?

Nominal Group – 8th July 2011, Keele Management Centre.

Meeting minutes recorded by DM.

1. Meeting began with introductions and a brief explanation of the purpose of the meeting.
2. JG gave a short presentation of the findings of the study to date. She outlined the themes from the patient interviews and the findings from the period of observation of the participant's current consultations. She stated that on 52% of occasions patient's failed to raise the issues that impacted on their quality of life. Nurses performed better when the needs of the patient were related to physical issues rather than when these were of a psychological or social nature. JG had provided attendees with laminated copies of the themes in order to discuss which should be included in the final template and circulated 3 draft copies of template designs as a starting point.
3. MW suggested the inclusion of nutritional needs/assessment, which had not currently been included. All members agreed that this would be an important additional area which is often overlooked. Issues with nutrition could arise due to pain, lack of sleep, etc. and as a result would lead to further exploration of potential issues that were impacting on quality of life. MUST tool was mentioned and the use of PROCAL shots to enhance patient nutritional intake.
4. JG mentioned that the theme of itching was prevalent in the literature but had not come out as a theme from the interviews/observations. JG asked whether reference to itching should be included. SM urged that this not be included directly as where a patient was not experiencing this symptom, just mentioning it may make encourage them focus on itching in the future. It was agreed that this, if it was an issue, would arise in some of the patient's responses in other areas and then could be explored further.
5. JG asked whether it was necessary to include a pain scale and if so, which one (copies of a number of scales were made available). All agreed that the inclusion of a scale was not necessary as a pain score is used within the general patient notes. All felt it was important to ascertain whether pain was deteriorating or improving.
6. SM commented that sections to be completed appeared too long in the draft templates and suggested that tick boxes would be better and more likely to be completed accurately.
7. SR recommended the inclusion of the term assessment within the tool, emphasising that explicit words would encourage actual assessments to be undertaken by the consulting nurses.

8. DG and HS both commented that the DN service is very restricted at the moment with visits limited to 10 minutes for a patient with bilateral 4 layer bandaging and suggested that for this template to be applied, it needs to be quick and easy to complete.
9. SM and HS commented that commissioners simply wanted the physical needs of the patient addressing, rather than using additional time looking at other needs of the patient. SR commented that there appeared to be a huge gap between this model of delivery and the need for prevention and education to heal and prevent recurrence of ulcers.
10. SR and DM urged that the tool needed to be holistic, not just clinical to avoid the psychological aspects of care from being overlooked. These factors would all lead into prevention and influence the cost implications of care delivery. From discussions it appears that commissioners are driving quantity and not quality, which this study may inform. The costing of such improvements need to be addressed. SM mentioned both QUIPP and CQUIN targets which next year will focus on leg ulceration.
11. SM asked where the patient voice fitted in with the template development. JG explained that she was planning to return to patients once the template had been agreed at this meeting to get their comments and suggestions.
12. SR again stressed the importance of having assessment in the template. SR also suggested a problem solving area as not all of the issues identified would be addressed or 'solved' during every consultation. These would serve to raise awareness for the nurse and alert them to particular areas that required attention.
13. DJ stressed the need for the template to be simple as time is of the essence due to the restrictions on the service.
14. SM suggested to remove the section entitled 'record your advice' into an overall nurse advice section at the end of the template.
15. In terms of Wound Management, SM argued that these areas should all be addressed anyway and included in the patient notes so she suggested replacing with a simple Yes/No tick box. HS agreed with this.
16. SM also suggested that pain could be a tick box and a question asked of whether analgesia offered or an alternative suggested. Sleeping – suggested a question of 'Where are you sleeping? Are you sleeping well? What stops you sleeping?'. Direct, simple questions to the patient that many DNs ask anyway but maybe do not clearly address currently.
17. SM suggested to start with the wound management whereas SR disagreed and felt that it should start with the psychological in order to enhance the importance of this area. After some discussion everyone agreed that wound management could come towards the end.
18. All agreed that one sheet for the template was a maximum.
19. SM suggested linking questions: mobility – are you able to get out and about? SM felt that such leading questions would be quick but also would reveal where problems lay, eg. What

did you do prior to the ulcer? Are you able to do what you did before? What stops you doing the things that you like? Almost trigger questions.

20. SM suggested of using a scribe to assist nurses to complete the form – JG said that this was unlikely as no funding but she would look into it.
21. SM suggested linking pain to nutrition and sleep as they are all factors that influence each other, eg. Are you sleeping well? If not, why? Are you eating a normal diet? Why not? Pain, has this improved since your last visit? Do you take analgesia regularly?
22. Also suggested and agreed to link personal hygiene (are you managing to shower or bathe?), to clothes (can you dress and wear the same shoes as before you had your ulcer?) and to tie fears into emotional issues – how are you feeling today?
23. It was agreed to put exudate and odour into the wound management section as this would be covered and documented along with the wound assessment. MW suggested responses to exudate and odour may prompt the nurse to reassess the need for change in dressing and frequency of visits. To include a tick box for this.
24. To include an additional information box at the end of the template (or ?problem solving) and a small comments box for each of the questions, following the tick box.
25. SM suggested including a question about would it be beneficial to have a leaflet explaining how to manage with ulcers?
26. All agreed with the need for completion guidance notes to prompt the nurse on the back of the template.
27. SM suggested gaining the signature of the patient and the nurse at the end of the form. Also a suggestion of the patient and/or carer completing the ADLs section together maybe prior to the nurse visit.

Appendix 17

Consultation template.

QUALITY OF LIFE & LEG ULCERATION TEMPLATE v4.

Patient Name:

Date:

Please complete this template during each consultation.
Assess the themes below with your patient. Record any interventions you make, advice that you give or problems that you solve in the comments boxes. Guidance regarding completion is provided overleaf.

Assessment of mobility & ability to get out & about:

Are you able to mobilise as you did prior to having an ulcer?

Yes: ☐

No: ☐

If not, what stops you?

Are you able to get out and about and socialise as you did?

Yes: ☐

No: ☐

Comments:

Assessment of sleep, nutrition and pain:

Where are you sleeping?

Bed: ☐

Chair: ☐

Comments:

Do you sleep well? If not, what stops you from sleeping?

Yes: ☐

No: ☐

Comments:

Are you eating a normal diet? If not, why?

Yes: ☐

No: ☐

Comments:

Is your pain better or worse since your last visit?

Better: ☐

Worse: ☐

Comments:

What pain killers are you taking? Do you take these regularly?

Medication dose & frequency taken:

Are they effective?

Yes: ☐

No: ☐

Comments:

Assessment of personal hygiene, clothes & shoes:

Are you managing to shower or bathe?

Yes: ☐

No: ☐

Comments:

Are you able to wear the clothes and shoes that you did prior to having an ulcer?

Yes: ☐

No: ☐

Comments:

If not, what are you wearing? Is this suitable?

Comments:

Assessment of emotional effects, relationships & fears:

Do your ulcers get you down? How are you feeling today?

Yes: ☐

No: ☐

Comments:

Do you have friends or family members who support you?

Comments:

Do you have any concerns about your ulcer?

Comments:

Assessment of wound management:

Have you documented your patient's treatment and the advice you have given to them in their notes?

Yes: ☐ No: ☐ Comments:

Are your patient's legs wet? Is there any odour?

Yes: ☐ No: ☐ Comments:

Are the dressing type and frequency of dressings appropriate?

Comments:

Have you made your patient aware of their wound assessment and their management plan?

Yes: ☐ No: ☐ Comments:

Template assessment guidance.**Assessment of mobility & ability to get out & about:**

- Are leg ulcers restricting mobility? Are you able to recommend anything to assist with mobility?
- Is your patient able to enjoy the activities that they did prior to having an ulcer? Is there anything you can recommend to improve this?

Assessment of sleep, nutrition and pain:

- Does the ulcer interfere with sleep? What advice have you given? eg. the timing of analgesia, positioning, etc. Where are they sleeping? Is this suitable?
- Is dietary intake sufficient? Is a full nutritional assessment necessary? Have suitable supplements been prescribed?
- Assess your patient's pain and ascertain whether this is improving or deteriorating? Is it intermittent or continuous? What makes the pain better or worse?
- What analgesia is currently being taken and is this effective? Does the medication need reviewing? What advice have you given in relation to non-pharmacological methods of pain relief such as positioning of the limb, timing of the visit, etc.?

Assessment of personal hygiene, clothes & shoes:

- Is your patient able to maintain their personal hygiene? Can you make any recommendations to improve this? Is it possible for legs to be washed or for any aids and appliances to be recommended?
- Is your patient struggling to wear clothes and shoes that they would like to? Is their footwear safe? Review any advice given.

Assessment of emotional effects, relationships & fears:

- How is your patient feeling today and how is their ulceration impacting on their daily life? Is there anything you can offer to support your patient?
- Does your patient confide in friends and family about their ulcers and do they feel well supported?

Assessment of wound management:

- Complete a full assessment of the wound and document the details in the patients' notes.
- Assess exudate and odour – are the dressing product suitable and the frequency of visits appropriate? How are these symptoms impacting on your patient?
- Does your patient understand their management plan and do they agree with this? Are they able to follow the advice given?

Problem solving / comments:

- This box is provided to record any problems that you have solved during your visit today. This may have been by making a referral to another service, undertaking a reassessment, giving advice or making a recommendation or by making a change to treatment in response to a problem that you have assessed. Discuss and agree your actions and the plan of care with your patient and document here.

Review the assessments you make, the advice you give and the interventions you recommend at each visit.**Comments and problem solving:**

Completed bySigned(nurse).....Signed(patient).....

PhD Research Project: 20/7/11. LREC Approval: 10/H1203/13
Any queries please contact Julie Green 01782 679605.

Appendix 18

Copy of Consultation Satisfaction Questionnaire (CSQ).

Appendix 18: Copy of CSQ

<p>CSQ</p> <p>Department of Health Sciences</p> <p>University of Leicester</p> <p>CONSULTATION SATISFACTION QUESTIONNAIRE</p> <p>The form contains a list of questions. They ask you what you think of your last visit to the doctor. Please answer all the questions. Your answers will be kept entirely confidential and will not be shown to the doctor so feel free to say that you wish. Please do not write your name on the form and be sure to place this form in the box provided before you leave today.</p> <p>Please answer all the questions. For each one draw a circle round the answer that is closest to what you think. "Neutral" means you have no feelings either way.</p> <p>For example:</p> <p>"This surgery is too big." Strongly Agree/Agree/ <u>Neutral</u> /Disagree/Strongly Disagree</p>		
1	I am totally satisfied with my visit to this nurse	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
2	This nurse was very careful to check everything when examining me	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
3	I will follow this nurse's advice because I think he/she is absolutely right	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
4	I felt able to tell this nurse about very personal things	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
5	The time I was able to spend with the nurse was a bit too short	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
6	This nurse told me everything about my treatment	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
7	Some things about my consultation with the nurse could have been better	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
8	There are some things this nurse does not know about me	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
9	This nurse examined me very thoroughly	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree

10	I thought this nurse took notice of me as a person	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
11	The time I was allowed to spend with the nurse was not long enough to deal with everything I wanted	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
12	I understand my illness much better after seeing this nurse.	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
13	This nurse was interested in me as a person not just my illness	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
14	This nurse knows all about me	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
15	I felt this nurse really knew what I was thinking	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
16	I wish it had been possible to spend a little longer with the nurse	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
17	I am not completely satisfied with my visit to the nurse	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree
18	I would find it difficult to tell this nurse about some private things	Strongly Agree/Agree/Neutral/Disagree/Strongly Disagree

How old are you? _____ years

Are you male _____ or female _____ (Tick which applies)

Do you have any other comments about the consultation?

Appendix 19

Copy of SF-12.

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing <u>several</u> flights of stairs.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. Were limited in the kind of work or other activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. Did work or other activities less carefully than usual	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

6. These questions are about how you feel and how things have been with you during the past 4 weeks. 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...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. Did you have a lot of energy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Have you felt downhearted and low?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Thank you for completing these questions!

Appendix 20

Copy of EuroQoL-5D.

Appendix 20: Copy of the EuroQol 5D

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

- | | |
|---|--------------------------|
| I have no problems in walking about | <input type="checkbox"/> |
| I have slight problems in walking about | <input type="checkbox"/> |
| I have moderate problems in walking about | <input type="checkbox"/> |
| I have severe problems in walking about | <input type="checkbox"/> |
| I am unable to walk about | <input type="checkbox"/> |

SELF-CARE

- | | |
|---|--------------------------|
| I have no problems washing or dressing myself | <input type="checkbox"/> |
| I have slight problems washing or dressing myself | <input type="checkbox"/> |
| I have moderate problems washing or dressing myself | <input type="checkbox"/> |
| I have severe problems washing or dressing myself | <input type="checkbox"/> |
| I am unable to wash or dress myself | <input type="checkbox"/> |

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

- | | |
|--|--------------------------|
| I have no problems doing my usual activities | <input type="checkbox"/> |
| I have slight problems doing my usual activities | <input type="checkbox"/> |
| I have moderate problems doing my usual activities | <input type="checkbox"/> |

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 moderately anxious or depressed ☐

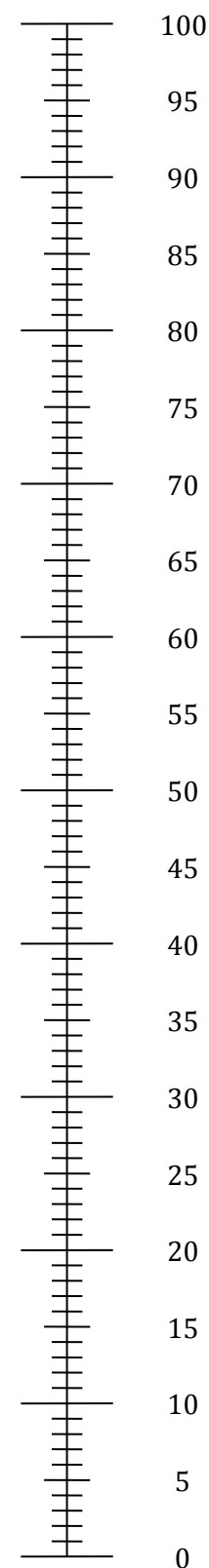
I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

Appendix 21

Copy of the Cardiff Wound Impact Schedule (CWIS).

Appendix 21: Copy of the Cardiff Wound Impact Schedule

Overall Quality of Life

How would you rate your overall quality of life during the past week?

Please circle a number below


How good is your quality of life?

My quality of life is the worst possible	0	1	2	3	4	5	6	7	8	9	10	My quality of life is the best possible
--	---	---	---	---	---	---	---	---	---	---	----	---

How satisfied are you with your overall quality of life?

Not at all satisfied	0	1	2	3	4	5	6	7	8	9	10	Very satisfied
----------------------	---	---	---	---	---	---	---	---	---	---	----	----------------

Overall Comment(s)



Wound Healing Research Unit

University of Wales College of Medicine

Cardiff Wound Impact Schedule

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Total

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The following questionnaire is concerned with the effects that your wound(s) has(have) on your daily life. Please answer the questions carefully by placing a tick in the box which most closely reflects how you feel; it should take about ten minutes to complete.

If you are unsure about how to answer a question, please tick the answer which is closest to how you feel. All answers are confidential.

Personal Details

M F

Patient Initials

Sex

Patient Number

Date of Birth

D D M M Y Y

Assessment

1st 2nd 3rd 4th 5th

Assessment Date

D D M M Y Y

Next Assessment Due

D D M M Y Y

Wound status

Healed

☐

Not Healed

☐

Do you live on your own?

Yes

☐

No

☐

How often do you see your family and friends?

Once a day

☐

Once a month

☐

Once a week

☐

Less than once a month

☐

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Social Life

How stressful has this experience been for you?

Not at all/ Not applicable Slightly Moderately Quite a bit Very

Difficulty getting out and about

☐

Relying more on others

☐

Your family/friends being over protective

☐

Unable to enjoy your usual social life (eg hobbies)

☐

Limited contact with family/friends

☐

Not going out for fear of bumping your wound site

☐

Wanting to withdraw from people

☐

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Have you experienced any of the following during the past week?

Difficulty getting out and about	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relying more on others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Your family/friends being over protective	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unable to enjoy your usual social life (eg hobbies)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Limited contact with family/friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not going out for fear of bumping your wound site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wanting to withdraw from people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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To what extent do you agree/disagree with the following statements?

I feel anxious about my wound(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel frustrated at the time it is taking for the wound(s) to heal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am confident that the wound(s) I have will heal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I worry that I may get another wound in the future	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The appearance of the wound site is upsetting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel anxious about bumping the wound site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I worry about the impact of the wound(s) on my family/friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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[illegible]

Physical Symptoms and Daily Living

Have you experienced any of the following during the past week?

	Not at all/ Not applicable	Seldom	Sometimes	Frequently	Always
Disturbed sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty in bathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Immobility around the home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Immobility outside the home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leakage from the wound(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pain from the wound site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discomfort from the bandaging/dressing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unpleasant odour or smell from the wound(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problems with everyday tasks (eg shopping)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty in finding appropriate footwear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problems with the amount of time needed to care for the wound site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Financial difficulties as a result of the wound(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Physical Symptoms and Daily Living

How stressful has this experience been for you?

	Not at all/ Not applicable	Slightly	Moderately	Quite a bit	Very
Disturbed sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty in bathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Immobility around the home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Immobility outside the home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leakage from the wound(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pain from the wound site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discomfort from the bandaging/dressing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unpleasant odour or smell from the wound(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problems with everyday tasks (eg shopping)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty in finding appropriate footwear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problems with the amount of time needed to care for the wound site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Financial difficulties as a result of the wound(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Appendix 22

Ethical approval phase 3.

South Staffordshire Local Research Ethics Committee

Medical Institute
Hartshill Road
Hartshill
Stoke-on-Trent
Staffordshire
ST4 7NY

Telephone: 01782 714980

Facsimile: 01782 714975

11 March 2010

Mrs Julie Green
Lecturer in Nursing
Keele University
School of Nursing and Midwifery
Clinical Education Centre,
UHNS,
Stoke-on-Trent
ST4 6QG

Dear Mrs Green

Study Title:	Does a patient focus to consultations in chronic venous leg ulcer care improve patient satisfaction and health related quality of life? (v2)
REC reference number:	10/H1203/13
Protocol number:	6

The Research Ethics Committee reviewed the above application at the meeting held on 03 March 2010. Thank you for attending to discuss the study. The coordinator explained that the Committee did not need to see you.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research (“R&D approval”) should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

Other conditions specified by the REC

The Committee was content to give a favourable opinion of phases one and two of the application with the following condition/s:

1. The reference to training in the information sheet for the district nurses should be removed as it relates to phase three
2. In the information sheets participants are asked three times to “please complete the enclosed consent form and return in the prepaid envelope provided within seven days”. The phrase is also included in the letters of invitation. Such repetition is unnecessary and should be taken out.

The Committee decided that phases one and two follow on naturally but phase three will require a separate application as, until phases one and two have been completed, there is insufficient detail relating to phase three to enable a decision to be made.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
Covering Letter		10 February 2010	
REC application		10 February 2010	
Protocol	6	25 January 2010	
Investigator CV		24 November 2009	
Participant Information Sheet: Phase 1 & 2	2	14 January 2010	
Participant Information Sheet: Phase 1 & 2 District Nurse	2	14 January 2010	
Participant Information Sheet: Phase 3	2	14 January 2010	
Participant Information Sheet: Phase 3 District Nurse	2	14 January 2010	
Participant Consent Form: Phase 1 & 2	3	14 January 2010	
Participant Consent Form: Phase 1 & 2 District Nurse	3	14 January 2010	
Participant Consent Form: Phase 3	3	14 January 2010	
Participant Consent Form: Phase 1 & 2 District Nurse	3	14 January 2010	
Evidence of insurance or indemnity		24 July 2009	
Letter from Sponsor		30 November 2009	

Referees or other scientific critique report		23 October 2009	
Questionnaire: Community Nurse Satisfaction			
Questionnaire: Medical Outcome short form			
Questionnaire: Cardiff Wound Impact Schedule			
CV Professor Jester		18 November 2009	
Letter of Invitation Phase 1 & 2	3	14 January 2010	
Letter of Invitation Phase 1 & 2 District Nurse	3	14 January 2010	
Letter of Invitation Phase 3	3	14 January 2010	
Interview Schedules/Topic Guides	2	25 January 2010	
Letter of Invitation Phase 3 District Nurse	3	14 January 2010	
Full Study Flow Chart	5	10 February 2010	
Phase 1 Flow Chart	2	10 February 2010	
Phase 2 Flow Chart	2	10 February 2010	
Phase 3 Flow Chart	4	10 February 2010	
Unfavourable Opinion Letter		12 January 2010	

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

With the Committee's best wishes for the success of this project

Yours sincerely

Professor Tim Reynolds
Chair

Email: Janet.Clarke@uhns.nhs.uk

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"*

Copy to: Nicola Leighton, Research and Enterprise Services, Keele University
Nemonie Marriot, Research and Development, North Staffordshire and Stoke-on-Trent PCT
Professor R Jester, School of Nursing, Keele University, Clinical Education Centre, UHNS, Stoke-on-Trent, ST4 6QG

South Staffordshire Local Research Ethics Committee

Attendance at Committee meeting on 03 March 2010

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>	
Mrs Sandra Chambers	Head Teacher (Retired)	Yes		
Mr Robert Edgar	Engineer (Retired)	Yes		
Dr Nitin Gupta	Consultant Psychiatrist	Yes		
Dr Brian Hynam	Retired Director of Pharmacy Services	Yes		
Dr Kathryn Kinmond	Senior Lecturer	Yes		
Dr Arabinda Kundu	Head of Contraceptive & Sexual Health Service	Yes		
Dr Diarmuid Mulherin	Consultant Rheumatologist	Yes		
Dr Laofe Oladele Ogundipe	Consultant Psychiatrist	Yes		
Professor Tim Reynolds	Consultant Chemical Pathologist	Yes		
Dr Sandie Sandbrook	Senior Lecturer	Yes		
Mr Victor Scofield	Legal Advisor, Banking (Retired)	Yes		

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>	
Mrs Barbara Cannings	Coordinator	

Appendix 23

Phase 3 R&D approval.

Staffordshire and 
Stoke on Trent Partnership
NHS Trust

RMG Department
Fenton Health Centre
Galsedale Road
Fenton
Stoke-on-Trent
ST4 3AQ

Tel: 01782 401000

paula.chivers@staffordshireccs.nhs.uk

14 December 2011

Mrs Julie Green
School of Nursing and Midwifery
Clinical Education Centre
UHNS
Stoke on Trent
ST4 6QG

Dear Mrs Green

Confirmation of Approval of Research Study

I can confirm that approval has been granted by the Staffordshire and Stoke on Trent Partnership NHS Trust Research Management and Governance Office for the following research study, which falls under the requirements set out in the NHS Research Governance Framework.

Title: Chronic venous leg ulceration and quality of life Phase 3 pilot (v1)

Study Reference: 77257

Chief Investigator: Mrs Julie Green

Sponsor: Keele University

Funder: West Midlands SHA

Research Location(s): District Nursing

NHS Trust(s): Staffordshire and Stoke on Trent Partnership NHS Trust

Proposed local study end date: 01/04/2012

You may begin this research study within the Staffordshire and Stoke on Trent Partnership Trust(s) noted above.

Please read carefully, the following additional information that is applicable to this confirmation of approval.

Please note that your research study may be monitored or audited by this research office or other relevant authority as part of the requirements set out in the Research Governance Framework for Health & Social Care (2005).

In order for us to continue to meet the requirements for Research Governance you are requested to provide us with the following documents (electronic or paper) relating to this study:

- A copy of all NRES Annual progress report(s) (if applicable)
- A copy of the NRES End of study declaration
- A copy of the final report no more than 6 months after completion of the study
- A completed monitoring form for Department of Health reporting purposes (the form will be sent to you for completion)

You are also requested to notify us about any of the following that are applicable to the Trust(s) for which this approval applies:

- Amendments to any documents that require REC approval
- Changes to study start and end dates
- Changes in personnel/members of the research team
- Any serious adverse events (e.g., SUSAR) within the timescales specified on the NRES website.

In addition, we will from time to time also request you to provide us with up-to-date details of all practices/ locations that you know will be, are or have been involved in this study.

Yours sincerely,



Dr Douglas Wulff
Medical Director (Interim)
Staffordshire and Stoke on Trent Partnership NHS Trust

Appendix 24

Participant letters, information leaflet and consent: phase 3.



K E E L E
U N I V E R S I T Y

Version 4, Date: 04/10/11.
LREC Number: 11/WM/0264.

Keele University School of Nursing and Midwifery,
Clinical Education Centre,
University Hospital of North Staffordshire NHS Trust,
City General Site,
Newcastle Road,
Stoke-on-Trent.
ST4 6QG.
Tel: 01782 679605.

Dear Sir or Madam,

I am currently studying for a PhD. The research I am undertaking explores chronic venous leg ulceration and the impact on the patients' quality of life. I have enclosed an information leaflet for you to read which outlines the pilot study in more depth and also what will be required of you if you agree to take part.

If you have any queries about the study, please do not hesitate to contact me on the above telephone number. If you do agree to take part then I would be very grateful if you could complete the enclosed consent form and contact details and return, in the prepaid, addressed envelope within seven days.

I am very grateful for your time and for the help that you can provide to this research project.

Yours sincerely,

Julie Green
Lecturer in Nursing.



K E E L E
U N I V E R S I T Y

Version 5, Date: 04/10/11.
LREC Number: 11/WM/0264.

Keele University School of Nursing and Midwifery,
Clinical Education Centre,
University Hospital of North Staffordshire NHS Trust,
City General Site,
Newcastle Road,
Stoke-on-Trent.
ST4 6QG.
Tel: 01782 679605.

Dear District Nurse,

I am currently studying for a PhD. The research I am undertaking is a pilot study and explores chronic venous leg ulceration and the impact this has on the patients' quality of life. You have been selected to take part in this pilot study.

I enclose an information leaflet to provide you with the full details of the study and have also attached a consent form for you. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read the information carefully and discuss it with your colleagues. If you do decide to take part, please complete the enclosed consent form and return it in the prepaid envelope provided within seven days. If you do not wish to take part, please simply destroy the enclosed literature.

If you have any queries about the study, please do not hesitate to contact me on the above telephone number. I am very grateful for your time and for the help that you can provide to this research project.

Yours sincerely,

Julie Green
Lecturer in Nursing.



KEELE UNIVERSITY

Patient Information Leaflet.

Version 5, Date: 04/10/11.

LREC Number: 11/WM/0264.

Study Title:

Chronic venous leg ulceration and health related quality of life – pilot study.

You are invited to take part in a research study.

Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and your District Nurse if you wish.

If there is anything that is not clear or if you would like more information, please feel free to contact Julie Green at the School of Nursing and Midwifery, Keele University on 01782 679605.

What is the purpose of the study?

Many people in the UK suffer from leg ulcers. This research will explore the day-to-day effects of having a leg ulcer.

Why have I been chosen?

Your District Nurse has been selected to take part in this study. The study will look at the patients they see who have leg ulcers. You have been selected as one of the patients currently receiving care for your leg ulcer.

Do I have to take part?

You are free to decide if you wish to take part or not.

If you do decide to take part, please complete the enclosed consent form and return it in the prepaid envelope provided, ideally within seven days.

If you do decide to take part, you can withdraw at any time and without having to give a reason. This will not affect your treatment or care for your leg ulceration.

If you do not wish to take part, please simply destroy the enclosed literature and be assured that your care will not be affected.

What will happen if I take part?

If you agree to take part in the study, I will contact you to arrange a convenient time to visit to complete four simple questionnaires about your condition. This visit will take around 15 minutes.

I will repeat this visit and the same questionnaires on another 3 occasions at 6 week intervals. All of these visits will be arranged at a time convenient to yourself.

During these visits, in the unlikely event of distress about nursing care or poor practice being disclosed I will be duty bound to report this, in accordance with the requirements of the Code of Conduct (NMC, 2008).

What do I have to do?

If you decide to take part you, please complete the enclosed consent form and return it in the prepaid envelope provided within seven days.

I will then contact you to arrange the first visit to complete the questionnaires.

What are the benefits of taking part?

It is hoped that the information gathered during this study will provide an understanding of the day-to-day lives of people with leg ulceration and may help to shape the care that is delivered in the future.

What are the possible disadvantages or risks of taking part?

There are no expected disadvantages or risks associated with taking part in this study.

What if something goes wrong?

I do not expect any problems to arise during this study.

If you have a concern about any aspect of this study, you should speak to me, Julie Green, and I will do my best to answer your questions. I can be contacted on 01782 679605.

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:- Nicola Leighton, Research Governance Officer, Research & Enterprise Services, Dorothy Hodgkin Building, Keele University, ST5 5BG.

Will my taking part be kept confidential?

All of the information collected during this study will be kept strictly confidential.

Your name and address will be removed from all documents and any other identifying information, including the consent form, will be kept in a locked drawer in a lockable office. Some information may be stored on a computer, but this will be protected by a password known only to myself.

What will happen to the results of the research study?

This research will form part of a PhD study. No one will be identifiable in this piece of work.

Who is organising and funding this research?

This research is a student project for a PhD. It has no funding available from any organisations or drug companies. Most of the work will be done in the researchers own time.

Thank you for your time in reading this information sheet.

If you agree to take part in this study then please complete the enclosed consent form and return in the prepaid envelope provided within seven days.

Many thanks,
Julie Green



KEELE UNIVERSITY

District Nurse Information Leaflet.

Version 5, Date: 04/10/11.

LREC Number: 11/WM/0264.

Study Title:

Chronic venous leg ulceration and health related quality of life – pilot study.

You are invited to take part in a research study.

Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with your colleagues.

If there is anything that is not clear or if you would like more information, please feel free to contact Julie Green at the School of Nursing and Midwifery, Keele University on 01782 679605.

What is the purpose of the study?

Leg ulceration affects many thousands of people in the UK. Dressing products and techniques are regularly reviewed but the impact of the ulceration on the day-to-day life of the sufferer is often overlooked. This research aims to explore the lived experience of a number of patients who suffer from leg ulcers.

Why have I been chosen?

You have been selected to take part in the study because you regularly see patients with leg ulceration. This selection has included all of the District Nursing Teams within your Primary Care Trust.

Do we have to take part?

You are free to decide if you wish to take part or not.

If you do decide to take part, please complete the enclosed consent form and return it in the prepaid envelope provided, ideally within seven days.

If you do not wish to take part, please simply destroy the enclosed literature.

What will happen if we take part?

If you decide to take part, I will arrange a short visit to explain your involvement in the study, at a time convenient to you.

I will then ask you to distribute a study pack to all of patients on your caseload who suffer from chronic venous leg ulceration. I will visit the patients who consent at the start of the study and after 6 weeks, to undertake baseline scores of patient satisfaction and quality of life.

I will then arrange to visit and train you and other consenting team members to implement a newly developed patient consultation template, developed as a result of earlier research that explored the day-to-day experiences of leg ulcer patients.

This training will take between 90-120 minutes and will be delivered at a time convenient to you. Following this training and during the next 12 weeks of the study, members of staff from your team, who have agreed to take part, will implement the consultation template during each visit to the consented patients.

Again all of the patients selected, with their consent, will complete patient satisfaction and quality of life questionnaires during a short visit from me after 6 weeks and finally after the 12 weeks. During these visits, in the unlikely event of distress about nursing care or poor practice being disclosed I will be duty bound to report this, in accordance with the requirements of the Code of Conduct (NMC, 2008).

What do we have to do?

If you decide to take part in the study, please complete and return the enclosed consent form in the prepaid envelope provided within seven days. I will then contact you to make arrangements to meet with you.

What are the benefits of taking part?

It is the aim that the information gathered from this study will determine whether focussing consultations for people with chronic ulceration on factors they deem to be important improves their health related quality of life and satisfaction. This, however, is not a guaranteed outcome.

What are the possible disadvantages or risks of taking part?

There are no expected disadvantages or risks associated with taking part in this study.

What if something goes wrong?

I do not expect any problems to arise during this study.

If you have a concern about any aspect of the study, you should speak to me, Julie Green, and I will do my best to answer your questions. I can be contacted on 01782 670605.

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:- Nicola Leighton, Research Governance Officer, Research & Enterprise Services, Dorothy Hodgkin Building, Keele University, ST5 5BG.

Will my taking part be kept confidential?

All of the information collected during this study will be kept strictly confidential.

Your name and address will be removed from all documents and any other identifying information, including the consent form, will be kept in a locked drawer in a lockable office. Some information may be stored on a computer, but this will be protected by a password known only to myself.

What will happen to the results of the research study?

This research will form part of a PhD study. No one will be identifiable in this piece of work.

Who is organising and funding this research?

This research is a student project for a PhD and has been funded by a West Midlands Strategic Health Authority Award.

Thank you for your time in reading this information sheet.

If you agree to take part in this study, please complete the enclosed consent form and return in the prepaid envelope provided within seven days.

Many thanks,
Julie Green.



K E E L E
U N I V E R S I T Y

Patient Consent Form.

Version 5, Date: 04/10/11.
LREC Number: 11/WM/0264.

Title of Project: Does a patient focus to consultations in chronic venous leg ulcer care improve patient satisfaction and health related quality of life – pilot study?

Name of Researcher: Julie Green.

Please Tick.

1. I confirm that I have read and understood the information leaflet and have had the opportunity to ask questions.....

☐

2. I understand that my participation is voluntary, that I can refuse to answer a question, or withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.....

☐

3. I am happy for the researcher to visit me, at a time convenient to me, in order to complete some brief questionnaires.....

☐

4. I agree to take part in the above study.....

☐

5. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records.....

☐

Please sign and date on the line below:

Name of Patient

Date

Signature

Name of Researcher

Date

Signature

Please provide me with your contact details below:

Your full name, address and telephone number.

Name:.....

Address:.....

.....

.....

.....

Telephone number:.....

Thank you for your help with this research study.

If you have any further questions about this study, you can telephone me, Julie Green, on 01782 679605.



K E E L E
U N I V E R S I T Y

District Nurse Consent Form.

Version 6, Date: 04/10/11.
LREC Number: 11/WM/0264.

Title of Project: Does a patient focus to consultations in chronic venous leg ulcer care improve patient satisfaction and health related quality of life – pilot study?

Name of Researcher: Julie Green.

Please Tick.

1. I confirm that I have read and understood the information leaflet and I have had the opportunity to ask questions.....

☐

2. I understand that my participation is voluntary, that I can refuse to answer a question or withdraw at any time, without giving a reason.....

☐

3. During the study, venous leg ulcer patients identified within my District Nursing caseload will be contacted to complete a number of questionnaires at 6 weekly intervals over 18 weeks. I agree to distribute study packs to patients with venous leg ulceration on the caseload.....

☐

4. I understand that I will be trained to implement the new consultation template which will then be used on a weekly basis with the patient participants, over a 12 week period.....

☐

5. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records.....

☐

Name of District Nurse Date Signature

Name of Researcher Date Signature

Please provide me with your work contact details below:

Your full name, work address and telephone number.

Name:.....

Work Address:.....

.....

.....

.....

Work Telephone number:.....

Thank you for your help with this research study.

If you have any further questions about this study, you can telephone me, Julie Green, on 01782 679605.

Appendix 25

Phase 3 Tests for Normality.

Appendix 25: Tests for normality.

In order to decide the appropriate statistical analysis to apply to the study data it was necessary to assess the distribution of scores for their normality. If normality is demonstrated, parametric testing can be undertaken as opposed to the non-parametric equivalents, which are deemed to be less powerful. SPSS (IBM, xxxx) allows such exploration via the Explore command and the chart below is generated (Pallant, 200x).

The Shapiro-Wilk Test of Normality is deemed to provide the more accurate assessment of normality where sample sizes are small, as is the case with this pilot study ($n=9$). Normality is assessed via its significance value. Where the Sig. value for this test is greater than 0.05, thus non-significant, the data are said to demonstrate normal distribution. If the significance is below 0.05, the data deviate significantly from normal distribution.

When reviewing the results for the first data collection point (M1) for phase 3 using the Shapiro-Wilk Test of Normality; of the 13 scores generated, seven scores demonstrate normality and 6 deviate from normality. Although the parametric tests are more powerful than their non-parametric alternative, in such situations where results are variable in terms of their normality, it is always deemed acceptable to apply the non-parametric tests.

Table 1: Tests for Normality.

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
CONSULTATION SATISFACTION QUESTIONNAIRE - GENERAL SATISFACTION	.242	9	.136	.819	9	.033
CONSULTATION SATISFACTION QUESTIONNAIRE - PROFESSIONAL CARE	.312	9	.012	.724	9	.003
CONSULTATION SATISFACTION QUESTIONNAIRE - DEPTH OF RELATIONSHIP	.308	9	.014	.748	9	.005
CONSULTATION SATISFACTION QUESTIONNAIRE - PERCEIVED TIME	.300	9	.019	.729	9	.003
PHYSICAL COMPONENT SUMMARY	.163	9	.200*	.946	9	.643
MENTAL COMPONENT SUMMARY	.183	9	.200*	.972	9	.908
EQ 5D 5L CROSSWALK SCORE	.144	9	.200*	.948	9	.666
EQ 5D 5L VAS SCORE	.257	9	.088	.805	9	.023
CWIS QOL SCORE	.227	9	.199	.926	9	.447
CWIS QOL SATISFACTION SCORE	.150	9	.200*	.943	9	.614
CWIS WELL-BEING SCORE	.190	9	.200*	.946	9	.649
CWIS PHYSICAL SYMPTOMS & DAILY LIVING SCORE	.159	9	.200*	.930	9	.485
CWIS SOCIAL LIFE SCORE	.300	9	.019	.815	9	.030

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Appendix 26

Paired difference over the control period.

Appendix 26: Paired difference over the control period, % and actual change during Phase 3.

	CSQGS	CSQPC	CSQDR	CSQPT	PCS	MCS	EQ5D	EQVAS	CWIS QoL	CWIS sat	CWIS WB	CWIS PS	CWIS SL
L4P1	+ 9% (8.33)	-5% (-5)	0% (0)	0% (0)	+11.68% (+4.3)	+10.16% (+5.14)	-10.97% (-0.062)	+15.38% (+10)	+16.67% (+1)	+12.5% (-1)	-12.49% (-7.14)	+31.82% (+21.88)	+16.67% (14.29)
L4P2	0% (0)	0% (0)	+5.27% (+5)	0% (0)	+54.94% (+10.56)	-17.85% (-13.57)	-19.58% (-0.159)	+65.5% (+25)	-25% (-2)	-44.45% (-4)	+26.58% (+13.29)	+7.23% (+6.25)	+9.8% (+8.93)
L4P3	0% (0)	0% (0)	0% (0)	0% (0)	+60.22% (+17.73)	+0.08% (+0.05)	-7.5% (-0.061)	0% (0)	0% (0)	0% (0)	+155.6% (+50)	0% (0)	+9.8% (+8.93)
L4P5	0% (0)	0% (0)	0% (0)	+9.08% (+8.33)	+2.33% (+0.98)	-12.25% (-5.11)	-12.6% (-0.08)	+7.14% (+5)	-20% (-1)	-87.5% (-7)	+151.5% (+21.51)	+34.05% (+16.67)	+4.35% (+3.57)
L5P1	-37.5% (-25)	0% (0)	0% (0)	-16.67% (-16.67)	-43.14% (-14.55)	+63.25% (+23.32)	-42.55% (-0.197)	0% (0)	+40% (+2)	+133.3% (+4)	-26.17% (-19.63)	-44.44% (-33.33)	-51.79% (-51.79)
L5P2	-50% (-25)	+4.35% (+3.57)	-6.25% (-5)	+25% (+8.34)	-22.45% (-10.22)	+122.6% (+16.29)	-7.12% (-0.042)	+9.1% (+5)	+60% (+3)	+37.5% (+3)	+30.02% (+10.72)	-21.94% (-9.37)	+6.27% (+1.79)
L5P3	+14.3% (8.34)	+16.66% (+10.71)	0% (0)	0% (0)	-15.64% (-5.99)	+8.71% (+5.07)	+130% (+0.464)	+25% (+15)	0% (0)	-33.34% (-2)	+75.01% (+21.43)	+16.25% (+13.54)	0% (0)
L5P4	-40% (-33.33)	-51.17% (-48.57)	-52.63% (-50)	-50% (-25)	+37.17 (+7.79)	-45.9% (-17.39)	0% (0)	+1000% (+10)	-300% (-3)	0% (0)	0% (0)	-37.52% (-9.38)	-81.82% (-16.07)

Appendix 27

Additional and subgroup analysis of phase 3 data.

Appendix 27: Additional and subgroup analysis of phase 3 data.

Although more detailed statistical analysis was not planned at the start of the study and caution needs to be applied to any results due to both the small sample size and nature of a pilot study, this additional exploration provides interesting information and may serve to indicate suitable designs for future study.

27.1 Baseline data from the outcome measures.

This section presents the baseline data for the participants derived from data collected at the first time point (M1) (Phase 3 timeline; figure 20, page 244). Where it was felt to be useful, the study population was also reviewed as two separate groups (L4 and L5) but any inferences have been treated with caution in view of the nature of the study and the small sample size (Sim and Lewis, 2011). Where the sample has been explored as two groups, the Mann Whitney U Test has been applied, the non-parametric test for differences between two groups (Pallant, 2007).

27.2 Baseline CSQ data.

Table 1 below provides the mean score and standard deviation for the four categories of the CSQ - general satisfaction, professional care, depth of relationship and length of consultation - for the participants in L4, L5. In addition, established scores from a large primary care study were used for comparison (Shum et al, 2001).

Table 1: Mean and SD scores for baseline CSQ Phase 3 and Shum et al (2001).

	L4 Scores (n=5)	SD	L5 Scores (n=4)	SD	Nurse study (n) (Shum et al, 2001)	SD
General satisfaction (mean)	98.3	3.72	64.58	14.23	78.6 (635)	16.0
Professional care (mean)	98.3	3.72	81.25	13.61	79.2 (662)	13.4
Depth of relationship (mean)	99.0	2.23	77.5	16.58	64.3 (618)	15.7
Length of consultation (mean)	98.3	3.73	64.58	29.17	73.3 (645)	16.9

The standard deviation of these scores represents the variation of distribution (Pallant, 2007). Here it reveals that the L4 study population, the clinic attenders with a single nurse, demonstrated far greater homogeneity (SD range 2.23 - 3.73) when compared to the L5 sample, the traditional home care group (SD range 13.61 - 29.17).

When the raw data was appraised, of the possible 20 scores for this subset of patients, 100% satisfaction was achieved on 17 of these occasions for the L4 participants whereas, for L5, a score of 100% was achieved on only one occasion of the total 16 available. Thus, mean baseline scores for L4 indicate higher levels of satisfaction overall than the L5 group and when compared to the nurse study (Shum et al, 2001). All four subscales reveal lower scores for the L5 patients when compared to L4 baseline scores, although scores for professional care and the depth of relationship were both above the means cited in Shum et al (2001). Mann-Whitney U tests were undertaken in order to establish whether the difference in scores between L4 and L5 were of significance. The test revealed significant differences in:

- General satisfaction outcome of L4 ($Md=100$, $n=5$) and L5 ($Md=62.5$, $n=4$), $U=0.000$, $z=-2.56$, $p=0.011$, $r=0.85$.
- Professional care outcome of L4 ($Md=100$, $n=5$) and L5 ($Md=82.14$, $n=4$), $U=0.000$, $z=-2.3$, $p=0.007$, $r=0.65$.
- Depth of relationship outcome of L4 ($Md=100$, $n=5$) and L5 ($Md=80$, $n=4$), $U=0.500$, $z=-2.45$, $p=0.014$, $r=0.67$.
- The test also revealed a difference in the perceived time outcome, but this was not deemed to be of statistical significance. L4 ($Md=100$, $n=5$) and L5 ($Md=62.5$, $n=4$), $U=3.0$, $z=-1.88$, $p=0.060$, $r=0.62$.
-

Baseline CSQ scores demonstrate that L4 were consistently more satisfied with their care than both L5 and Shum et al (2001).

27.3 Baseline SF-12 data.

The SF12 results provide the physical and mental health composite scores (PCS and MCS) that have established UK norms (Gandek et al, 1998). When the participants were treated as a single group ($n=9$) and means compared to the UK norm (Gandek et al, 1998), a comparison of PCS and MCS outcomes was again undertaken using the Mann-Whitney U test in order to detect whether differences were of significance (table 2 below). The test revealed:

- No significant difference in the PCS of the overall sample ($Md=32.05$, $n=9$) and the UK norm ($Md=50.9$, $n=1751$), $U=0.000$, $z=-1.00$, $p=0.317$, $r=-0.706$.
- No significant difference in the MCS of the overall sample ($Md=46.92$, $n=9$) and the UK norm ($Md=52.1$, $n=1751$), $U=0.000$, $z=-1.00$, $p=0.317$, $r=-0.18$.

Table 2: Mean and SD scores for baseline SF-12 Phase 3 and Gandek et al (1998).

	All Scores (n=9)	SD	Gandek et al (1998) (n=1751) UK norm scores.	SD
PCS-12 (mean)	32.05	9.5	50.9	9.4
MCS-12 (mean)	46.92	17.99	52.1	8.7

Baseline scores are displayed in table 3 below and reveal both L4 and L5 to have substantially lower PCS-12 scores at 29.99 and 34.6 respectively, when compared to the UK norm score (Gandek et al, 1998) of 50.9. In contrast, the L4 MCS-12 value (55.21) was higher than both the UK norm (Gandek et al, 1998) (52.1) and the L5 score, which at 36.55 was significantly below the norm.

Table 3: Mean and SD scores for baseline SF-12 Phase 3 and Gandek et al (1998).

	L4 Scores (n=5)	SD	L5 Scores (n=4)	SD	Gandek et al (1998) (n=1751) UK norm scores.	SD
PCS-12 (mean)	29.99	9.53	34.63	10.33	50.9	9.4
MCS-12 (mean)	55.21	14.18	36.55	18.35	52.1	8.7

These results demonstrate poorer physical functioning than the UK norm for both groups. Also, reduced mental functioning for the L5 group. In contrast, mental functioning above that of the UK norm was demonstrated at baseline for the L4 participants.

When the participants were treated as two independent groups, a comparison of PCS and MCS outcomes was undertaken, again using the Mann-Whitney U test, in order to detect whether any of these differences were of significance. The test revealed:

- No significant difference in the PCS of L4 ($Md=100$, $n=5$) and L5 ($Md=62.5$, $n=4$), $U=7.0$, $z=-0.735$, $p=0.462$, $r=-0.23$.
- A difference in MCS, but did not deem this to be of statistical significance, between L4 ($Md=100$, $n=5$) and L5 ($Md=82.14$, $n=4$), $U=3.0$, $z=-1.715$, $p=0.086$, $r=0.49$.

Table 4 below displays age-matched PCS and MCS scores for the sample as a whole ($n=9$) and demonstrates that the lowest overall scores for both of these outcomes was in the under 45 years age range, demonstrating severely compromised PCS (21.72) and compromised MCS (41.35) when compared to other age ranges and the UK norm (Gandek et al, 1998).

Table 4: Comparison of SF-12 PCS & MCS scores with age-matched general population.

Age (banded)	N	SF-12 PCS & MCS Mean Values.		Population Value. (Gandek et al, 1998)	
		PCS Mean	MCS Mean	PCS Mean	MCS Mean
Under 45	2	21.72	41.35	53.4	52.2
46 - 64	1	42.0	41.71	48.7	51.4
65 – 74	4	34.57	52.14	44.8	53.2
Over 75	2	32.38	44.66	Not available.	

Baseline SF-12 data demonstrates that L4 participants were the most physically compromised, but both groups fall below the UK norm. In contrast L4 displayed greater mental functioning than both L5 and UK

values. The younger patients were, overall, more compromised in physical and mental health than other age ranges and the UK values (Gandek et al, 1998).

27.4 Baseline EQ-5D data.

The scores from the EQ-5D provide a Crosswalk score for the EQ Index value and a visual assessment scale score (VAS) are recorded in table 5 below. This instrument is again well used with established UK norms. Baseline scores for both L4 and L5 are below the EuroQol (1990) published data (0.76) (table 5 below). L5 is particularly compromised at 0.362. Again, both L4 and L5 demonstrated compromised EQ VAS scores at 59 and 41.25 respectively compared to a population norm of 84 (EuroQol, 1990).

Table 5: Mean and SD scores for baseline EQ-5D Phase 3 and EuroQol Group (1990).

	L4 Scores (n=5)	SD	L5 Scores (n=4)	SD	EuroQol (1990) (n=110)	SD
EQ Index Value (mean)	0.63	0.21	0.362	0.24	0.76	0.015 (Standard error)
EQ VAS (mean)	59.0	13.416	41.25	27.8	84.0	12.6 SD

Applying the Mann-Whitney U test in order to detect the significance of these differences revealed:

- No significant difference in the EQ Index Value between L4 ($Md=.635$, $n=5$) and L5 ($Md=.41$, $n=4$), $U=4.0$, $z=-1.476$, $p=0.140$, $r=0.51$.
- No significant difference in EQ VAS score between L4 ($Md=65.0$, $n=5$) and L5 ($Md=52.5$, $n=4$), $U=5.500$, $z=-1.112$, $p=0.266$, $r=0.377$.

As with the SF-12, when the results were reviewed in terms of age range (table 6), the under 45 years were most severely compromised at 0.173 compared to a population value for that age range of 0.9 (Dolan, 1997).

Table 6: Comparison of EQ-5D scores with age-matched general population.

Age (banded)	N	EQ-5D Crosswalk Utility Mean Value	Population Value (Dolan, 1997)
Under 45	2	0.173	0.90
46 - 64	1	0.635	0.82
65 – 74	4	0.55	0.78
Over 75	2	0.702	0.73

A review of baseline data for EQ-5D scores demonstrated compromised scores for both L4 and L5, with the L5 participants being the most severely compromised. Again, those under 45 demonstrated the greatest deficits.

27.5 Baseline CWIS data.

The CWIS provides five areas of scoring: physical symptoms, social life, well-being along with two HRQoL measures, global HRQoL and participant satisfaction with their HRQoL. Table 7 below provides a comparison of means for L4, L5 and established scores derived from Price and Harding's (2004) data.

Table 7: Mean and SD scores for baseline CWIS Phase 3 and Price and Harding (2004).

	L4 Scores (n=5)	SD	L5 Scores (n=4)	SD	Non-healed (n=89) (Price & Harding, 2004)
Physical symptoms (mean)	70.68	24.99	56.51	27.35	71.7
Social life (mean)	78.93	19.54	62.05	43.97	76.1
Well-being (mean)	36.41	17.23	37.5	27.12	38.7
Global HRQoL (mean)	6.2	1.30	5.0	1.63	6.9
Satisfaction with HRQoL (mean)	7.2	1.92	3.25	2.36	6.7

Baseline scores for L4 indicate higher levels of functioning in the areas of physical symptoms and everyday living, when compared to both L5 patients and for the Price and Harding (2004) study. L5 scores for all three subscales, physical functioning, social life and well-being, are all lower when compared to Price and Harding's (2004) data. Global HRQoL has the highest values in Price and Harding (2004) study at 6.9. L4 participants generated a mean of 6.2 for their global HRQoL whereas L5 was more compromised in this area with a score of 5.0. The L4 participants were most satisfied with their HRQoL (7.2), followed by Price and Harding (2004) at 6.7. L5 patients were much less satisfied with their HRQoL at baseline with a score of only 3.25.

Where the participants were treated as two independent groups and the five outcomes compared using the Mann-Whitney U test in order to detect the significance of any differences, the test revealed:

- No significant difference in the physical symptoms outcome of L4 ($Md=68.75$, $n=5$) and L5 ($Md=58.85$, $n=4$), $U=7.000$, $z=-0.735$, $p=0.462$, $r=0.261$.
- No significant difference in the social life outcome of L4 ($Md=85.71$, $n=5$) and L5 ($Md=64.29$, $n=4$), $U=10.000$, $z=0.000$, $p=1.0$, $r=0.24$.

- No significant difference in the well-being outcome of L4 ($Md=32.14$, $n=5$) and L5 ($Md=32.14$, $n=4$), $U=9.50$, $z=-0.123$, $p=0.902$, $r=-0.024$.
- No significant difference in the global HRQoL outcome between L4 ($Md=6$, $n=5$) and L5 ($Md=5$, $n=4$), $U=5.50$, $z=-1.157$, $p=0.247$, $r=0.38$.
- The test did however reveal a significant difference in satisfaction with the HRQoL outcome between L4 ($Md=8$, $n=5$) and L5 ($Md=4$, $n=4$), $U=2.0$, $z=-1.976$, $p=0.048$, $r=0.68$, demonstrating that the L4 participants were more satisfied with their HRQoL.

A review of CWIS data revealed that L4 had improved functioning in physical symptoms and social life when compared to the L5 participants, but reduced well-being. Global HRQoL and participant satisfaction with their HRQoL was compromised for the L5 participants.

When reviewing CWIS, QoL and satisfaction with QoL were noticeably diminished for the younger participants. Paul (34), who lived alone, in L4 revealed a QoL score of 5 and a satisfaction of 4 and Cath (45), who lived with her supportive family, in L5 a QoL score of 3 and a satisfaction score of 0 at the first data collection point.

27.6 Summary of baseline data.

This section has provided a review of the baseline scores for all outcome measures for phase 3 participants and compared these to established UK norm scores, where available. This data has provided an insight into the characteristics of the study population at the start of this quantitative phase. Mann Whitney U Tests were applied in order to establish whether L4 and L5 data differ significantly at baseline.

Where the participants were treated as two independent groups, L4 and L5, a comparison of all scores at each time point was undertaken using the Mann-Whitney U test in order to detect whether the L4 participants differed from those in the L5 group.

Mann Whitney U Test M1.

Table 8: Mann Whitney U Test of all scores between L4 and L5 at M1.

	<i>U</i>	<i>Z</i>	<i>p</i>	<i>r</i>	<i>Md Grp 1</i>	<i>Md Grp 2</i>
CSQ – GS	0.00	-2.558	0.01	0.85	100	62.5
CSQ – PC	0.00	-2.697	0.01	0.9	100	82.14
CSQ – DR	0.5	-2.453	0.01	0.82	100	80.0
CSQ – PT	3.0	-1.878	0.06	0.62	100	62.5
PCS	7.0	-0.735	0.46	0.25	29.44	36.02
MCS	3.0	-1.715	0.09	0.57	50.57	37.38
EQ5D Cross	4.0	-1.476	0.14	0.49	0.635	0.41
EQ5D VAS	5.5	-1.112	0.27	0.37	65.0	52.50
CWIS QoL	5.5	-1.157	0.25	0.39	6.0	5.0
CWIS Satis	2.0	-1.976	0.05	0.66	8.0	4.0
CWIS WB	9.5	-0.123	0.9	0.04	32.14	32.14
CWIS PS	7.0	-0.735	0.46	0.25	68.75	58.85
CWIS SL	10.0	0.000	1.0	0	85.71	64.28

Table 8 above demonstrates that three of the four composite scores (general satisfaction, professional care, depth of relationship) of the CSQ demonstrated a statistically significant difference between the L4 participants and those in the L5 group, with L4 demonstrating higher levels of satisfaction when compared to

L5. In addition the CWIS satisfaction with QoL also demonstrated a statistically significant difference between the L4 and L5 participants, with the L4 participants being more satisfied with their QoL score than L5.

27.8 Mann Whitney U Test M2.

Table 9: Mann Whitney U Test of all scores between L4 and L5 at M2.

	<i>U</i>	<i>Z</i>	<i>p</i>	<i>r</i>	<i>Md Grp 1</i>	<i>Md Grp 2</i>
CSQ – GS	0.000	-2.588	0.01	0.86	100.0	45.84
CSQ – PC	0.000	-2.588	0.01	0.86	100.0	78.57
CSQ – DR	0.000	-2.588	0.01	0.86	100.0	65.0
CSQ – PT	0.000	-2.57	0.01	0.86	100.0	58.34
PCS	6.0	-0.98	0.33	0.33	32.5	30.5
MCS	8.0	-0.49	0.62	0.16	55.71	44.885
EQ5D Cross	8.0	-0.49	0.62	0.16	0.555	0.407
EQ5D VAS	5.5	-1.126	0.26	0.38	70.0	55.0
CWIS QoL	7.0	-1.126	0.44	0.38	6.0	7.0
CWIS Satis	10.0	0.000	1.0	0	5.0	5.0
CWIS WB	7.5	-0.615	0.54	0.21	50.00	48.2
CWIS PS	7.0	-0.738	0.46	0,25	90.63	37.5
CWIS SL	3.5	-1.663	0.1	0.54	100.0	39.285

Table 9 demonstrates that when the Mann Whitney U Test was repeated at M2, all four composite scores of the CSQ (general satisfaction, professional care, depth of relationship and perceived time) demonstrated a statistically significant difference between L4 and L5, with L4 being more satisfied at each time point compared to L5.

At M3 just two of the composite scores (depth of relationship and perceived time) of the CSQ and the PCS scores demonstrated a statistically significant difference between L4 and L5, with L4 again being more satisfied at each time point when compared to L5 and also having a higher physical functioning composite score (table 10 below).

Table 10: Mann Whitney U Test between groups at M3.

	<i>U</i>	<i>Z</i>	<i>p</i>	<i>R</i>	<i>Md Grp 1</i>	<i>Md Grp 2</i>
CSQ – GS	0.000	-2.697	0.07	0.9	100.0	54.17
CSQ – PC	5.00	-1.677	0.09	0.6	100.0	82.15
CSQ – DR	0.000	-2.683	0.01	0.89	100.0	57.5
CSQ – PT	2.500	-2.196	0.03	0.73	100.0	4.165
PCS	2.00	-1.96	0.05	0.653	40.48	27.445
MCS	4.00	-1.47	0.14	0.49	57.47	40.655
EQ5D Cross	7.00	-0.738	0.46	0.25	0.654	0.464
EQ5D VAS	6.500	-0.878	0.38	0.29	70.0	45.0
CWIS QoL	9.500	-0.135	0.89	0.05	7.0	6.0
CWIS Satis	4.00	-1.535	0.13	0.51	7.0	5.0
CWIS WB	10.00	0.0	1.0	0	60.71	44.645
CWIS PS	7.00	-0.735	0.46	0.25	80.36	44.275
CWIS SL	6.00	-0.997	0.32	0.33	94.64	54.46

Finally, at M4 two of the composite scores (general satisfaction and perceived time) of the CSQ continued to demonstrate a statistically significant difference between L4 and L5, with L4 being more satisfied at this time point compared to L5 (table 11 below).

Table 11: Mann Whitney U Test between groups at M4.

	<i>U</i>	<i>Z</i>	<i>p</i>	<i>r</i>	<i>Md Grp 1</i>	<i>Md Grp 2</i>
CSQ – GS	0.000	-2.697	0.01	0.9	100.0	70.84
CSQ – PC	3.00	-1.878	0.06	0.63	100.0	83.93
CSQ – DR	3.00	-1.878	0.06	0.63	100.0	70.0
CSQ – PT	0.000	-2.683	0.01	0.9	100.0	50.0
PCS	8.00	-0.49	0.62	0.16	35.64	30.01
MCS	9.00	-0.2545	0.81	0.08	45.07	47.255
EQ5D Cross	7.00	-0.735	0.46	0.25	0.65	0.48
EQ5D VAS	10.00	0.00	1.0	0	60.0	60.0
CWIS QoL	6.50	-0.876	0.38	0.29	7.0	5.5
CWIS Satis	9.00	-0.254	0.8	0.08	7.0	5.0
CWIS WB	8.00	-0.49	0.62	0.16	50.00	50.00
CWIS PS	7.50	-0.615	0.54	0.21	91.66	54.17
CWIS SL	4.50	-1.407	0.16	0.47	100.00	66.08

These Mann Whitney U scores demonstrate overall differences between L4 and L5 in relation to the composite scores of the CSQ at all four time points, with a large effect size, demonstrating increased satisfaction with all areas of care for the L4 participants at each time point.

Appendix 28

Phase 3 Staff Questionnaire.

QUALITY OF LIFE & LEG ULCERATION – STAFF QUESTIONNAIRE.

Please complete this questionnaire and return in the stamped addressed envelope provided.
Thank you.

You have recently been involved in using a new consultation template with your chronic venous leg ulcer patients. These questions will help to evaluate the effectiveness of this template.

1. Was the model consultation template useable?

Yes: ☐ No: ☐

Comments:

2. How long did it take to complete?

Comments:

3. Did you use the template during each patient consultation?

Yes: ☐ No: ☐

Comments:

4. Do you feel that the template had an impact on the consultation?

Yes: ☐ No: ☐

Comments:

PhD Project LREC Approval:

Any queries please contact Julie Green 01782 679605.

5. If so, was this impact positive or negative?

Positive: ☐ Negative: ☐

Comments:

6. How could the template be improved?

Comments:

Appendix 29

Conference Presentations.

Conference Presentations.

Regional Conference Presentations:

Green, J. (2010). *"My leg ulcers are ruining my life..."* Poster presented at the Keele University Research Symposium, 5th May 2010.

Green, J. (2012). *Do patient centred consultations improve quality of life for people with chronic venous ulcers?* Institute of Primary Care and Health Sciences Symposium, Keele University 28th May 2012.

National Conference Presentations:

Green, J. (2012). *Patient centred consultations in chronic venous leg ulcer care*. 'Living and Researching Later Life', Emerging Researchers in Ageing Conference, Keele University 10th July 2012.

Green, J. (2012). *Nurse-patient leg ulcer consultations in primary care – do patients disclose their concerns?* Society of Academic Primary Care (North) Conference, Kendal, 22nd November 2012. Winner of Best in Research Award.

Green, J. (2013). *Nurse-patient leg ulcer consultations in primary care – do patients disclose their concerns?* Ageing Conference, Aston University, Birmingham, 25th April 2013.

International Conference Presentations:

Green, J. (2010). *'Chronic venous leg ulcers and quality of life'*. Poster presented at Wounds UK Conference, Harrogate, 15 - 17th November 2010.

Green, J. (2011). *What are the factors that impact on the day-to-day lives of people with leg ulcers?* Concurrent session presented at the Royal College of Nursing International Research Conference, Harrogate 17th May 2011.

Green, J. (2011). *Are we missing the point? What factors impact on the daily lives of people with leg ulcers and do we currently address these during their consultations?* Free Paper presented at Wounds UK Harrogate, 15th November 2011.

Green, J. (2012). *The application of the nominal group technique in the design of a consultation template for use with patients with leg ulceration*. Concurrent session presented at the Royal College of Nursing International Research Conference, London 24th April 2012.

Green, J. (2012). *Nurse-patient leg ulcer consultations in primary care – do patients disclose their concerns?* Wounds UK Patient Wellbeing winning presentation, 13th November 2012.

Green, J. (2013). *Nurse-patient consultations in primary care*. Transforming Community Health International Conference, Edinburgh, 13-14th March 2013.

Green, J. (2013). *Nurse-patient leg ulcer consultations in primary care – do patients disclose their concerns?* European Wound Management Association Conference, Copenhagen, 15th May 2013.

Appendix 30

Publications from the study.

Health-related quality of life and chronic venous leg ulceration: part 1

Julie Green, Professor Rebecca Jester

Julie Green is a Lecturer in Nursing and Professor Rebecca Jester is Head of School, Keele University.

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Many thousands of people in the UK are affected by leg ulceration, mainly as a consequence of chronic venous insufficiency, with annual costs for care conservatively estimated to be in the region of £200 million (Posnett and Franks, 2007). The personal cost to the sufferer is consistently underestimated, misunderstood and often simply overlooked (Rich and McLachlan, 2003).

Over the course of the last 20–30 years there has been a developing interest in the concept of health-related quality of life (HRQoL) – the self-reported appraisal of health in physical, psychological and social domains – of patients in all areas of health-care delivery (Bowling, 2005). Such increasing interest is attributed to factors such as the changing roles of health professionals, the growth of evidence-based practice and the development of patient empowerment which have heightened our need to gauge the effects of chronic illness and treatment on the day-to-day lives of the sufferer (O’Boyle, 2008). In the area of chronic venous leg ulceration, research unequivocally demonstrates a decline in the HRQoL, with many patients suffering from ulceration for extended periods (Franks and Moffatt, 2001).

Literature search

A systematic search strategy was implemented to identify studies that investigated HRQoL and venous leg ulceration, and 21 studies were found to comply with the search criteria; 14 of the studies were quantitative and 8 were qualitative in their design. These studies were analysed for themes which included pain, sleep disturbances, social isolation and loneliness. The qualitative approach enhances our insight into the patients’ own experiences of life with venous ulceration

and are presented here in part 1 of this two-part series. Those studies that have approached the subject from a quantitative design are presented in a second article.

Physical functioning Pain

Pain is the most frequently reported symptom of leg ulceration and was highlighted by every study reviewed, irrespective of study design. A factor in direct contrast with earlier published research that suggested that pain was not associated with venous ulceration (Roe et al, 1993). Pain was often exacerbated during dressing changes and was reported to be inadequately managed on occasions (Hollinworth and Collier, 2000; Douglas, 2001).

The qualitative studies selected all gave sufferers the opportunity to talk freely about their symptoms and this exposed the enormity of the problem. Walshe (1995) undertook semi-structured interviews with 13 patients suffering from venous ulceration and found pain to be an overwhelming feature that profoundly affected the life of the sufferer. Participants described pain as a constant reminder of their ulceration, which was unremitting and contributed to their feelings of a loss of control. Difficulties controlling the pain were also a factor, with analgesia being deemed ineffective against ulcer-related pain. The short duration of the study and purposeful nature of the sampling may limit the validity of the responses elicited.

Chase et al (1997) conducted a comparatively large qualitative study (n=37) of venous ulcer patients over a 12-month period using participant observation at weekly dressing changes. They described the unique nature of the chronic pain related to venous ulceration, with, as described by Walshe (1995), the ulcer constituting a constant reminder of the disease process.

Ebbeskog and Ekman (2001) conducted a hermeneutic phenomenological study of 15 elderly patients in Sweden who were suffering from venous leg ulceration. The short duration of the study may have limited the results but they reported that the pain, when present, was central to the life of participants, it controlled their existence making them sad, angry and made them cry in despair.

Mobility and daily living

Walshe (1995) reported major restrictions to participants’ mobility, a symptom attributed primarily to ulcer-related

ABSTRACT

Leg ulceration is a debilitating condition characterized by long periods of ulceration and a high incidence of recurrence. The quality of life of sufferers is compromised by many issues including pain and social isolation. Day-to-day care focuses predominantly on the provision of wound care, often with limited attention to the wide-ranging effects that the ulceration poses to the life of the sufferer. Part 1 of this two-part series provides a review of qualitative studies that explore the health-related quality of life of patients with chronic venous leg ulceration. Part 2 will be published in the June 2010 Wound Care Alliance supplement.

KEY WORDS

• Venous ulceration • Leg ulcers • Health-related quality of life



pain (Hyland et al, 1994). Such reduced mobility was often complicated by the leakage of exudate from the dressing and the associated odour. In Walshe's (1995) study (n=13), most respondents were virtually housebound, features attributed either directly to their ulceration or self-imposed to avoid recurrence of healed ulceration.

Douglas (2001) used a grounded theory approach with 8 venous ulcer patients. The participants underwent semi-structured interviews on a single occasion. Participants reported their inability to maintain their personal hygiene which affected wellbeing and contributed to their social isolation. Such difficulties relating to the maintenance of personal hygiene featured in a number of the studies, with patients reflecting on when they last had their feet washed or had bathed and the difficulties that personal hygiene issues caused (Ebbeskog and Ekman, 2001).

Problems finding adequate, comfortable footwear and clothing that would conceal the dressings was also frequently reported (Rich and McLachlan, 2003). Indeed Hyde et al (1999), in their Australian study of female participants with chronic leg ulceration, found respondents modified their clothing to conceal their ulceration and referred to such limitations as yet another restriction to their personal style and a further erosion to their femininity. Such single-gender studies are unusual but the nature of the participants' responses provides an informative and enlightening viewpoint.

Sleep

Walshe (1995) reported that sleep disturbances were a prevailing feature for leg ulcer patients, again attributed to ulcer-related pain. Participants frequently reported that it was rare to experience a full night of sleep. Douglas (2001) saw these limitations to sleep as significant, owing to the role of sleep in effective tissue regeneration. Ebbeskog and Ekman (2001) similarly reported the problem of sleep loss caused by ulcer pain which resulted in day-time tiredness and a lack of strength and energy.

Exudate and odour

Exudate and odour were cited as major symptoms of leg ulceration that are also so often overlooked. Rich and McLachlan (2003) conducted a short, small scale (n=8) phenomenological study, using in-depth, semi-structured interviews. Participants reported that their exudate was profuse and unbearable and that the associated odour was inadequately managed. There were reports of wet shoes, wet bedding and concerns of what people might think – a problem made worse when the patient was working (Douglas, 2001; Hyde et al, 1999).

Participants felt that methods employed to manage exudate were often inadequate, with the odour being described as the 'worst thing' associated with ulceration leading to limited social contacts, increased self-consciousness and a feeling that private matters had become public (Walshe, 1995). Chase et al (1997), similarly reported that malodorous wounds limited the patients' opportunity to have social contact and reported an objectification of the leg by the patient, acting as if the ulcer, and sometimes the leg, did not belong to them.

Jones et al (2008) recently conducted a mixed methods study to investigate the links between depression, exudate and chronic venous leg ulceration. Their study revealed a direct correlation between problematic exudate and the associated odour with depression and anxiety for the sufferer. Their study recommends the need to holistically and sensitively assess the patients' need for treatment, support and advice.

Social functioning

Hopkins (2004) conducted a small-scale (n=5) study of patients with venous ulceration on a single occasion, with an additional completion of a diary over a 2-week period, which demonstrated that leg ulceration had a major impact on social life, especially as a result of exudate and odour. Participants reported that they were often unable to control these upsetting symptoms and feared how people would react. As a result of these concerns, sufferers reported that they would voluntarily exclude themselves from society, in an attempt to avoid the associated embarrassment (Rich and McLachlan, 2003). Ebbeskog and Ekman (2001) also referred to a limitation of social contacts to immediate family and friends, consciously not subjecting others to the symptoms of ulceration. Walshe (1995) reported similar issues, with patients looking forward to an end of ulceration so that they

could initiate social interaction – time was referred to as 'wasted days'.

Chase et al (1997) reported situations where ulceration, exudate and odour had limited participants' ability to work. One gentleman even reported having to finish working owing to his ulcer, a situation he was resigned to, but felt that the ulcer had cost him his freedom and his livelihood. Such employment factors are almost entirely overlooked within the research available, a factor possibly attributed to the prevalence of ulceration in advancing age (Franks and Moffatt, 2007). Despite this, it is essential that the effects the condition has on earnings and livelihood are taken into account when care is planned for leg ulcer patients.

As a direct response to the prevalence of social isolation and depression exhibited by sufferers of ulceration, the concept of the Lindsay Leg Club model of care was conceived. Leg Clubs have been extremely successful in removing the stigma of leg ulceration for sufferers and reintegrating those who are otherwise isolated. Such care delivery, with its collaborative partnership approach, has resulted in many encouraging benefits including improved concordance, positive healing outcomes and reduced recurrence rates (Lindsay, 2004).

Psychological functioning

Hopkins (2004) clearly detected a concept of 'biographical disruption', where a clear distinction was perceived by participants between life before and after ulceration, with a marked effect on their physical and social activity. But despite such feelings of loss, they also had hope for the future. This disparity between hope and expectations was seen as an important part of coping with the condition (Ebbekog and Ekman, 2001). Hyde et al (1999) reported an inner strength held by their participants, a determination to cope, stoicism, resilience and hope for the future, always hopeful that their ulcers would heal.

Many sufferers demonstrated an unhealthy preoccupation with their ulcer, which they felt was constantly in their thoughts. For some, while endeavouring to cope, there was an intentional attempt to normalize the ulceration or to bracket it off in an effort to live a normal life (Hopkins, 2004). Walshe (1995) reported a number of participants (n=13) had difficulties with their self-image, with feelings of self-disgust and pessimism in relation to the likelihood of healing – an uncertainty that was echoed by their nurses. Chase et al (1997) described this lengthy healing process as a 'forever healing', the chronic nature of the wounds impacting on the sufferers daily living and making them almost want to hide their bodies.

Hyland et al's (1994) participants (n=22) described feelings of regret, dysphoria, loss of power, helplessness and a lack of cleanliness. For Douglas (2001) many participants felt there had been a role reversal between themselves and their family, with those who had previously been the head of the family now being dependent on other members for help and support.

Fostering a positive and trusting relationship, continuity

of care and ensuring clear communication with the patient are all reported to assist in the development of a concordant relationship between the patient and the nurse. Such factors enhance the patient's internal locus of control, the extent to which the patient feels in control, and supports their self-efficacy, the patients' belief in their ability to accomplish change (Morris and White, 2007).

Charles (1995) investigated whether her participants had an internal or external locus of control – those with an internal locus assumed an active approach to their ulcer management, believing that they have control over events whereas those with an external locus believe that they are under the control of others. Interestingly, in Charles' (1995) research, even those with an internal locus of control gave up in the face of recurrence and ulcer management issues – in Charles' (1995) opinion they lost their faith.

The fostering of such a therapeutic relationship, with patient empowerment and involvement in care is encouraged, is vital and, research claims, may result in improved healing rates and reduced ulcer recurrence (Dillaway, 2008). Claims clearly reinforced by the Lindsay leg Club approach to care delivery (Lindsay, 2004). In contrast, the negative psychological effects of venous ulceration, owing to pain and sleeplessness, may have a detrimental effect on the patient's feelings of wellbeing, leading to a 'learned helplessness'. If nurses fail to acknowledge the negative factors surrounding chronic venous leg ulceration, patients may become increasingly frustrated, which may potentially delay the healing process (Charles, 1995). Warren and Alstrom (2000) suggest that patient involvement, clear communication and health promotion, all act as a catalyst to patient engagement, as partners, in their treatment regime.

Treatment and the nurse-patient relationship

A high proportion of the care for patients with leg ulcers is provided in the community environment, primarily by district nurses and their role is seen as a significant throughout most studies. For many patients, this relationship was often seen on as the only positive aspects of the process, commenting that nurses went beyond the necessity of their visits and enjoyed a 'laugh and a joke' (Walshe, 1995; Chase et al, 1997). Participants reported feeling confident in their nurses' ability, but feeling less comfortable with agency nurses. Some participants did cite nurses as contributing to their 'wasted days' owing to the need to wait for visits and dressings to be performed. Walshe (1995) reported that participants felt a need to understand their treatment but that they also felt that they wanted to 'hand over' their care to the nurses. Some studies reported inconsistencies in the care provided by nurses, but, despite such reports, participants were still grateful to and trusting of their nursing staff (Hyland et al, 1994). In Rich and McLachlan's (2003) study, participants reported some lack of confidence in nursing staff if there were inconsistencies in treatment provided, but in general, an overall satisfaction with the care provided.

In Douglas' (2001) and Chase et al's (1997) studies,

participants reported a lack of understanding of the causes and treatment of ulceration, which they felt contributed to their feelings of powerlessness. This factor could so easily be remedied by nursing staff. Chase et al (2000), in a further quantitative study, found significant deficits in the knowledge and understanding of patients in relation to their ulceration, concluding that such deficits contribute to reduced self-efficacy and may delay healing. Chase et al (1997) saw this as an important factor that again could be remedied by nurses during their visits, with potentially positive effects on healing.

Implications for clinical practice

This review highlights a number of significant issues that directly impact on the HRQoL of the leg ulcer sufferer with important implications for clinical practice (see Table 1).

In 2006 the Royal College of Nursing (RCN) updated their *Clinical Practice Guidelines* relating to the management of venous leg ulcers (RCN, 2006) outlining best practice in the management of the symptoms that impact on the patients' physical functioning. Factors that impact on the social and psychological functioning of the sufferer are also highlighted with an emphasis on the need for joint decision making in leg ulcer management and the provision of information for patients and carers (RCN, 2006).

Jones et al (2002) found that the emotional distress of patients often goes undetected by those who provide care. Hollinworth and Hawkins (2002), in their study of 50 qualified nurses, demonstrated that feelings of both distress and misery were identified during consultations but these were often overlooked by nurses who were too busy dealing with the clinical aspects of wound management. In order for the care we deliver to be truly holistic, we need to meet all of the needs highlighted by the patient and look beyond merely providing wound management.

Conclusion and recommendations

Qualitative research has the ability to demonstrate an insight into the lives of those studied. Leg ulceration is a debilitating condition and significant, life-limiting symptoms are a common throughout the research presented. Indeed, if the care delivered to patients with leg ulceration is to improve and their distress is to be alleviated, it is essential that the care delivered focuses on those factors that affect the HRQoL of the sufferer, rather than concentrating solely on the management of the wound. It is only when the management of leg ulceration takes a truly holistic approach that the care provided will be optimised.

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Table 1. Key recommendations from the literature

- Effective assessment and management of pain for sufferers of leg ulceration.
- Individualized strategies to effectively manage wound exudate and malodour.
- Comprehensive care pathways for management of leg ulceration (RCN, 2006).
- Collaborative practitioner-patient relationship.
- Patient and carer resources, and educational materials.
- Comprehensive and accessible staff education on leg ulcer management.
- Fostering a patient-focus to leg ulcer consultations.
- Further research on chronic venous leg ulceration and health-related quality of life.

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KEY POINTS

- Chronic venous leg ulceration results in a significant decline in health-related quality of life for the patient.
- Often the nurse has wound healing as central focus in the care that they provide. Much of the research indicates that the needs of leg ulcer sufferers go far beyond their actual wound care.
- Holistic assessment of the needs of those patients suffering from venous leg ulceration is essential if their overall experience is to improve.

Health-related quality of life and chronic venous leg ulceration: part 2

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This article is the second of a two-part series reviewing the effects of chronic venous leg ulceration on the health-related quality of life of the sufferer. Part 1 comprised a review of the qualitative literature (Green and Jester, 2009) and part 2 presents a critique of the quantitative literature related to the impact of leg ulceration on health-related quality of life.

As outlined in part one of this series, leg ulceration currently costs the NHS many millions of pounds and has widespread detrimental effects on the health-related quality of life (HRQoL) of the sufferer (Persoon et al, 2004; Moffatt et al, 2004; Posnett and Franks, 2007). Despite consensus among practitioners of this personal cost to the sufferer, the actual impact that the ulceration poses is poorly understood and often overlooked, with care focussed on wound management rather than the more diverse needs of the patient (Rich and Lachlan, 2003; Persoon et al, 2004).

This literature review aims to synthesize key elements of the quantitative research surrounding the impact of leg ulceration on the HRQoL of the sufferer. Such research, with its focus on quantifying and measuring characteristics, has concentrated on the use of instruments to assess HRQoL, with the respondent subjectively selecting an appropriate response for each of the questions posed. Instruments are either generic in their design, devised to assess the HRQoL of the population in general or disease specific; devised to focus on a particular disease and to be sensitive to precise aspects of that condition.

The generic HRQoL measures are broad-ranging and well established, often having been used extensively with

many disease processes (Bowling, 2005). Generic tools have been used in the area of venous ulceration, most notably the Medical Outcome Study Short Form-36 (SF-36) (Ware and Serbourne, 1992), the Nottingham Health Profile (NHP) (Hunt et al, 1986) and the EuroQol (EQ) (EuroQol Group, 1990). These instruments require the respondent to subjectively rate their perception of their current health status according to a number of pre-defined and rated responses. Such questions include, 'In general, would you say your health is', with the respondent selecting a response from the following: excellent, very good, good, fair or poor (SF-36, Ware and Serbourne, 1992) or 'I'm tired all of the time', with a response of either yes or no (NHP, Hunt et al, 1986).

The disease-specific quality of life questionnaires differ in that they are designed to specifically focus on characteristics of a particular condition and aspire to be responsive to even minor changes in the health of the sufferer (Bowling, 2005). Such disease-specific tools are a growth area, a factor which is often attributed to a growing acknowledgement of the importance of patients' assessments of their health outcomes (Garraff et al, 2002; Haywood, et al, 2004). Development in the area of disease-specific tools has, to date, had a tendency to focus on high-profile conditions, most notably cancer and cardiovascular disease. Some progress has been made in the development of disease-specific tools in the area of tissue viability, especially chronic leg ulceration (Teare and Barrett, 2002). In order for these disease-specific tools to be effective, the validity and reliability of the instrument has to be tested and established along with their practicality, sensitivity and specificity – their ability to identify cases, to evaluate changes in symptoms and reflect the effectiveness of any treatment interventions (Hareendran et al, 2005; Palfreyman, 2007).

A number of the studies reviewed utilise both disease-specific HRQoL tool(s) and generic tool(s) (Iglesias et al, 2005; Palfreyman, 2008; Price and Harding, 2004; Smith et al, 2000). These studies, as a result, have enhanced reliability and validity (Bowling, 2005) and provide a wide range of information and a more complete picture of the patient experience.

Literature search

As detailed in part 1, a systematic search strategy was implemented to identify studies where the relationship

ABSTRACT

Leg ulceration is a debilitating condition which compromises the quality of life of the sufferer, owing to factors such as pain, exudate, odour and social isolation. As nurses, much of the daily care provided for such patients focuses on the provision of wound care; often failing to fully address the wide ranging effects that the ulceration is having on the life of the sufferer. This article reviews the quantitative studies that have explored the health-related quality of life of patients with chronic venous leg ulceration and presents a synthesis of their findings.

KEY WORDS

• Venous ulceration • Leg ulcers • Health-related quality of life

between HRQoL and chronic venous leg ulceration was investigated. This search produced a total of 21 studies in line with the search criteria, 14 of which were essentially quantitative (Table 1) and eight qualitative in their design. Eight of the studies had an exclusive focus on generic HRQoL tools and six focused on either a disease-specific HRQoL instrument or a combination of the two. Articles that exclusively focused on the evaluation of the validity and reliability of an instrument, without a patient focus, were excluded from the review. A process of thematic

analysis was undertaken for all studies, whether generic, disease specific or a combination of both, which resulted in the identification of a number of themes, including pain, mobility and social functioning.

Impact on physical functioning

The theme of physical functioning includes a range of the physical implications of chronic venous leg ulceration highlighted in the responses of participants, including pain, mobility issues and limitations to daily functioning

Table 1. Quantitative studies

Author, year and location of study	Name and type of HRQoL instrument	Inclusion criteria – aetiology	Treatment during study
Charles (2004) UK	Short Form-36 Generic	Venous - compared AEN	Short-stretch compression bandaging
Chase et al (2000) USA	Short Form-36 and 10 item Venous ulcer test. Generic and ulcer specific	Venous - compared AEN	Current treatment
Franks and Moffatt (1998) UK	Nottingham Health Profile Generic	Not specified	Current treatment
Franks and Moffatt (2001) UK	Nottingham Health Profile. Generic	Venous	High-compression bandaging
Franks et al (2003) UK	Short Form-36 Generic	All aetiologies - compared to AEN	Clinical preference
Franks et al (2006) UK	Nottingham Health Profile Generic	All aetiologies	Current treatment
Hamer and Roe (1994) UK	Nottingham Health Profile, Life Satisfaction Index, Hospital Activity and Depression Scale, Short Form McGill Pain Scale, Health Locus of Control Scale Interviews and generic	No information on aetiology Control sample (70 healthy elderly)	Current treatment
Hareendran et al (2005, 2007) UK	Venous leg ulcer quality of life questionnaire – modified SKINDEX Ulcer specific	Venous	Current treatment
Hyland (1994) UK	Hyland. Ulcer specific	Not stipulated	Current treatment
Iglesias et al (2005) UK	Short Form-12, EuroQoL-5D, Hyland Generic and ulcer specific	Venous	RCT – 2 bandage systems.
Palfreyman (2008) UK	Sheffield tool, Ulcer-5D EuroQoL, SF-6. Generic and ulcer specific	Venous and healed	Current treatment
Price and Harding (2004) UK	Cardiff Wound Impact Questionnaire, Short Form-36 Generic and wound specific	75% leg ulcers / 25% diabetic foot ulcers	Current treatment
Smith et al (2000) UK	Charing Cross Venous Questionnaire, Short Form-36 Generic and ulcer specific	Venous	Current treatment
Walters et al (1999) UK	Short Form-36, EuroQoL, Short Form McGill Pain Scale, Frenchay Activities Index	Venous > 3 months	RCT – random sampling for four- layer bandaging or current treatment.

and general health. Data surrounding vitality or energy levels featured prominently in the generic data, but was a not a term used in the disease-specific tools examined.

Pain

The experience of pain as a result of leg ulceration was found to be the most significant and consistently reported symptom throughout all of the studies reviewed, irrespective of design. Although research indicates such chronic wound pain is exacerbated by wound dressing changes, such variations were not reflected in by either the generic or disease-specific HRQoL tools (Briggs and Torra i Bou, 2002). The most prevalent variation in the reporting of this debilitating symptom captured was related to the severity of pain experienced by the sufferer. Hamer and Roe (1994) conducted a complex study of older patients ($n=158$), 88 of whom had active leg ulceration and 70 were in good health, using semi-structured interviews and the completion of five generic HRQoL tools. Over a third of Hamer and Roe's (1994) respondents reported that pain was the worst thing about having an ulcer and, worryingly, these respondents cited that this was an area that was frequently overlooked by practitioners.

Chase et al (2000) conducted a small scale study ($n=20$) of venous leg ulcer patients at an outpatient department in the US, where respondents completed the SF-36 (Ware and Sherbourne, 1992) and a short test to assess their overall understanding of leg ulceration. Results were compared to an age/sex equivalent norm but in contrast to Hamer and Roe's (1994) findings, Chase et al's (2000) respondents reported pain to be of less significance, with only 10% of their respondents reporting severe pain, 19% moderate and 38% with pain of mild to moderate severity – 33% of their sample reported no pain. Chase et al (2000) found a positive correlation between reports of pain improving and the ulcer healing but results were limited by the small scale and duration of their study and their mode of sample selection, which may have resulted in the exclusion of those sufferers who were housebound by their condition and unable to attend an outpatients department.

The positive correlation between improvements in reported pain and ulcer healing was supported by Charles (2004). Charles (2004) used the SF-36 (Ware and Sherbourne, 1992) ($n=65$) and was able to demonstrate consistent deficits in the HRQoL of leg ulcer patients as a direct result of pain. Charles (2004) noted that improvements in reported pain were demonstrated by all respondents after 12 weeks of treatment, with the most significant improvements demonstrated where the ulcer had healed. The results are supported by studies by Franks et al (2001; 2003). Walters et al (1999) also conducted a large scale study ($n=233$) over a 12-month period which compared four generic tools. Walters et al (1999) demonstrated the most significant improvements in reported pain in those participants where the ulcer healed – a factor that was most effectively demonstrated by the McGill Pain Scale (Melzack and Torgerson, 1971).

Franks et al (1998) conducted a large study ($n=758$) using the Nottingham Health Profile (NHP) (Hunt et al, 1986) and specifically considered the effects of gender differences on ulcer-related pain and HRQoL, a factor overlooked by many studies. The results demonstrated that males exhibited greater HRQoL deficits as a result of ulcer pain, although this has been criticized owing to the short duration of the study. Hareendran et al (2005) used a mixed-methods approach to develop a modified version of the established SKINDEX tool (Chren et al, 1996), using interviews and the completion of the modified questionnaire ($n=38$). Hareendran et al's (2005) data, in contrast to Franks et al (1998) study, while employing a disease-specific tool, demonstrated a reduced HRQoL for their female respondents. This factor may indicate a heightened gender sensitivity for their disease-specific tool but certainly highlights this as an important area for further research.

Franks et al (2006) conducted further research using the NHP (Hunt et al, 1986) ($n=113$) with an extended duration of 48 weeks, in an attempt to assess the longer-term effects of leg ulceration. This study revealed increased reported pain during the initial 24 weeks, but improvement by 48 weeks. Contrary to the findings of previous studies, the overall pain experienced between the healed and unhealed groups was demonstrated to be similar, a factor attributed to the inability of generic tools to distinguish symptoms specifically related to a particular condition.

Disease-specific HRQoL tools designed for use with sufferers of chronic venous leg ulceration are designed both to assess the effects of ulceration on the HRQoL and to differentiate those symptoms that are directly attributed to the ulceration, rather as a result of co-existing conditions. Hyland et al (1994) developed an ulcer-specific questionnaire which was completed by 50 leg ulcer patients on a single occasion, a factor which may limit the validity of the results. The questionnaire was based on amalgamated findings from six focus groups that explored the frequency, prevalence and importance of leg ulcer-related symptoms. Ulcer-related pain was reported as significant for all, with 44% of respondents scoring their ulcer as painful, very painful or excruciatingly painful. The timing of pain varied between respondents, ranging from daily to seasonal variations. Hyland (1994) concluded that the pain experienced by the leg ulcer patients was a major determinant of their lived experience of the condition.

Iglesias et al (2005) conducted a 15 month study ($n=387$) of venous leg ulcer patients, within a randomized control trial of four-layer compression bandaging. Participants completed the Hyland (Hyland et al, 1994) questionnaire along with two generic tools, the SF-12 (Ware et al, 1996) and the EuroQol-5D (EuroQol Group, 1990). Iglesias et al (2005) demonstrated that pain, of all reported symptoms, had the most significant impact on the HRQoL of the ulcer sufferer, with 12–21% of respondents reporting severe pain. Similarly, Hareendran et al (2005) reported pain to be the most commonly reported cause

of functional limitation, with subsequent restrictions to social life reported by 38% of their respondents.

The Sheffield Preference-based Venous Ulcer-5D, a recently developed tool, was completed on a single occasion by respondents with both active and healed venous ulceration ($n=266$) (Palfreyman, 2008). Eighty percent of respondents reported that they experienced pain, but improvements were demonstrated once healing had occurred. Findings supported by Price and Harding (2004).

The overwhelming nature of leg ulcer pain captured by both the generic and disease-specific HRQoL instruments, emphasizes the dominance of this symptom for patients, a factor in direct contrast with previous research (Roe et al, 1993; London and Donnelly, 2000). Generic tools consistently demonstrated pain to be a significant problem for leg ulcer patients but these results were limited as the generic tools are unable to accurately differentiate between pain that is directly related to leg ulceration and that experienced owing to co-morbidities. Ulcer-specific tools were more accurate in making this distinction. As with the qualitative studies explored in the first of this series of articles, these findings emphasize the need for holistic assessment and management of pain.

Mobility and daily living

Difficulties associated with the completion of day-to-day physical activities featured in studies using both the generic or ulcer-specific HRQoL tools and were attributed either to the leg ulceration itself, as a result of the associated treatment or a combination of the two. Chase et al (2000) reported that respondents had significant deficits when compared to the general population, which limited their ability to perform physical activities such as bathing, dressing, walking, climbing stairs and lifting. Charles (2004) demonstrated similar deficits but found the problems to be of most significance for their female respondents. In contrast, Franks and Moffatt (1998) found mobility to be a deficit for all, but reported the greatest deficit in this area for their younger male participants.

Both Walters et al (1999) and Hamer and Roe (1994) recorded that 50% and 30.7% of their respondents, respectively, experienced major mobility problems due to their leg ulceration. Franks et al (2006), in their longitudinal study, found mobility issues to be an increasingly dominant deficit, especially where ulcer healing was not achieved.

Limitations to physical activity were also prevalent in the ulcer-specific studies and were attributed either directly to the ulceration or, for some, as a result of the pain. Hyland et al (1994) reported that 29 ($n=50$) of his participants were housebound, with 16 respondents attributing this limitation directly to their ulceration. Difficulties included general mobility and issues climbing stairs. Iglesias et al (2005), in their US study, similarly found that all respondents ($n=387$) reported detriments in physical health when compared with the general US population, with improvements seen when ulcers healed.

Price and Harding (2004) reported similar difficulties with mobility and daily activities, with respondents struggling to perform everyday tasks, including difficulties maintaining personal hygiene. Interestingly, Palfreyman (2008) reported more specific ulcer-related symptoms that impacted on his respondents. Seventy-five percent reported issues relating to ulcer exudate, 56% had issues due to odour and 65% reported insomnia attributed to ulcer-related pain. As reflected in other studies, improvement in symptoms was demonstrated when the ulcer healed.

Hareendran et al (2005), on analysing data from their modified questionnaire, revealed that 80% of their respondents reported experiencing pain, 66% itching at their ulcer site, 57% reported loss of sleep and 58% loss of function owing to the ulceration. Interestingly, Hareendran et al's (2005) study failed to find a significant correlation between ulcer size, a key end point used in the evaluation of clinical trial treatment protocols, and HRQoL.

Studies indicate that limitation of mobility and the challenges faced in order to complete daily activities pose a significant problem for many leg ulcer sufferers, although there is conflicting evidence as to which group of respondents find these problems to be most limiting.

Vitality

The notion of vitality was only specified by studies that used certain generic HRQoL tools, as the term did not feature in any of the ulcer-specific instruments. Franks and Moffatt (2001), in a large scale ($n=383$) study using the NHP (Hunt et al, 1986) over a 12 week period, found that all respondents reported improvements in their energy levels at 12 weeks, with the greatest improvements cited by respondents whose ulcer had healed (37%). A similar reduction in vitality was demonstrated by Franks et al (2006), again using the NHP (Hunt et al, 1986), with respondents reporting an improvement in energy levels with ulcer healing. Chase et al (2000) reported large deficits in energy levels for sufferers of leg ulceration, even when compared with other chronic conditions such as type 2 diabetes and cardiovascular disease – a significant factor which may contribute to the ability of such patients to self-manage.

Some studies, such as Frank and Moffatt (1998) ($n=758$), were able to demonstrate a diminished overall quality of general health in their respondents, clearly revealing a lower level of perceived health in their respondents when compared to the age/sex equivalent norm, although the short duration of the study was a limitation. Walters et al (1999) found that general health deteriorated throughout their 12-month study ($n=233$) for all respondents, interestingly, even for those who had experienced healing.

Some studies failed to distinguish any deterioration in the general health of respondents when compared to the general population (Chase et al, 2000; Franks et al, 2003;

Charles, 2004). The generic HRQoL tools, even when a deterioration was demonstrated, were unable to distinguish between effects on general health due to the leg ulceration and those as a result of co-morbidities.

Impact on social functioning

The areas of social functioning and social isolation were inconsistently reported by the studies. Charles' (2004) saw significant deficits in the area of social functioning, but reported improvements for all participants after 12 weeks, of most significance where healing had taken place. In contrast, Franks et al (2006) found that patients were socially isolated as a result of their symptoms, and saw little improvement over their extensive 48-week study, for both respondents where healing had been achieved and for those whose ulcer had remained unhealed. This social isolation may have been as a result of co-existing conditions but the studies were not able to demonstrate this distinction. Franks and Moffatt (1998) also found social isolation to be a significant factor for leg ulcer patients and, when analysed according to gender, demonstrated the most significant detriment to social functioning in younger male respondents.

Two of the studies that employed ulcer-specific instruments considered social functioning and patient isolation. Hyland et al (1994) reported that those with leg ulceration often restricted their own social activity, with a view to preventing any further damage to the leg or to reduce the likelihood of recurrence. Thirty four percent of respondents (n=50) reported that they avoided contact with cats and 38% avoided attending crowded places such as doing their shopping. Smith et al (2000), in their study of 98 venous ulcer patients using the Charing Cross Venous Questionnaire (Launois et al, 1996) and the SF-36 (Ware and Sherbourne, 1992), reported that 80% of respondents stated that their ulcer did not prevent them from earning a living. This response may well have been a reflection of the age of the respondents and, in order to limit any bias, was removed from the finalized questionnaire.

Hareendran et al (2005) reported 97% of their respondents having some limitation to their physical functioning, with reports of affects on family life and dependency on partners to provide care. Social life was restricted by pain, odour, inability to dress appropriately and bandage appearance.

Impact on psychological functioning

The area of psychological functioning reviewed issues such as pessimism, body image and negative emotions experienced as a result of ulceration. Franks et al (2003) used the SF-36 (Ware and Sherbourne, 1992) in a 12-week study and clearly demonstrated that leg ulceration had significant effects on the mental health of the sufferer, with improvements demonstrated when the ulcer healing had been achieved. Charles (2004), again with the SF-36 (Ware and Sherbourne, 1992), demonstrated significant

improvements in the psychological health of participants during their study but noted some variation in the ability of her respondents to deal with the day-to-day problems and restrictions of living with leg ulceration.

Psychological detriments as a result of leg ulceration were also consistently reported in the studies using ulcer-specific questionnaires. Hyland (1994) reported that respondents felt dysphoric, an emotional state characterized by both anxiety and depression, as a direct result of their ulceration. 32% (n=50) Hyland's (1994) respondents felt that their ulcer dominated their body, 24% reported episodes of crying owing to their ulceration and some reported spending up to 2 hours daily thinking about their ulcer (Hyland, 1994). Iglesias et al (2005), again using the Hyland (Hyland, 1994) questionnaire, reported a 36% detriment in mental health for respondents, data which supports Hyland's (1994) earlier results. Palfreyman (2008) reported that 65% (n=266) of his respondents reported feeling depressed, most often as a result of the pain associated with their ulceration, but in line with other studies, demonstrated improvements in mood as a result of healing.

Hareendran et al (2005) reported 44% of their respondents felt low or depressed, with experiences of reduced self-confidence being common and frustration that their ulcer would ever heal. The mixed method approach to data collection adopted for Hareendran et al's (2005) study allowed for rich data, beyond that normally available from the HRQoL questionnaires in isolation, to be included.

As individuals, our experience of physical and psychological health are inextricably linked, but often the presenting somatic condition takes precedence in the care delivered by health practitioners (Snaith, 2003). The debilitating day-to-day symptoms faced by sufferers of leg ulceration have been shown to have a detrimental effect on the mental health of the sufferer, which, research demonstrates, may have a profound influence on healing (Persoon et al, 2004; Moffatt et al, 2008). A recent European Wound Management Association (EWMA) position statement (Moffatt et al, 2008) published in 2008 emphasized the links between psychological well being and the essential physiological processes involved in wound healing, with the potential to delay healing. This often results in a vicious circle, with delays in the healing process further exacerbating mental health issues. The EMWA document (Moffatt et al, 2008) recommends referrals to appropriate agencies and the provision of support to prevent such a negative spiral.

Implications for clinical practice

The issues identified by the quantitative research into HRQoL and chronic venous leg ulceration are similar to those acknowledged in the qualitative studies. Pain is at the fore, followed by physical symptoms suffered often as a result of pain – reduced mobility, limitations to daily functioning and a lack of vitality, social isolation and detriments to

Recommendations for nursing practice and future research

- To effectively assess and manage the pain experienced by sufferers of leg ulceration, especially at wound dressing changes.
- To develop effective strategies to manage wound exudate and odour.
- The adoption of comprehensive care pathways for the management of leg ulcers, such as the Royal College of Nursing document (2006).
- To foster the development of a collaborative, concordant practitioner-patient relationship.
- To develop comprehensive patient resources and educational materials relating to leg ulceration.
- To educate staff to accurately assess and successfully manage leg ulceration.
- To develop a patient focus to nurse-patient consultations.
- To conduct mixed method research to enhance the nurse's understanding of the patient experience.

psychological wellbeing. The quantitative studies are not designed to allow any flexibility of expression from the respondent, other than that within the predetermined responses, so these studies fail to truly capture the daily impact of the symptoms that are identified.

As with the qualitative studies, there remains a need to adopt and maintain evidence-based clinical guidelines such as those developed by the Royal College of Nursing RCN (2006). These guidelines focus on the management of the physical symptoms of venous leg ulceration but there is a pressing need, made clear in all of the studies reviewed, to also take into account the patient identified psychosocial factors when holistically assessing the patient. The Lindsay Leg Club Model (Lindsay, 2004), as described in part 1 (Green and Jester, 2009), has successfully combined a partnership approach that effectively meets the physical, social and psychological needs of many of its patients with chronic venous leg ulceration. The lessons learned from this model need to be rolled out more widely and applied to the care of those patients for which such an approach is not suitable.

Conclusion

Despite the widespread use of generic HRQoL tools in the area of leg ulceration, critics continue to question the ability of such tools to distinguish between deficits directly owing to leg ulceration and those caused by co-morbidities – a criticism that is common wherever generic tools are used in disease-specific studies (Walters et al, 1999; Franks and Moffatt, 2001; Franks et al, 2003; Charles, 2004; Iglesias et al, 2005). In response to this criticism, many researchers have concentrated their efforts on demonstrating the discriminative and evaluative properties of the questionnaires, in an attempt to confirm the usefulness of the resultant data to disease-focused research (Bowling, 2005; Walters et al, 1999). Apart from minor discrepancies between the effectiveness of the tools (Franks and Moffatt, 2001; Walters et al, 1999), they

are generally well tested for validity and reliability, short, concise and acceptable to patients. Their sensitivity to changes in HRQoL status where the respondents' ulcer failed to heal remains an area of debate, but all tools were able to demonstrate such improvements when the ulcer had healed. The finding of all studies, however, support the hypothesis that suffering from chronic venous ulceration results in deficits in the sufferers' HRQoL, with data demonstrating the most significant scoring differences in the areas of pain, mobility and mood, when compared to the population in general.

The ulcer-specific HRQoL tools supported the importance of pain for the leg ulcer sufferer, along with specific concerns relating to sleep disturbance, exudate, odour, social isolation and low mood. These tools all proved able to effectively discriminate between participants with active ulceration and those whose ulcer has healed, as did the generic, but again there were variations in the degree of sensitivity to alterations in ulcer condition. Although designed to distinguish between issues that were experienced as a direct result of leg ulceration and those as a result of other underlying conditions, this was not obviously demonstrated by all instruments.

All of the studies unanimously demonstrate the significant deficits in HRQoL caused by leg ulceration, but each of the approaches adopted has inherent limitations. The generic HRQoL tools, although widely used, provide valid and reliable statistical information to support treatment modalities and medical interventions but lack the ability to distinguish effectively between specific conditions. Leg ulcer-specific HRQoL tools, of which there are a number of promising questionnaires, are able to focus more closely on disease-specific information, but as a result are only relevant for use within that population. In view of these limitations, a number of researchers recommend a studies that combine the two tools; a generic and a disease-specific, to provide a more complete view of the effects of leg ulceration on the patient (Smith et al, 2000; Price and Harding, 2004; Palfreyman, 2008).

Recommendations from part 1 and 2

This series of articles have provided a review of the qualitative (part 1 (Green and Jester, 2009)) and quantitative studies (part 2) of the effects of chronic venous leg ulceration on the HRQoL of the sufferer. Significant, life-limiting symptoms are a common theme throughout all of the research presented, with pain and the effects of ulceration on the physical and psychological well-being of the sufferer featuring at the fore. There is unanimous agreement, irrespective of the methodology used, that leg ulceration causes significant deficits in HRQoL for the sufferer.

Further research is required if the care delivered to these patients is to be effective and is to be directed to meet their specific patient-focused needs. Future studies that adopt a mixed methods approach to the research question would appear to be ideally suited to providing

KEY POINTS

- Chronic venous leg ulceration results in a significant decline in health-related quality of life for the patient.
- Often the nurse has wound healing as central focus in the care that they provide. Much of the research indicates that the needs of leg ulcer sufferers go far beyond their actual wound care.
- Holistic assessment of the needs of those patients suffering from venous leg ulceration is essential if their overall experience is to improve.

us with a more complete insight into the needs of this patient group. Mixed methods research incorporates both qualitative and quantitative approaches within a single project, which ensures the accuracy of findings, allows for the triangulation of results and provides an holistic approach to the research problem (Meadows, 2003; Denscombe, 2007; Dodd, 2008). Pope and May (1995) view the use of such a multi-method approach as complementary, with qualitative research often being used to provide a preliminary base where there is a lack of prior study or limited knowledge and quantitative research testing the hypotheses that are generated. *BJCN*

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Patient perspectives of their leg ulcer journey

- **Objective:** To understand the personal impact of venous leg ulceration from the patients' perspective.
- **Method:** Face-to-face, unstructured interviews were conducted with nine patient participants with venous leg ulcers. The interviews were digitally recorded, transcribed verbatim and, using thematic analysis, the themes and subthemes which impacted on quality of life were identified.
- **Results:** Four core themes were identified: the ulcer, symptoms, wound management and effects on daily life, with 16 subthemes that negatively impacted on quality of life (QoL) also identified.
- **Conclusion:** This qualitative study offers a valuable insight into the complex issues that impact on daily living for this patient group. The implications of the findings are far reaching and suggest that proactive symptom management and the fostering of a patient focus to consultations may improve QoL and encourage the patient to engage as an active partner in his/her management plan; both of which are explored in the subsequent phases of the larger study.
- **Declaration of interest:** This study was funded by West Midlands Strategic Health Authority. The authors have no conflicts of interest to declare.

chronic venous leg ulcers; community nursing; interviews; quality of life; wound care

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Due to the debilitating symptoms and the recalcitrant nature of the condition, people with chronic venous leg ulcers (VLU) experience diminished quality of life (QoL).¹⁻⁴ Over 40% of patients' ulcers last 12 months or more (median 6-9 months, range 4 weeks-72 years) and often recur (26-69%),^{1,5-9} with statistics improving little over the last 20 years.^{7,10} For some, ulcers last for much of their lifetime.

The chronicity of VLUs can be devastating, with effects on many areas of the life of the patient.^{11,12} Life is complicated by issues including pain, limited mobility, odour, depression and social isolation.^{1,13,14} Care is predominantly delivered in the community and is of varying quality, focusing primarily, if not solely, on the provision of wound care; often with little regard for the wider impact that ulceration poses.^{1,4,12,15}

This project aims to build on previous research and to establish those factors that impact on the daily lives of people with chronic VLUs.^{16,17}

Method

A phenomenological design was employed to collect data via face-to-face, unstructured interviews. Such interviews allow participants to fully articulate their experiences and provide an excellent opportunity to understand behaviour.¹⁸

A two-stage sampling procedure was used. The first stage was of district nurse (DN) participants who cared for patients with VLUs and the second of patients with VLUs from their caseload. Nurses were recruited from two teams in two local primary care

trusts (PCTs). Nurse participants were experienced in the care of patients with VLUs. All consenting nurse participants then purposively selected potential patient participants from their caseload, thus protecting confidentiality, and distributed study information and consent forms. The inclusion criteria for patients were chronic leg ulceration of venous or mixed aetiology for over 6 weeks and the ability to provide written informed consent.

Data were collected between June 2010 and January 2011; individual interviews were conducted, at times and locations convenient for the patients. Interviews were initiated using a single open-ended question ('What is your experience of leg ulceration?'), to invite the participants to reveal their experience of living with their VLU. Interviews were digitally recorded with the participants' permission and lasted between 30-120 minutes. Immediately after each interview, a reflective journal was completed to record observations about the interview and ideas about future coding. Interviews continued until data saturation was reached and no new themes were evident during analysis.¹⁹

Digital recordings were transcribed verbatim, and transcripts were checked for accuracy and analysed using thematic analysis.²⁰ This six-stage analysis process²⁰ commenced with immersion in the data, the logging of initial codes and more formal coding processes with themes formed. A thematic map of the data was created, providing the scope and content of themes. A final analysis of the data was then undertaken and written up to complete the process. This auditable process continued until no new themes were identified.

Table 1. Patient participant demographics

Participant pseudonym	Age (years)	Gender	Marital status	Residential status	Duration of ulceration	No. of episodes
Tom	76	Male	Married	With wife, own adapted bungalow	10 years	2–3
Mary	72	Female	Married	With husband, own adapted bungalow	30 years	> 5
Evan	76	Male	Single	Private residential home	35 years	> 5
May	99	Female	Widow	Private residential home	3 years	1
Pam	78	Female	Married	With husband, own house	30 years	3
Ellen	80	Female	Widow	Private residential home	2 years	1
Steve	39	Male	Single	Alone, upstairs local authority flat	14 years	1
Margaret	72	Female	Widow	With dog, upstairs local authority flat	20 years	> 5
Sam	86	Male	Married	With wife, own house	40 years	> 5

When a qualitative approach to research is employed, the data are not purported to be generalisable to the wider population. However, the internal validity of the study remains important. Veracity and auditability are vital,²¹ and these were enhanced by an ongoing reflexive approach to the research process. Consistency of both the collection of data and the analysis process was assured by a single researcher conducting all of the interviews and transcription. Braun and Clarke's structured framework²⁰ was systematically applied to the interview data and, to confirm the accuracy of the analysis process and to optimise rigour, data from the interviews were also coded independently by an educational supervisor, ensuring transparency of the process.

Ethical approval for the study was granted by Mid-Staffordshire Local Research Ethics Committee. All participants received clear, written information about the study and their involvement. Written consent was gained prior to commencement.

Results

Participant demographics

The 13 nurse participants had worked in primary care for a median of 5 years (range 6 months to >20 years). Nine patients took part in the study; four were male (44%), two lived alone, four with a partner and three lived in residential care. Patient participants had a median age of 76 years (range 39–99 years; Table 1).

Themes and subthemes

Four core themes were identified from the analysis of the interview transcripts: the ulcer, symptoms, wound management and the effects on daily life, with each theme encompassing a number of subthemes (Fig 1).

Each core theme, and the respective subthemes, are summarised and illustrated with verbatim quotations from the interview transcripts below. As strong local dialect was evident in many of the quotations, where necessary, meaning is explained in parentheses. Participants are identified by pseudonyms.

Theme 1: the ulcer

All participants were keen to describe their 'ulcer journey' and used the interview as an opportunity to outline the story of their ulceration. Reflections included their family history, any comorbidities and details about the ulcers, such as the cause, position and duration of ulceration.

Three participants' family history of VLU were significant. Where such a history was present, participants seemed to be almost resigned to their apparent 'susceptibility' to VLUs.

'My sister has ulcers as well. All my mother's sisters had it, and my mother—runs in my family it does with us.' Tom

'My Mum had them and they've told me they can be hereditary.' Margaret

Comorbidities were common; three participants had no comorbidities, three had one and the remaining had two or more, which included rheumatoid arthritis (n=2), osteoarthritis (n=3), cardiovascular disease (n=1) and sight problems (n=2). Participants who suffered from comorbidities reflected that these were often exacerbated by problems related to their ulceration; for others, the ulcer was merely a minor irritation compared with the impact of other conditions.

'The ulcers are a damn nuisance.' Tom

Participants all spoke about the cause and the time span of their ulceration. For some a cause was clear; for others, their ulcer had simply appeared without warning. Others considered whether occupational factors had predisposed to their development of ulcers.

'Well, I've always had a job standing. Whether that has caused it...' Sam

Some reflected on their self-management of the initial ulcer, before eventually having to accept that professional management was required. Often expert advice had become essential due to wound deterioration or the presence of infection. Others spoke of periods of avoiding professional management later in the course of their ulceration and of becoming non-concordant when the situation became too much for them:

'You just go through mad stages. Just trying not go, just thinking "I've done it." I'd phone and say "Sister, I don't need to come today, me bandages haven't leaked through." "Are you sure cause we can change them or come to you?" I'd say "No, you're alright, they haven't leaked through or nothing", but I'd done it myself. It was just a stage I went through with them; just trying not to have to go—three times a week—I mean, come on—it's tedious isn't it? They put them on on Monday, you go up Monday afternoon, you've got Tuesday all day and I'm back there on Wednesday; so it's only a day and a half they're staying on and then they're being changed.' Steve

Most had experienced some healed episodes (n=7), although not all. For one participant in particular, it was taking years.

'This Christmas it'll be just over about 14 years. It's just been millimetres—millimetres all the time just going in very, very slow, cause I've not been anywhere, not done nothing for 12, 13, 14 years. All me life's been is... is doctors and hospitals and nurses and surgeons—you know, it does get to you [...] but I haven't let it get me down and I've stuck with it and yes, I'm doing alright now like, I'm getting there. It's getting there.' Steve

Lack of healing presented a significant challenge to some participants. Similarly, recurrence following an episode of healing was frustrating and disheartening.

'Off and on. I must have had them at least a dozen times.' Sam

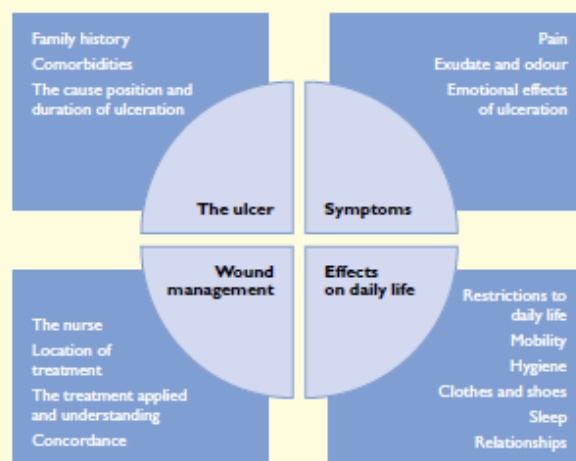
'I think I've had about three or four, but the last two have been horrendous.' Margaret

The interviews revealed the personal narrative associated with leg ulceration. Comments were consistent and unprompted by all participants. These stories provided an insight into the person behind the ulceration, the extent of the impact of VLU on daily life and provided a background to their personal journey.

Theme 2: symptoms

All participants reported a range of debilitating symptoms due to their ulcers, providing three subthemes.

Fig 1. Themes and subthemes identified from interviews



• **Pain** Pain dominated the lives of the participants and was the focus of every interview. Similarities in the descriptions of pain included its unceasing nature, and the severity and timing of the pain experienced, especially throughout the night.

'It was getting more painful, it was like one time it was like burning pain, then it was more like a stabbing pain, then. Now it's real sore, like someone is just rubbing, rubbing, rubbing, all the time. Oh, the pain—it's just unbearable.' Steve

'All through the night [...] you just can't get any rest.' Mary

'I have never had so much pain and they've made me feel so ill.' Margaret

One participant reflected:

'It's just the same pain, 24/7. I just have put up with it.' Steve

For all participants, there was a reluctance to take analgesia, often due to a cocktail of medication taken for their comorbidities.

'With all that I take for my arthritis, I figured it was covered.' Tom

Where analgesia was taken, it was felt by many to be ineffective for the type and intensity of pain experienced.

'[...] but I do take the paracetamol—they're not brilliant, you know.' Margaret

'I don't take them unless I have to. I'd rather not take painkillers.' Sam

Pain was a central issue in every interview and was vividly described in terms of its severity and incapacitating nature.

• **Exudate and odour** The impact of exudate and odour was powerfully described by respondents and included reflections on the challenges that these issues posed to daily lives. These devastating symptoms were present for many of the participants and caused embarrassment, shame and stress.

'Oh, and when you first have them, I wondered what the smell was—it's terrible the smell, it all comes out, a lot of rubbish. When you went anywhere, you didn't get too close to people, because I can smell it, terrible.' Ellen

'It was a really offensive smell—you know what I mean, like it was like rotting flesh, it was horrible and, I smelled worse than a fishmongers, you know?' Steve

For some participants, in order to control the devastating effects of odour and exudate on their lives, they limited their contact with others and created a self-imposed isolation. This was seen as preferable to the embarrassment the symptoms caused.

'Social life? Err, I haven't got one. I just don't bother cause I know I've got to get myself better' Steve

'They stop you from going anywhere really. You know, you can't get about, not the same.' Ellen

• **Emotional effects of ulceration** Participants reported a range of emotional effects due to their ulceration, including depression, poor self-image and a fear of people's reactions. The interviews revealed a range of coping strategies adopted by participants. Some were striving to maintain their 'normal' functioning, whereas others suffered from anxiety and depression, with one respondent disclosing that he had had suicidal thoughts.

'It's just depressing really, if you think about it. I am on antidepressants. I just have to put up with it—it's either that or kill myself.' Steve

'Terrible. Really down.' Evan

In contrast, another participant stated that, despite the profound impact of her ulceration, she endeavoured to continue her activities as before:

'It feels... I don't cry, but I could cry.' Margaret

Despite this, she went on to say:

'I tell you—you have to shake yourself. You have to shake your feathers and when you go out you have to put your outside face on. You know, you just have to.' Margaret

Despite the negative psychological impact of long-standing VLU, the theme of hope was evident in many of the interviews; even for Steve who had experienced 14 years of ulceration.

'Yeah, I'm doing alright now like, I'm getting there. It's getting there.' Steve

These three debilitating subthemes were common across all interviews and were described clearly by participants.

Theme 3: wound management

Participant discourse about their wound management revealed the importance they placed on the physical management of their wounds. The central involvement of health professionals in the leg ulcer journey was present in all of the interviews. A number of participants reflected on their preference for consistency in their nursing team;

'[...] with the consistency of a team, much better. They did once send another from another surgery out, it wasn't the same. When you're seeing someone only once, it isn't the same. Nothing wrong with her, did the job just the same—fine—but I wasn't used to her.' Tom

Similarly, other participants said:

'It would be better if you saw the same nurse really, cause they would get to know what it's like.' Sam

'[...] you'd go and there would be girls there and you'd perhaps see them twice and then you wouldn't see them again. So, you'd get somebody else, so somebody else has a different way of doing it; so you didn't know where you were.' Margaret

For many, their relationship with the nurse was special; some were seen as friends, with close bonds made over the course of many visits.

'[...] had some lovely nurses—they've been brilliant.' Tom

Some participants attended clinics for their wound management, while others were seen at home. Some reflected on the time wasted waiting for nurses to

visit. One gentleman in a residential home reflected on missing activities while waiting for his visit.

'Sometimes... sometimes when the nurses were late I'd have to wait.' Evan

The decision to attend clinic had been a conscious one for some participants, in order to be in control.

'You know, when I first went they said which would you prefer—do you want to come here or do you want us to come to your house? And I just said that I'd come up to clinic. I just thought moving about a bit would be better, might do me better than just sitting about.' Sam

One participant reflected on difficulties travelling home from clinic following their dressing change:

'They have a clinic down at our doctors, on three days a week for dressings. I'll go to it, but sometimes, you know, sometimes I have a job to come home when it's just been dressed.' Mary

All participants mentioned the wide variety of wound-care products that had been used on their ulcers over time. Many demonstrated excellent knowledge about the products on offer. One stated:

'You name it, all the different patches with stuff in and creams and the patches come out with the silver in and we went through every one of them. Errr... I've gone through loads of different stuff—they've put, I've had trials of different stuffs put on and some worked and some hasn't.' Steve

'Yes, they tried all sorts, you know. I think I've had iodine and different sorts of things.' Ellen

In contrast, one participant reflected on a difficult relationship with her nurses due, she felt, to their perception of her as being non-concordant. This participant felt she had been reprimanded by the nurses on a number of occasions for removing her dressing in between clinic visits and reflected:

'As I say, they're [nurses] great with me on the whole, but then they started getting cross that I washed me feet at night... er, apart from showering I do wash me feet at night before I go to bed anyway, and they got a bit cross.' Pam

The relationship with the nurse was extremely important to all participants. The interviews demonstrated a distinct focus on wound healing as the goal of treatment, with many participants reflecting that this was often elusive and, when achieved, difficult to maintain.

'I think I've had about three or four, but the last two have been horrendous.' Margaret

'I've had them twice this year.' Sam

Theme 4: effects on daily life

A number of subthemes referred to the effects of ulceration on the participant's daily life.

• **Restrictions to daily life** Some participants reflected that they stayed at home because the activities usually undertaken each day had become more difficult. Others stayed at home in order to limit their contact with others or to avoid further injury. For whatever reason, normal daily life was interrupted for many as a result of ulceration.

'I'm frightened in the supermarket. I am frightened when I'm out, when I have been at the supermarket cause some people, they do push their trolleys everywhere. So it means that you're on your guard all the time.' Margaret

'Well, they stop you from going anywhere really. You know, you can't get about, not the same.' Ellen

Some felt they rose to this challenge and, with determination, went out despite their ulceration.

'I don't let anything restrict my life.' Pam

This, for some, was their attempts to almost fight back against the limitations their ulcer imposed, in order to maintain normal functioning.

• **Mobility** Many respondents reported difficulties with walking, either due to discomfort from their wound or due to the dressings. Many also had a fear of falling.

'I can't walk. Yes, you walk but I'm frightened, because I put my foot out, you're frightened of falling.' Margaret

• **Personal hygiene** The maintenance of personal hygiene was extremely important, but difficulties in this area were raised by most participants. Discussion focused on problems bathing or showering due to the dressing. Some had used a new leg appliance that had improved functioning in this area. Others spoke of the need to have their legs washed between dressing applications. One lady talked about the dressing procedure undertaken by her nurses', stating that her legs were not washed, which upset her:

'No, they cut it all off and then she just puts a bit of cream on and that's it. Another bandage on.' Ellen

• **Limited choices for clothes and shoes** All participants raised issues with restricted choices for

clothes and shoes. Problems were most often attributed to the bulkiness of the dressings required, which made choices of shoes difficult. Others felt a need to conceal their dressings.

'It's horrible—you can't dress as you want to. I've got nice fine skirts as I could have, you know, printed skirts for the summer, ever so nice.' Margaret

'I can't get my shoes on.' Evan

'I have to undo the laces and untie 'em [them] like, so if I do go for a pair of trainers like, it's hard—I have to get a pair a size bigger, cause of all the bandages. I mean I take 9s, these are 10s and I went to buy a pair the other day and they were 11s, and they just looked like that and I thought I can't wear them, they look like boats.' Steve

• **Sleep** was an issue for all respondents, most often due to pain. One participant commented that night times were particularly difficult:

'It is—when you've been in bed, it wakes you up.' Ellen

'Some nights, err... I had no sleep with it all night—it was going like this [indicates clenching motion] every few minutes, and you're there trying to find somewhere to put your leg, you know. It's awful.' Margaret

The lack of sleep accentuated the debilitating nature of the condition and made day-to-day functioning more difficult.

• **Relationships** A number of the interview participants reflected on the effect of their ulceration on their relationships. Some required family members to assist them with daily activities and, in some cases, carers had become the cared for. One participant sadly reflected on his inability to provide the level of care for his wife that he usually did:

'I haven't been able to go round the supermarket I just haven't been able to manage it—I'd have to sit down and my wife would struggle round.' Sam

The youngest participant reflected on the effects of his ulcers on forming intimate relationships. He reflected:

'[...] but relationship wise, er no chance. I couldn't, once these have healed then, obviously yes, but it's just, you know, with these on me legs all the time—there was one girl and I tried, she said "what's all that on yer [your] legs?" and I tried make out that I'd been in a fire and I'd burned myself [myself], but with the smelling and that, it dimma [didn't] last and I've just sort of put it off.' Steve

Day-to-day living for all participants was a challenge, with leg ulceration impacting on every aspect of their lives.

Discussion

The findings of this study clearly establish the pervasive and profound effect of VLUs on the daily lives of the patient. The impact on physical, psychological and social functioning and QoL is overwhelming for many of these participants. Participants demonstrated a range of responses to the impact of their ulcers; some participants saw it as a challenge and, despite their difficulties, did all they could to maintain usual functioning. In contrast, others withdrew from their normal activities, limiting their contact with others until their condition would improve.

This study reinforces and extends our understanding of the impact of VLUs. Pain overwhelmingly dominated the lives of participants and impacted on every aspect of their functioning. It interrupted sleep, limited mobility, lowered mood and proved difficult to manage. Pain was portrayed as 'continuous' and 'unbearable', a constant reminder of ulceration throughout a number of studies.^{2,11,12,22,23} Ebbeskog and Ekman²⁴ reflected that pain was central to their participants' lives, making them 'cry in despair'. Difficulties controlling the pain have similarly been reported, with analgesia deemed to be ineffective against ulcer related pain. The enduring nature of the pain experienced and the inadequacy of the analgesic options available to these study participants are themes not disclosed as compellingly in earlier studies and serve to highlight the need for further research into this area, to successfully manage symptoms and meet the needs for effective pain relief for this patient group.^{24,25}

Difficulties managing wound exudate and odour were evident for all and had profound effects on every aspect of functioning, resulting in embarrassment, shame and social isolation. The sheer embarrassment of odour, its impact of self-image and the resultant self-imposed isolation as a way of preventing others from being exposed to this humiliating symptom were also key findings. Odour and leakage were similarly acknowledged in other studies,^{1,4,24,25} serving to highlight the need for more effective wound management strategies.

The composite effect of pain, exudate and odour was to severely limit social functioning and to lower mood, even prompting thoughts of suicide for one participant. Despite these serious limitations, others fought to maintain their functioning; attempting to engage as they had before their current episode of ulceration and a theme of hope, especially for healing, was evident for all. For many, where the healing process is prolonged and their ulcer recurrence almost inevitable, the focus of care on healing as the sole outcome of care has been questioned. Indeed,

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Briggs and Flemming¹ recommend the adoption of the management of leg ulceration as a chronic condition; suggesting that the focus on healing may actually intensify the 'hopelessness' felt by the patient. They recommend that a renewed focus may improve coping strategies, serve to enhance the patient focus of consultations and encourage the nurse to move away from a focus solely on the wound.⁴

All participants reflected positively about the expertise and support offered by their nurses. Many commented on their preference for a consistent nurse, citing this as a key factor in improving the personal nature and the effectiveness of the care they received. Consistent care, competence in dressing application and regular feedback on wound progress was all considered key factors in the quality of the care delivered. Participants had experienced a wide variety of wound care products over time and were knowledgeable about their wound management strategy; often seeing themselves in partnership with their nurse against the ulceration. Other studies highlight similar positive effects of the nurse-patient relationship.^{24,26} For just one participant in this study the nurse-patient relationship had become difficult; a finding supported in some earlier studies where negative effects of the nurse-patient relationship were highlighted as often being the result of perceived non-concordance to treatment recommendations.^{2,11}

For many studies, as with this, the physical effects of VLUs dominated participant reflections. Daily living was a challenge for all. Getting out and about, mobility and maintaining personal hygiene were impaired due to the wound, the dressing or both; as were choices in what to wear. Sleep was regularly disturbed, most often by pain, and relationships were altered with carers becoming cared for and intimacy avoided. Participants were fearful of what people thought, of wounds deteriorating, of recurrence and, ultimately, of not healing. Ulceration affected every area of functioning over long periods of time. Other studies have similarly found that the dominance of the physical effects of ulceration may dilute the disclosure of psychological and social issues during

interviews²⁶ — this did not appear to be the case during this study. Participants spoke at length about the impact on their psychological functioning; describing the influence on their mood, motivation and engagement in activities. Often, when combined with the physical symptoms of ulceration, these two areas served to limit social functioning.

Further research

Reflections on the 'journey' of leg ulceration were common to all participants in this study; using the opportunity to speak unhindered to describe their experiences of healing and recurrence over time has also been described by Briggs and Flemming.¹ Telling the story of the ulcer seems to be an important component of care for VLUs and is often overlooked in current care delivery.^{1,13} Fostering of a therapeutic relationship, where the patient feels valued, supported and listened to and where the chronicity of their ulceration is understood, is vital and, research claims, may result in improved healing rates and reduced ulcer recurrence.^{1,20} Research is needed to determine whether this is so.

Conclusion

This study suggests that the QoL of patients with VLUs is impaired in physical, social and psychological domains. The impact of ulceration is described together with the life-changing, debilitating symptoms, which can be unsuccessfully managed and have an enervating effect on all aspects of daily living. Understanding this 'lived experience', listening to the patient and providing effective symptom management for this chronic condition during consultations seems crucial to improving the QoL of this patient group. Further phases of this study will explore current consultations and pilot a tool designed to enhance patient centredness. The importance of the nurse-patient relationship and the need for consistency of care provision highlighted by this study is an area, in the light of these widespread NHS changes, that needs to be of central importance for decision makers. ■

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Nurse–patient consultations in primary care: do patients disclose their concerns?

- **Objective:** To quantify the extent to which patients disclose their concerns to community nurses during wound care consultations.
- **Method:** Using an 'observation checklist' based on themes and subthemes that were identified in a previous study of the same patients, 20 wound care consultations were observed. The non-participant observer completed the checklist and made field notes regarding the context and nature of interactions.
- **Results:** Patient participants had 160 opportunities to raise concerns regarding previously-identified pain, exudate and odour, yet they did not do so on 64 (40%) occasions. They had 28, 32 and 84 opportunities to raise emotional, wound care and daily living issues, respectively, and they did not on 16 (56%), 3 (9%) and 32 (38%) occasions. Overall, patients did not raise 38% of their concerns. Of the concerns that were raised, 8% were either not acknowledged or were disregarded by their community nurse.
- **Conclusion:** If these data are representative, this has profound implications for person-centred care and shared decision-making models of care, which are predicated on patients articulating their needs. They also have implications for the development of practitioners' communication and consulting skills.
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venous leg ulcers; community nursing; consultations; patient-centred care; observation; interviews

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Patient-centred care (PCC) expands the focus of clinical encounters to include the patient's psychological and social context.¹ It embraces shared decision-making (SDM), wherein health-care decisions are jointly made by the patient and practitioner.² Stewart suggested that consultations result in improved health outcomes, largely through their impact on patient behaviour.³ With greater agreement between patient and practitioner and, consequently, increased concordance with a management plan, PCC and SDM should result in enhanced behaviour and improved health outcomes, with a greater likelihood of improvements in functional status, self-care and patient satisfaction.⁴ PCC is recognised as an indicator of the quality of health care.^{5–7}

Despite the relative simplicity of PCC and SDM, medical and nursing practitioners often fail to elicit patients' concerns and negotiate treatment options.^{8–10} In a series of observed general practice consultations, it was found that 54% of patient problems and 45% of patient concerns were subsequently unknown to the doctor.¹¹ A similar series of observed consultations found that the general practitioner only attempted to elicit the patient's view of

their diagnosis in 6% of consultations,¹² and another study found that physicians and patients failed to agree on the presenting problem in as many as 50% of consultations.¹³ Nurses also fail to communicate well on occasion, with a tendency to approach patients when dealing with administrative and functional issues.^{14,15} Patients often feel intimidated and reluctant to express their needs,¹⁶ which is compounded by poor clinical communication.^{10,15}

Venous leg ulcers

Chronic venous leg ulceration (VLU) is common, intractable and often recurrent.^{17,18} The care of such patients is often focused on healing the ulcer^{19,20} and frequently neglects to address issues of pain, odour, depression, anxiety and social isolation.²¹ The impact of VLU on the patient and his or her quality of life (QoL) is consistently underestimated,^{17,22} so offers a rich context in which to investigate PCC and its impact on patient outcomes. This article describes the second phase of a two-phase study to investigate PCC in people with VLU.

Method

In phase I, we systematically identified factors that were important to people with chronic VLU, which

Table 1. Consultation checklist items**Symptoms**

Presence of pain:

- Cause of pain
- Type of pain
- Timing and duration
- Use and effectiveness of analgesia

Advice on pain management:

- Comfort of dressing
- Discomfort during dressing change

Exudate:

- Odour

Depression:

- Fears and concerns
- Self-image
- Fear of people's reactions
- Fear of recurrence

Wound management

Update on the wound:

- Wound measurement
- Nurse advice
- Patient understanding of dressings

Effects on daily life

Sleep

Personal hygiene

Leg washing

Mobility

Clothes and shoes

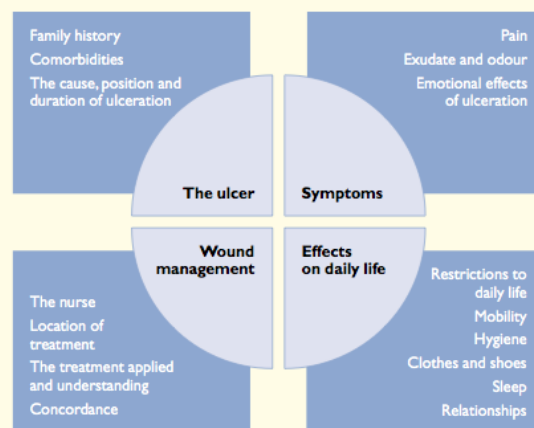
Opportunities for work and leisure:

- Isolation
- Relationships
- Financial issues

are briefly described in Fig 1.²³ In phase II (reported here), we observed five of the same people's wound care consultations. Using a checklist based on the findings of phase I, we were able to identify which factors were raised by patients during these consultations and the extent to which they were addressed by experienced nurses. This was preparatory work for a pilot study of an intervention to increase PCC in VLU care.

Study population

Nurse participants were recruited by advertising to community nurse teams in two primary care trusts. Inclusion criteria were that the nurse had been working in primary care for at least 6 months, had patients with chronic VLU on his or her caseload,

Fig 1. Themes and subthemes identified from interviews²³

and consented to the recruitment of these patients into the study with subsequent peer observation of consultations.

The patient participants were recruited from nurse participants' caseloads. These nurses gave potentially eligible patients a letter of invitation, a participant information leaflet, a consent form and an addressed, freepost envelope. Potential participants contacted JG, who formally consented those who were eligible. Patient participant inclusion criteria were VLU for more than 6 weeks and competence to provide informed consent.

Thirteen community nurses were recruited into the study. All were women and they had worked in primary care for a median of 5 years (range: 6 months to 20 years). Nine patients (four male; 44%) were recruited for the phase I interviews (median age: 76 years; range: 39–99 years). Five patients (three male; 60%) were recruited to phase II (median age: 76 years; range: 39–86 years), of which two had healed ulcers, one was in hospital following a fall, and one had been discharged.

Ethical approval for the study was granted by the Mid Staffordshire NHS Foundation Trust Local Research Ethics Committee.

Data collection

Having identified themes and subthemes from the phase I interviews (Fig 1),^{23,24} JG and AP independently developed checklist items from these themes and subthemes. They agreed on a checklist of 28 items. This was verified in discussion with RJ. The checklist formed a predetermined observation schedule (Table 1).²⁵

For ease of completion, tick, comment and 'scoring'

Table 2. Scores for checklist themes

Score	Criterion
0	Theme not raised by nurse or patient
1	Nurse did not identify cue from patient
2	Nurse picked up cue only
3	Nurse identified patient cue and asked about the issue
4	Nurse picked up cue and partially dealt with it
5	Nurse picked up cue and dealt with it fully

boxes were included in the checklist, thus minimising distraction for the researcher when recording whether an issue was raised by the patient or the nurse participant and the depth to which it was explored. A 'scoring' scale, based on those used in similar studies,²⁶ facilitated rapid assessment and the recording of depth of exploration of each theme (Table 2).

Procedure

JG observed four successive consultations between the patient and nurse participants, either in the patient's home or at the clinic, to determine the extent to which themes and subthemes patients had disclosed during phase I were being explored in subsequent consultations with members of the community nursing team. JG had the role of non-participant observer, completing the checklist during consultations and making field notes regarding the context and nature of interactions immediately after consultations. Each observation lasted for between 20 and 30 minutes.

Data collection for both phases was conducted between January 2010 and December 2011, and

data analysis was concurrent and cumulative. Analysis included the proportion of consultations at which patient participants raised themes that they had already disclosed during phase I, and the extent to which participating nurses addressed these themes.

Results

Five patient participants consulted with 13 nurse participants in 20 observed consultations. Results for the themes and subthemes are displayed in Table 3. Overall, 38% of concerns were not disclosed by patients. Of the 62% that were disclosed, 8% were missed or ignored by the nurse, 30% were discussed but not managed and 24% were managed, at least partially. These results are statistically significant ($\chi^2=55.0$; $df=20$; $p<0.0001$).

It was found that 56% of patient participants' emotional issues were not raised, whereas 91% of their wound care issues were. Based on these findings, it may be that concerns relating to the emotional effects of VLU are less likely to be disclosed and managed than concerns relating to wound management.

Discussion

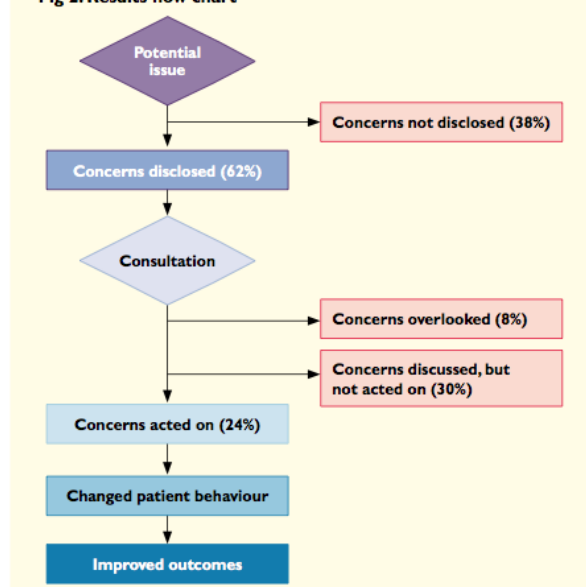
This small group of people, in whom concerns had been identified, did not raise 38% of their concerns during four consecutive consultations with their community nurses. Of the 62% of concerns that were raised, the nurse overlooked or 'blocked' 8% and discussed but did not act on 30%. Thus only a quarter (24%) of patients' concerns were addressed to some degree during the consultation.

Fig 2 combines Stewart's³ mechanism to explain the link between consultations and improved patient outcomes with the results of this study. We found that 38% of patients' concerns were never disclosed and thus 'lost' to the consultation, a fur-

Table 3. Observation results

Issue (total number of potential occurrences of each issue)	Not raised (score=0)	Cue not identified (score=1)	Cue blocked (score=2)	Discussed (score=3)	Partially dealt with (score=4)	Fully dealt with (score=5)
Pain (n=132)	55 (42%)	9 (7%)	1 (1%)	36 (27%)	9 (7%)	22 (16%)
Exudate and odour (n=28)	9 (32%)	1 (4%)	1 (4%)	5 (18%)	1 (4%)	11 (38%)
Emotional effects (n=28)	16 (56%)	2 (7%)	1 (4%)	8 (29%)	0 (0%)	1 (4%)
Wound management (n=32)	3 (9%)	0 (0%)	1 (3%)	9 (28%)	4 (13%)	15 (47%)
Effects on daily life (n=84)	32 (38%)	8 (10%)	1 (1%)	33 (39%)	3 (4%)	7 (8%)
Total (n=304)	115 (38%)	20 (7%)	5 (1%)	91 (30%)	17 (6%)	56 (18%)

Fig 2. Results flow chart



ther 38% were either ignored by the nurse or were discussed, but without any proposed or agreed changes in care, and only a quarter (24%) of patients' concerns were acted upon.

These results echo those of Stewart et al.,¹¹ who demonstrated that some 50% of patients' problems and concerns were unknown to the doctor (although the proportion of concerns that the patient failed to disclose was not identified). The present study unpicks these data to reveal that many concerns may not have been raised by patients during consultations. The effectiveness of consultation relies on both members of the patient-practitioner dyad engaging in SDM behaviours.²⁷ The particular importance of this study is to show that effective interventions will likely include enhancement of patient disclosure as well as clinician training.

Strengths of this study include having a single observer, the rigorous identification of patients' concerns (through paired, thematic analysis), development of the consultation checklist, the multiple observations (which increased the likelihood of observing an issue being raised and reduced the Hawthorne effect²⁸) and the careful field notes taken by JG. It adds to previous work by demonstrating that of the large proportion of patient problems and concerns of which practitioners may not be aware,¹¹ half were not disclosed by patients and half were

either not acknowledged or ignored by practitioners.

Weaknesses of this study include the potential for observation to affect the patient-practitioner interaction and the possibility that issues and concerns identified at the initial interview may have resolved before the observed consultations. We assumed that all concerns were still current and that patients' ulceration was ongoing.¹⁸ JG's field notes indicate that this was the case.

Recommendations to enhance PCC generally focus on interventions that change practitioner behaviour, such as enhancing consultation style,²⁹ or patient-mediated interventions, such as decision aids.^{30,31} This study offers a rich and unique, albeit situated, insight into the gap between the concerns that people may have with respect to their condition and those that they share with their health professionals. A large proportion of patient need is not being disclosed and interventions to enable patient disclosure may result in substantial gains.^{32,33} This has important consequences for PCC.

Patient-practitioner communication has long been a subject of research³⁴ and barriers to effective communication have been attributed to: 'asymmetry of the physician-patient relationship' (p. 32);³⁵ poor communication;³⁶ organisational constraints;³⁷ delays in answering patients' questions;³⁸ and a focus on functional activities.¹⁵ Research has largely focused on practitioners, with little attention being paid to patients' non-disclosure of their problems and concerns. This paper quantifies the relative importance of these facets of poor communication: for every issue that was raised by a patient and not dealt with by a nurse, another issue was not disclosed. The focus of research into patient-practitioner communication must be widened to include the patient.

Conclusion

The findings of this study—albeit one that is embedded in a local clinical context—offer insight into the nature of information-sharing during consultations, and the nature of PCC and SDM. Our findings have implications for people with VLU and those who provide their wound care, and they offer food for thought for all practitioners who are seeking to provide PCC and SDM. We may thoroughly address the expressed agenda of our patients, and yet still miss over a third of the potential of consultations.

PCC is the product of effective collaboration between patients and health professionals. Unless patients are enabled to articulate their concerns, many issues will not be acknowledged and, therefore, not be managed. Urgent work is therefore needed to determine how we, as health-care practitioners, can enable our patients to share their concerns, so that we can address them together and improve health outcomes. ■

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