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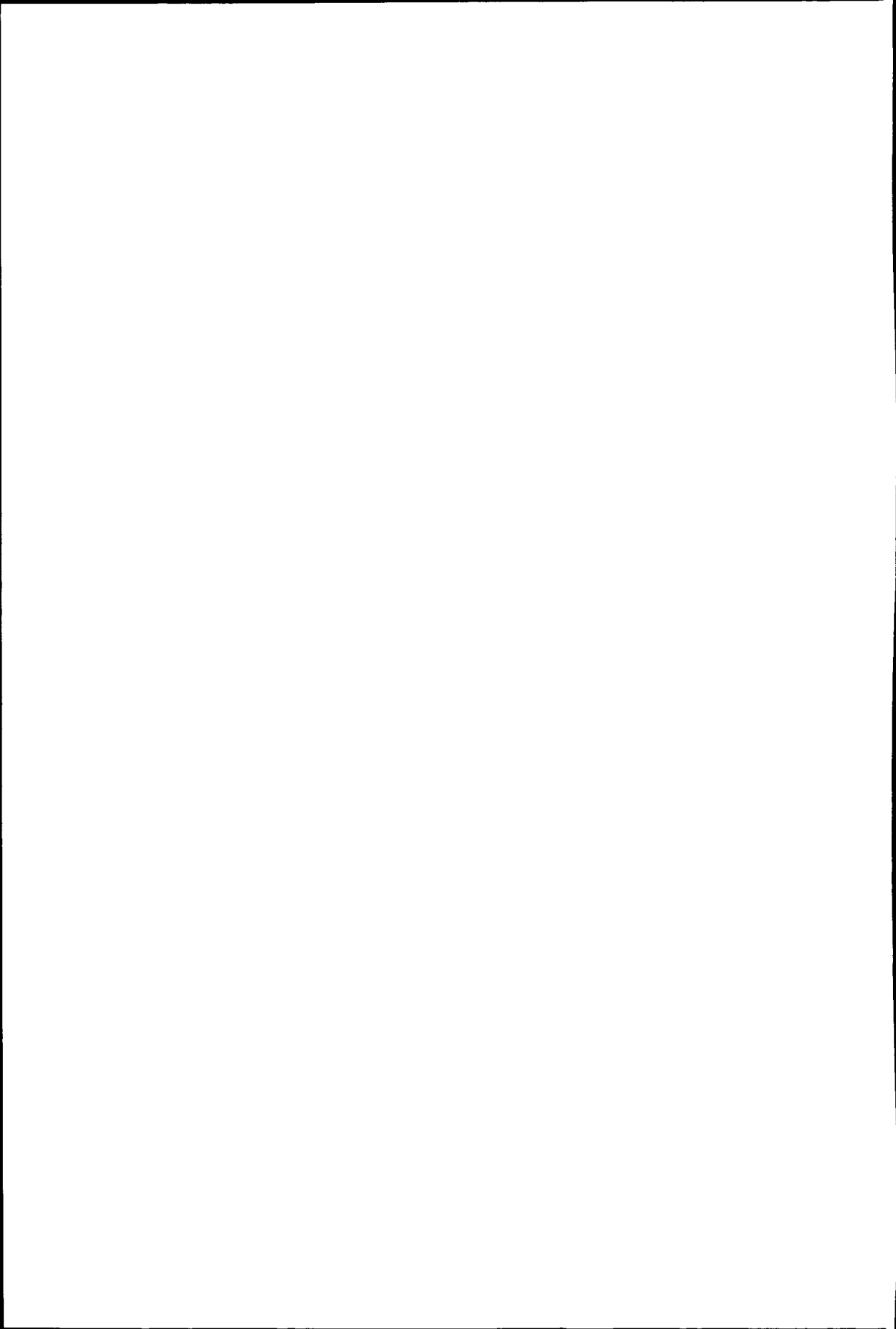
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Beyond wound care

Health behaviours and patient problems
in venous leg ulcer patients

Maud Heinen





**Beyond wound care:
Health behaviours and patient problems
in venous leg ulcer patients**

*Voor Pauline
Voor een betere zorg*

The studies presented in this thesis have been performed at the nursing science section of the Centre for Quality of Care Research (WOK). This centre is part of the Nijmegen Centre for Evidence Based Practice (NCEBP), one of the approved research institutes of the Radboud University Nijmegen and the Netherlands School of Primary Care Research (CaRe), acknowledged by the Royal Dutch Academy of Science (KNAW).

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Beyond wound care: Health behaviours and patient problems in venous leg ulcer patients

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op het gebied van de Medische Wetenschappen

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Introduction

1

Leg ulcer related patient problems and health behaviours are the key issues in this thesis. The aim of the present thesis is to study leg ulcer related patient problems and the possible need for and content of interventions directed at improving nursing care at outpatient dermatology clinics. Studies on these topics were performed to guide the development of a nurse delivered training program for venous leg ulcer patients. In this introduction, background information is given on pathology, epidemiology, treatment and nursing care of patients with venous leg ulceration, followed by what is known about ulcer related patient problems, health behaviours, behaviour change and adherence with compression therapy. Also a brief introduction is given on program development and implementation. Finally the aim and outline of this thesis will be given.

Pathology

Ulcus cruris, or 'leg ulcer' is a wound on the lower legs caused by a disturbance in the venous or arterial circulation, the microcirculation or a combination of these. A venous leg ulcer, or ulcus cruris venosum, is defined as a chronic ulcer in pathologically changed tissue of the lower legs based on chronic venous insufficiency¹. In 70% of the cases leg ulceration is caused by a chronic venous insufficiency (CVI)². The ulcus cruris venosum is a symptom of severe chronic venous insufficiency, where other symptoms are atrophy blanche and dermato and liposclerosis, hyperpigmentation, oedema and eczema. All these symptoms indicate a severe distortion of the micro-circulation caused by increased ambulant venous pressure. Varicose veins and post trombotic syndrome are the main causes for an increased venous pressure and CVI. With varicose veins, the veins are dilated and the valves in the veins cannot be closed which causes reflux in the veins (figure 1). Deep venous thrombosis causes damage to the veins and the valves with the same result.

Also a disturbed calf muscle pump function can cause or contribute to CVI. The calf muscle pump supports the venous circulation from the lower legs upwards in the direction of the heart, and is a result of the expansion and contraction of the calf muscle during walking (figure 2). A diminished or even absent calf muscle pump function will cause high venous pressure in the lower legs.

There are several physical examination methods to determine the severity and exact cause of venous insufficiency like duplex and Doppler investigations, plethysmography and phlebography². The CBO-guideline¹ on diagnostics and treatment of the ulcus cruris venosum recommends duplex investigations in all ulcer patients. Measurement of the

ankle/brachial pressure index (ABPI) is strongly recommended to determine the presence and severity of arterial insufficiency. An ABPI of $<0,8$ indicates arterial insufficiency whereby treatment essentially differs from treatment of leg ulcers entirely caused by venous insufficiency.



A typical venous ulcer, located at the medial malleolus with signs of atrophie blanche. Crustae of dried-up exsudate are visible on the edges of the wound. There is some erythema around the wound.



Venous ulcer with granulation tissue. Remains of treatment with zink-ointment and compression bandages are visible in this picture.

Epidemiology

Estimates of the prevalence of leg ulcers in studies from the USA and Western Europe vary from 1 or 2 per 1000 to 1 per 100 in the general population³⁻⁶. The prevalence of leg ulcers is higher in women and older adults; a prevalence of 12 per 1000 is reported in a study among women above the age of 75⁷. Half of the patients suffering from leg ulcers have open wounds during a period of one to five years^{3,8}. After healing there is a high risk of recurrence: 45% of the patients with an ulcer suffer from recurrence^{9,10}.

Treatment

This thesis concerns the non-invasive treatment of venous leg ulcers which beholds ambulant compression therapy and activation of the calf muscle pump through physical activity and leg exercises. Although wound-care is an essential part of the treatment of venous leg ulcers, which requires a lot of time and expertise of dermatology and home

health care nurses, it is merely beyond the scope of this thesis and therefore will not be discussed in detail here.

Ambulant compression therapy improves the effect of the calf muscle pump, reduces venous volume, lowers venous pressure, increases current velocity, improves the microcirculation and prevents or reduces oedema². Compression therapy can be applied by means of bandages or therapeutic elastic stockings. Bandages are mostly used in case of a wound or/and when there is oedema of the lower legs. Patients need to wear their bandages for 24 hours a day, seven days a week. When the wound has healed patients are instructed to continue compression therapy using therapeutic elastic stockings which have to be worn during the daytime, from the moment of rising until the moment of going to bed at night.

Patients with large and recurrent wounds that are healing insufficiently or are of mixed etiology, are often referred to outpatient dermatology clinics. Patients with wounds with a tendency towards healing are mostly treated by their family physicians and home health care nurses.

Nursing Care

Current nursing care for venous leg ulcer patients mainly consists of applying compression therapy and wound-care. Once or twice a week the bandages and wound-dressings are changed by trained nurses. In current regular practice, patients are usually informed that walking in combination with compression therapy enhances wound healing and helps to prevent recurrent wounds. Adherence to compression therapy is only incidentally discussed or monitored. Nurses however, frequently observe ulcer related patient problems, non adherence with compression therapy and unhealthy lifestyles in venous leg ulcer patients who are often repeatedly visiting the outpatient clinics with recurrent wounds. Nurses often experience limitation in time, means and/or expertise to address these problems yet. Consequently it can be assumed that addressing ulcer related problems and lifestyles would not only improve the patient's quality of life but would also be beneficial to the healing and prevention of recurrent wounds. Furthermore, in order to provide high quality of care, nursing practice needs to be evidence based¹¹, and as formulated by Ingersoll¹² "it is the nurse's role is to bridge the divide between research and practice via improvement of clinical care on the basis of the evidence regarding best practice".

Leg-ulcer related problems

There is lack of a clear description of leg ulcer related patient problems. There are some studies that describe pain as a common problem for many patients¹³⁻¹⁵. Other reported problems experienced by patients suffering from leg ulceration are sleeping problems, decreased mobility and dependency¹⁶⁻¹⁸. Until now, little attention has been paid to these patient problems, resulting in a lack of recognition, prevention and therapy of these problems by health care providers. Given the duration of complaints, many patients suffer over longer periods of time. Relevant literature reviews could not be identified.

Leg ulcer related health behaviours & adherence with compression therapy

According to guidelines from the Royal College of Nursing¹⁹ and the Dutch institute for healthcare (CBO)¹ relevant lifestyle topics in the population of venous leg ulcer patients are, physical activity and leg-exercises, leg elevation, smoking cessation, healthy nutrition and a healthy weight. However, the evidence in relation to venous leg ulceration is not yet fully understood, nor proven, and has not yet systematically been reviewed. Furthermore, research on determining current health behaviour of venous leg ulcer patients on the most effective ulcer related health behaviours has not been conducted yet.

In addition to health behaviours, compression therapy in patients with venous insufficiency is proven to be effective²⁰⁻²¹, but adherence to this treatment is essential. The few studies on adherence to compression therapy in venous leg ulcer patients are indicating high rates of non-adherence with compression therapy varying from 10-68%²²⁻²⁴. Systematic coaching to support lifestyle adjustment e.g. in adherence or ulcer related health behaviours is not yet provided at outpatient dermatology clinics.

Behaviour change

Health behaviour theories like social cognitive theory²⁵⁻²⁶, theory of planned behaviour²⁷ and the health belief model²⁸ are useful to understand and select relevant determinants of behaviour. In order to promote behaviour change in a specific group it is necessary to identify relevant determinants for this group.

From the theories and related research on behaviour change a number of individual and environmental determinants of health behaviours can be identified. Individual factors include knowledge and beliefs about the relation between the behaviour and health outcomes, motivation for behaviour change and self-efficacy to perform the activity²⁵⁻²⁷⁻²⁹⁻³⁰. In addition, physical limitations have to be taken into account for patients

with long lasting health problems such as leg ulcers. Environmental factors refer to the objective factors that can affect a person's behaviour but that are physically external to that person as well as the person's perception of these environmental factors^{25, 26, 31}. Environmental factors mainly refer to interpersonal or organizational factors that hinder or facilitate the performance of the behaviour, e.g. social support, accessibility of health care systems or personal aids.

To learn about health behaviours in leg ulcer patients, generic as well as population-specific determinants of health behaviour have to be explored to facilitate the development of therapeutic possibilities to stimulate health behaviour changes by professionals.

Development and implementation of Lively Legs

In view of the lack of attention for individual health behaviours, a training program, Lively Legs, directed at leg ulcer related health behaviours in leg ulcer patients was developed. For the development of the program we used a method for systematically developing theory and evidence based health promotion programs called Intervention Mapping²⁹. Intervention mapping (IM) is a method existing of five steps. Relevant behavioural determinants need to be identified, followed by reviewing theory and evidence from international literature to select effective methods and strategies for behaviour change. In addition to the development of a program, planning for adoption and implementation is also an explicit part of intervention Mapping²⁹. Adoption is a positive attitude and decision to change personal routine^{32, 33}. Implementation can be described as a planned process and systematic introduction of innovations and / or changes of proven value; the aim being that these are given a structural place in professional practice, in the functioning of organisations or in the healthcare structure³⁴. Adoption and implementation are crucial in the effectiveness of a program or intervention; the impact of a program or intervention will be determined not only by the effectiveness of the program but also by the quality of program implementation and adoption¹⁵.

Aims

The aim of this thesis is to provide insight in leg ulcer related patient problems and health behaviours in leg ulcer patients, and to develop an evidence-based program on health behaviours in leg ulcer patients treated at dermatology outpatient clinics.

This thesis can be divided in three parts. In part one (chapter 2 & 3) leg ulcer related problems and care deficits are identified. In part two (chapter 4, 5 & 6) we focussed on leg ulcer related health behaviours. Specifically we address the following questions: a) what is the evidence for effective pain related interventions and for the effect of nutrition, leg elevation and exercise on the healing of leg ulcers; b) What is the level of physical activity in leg ulcer patients and to what extent do patients adhere to compression therapy, and c) what are determinants of physical activity in leg ulcer patients. Part 3 (chapter 7) is about the development of "Lively Legs", a lifestyle program for leg ulcer patients focussing on leg ulcer related health behaviours. Finally in chapter 8 our findings on patient problems and health behaviours are discussed in relation to the development of the Lively Legs program.

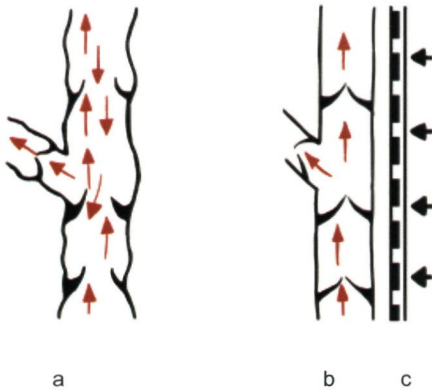


Figure 1:

(a) the vein is dilated and the valves in the vein are not closed, there is a reflux of blood,
 (b) the valves in the vein are closed and prevent reflux of blood
 (c) pressure (from bandages or stockings) prevents the occurrence of oedema.

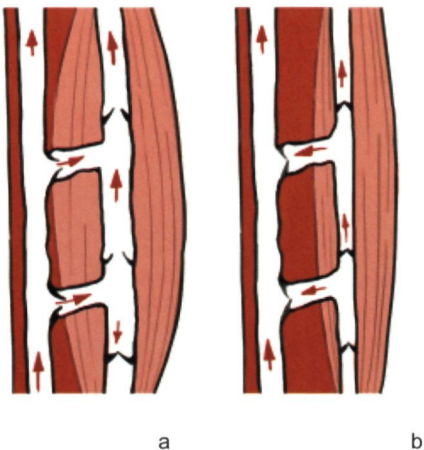


Figure 2:

(a) the muscle is in relaxation, the bloodstream goes from the superficial system through the vena perforantes to the deep system
 (b) while walking the muscle is pulled tight and gives instant pressure on the deep vein (calf muscle pump function), the valves in the vein prevent the reflux of the venous blood, also the valves in the vena perforantes are closed, preventing reflux of blood to the superficial system.

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Leg ulcers: a review of their impact on daily life

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Journal of Clinical Nursing 2004, 13 341–354

2

Abstract

Background. Current nursing care for leg ulcer patients often focuses on wound care and providing compression therapy. Nurses perceive leg ulcer patients as ‘underserved’ with regard to problems patients experience in daily life. An overview of patient problems is a first and essential step in the development of comprehensive nursing care.

Aims and objectives. To gather information about the impact of leg ulcers on patient’s daily life as described in quantitative and qualitative studies.

Design. Systematic literature review.

Methods. Medline and Cinahl databases were searched for venous leg ulcer studies, up to 2002; this was followed by the ‘snowball method’. Studies were selected in accordance with preset criteria.

Results. A total of 37 studies was included. All studies report that leg ulcers pose a threat to physical functioning. Furthermore, a negative impact on psychological functioning is reported and, to a lesser degree, on social functioning. Major limitations are pain and immobility, followed by sleep disturbance, lack of energy, limitations in work and leisure activities, worries and frustrations and a lack of self-esteem. Patients have a significantly poorer quality of life compared with healthy people. Finally, patients report problems with regard to follow-up treatment.

Conclusions. Having a leg ulcer has a major impact on a patient’s life. There are indications of under-treatment of pain. Relevance to clinical practice. Keeping in mind that leg ulceration is notorious for its chronic character, the negative impact on patient’s life implies that many patients suffer over longer periods of time. This emphasizes the need to focus on quality of life aspects in patient care. There is much to gain, especially concerning pain and mobility. The development of comprehensive care programmes is essential.

Introduction

Many choices in everyday nursing are influenced by the intention of providing good quality and evidence-based care. This review study was largely motivated by similar intentions. Nurses from several dermatological outpatient clinics in the Netherlands perceived the population of leg ulcer patients as being 'under-served' and experienced the need to develop care programmes for this group. Pain, sleeping problems and negative emotions, such as shame, are only a few examples of the many patient problems nurses encountered.

Current nursing care for leg ulcer patients often focuses on wound care and providing compression therapy. Problems directly or indirectly resulting from having ulcers are not systematically monitored or treated. Nurses meet the challenge to broaden the scope of nursing from wound care to comprehensive care. An overview of patient problems is a first and essential step in the development of comprehensive nursing care.

The aim of the study was to gather information about the impact of leg ulcers on patient's daily life as described in quantitative and qualitative studies. The results from this review are presented in this article.

Leg ulcers are commonly defined as chronic ulcers of varying aetiology that occur below the knee¹. Most ulcers are the result of several aetiological factors operating together, but the most important factor is chronic venous insufficiency². Ulcers can heal within several weeks, but are often chronic and longstanding.

Harrison et al.³ found that 60% of ulcers exist for more than 6 months and 33% for more than 1 year. Much longer durations are also known; Price & Harding⁴ reported 20% of the recent ulcers lasting for more than 5 years. After healing, there is a high risk of recurrence: 45% of the patients with an ulcer suffer from recurrence^{3,5}. The prevalence of ulcers varies from 1.8 per 1000 for leg ulcers exclusively⁶ and 3.0 per 1000 for both leg and foot ulcers⁷. The occurrence of leg ulcers appears to be related to both age and sex: a prevalence of 12 per 1000 is reported in a study among women above the age of 75 years⁸.

Methods

A review of the literature was conducted in which studies were included by three steps.

Step 1

Original papers concerning venous leg ulceration published within the period 1985–2002 were retrieved using the CINAHL database. Only articles describing findings from original studies were used for this review. Furthermore, two independent researchers

checked the abstracts of all articles: (i) to exclude studies with populations of (mainly) arterial aetiology or diabetic aetiology, infected wound or other specific comorbidity; (ii) to include only studies that analysed findings at the level of patients (and not at the level of wounds or ulcers) and (iii) to exclude studies in populations with healed wounds. When other patient groups were involved, inclusion was only justifiable if results for leg ulcer patients were described separately. Two independent researchers checked the abstracts, and in the case of discrepancy, abstracts were included. After this first selection of abstracts, full versions of papers were read, still excluding studies which did not meet the above-mentioned criteria or which did not describe results clearly.

Step 2

The 'snowball method' was applied. References from the papers were screened thoroughly for possibly relevant studies using the same criteria cited above.

Step 3

Additionally, a search was performed in MEDLINE (1985–2002); the same inclusion and exclusion criteria were applied.

We did not select on study design; because of the explorative character of our research question we were interested in results from quantitative and qualitative studies. A data extraction format was used to gather relevant information. In this review, only data from patients' baseline characteristics were included in case of experimental or longitudinal designs. In the case of a control group with a population of leg ulcer patients, data from this control group and the experimental group were combined and recalculated. Results of quantitative studies were categorized into preset domains: impact on physical aspects, psychological and social aspects and quality of life (QoL). Results of qualitative studies were categorized only after investigating the outcomes, three domains emerged from the data: impact of the leg ulcer on physical aspects, psychological and social aspects and impact of the treatment.

Results

Impact as described in qualitative studies

Eight studies were traced which described the impact of living with leg ulcers using qualitative methods (see for design and ulcer characteristics Tables 1 and 4, respectively). In general, the goals of the qualitative studies were to explore patients' experiences of living with leg ulcers. All studies used patient interviews with an open interview

technique, except one that chose the focus-group method⁹ Samples were selected purposively and sizes were small

Authors	Sample	Inclusion criteria	Aetiology	Age	Female
Bland ¹⁵ N-Zealand	9	Purposeful	-	range 56-81	4/9
Charles ¹³ UK	4	Purposeful	Venous	43 54 60 62	1/4
Chase et al ¹⁶ USA	37	Purposeful	-	-	-
Douglas ¹⁴ UK	8	Purposeful	Venous	-	6/8
Hyde et al ¹¹ Australia	12	Female Age>70 yrs Ulcer duration>3 yrs	-	range 70-93	12/12
Hyland et al ⁹ UK	22	-	-	-	-
Krasner ¹² USA	14	Purposeful	Venous	range 30-86	7/14
Walshe ¹⁰ UK	13	Purposeful	Venous	>85=50%	12/13

Four studies included patients with leg ulcers resulting from venous insufficiency, in the other samples the leg ulcer aetiology was not reported. The methods used to conduct and interpret the interviews were not always clearly described, therefore, it is difficult to judge the validity of the results. The results are listed in Table 3, in which we distinguished three domains: physical impact, psychological and social impact, and aspects of treatment.

Impact on physical functioning

Four themes related to physical impact emerged from the qualitative studies: pain, impaired mobility, sleep disturbances and problems related to wound characteristics. Patients in all studies mention pain as the first and most dominant experience related to having a leg ulcer. Various types of pain are described, of which the milder type is merely irritating but can, however, aggravate into intense pain^{9,11}. In some cases, pain intensity is stable over time¹⁰, whereas in others there are reports of day-to-day variation, increased pain intensity during the night, or effects caused by weather and seasonal influences^{9,11}. Swelling also exacerbates pain¹². Furthermore, Krasner¹² found that patients consider pain to be a normal or expected aspect of having a leg ulcer. Finally, pain may lead to disturbed sleep, as mentioned in four studies^{10,11,13,14}.

Impaired mobility is mentioned in all but one qualitative study and often seems pain-related. Standing and walking tend to aggravate pain and are avoided by some patients^{10,12}. Limitations in mobility also result from wound dressings, swollen legs, leakage and the need to wear large shoes. In addition, some patients mention avoiding physical activity because they believe this activity contributes to the development of new

leg ulcers^{9,11}. Restrictions in daily activities are mentioned in relation to impaired mobility. For instance, patients report difficulties in maintaining personal hygiene. Having a wound itself generates negative experiences. Some wounds can ooze copiously. Patients describe wet shoes, wet stockings and wet sheets and bed covers. Bland¹⁵ found that patients are aware of the unpleasant smell that accompanies infected leg ulcers. Disturbed sleep is mentioned in four of the eight studies. It is related to pain and uncomfortable sleeping position^{10,11,13,14}.

Impact on psychological and social aspects

In most studies, subjects mentioned negative effects on mood and feelings. Feelings of regret, depression, loss of will power, loss of control and feelings of helplessness and hopelessness are reported^{9,13,14}. Most patients take a pessimistic view of the healing potential of their ulcerated limbs, a view which is often shaped by a long history of previous ulceration. Although some patients never stop hoping that healing will take place one day^{10,11,15}, having leg ulcers becomes a way of life after some time passes. Leakage and odour are accepted as part of having a leg ulcer, but lead to embarrassment and difficulties in maintaining dignity and outward appearance^{10,11}. Some patients report feelings of being unclean. It is difficult to get shoes that fit over bulky bandages, and clothes are selected to hide the fact of ulceration. Hyland et al.⁹ reported that female patients are sensitive to perceived loss of femininity. In one study, patients report being preoccupied with their ulcer and its treatment¹¹. The duration of the problem and the uncertainty about treatment are also a cause of concern⁹.

Several coping strategies are mentioned. Walshe¹⁰ reported that some patients are able to accept leakage and discharge as part of having an ulcer. Three studies found that patients try to maintain a positive attitude to carry on and to make life changes to find new satisfaction^{9,11}. Walshe¹⁰ described four main strategies for coping: coping by comparison, feeling healthy, altered expectation and being positive.

Table 3 Qualitative studies: samples, methods, reported patient problems (n=8)

Authors	Sample / Method	Reported patient problems		
		Physical	Psychological & social	Treatment
Bland ¹⁵	9 patients/ interviews	Pain Infection ooze and odour	Professionals invade privacy Never stop hoping	Different advices from professionals Not always able to comply
Charles ¹³	4 patients/ interviews	Pain Sleeplessness Impaired mobility	Nobody listens or explains Hopelessness Helplessness Lack of control Negative effects on work Negative effects on interaction	
Chase et al ¹⁶	37 patients/ interviews	Pain An interminable healing process Limitations to mobility and activity	Powerlessness Who cares? A forever healing process	
Douglas ¹⁴	8 patients/ interviews	Pain (by ulcer and treatment) Sleepless nights Leakage, odour Impaired mobility	Negative feelings body image Loss self-worth Frustration Pessimistic about healing, and recurrences	Lack of understanding about leg ulcer management: conflicting advice and using different dressings Patients don't know underlying cause
Hyde et al ¹¹	12 patients (all female)/ interviews	Nagging pain, interference with sleep Infection Leakage, odour Impaired mobility	Gaining and maintaining control Fighting for skin and limb integrity Embarrassment because of odour/clothing Wearing non-preferred apparel Loneliness Hope, determination, stoicism Negative mood and feelings	Uncertainty over treatment Conflicting messages from health professionals
Hyland & Thomson ⁹	22 patients (4 focus groups)	Pain Restricted activity (due to pain) Avoidence of activities to prevent further ulcerating	Ulcer preoccupation and treatment Loss of femininity	Conflicting messages from health professionals
Krasner ¹²	14 patients/ interviews	Pain, various descriptions Pain is normal & predictable Swelling equals pain Limitations in standing position	To maintain a positive attitude Feeling frustrated Interfering with the job Having to make lifestyle changes Finding satisfaction in new activities	Not always able to comply treatment (stockings, diuretic and elevation of leg) reduce pain
Walsh ¹⁰	13 patients/ interviews	Pain Leakage and odour Impaired mobility Disturbed sleep	Negative evaluation of own appearance Uncertainty and worry Pessimistic view of healing Coping by comparison, feeling healthy, altered expectation and by being positive	Dressings and bandages must be comfortable Don't always understand treatment

Treatment

Patients mention that treatment often produces intolerable side-effects that complicate their lives. For example, patients report not being able to wash their feet because of bandages that are uncomfortable and need to stay in place or difficulties in finding and wearing larger size shoes¹⁵. The usual recommendation, 'rest the leg', is insufficient as little information is given on how this can be performed or for how long. Especially when the patient is the main breadwinner, resting can be difficult and job security can become a real concern¹⁵. Additionally, Hyland et al.⁹ and Chase et al.¹⁶ found that participants are sometimes not able to adhere to recommended regimes.

Patients' descriptions of treatment demonstrate a perceived inconsistency. Remarkably, in five studies, patients report being dissatisfied with professionals because they did not always explain what treatment they need to follow, did not listen and provided inconsistent messages or advice^{9 10 13 15}. However, patients are grateful, often because of the personal characteristics of nurses and other professionals.

Impact as described in quantitative studies

Description of study samples

Twenty-nine studies described elements of the impact of leg ulceration on daily life using quantitative methods. Some studies were described in two or more papers, as shown in Table 2. All papers but one were dated 1993 or later. Some papers mainly focused on the impact of leg ulceration (e.g. ^{9 17 21}). They used a variety of questionnaires, which were sometimes developed by the researchers themselves. Other papers focused on the effect of an intervention (bandaging, types of creams, introduction of a nursing clinic and electromagnetic therapy) in which patients' experience is merely a secondary outcome (e.g. ^{22 24}). These studies often used pain-scales and nondisease specific health-related QoL instruments.

Description of the patients' samples is as follows. Patients are often older; mean ages are within a range of 62–79 years and in general, more than 60% of the patients are female. The living arrangements indicate that around half of the respondents live alone ^{4 23 25}. In four studies the body mass index (BMI) was calculated and in all studies mean or median values indicated overweight (^{26 29}). Employment was reported in two studies: mean percentages were 20 and 31%^{18 30}.

Table 2 Quantitative studies: study design and general patient characteristics (n=29)

Authors	Design	Sample	Inclusion criteria: current leg ulcer +	Aetiology	Mean age	Female
Bjellerup et al. ²⁶ Sweden	Longitudinal	22	Ulcer duration>1 yr	Venous=90% Ven-art=10%	median=76	40%
Callam et al. ³⁹ UK	Survey	600	--	Venous=79% Ven-art =21%	--	--
Charles et al. ³⁴ UK	Experiment	91	Diameter>2 cm and < 12 cm	Venous=100%	72 range=53-91	56%
Chase et al. ²⁹ USA	Survey	21	--	Venous*	72	40%
Daniels et al. ³⁵ USA	Longitudinal	11	Area> 2 cm ² Diameter < 6 cm	Venous=100%	58	55%
Flett et al. ¹⁷ New Zealand	Survey + comparing 2 groups	14 patient (+14 healthy)	--	Venous*	--	75%
Franks et al. ⁴¹ UK	Experiment	200	Ulcer duration>2 months Diameter>10 mm	Venous=100%	70	66%
Franks & Moffat ³⁷ UK	Survey	758	--	--	75	64%
Franks et al. ^{47 23} UK	Experiment	182	--	--	76	64%
Hamer et al. ⁵ UK	Survey + comparing 2 groups	88 patient (+70 healthy)	Age>65 yrs	--	--	--
Hansson et al. ³² Sweden	Experiment	43	Area>1 cm ² and <50	Venous=100%	range=42-90	56%
Harrisson et al. ³ Canada	Survey	192	--	--	<65=26% 65-75=29% >75=45%	50%
Hofman et al. ¹⁹ UK	Longitudinal	140	--	Venous=67% Arterial=3% Ven-art =30%	65	62%
Hyland et al. ⁹ UK	Survey	50	--	--	77	74%
Johnson ³¹ Australia	Longitudinal	156	Age>60 yrs Ulcer duration >6 wk	Venous=57% Arterial=11% Ven-art=32%	78	58%
Keeling et al. ²⁰ UK	Longitudinal	15 leg ulcers (+15 diab foot)	--	--	70	66%
Kenkre et al. ²⁴ UK	Experiment	19	Ulcer duration >4 weeks	Venous=100%	71	

Table 2 Quantitative studies: study design and general patient characteristics (n=29)

Authors	Design	Sample	Inclusion criteria: current leg ulcer +	Aetiology	Mean age	Female
Liew et al ⁴⁸ Australia	Longitudinal	57	--	Venous=74% Arterial=2% Ven-art=11%	72 range=41-88	61%
Lindhalm et al ¹ Sweden	Survey	125	Ulcer duration >6 months	--	77 median=80-85	60%
Loftus ³⁸ UK	Experiment	24	--	Venous=100%	74 range=41-86	54%
Morrell et al ²⁸ UK -Walters et al ⁴² UK -Collins et al ⁴⁹ UK -Brereton et al ³³ UK	Experiment	233	Ulcer duration >3 months	Venous=100%	73	67%
Philips et al ¹⁸ USA	Survey	62	--	--	62	60%
Pieper et al ^{21,30} USA	Survey	32	History of IV drug use	Venous*	45	28%
Price & Harding ⁴³ UK	Survey	32 (+17 ac wounds)	Ulcer duration>3 months	Venous*	61	59%
Price & Harding ⁴ UK	Survey	55	Ulcer duration>3 months	--	70	67%
Rotchell ²² UK	Experiment	321	--	Venous & Ven-art*	--	--
Stevens ³⁶ UK	Experiment	567	--	Venous=87% Arterial & Ven-art=13%	77	66%
Wissing & Unosson ²⁵ Sweden	Survey	70	Age>65 yrs Ulcer duration >1 month	Venous=51% Arterial=9% Ven-art=40%	79	70%
Wissing et al ²⁷ Sweden	Survey	9	Female Age>60 yrs Ulcer duration >6 months	--	79	9/9

The venous aetiology is not based on an Ankle Brachial Index

The characteristics of the ulcers are presented in Table 4.

Table 4 Ulcer specific characteristics (a) in qualitative studies (n=5)¹ and (b) in quantitative studies (n=20)²

Authors	Sample	Duration current ulcer	Ulcer size (cm ²)	Time since first ulcer	Other
(a)					
Bland ¹⁵	9	--	--	range=8 mths-6 yrs	--
Charles ¹³	4	range=5-35 yrs	--	--	--
Hyde et al ¹¹	12	range= 5-54 yrs	--	--	--
Krasner ¹²	14	range= 2 mths-7 yrs	--	--	--
Walshe ¹⁰	13	range=4 mths-10 yrs	--	range=1-38 yrs	first ulcer=5/12
(b)					
Bjellerup et al ²⁶	22	--	range=1-20 yrs	range=2-59 yrs	--
Callam et al ³⁹	600	--	<1 yr=59% 1-5 yrs=33% >5 yrs=8%	<5 yrs=43%	first ulcer=45%
Charles ³⁴	91	range=2-38	range=1w-30 yrs	--	--
Franks & Moffat ³⁷	758	--	median=11 mths	--	--
Franks et al ^{23 47}	182	>10=18%	median=7 mths range=1-63 yrs	range=16-97 yrs	--
Hamer et al ⁵	88	--	--	--	first ulcer=45%
Hansson et al ³²	43	range=1-60	range=1m-42 yrs	--	first ulcer=45%
Harrisson et al ³	192	--	<6 mths=40% 6-12 mths=27% >12 mths=33%	--	first ulcer=45%
Johnson ³¹	156	mode=6 range=0,5-54	median=1 yr range=2-32 yrs	--	--
Keeling ²⁰	15	--	--	Range=3-21 yrs	--
Kenkre ²⁴	19	--	--	range=8 mths-50 yrs	first ulcer=21%
Liew et al ⁴⁸	57	--	>7mths=42%	--	--
Lindholm et al ¹	125	--	--	Shop workers md=20 yrs Others md=1,2 and 4 yrs	--
Morrell et al ²⁸	233	median=6 p75%=16	median=7 mths p75%=3 yrs	median= 7 yrs p75%=20 yrs	--
Philips et al ¹⁸	62	--	range=1-36 yrs	--	first ulcer=37%
Price & Harding ⁴	55	--	<2 yrs=56% 2-5 yrs=24% >5 yrs=20%	--	first ulcer=38% earlier episodes=1-9
Rotchell ²²	182	>10=32%	median=7 mths	--	--
Stevens ³⁶	150	>10=43% ³⁾	>6 mths=65%	--	--
Wissing & Unosson ²⁵	70	--	<1 yr=57% 1-5 yrs=32% >5 yrs=11%	--	--
Wissing et al ²⁷	9	--	--	median=2 yrs range=1-4 yrs	# of ulcers 1-3

1) Three studies did not describe ulcer characteristics ^{16 14 9}

2) Nine studies did not describe ulcer characteristics ^{29 35 17 41 19 9 38 30 43} 3) Calculated from data in paper

In two studies the median size of the ulcer and the mode are 6 cm². Apparently, in three studies, the percentage of wounds larger than 10 cm² ranges from 18 to 48%. The duration of the ulcers can be quite long: in four studies, 40% of the ulcers had existed for more than 1 year and around 10% more than 5 years. The total range of the duration of the wound is between 1 week and 63 years.

Prior episodes of ulceration are reported in several studies and it appears that only 21 to 45% are first time ulcers. The periods of leg ulceration as the first occurrence of an ulcer vary from medians of 2 years to 20 years (the latter median was found in a subgroup of shop workers¹). Moreover, Kenkre et al.²⁴ reported a range of 8 months to 50 years of ulceration.

Impact on physical functioning

As in the qualitative studies, pain is the major issue in the studies that used a quantitative design. Table 5 summarize the results for all studies that used pain scales. The prevalence of patients who do not experience pain ranges from 0 to 37%, with the exception of one study where the percentage was 50%. However, the severity of pain varies. Mean pain intensity scores vary between 2.2 and 5.5 (on a 0–10 scale, where 0 represents no pain; Table 5a).

Hyland et al.⁹ reported that 20% of the sample have ‘very painful’ ulcers, and 4% have ‘excruciating’ pain. In a subgroup of patients with ulcers of venous aetiology, Hofman et al.¹⁹ described much higher scores: 28% of the patients have ‘horrible’ pain and 36% ‘excruciating’ pain. In addition to pain intensity, Johnson³¹ investigated pain during mobility (walking indoors, climbing stairs and rising from a chair) and these pain scores appear to be rather low: a mean of 1.4 was ascertained (on a 4- point scale, where 1 represents no pain). However, in the group of patients with pain, Pieper et al.³⁰ differentiated between the interference of pain with walking (mean 4.3), general activities (mean 4.9), mood (mean 4.1), sleep (mean 4.6) and the interference of pain with relationships (mean 3.1), on a range of 0–10 where a score of 0 represents no interference. Pain while dressing is reported in various studies (^{3,32,35}).

Several studies compared pain intensity in leg ulcer patients with that in healthy individuals. All but one study reported significantly higher pain levels in the patient group^{1,4,17,36,37}. Only Chase et al.²⁹ found comparable pain intensity levels for patients and subjects in an age-norm group.

Table 5 Overall pain scores (a) on a 10-point Likert scale* and (b) on various Likert-type scales*

Authors	Sample Size	Pain questionnaire	Scale low score = no pain	Having 'no pain' (%)	Mean
(a)					
Kenkre et al. ²⁴	N=19	VAS	0-10 ¹⁾		5.5
Pieper et al. ³⁰	N=32	Pain 'now', Am. Pain Society Q	0-10	16	4.9 ²⁾
Walters et al. ⁴²	N=233	Subscale of MOS SF-36	0-10 ³⁾	25	4.4
Rotchell ²²	N=226	Subscale of NHP	0-10 ³⁾		4.4
					2.6
Pieper et al. ³⁰	N=32	Pain Interference, Am. Pain Soc. Q.	0-10	16	4.2 ²⁾
Charles et al. ³⁴	N=91	VAS	0-10	26	4.1 ²⁾
Stevens ³⁶	N=417	Subscale of NHP	0-10 ³⁾		3.3
					2.7
Franks et al. ⁴¹	N=200	Subscale of NHP	0-10 ³⁾		3.3
Franks et al. ³⁷	N=758	Subscale of NHP	0-10 ³⁾		3.1
Walters et al. ⁴²	N=233	Pain 'now', McGill Pain QoL	0-10		3.1
Chase et al. ²⁹	N=21	Subscale of MOS SF-36	0-10 ³⁾	33	2.4
Bjellerup et al. ²⁶	N=22	VAS scales	0-10 ¹⁾	50	2.2 ²⁾
(b)					
Walters et al. ⁴²	N=233	PRI-Sensory, McGill Pain Q	0-33		8.7
Walters et al. ⁴²	N=233	PRI-Affective, McGill Pain Q	0-11		1.9
Pieper et al.	N=32	Subscale QoL with a leg ulcer Q	1-7 ⁴⁾		5.1
Hofman et al. ¹⁹	N=94	Pain intensity, verbal	1-7 ²⁾	10	4.4
Hyland et al. ⁹	N=50	Subscale of Exeter Leg Ulcer Q	1-7 ⁴⁾	10	3.4
Flett et al. ¹⁷	N=28	Pain during last 3 months	1-7 ⁴⁾		3.3
Chase et al. ²⁹	N=21	Pain intensity	1-4 ⁴⁾		2.5
Daniels et al. ³⁵	N=11	Pain intensity	1-4 ⁴⁾	0	2.2
Johnson et al. ³¹	N=156	Pain in mobility	1-4		1.4
Philips et al. ¹⁸	N=62	Pain intensity	1-4	15	
Liew et al. ⁴⁸	N=57	Pain intensity		12	
Franks et al. ⁴⁷	N=182	Pain intensity		22	
Harrison et al. ³	N=192	Pain intensity		34	
Wissing et al. ²⁵	N=70	Pain intensity		37	

* From experimental and longitudinal studies only baseline data are presented. If a control group was a leg ulcer population, baseline data from control and experimental group were recalculated to one mean.

1) Means calculated from data in paper.

2) Only patients with pain were included.

3) Recoded from 0-100 to a range of 0-10, or negative/positive recoded in such a way that low scores represent 'no pain' or 'no impact on daily life'.

4) Recoded negative/positive recoded in a way that low scores represent 'no pain' or 'no impact on daily life'.

The size of the ulcer is mentioned both as a predictor of pain intensity³⁰ and as having no impact on pain¹⁸. Results concerning the relationship between gender and pain are inconclusive. Higher pain intensity scores for women than for men were found by Lindholm et al.¹ and Phillips et al.¹⁸. However, Franks & Moffatt³⁷ and Pieper et al.³⁰ found the opposite; the latter also mentioned higher pain interference scores for women. Although women report higher pain intensity, Franks & Moffatt³⁷ state that the impact of pain on men is greater when compared with age-norm groups.

Seldom have studies reported the use of pain-killers Bjellerup et al²⁶ showed that 9 out of 11 patients with pain use pain-killers Kenkre et al²⁴ reported that 74% of the respondents use pain-killers, although the pain intensity score was still 5.5 on a 0–10 scale where 0 represents no pain Pieper et al³⁰ found that 78% of the patients (a sample of former illicit drug users) took analgesic medication For 68% of this group, pain decreased considerably or disappeared altogether Hyland et al⁹ stated that 25% of the patients never take pain-killers Finally, Hofman et al¹⁹ reported that one quarter of the patients having ‘horrible’ or ‘excruciating pain’ do not take pain-killers In this last study leg elevation reduced pain in half of the population

Several studies confirmed that patients experience impaired mobility in some way In a study by Loftus³⁸, 25% of the respondents reported having no problems with mobility and 75% reported some because of having an ulcer In line with these findings, Phillips et al¹⁸ reported that 81% of the population experienced impaired mobility, and that this immobility was severe for 57% Both moderate and severe limitations of activities because of ulcers are reported by Callam et al³⁹ This is confirmed by Hyland et al⁹, who described difficulties in climbing stairs and travelling by bus However, Kenkre et al²⁴ found only 33% with some problems in daily activities and 66% with no problems Immobility scores in leg ulcer patients’ samples are significantly higher than scores for standard healthy population groups^{4 22 36 37}

The results for disturbed sleep are somewhat contradictory Two studies described disturbed sleeping patterns because of the leg ulcer in two-third of the patients^{9 19} Nonetheless, in two other studies, patients’ scores on the sleep-subscale of the Nottingham Health Profile (NHP) are not significantly higher than those in an age-matched normal group^{36 37}

Other patient problems which are mentioned are lack of energy or decreased vitality as reported in four studies^{29 30 36 37}, itching, described in 58% of the patients¹⁸, bad odour³⁸, discharge and leaking of the wound in 20 to 79% of the patients^{18 33}, and swelling^{18 30 31 40} Swelling appears to be a major predictor of impaired mobility, impaired working capacity and negative financial and emotional impact¹⁸

Impact on psychological and social aspects

The psychological impact of leg ulceration has been investigated in various studies with contradictory results Chase et al²⁹ found no emotional deficit in her leg ulcer population, and Flett et al¹⁷ who found no differences compared with a group of healthy people on

the dimensions of loneliness, satisfaction with relationships and life satisfaction. In contrast, three studies reported scores in emotional well being that are significantly lower ($P < 0.05$) than those in the normal population^{4,36,37}. Leg ulcer patients also score higher on negative affect and lower on self-esteem^{17,18}. In addition higher scores are found in emotions such as fear, depression and anger¹⁸. Psychological adjustment to living with ulcers was addressed by Pieper et al.³⁰ and Keeling et al.²⁰, but the results are inconclusive because of small sample sizes.

Several studies have investigated the impact of ulcers on social life. Callam et al.³⁹ reported that 40% of the patients experienced moderate to severe restrictions in leisure activities because of their leg ulceration. Similar results were found by Kenkre et al.²⁴, who stated that patients went out less since their ulceration (63%). Most studies reported more social isolation in leg ulcer patients when compared with non-patient groups^{4,22,36,37}. Of patients who were not retired, 50–100% experience moderate to severe problems at work^{18,39}. Lindholm et al.¹ identified higher levels of social deprivation in younger men. Keeling et al.²⁰ reported that most patients felt that they received little social support.

Impact on quality of life (QoL)

Hyland et al.⁹ developed the Exeter Leg Ulcer Questionnaire. Part 1 of the questionnaire investigates four issues (pain intensity, sleep disturbance, time spent trying to heal the ulcer and time spent thinking about the ulcer); part 2 contains issues concerning functional limitations, dysphoric mood and treatment (29 items on a four-point scale). The investigators found that patients experience a variety of QoL deficits: pain, sleep disturbance, impairment of mobility and a number of dysphoric states.

Pieper et al.³⁰ modified an instrument originally developed with a view to examine QoL in individuals with inflammatory bowel disease into 'QoL with a Leg Ulcer Questionnaire'. Their instrument contains nine items including fatigue, cancelling plans, participating in activities, pain, depression, wound drainage, odour, relaxation and anger. In a small study with patients with a history of drug use³⁰ the means of the QoL items range from 2.9 to 4.7 (scale 1–7, with 1 representing the worst score) with the item 'troubled by pain' having the worst score.

A condition-specific QoL instrument originally for patients with acute wounds was tested for patients with venous leg ulcers by Price & Harding⁴¹: the Cardiff Wound Impact Schedule (CWIS). It is divided into four sections: physical symptoms and daily living (12 items), social life (seven items), well being (seven items) and overall health

related QoL (two items). The overall health-related QoL score is 68 for patients with leg ulcers (on a scale of 0 up to 100 where a higher score indicates a better reported QoL) which is a better QoL compared with patients with acute wounds (score 58).

Flett et al.¹⁷ compared the general health of leg ulcer patients with that of age-matched controls. The leg ulcer patients report significantly greater lack of mobility, more pain, more worries and concerns about health and lower levels of self-esteem, combined with higher levels of negative effect. No differences were found with regard to feelings of loneliness, dissatisfaction or lack of social relationships.

The NHP was used in five studies to assess the QoL, as shown in Table 6. Three studies presented a lower QoL on all subscales for leg ulcer patients than for age- and sex-related healthy groups^{1,36,37}. Rotchell²² found roughly the same levels on subscales, indicating a poor QoL. The results of Franks et al.⁴¹ were more positive, there are only significant differences with the healthy patients on two scales: for pain and physical mobility.

Table 6 Quality of life measured with NHP (n=4)^{1) 2) 3)}

Dimensions	Franks et al. ⁴¹		Rotchell ²²	Franks & Moffat ³⁷		Stevens ³⁶	
	N=200	Norm	N=240	N=758	norm	N=79	norm
Energy	24	20	35	34 **	12	39*	30
Pain	33**	11	35	31 **	6	33*	13
Emotions	10	11	20	18 **	10	17*	13
Sleep	25	22	34	29 **	13	24	26
Social isolation	5	7	15	13 **	4	12	9
Physical mobility	30**	13	34	36 **	3	44*	15

¹⁾ Range of NHP is 0-100, low scores indicate high quality of life

²⁾ From experimental and longitudinal studies only baseline data are shown. If a control group was a leg ulcer population, baseline data from control and experimental group were recalculated to one mean.

³⁾ The study of Lindholm et al.¹ is not included because results are described only in relation to normal groups.

* Statistically significant difference from age normal population at $p < 0.05$

** Statistically significant difference from age/sex normal population³⁶ or age/sex/social class⁴¹ at $p < 0.001$.

Three studies used the SF-36 to measure the impact of leg ulcers on health (see Table 7). Price & Harding⁴ confirmed significantly poorer QoL compared with an age-related healthy group on all but one subscale. Remarkably, Walters et al.⁴² reported that after 12 months, the scores on five subscales had deteriorated (indicating poorer QoL), even for individuals whose initial ulcer had healed and had not recurred.

Table 7 Quality of life measured with SF-36 (n=3)^{1) 2)}

Dimensions	Price & Harding ⁴		Walters et al. ⁴²	Chase et al. ²⁹	
	N=55	Norm	N=200	N=21	Norm**
Physical functioning	30*	59	43	56	69
Role limitations-physical	22*	54	51	68	65
Bodily pain	45*	68	56	76	69
General health	46*	58	65	72	63
Vitality	43*	60	53	50	60
Social functioning	52*	76	67	84	81
Role limitations-emotional	46*	73	66	81	82
Mental health	66	68	70	80	77

¹⁾ Range of NHP is 0-100; high scores indicate high quality of life.

²⁾ From experimental and longitudinal studies only baseline data are shown. If a control group was a leg ulcer population, baseline data from control and experimental group were recalculated to one mean.

*: Statistically significant difference from age normal population, 70-74y, at $p \leq 0.01$

** No statistically significant differences were found for any dimension from an age normal population, 65-74y.

Some studies described possible predictors for the QoL of patients with a leg ulcer. In one study⁹, pain intensity is significantly correlated with QoL, i.e. increased pain correlates with reduced QoL; however, this is not confirmed in the studies by Pieper et al.³⁰ and Walters et al.⁴². Pieper et al.³⁰ found strong associations between the extent to which pain interferes in daily activities and QoL. In this same study, larger wounds are strongly associated with lower QoL, but Walters et al.⁴² did not confirm this. As expected, older patients experience lower QoL, but the impact on younger patients is higher when compared with the age-norm group³⁷. However, Price & Harding⁴ found no age-related differences. There are associations with sex: women have lower QoL scores than men. Although differences in QoL levels with healthy groups are highest for men compared with women^{1,37}. Patients with ulcers of duration more than 24 months experience higher QoL levels⁴, but this was not confirmed in the study of Walters et al.⁴². In this same study, mobility was found as a factor of influence (to walk freely) is associated with a higher QoL than walking with an aid or being bed or chair bound. Finally, sleep disturbance and the amount of time spent thinking about the ulcer are also associated with lower QoL levels⁹.

Conclusions

Before drawing conclusions in this review, we would like to mention some limitations of this study. Firstly of all, our main interest is the impact of ulcers that are exclusively because of venous aetiology. Although we excluded studies with populations with impairments of arterial origin, we found studies in which the results did not differentiate

between the mainly venous objects in the sample and the small amount of other causes. Furthermore, the general recommended diagnostic measurement, the Ankle Brachial Index, was not always used. Secondly, it is difficult to draw conclusions on the basis of the various types of studies. Nevertheless, we studied the papers thoroughly and conscientiously, discussed results and were reticent with drawing conclusions.

Strong points of the present study include the systematic search and the selection of the abstracts by two independent reviewers. In addition, the good correspondence between results from studies based on quantitative and qualitative methods indicates validity of the findings.

The conclusion of this review is that a leg ulcer has a major impact on a patient's life. Pain is the dominant effect of having a leg ulcer, but differences in prevalence and severity of pain are reported. The small number of patients with arterial impairment who were included in some samples cannot explain the differences away. The information about the use of pain-killers is limited, but suggests severe under-treatment of pain. Other major problems reported include immobility, sleep disturbance, lack of energy, limitations in work and leisure activities, worries and frustrations and lack of self-esteem. Patients with ulcers have a significantly poorer QoL than healthy people. There are indications that QoL is associated with age, sex, pain intensity, pain interference in daily life, duration of the ulcer, ulcer size, mobility and sleep disturbance, but the evidence is not conclusive. Problems related to treatment are also reported, such as unclear and contradictory advice from professionals, and advice with which the patient is unable to comply.

Relevance to clinical practice

The pain experience of many patients is contrary to the general ideas held by professionals about leg ulcers. Hofman et al.¹⁹ state that pain is not reported in nursing or medical reports; at most it is cited as a sign of arterial disease or infection, but not as an effect of ulceration. In addition, Roe et al.⁴⁴ found that 55% of nurses did not report patients' experience of pain as a part of their assessment. This review suggests an under-treatment of pain, and from this point of view, this leg ulcer patient group is an 'underserved' group. An additional omission is that professionals do not focus on mobility problems, although these have a major impact on daily leisure and work activities. Most probably, mobility problems increase the worries, frustrations, negative self-esteem, and negative effect that patients experience. Keeping in mind that leg ulceration is notorious

for its chronic character, this implies that many patients suffer unnecessarily over longer periods of time.

We strongly recommend that the scope of nursing practice regarding leg ulcers be expanded to include not only wound dressings and compression therapy, but also patients' problems. During this process, special attention is needed for potential problems such as pain (intensity and interference with daily life), sleep disturbances, impaired mobility and activities (at home, during leisure activities and at work), reduced vitality, worries and lack of self-esteem. Meaningful interventions should be developed and evaluated. Especially, pain treatment is important and should be evaluated for the individual patient regularly. Furthermore, leg ulcer guidelines should be adjusted to the expanded scope of nursing care and should also focus on problems patients may experience. For example the guideline of the RCN Institute⁴⁵ does mention pain and pain relief, however other patient problems are neglected up to now. Besides the improvement of nursing care, the development of integral programmes in a multidisciplinary setting is essential.

The study of Hofman et al.¹⁹ about pain interventions is a very good start. An intriguing question is whether the problems experienced because of the ulcers influence the healing time of ulcers. It is quite possible that reducing pain levels and improving mobility capacity will have a positive effect on wound healing.

Nursing research

As Walters et al.⁴² concluded, a sensitive conditionspecific, well-validated and reliable instrument is mandatory for assessing the needs of patients. Three condition-specific instruments are of interest: for leg ulcers, wound, and venous insufficiency. The ulcer-specific QoL instruments of Hyland et al.⁹ and Pieper et al.³⁰ need more research on their validity and reliability. Information about the woundspecific QoL instrument (the CWIS) is scarce; Price & Harding⁴⁵ conclude the CWIS is both reliable and valid. A promising assessment tool is the Chronic Venous Insufficiency Questionnaire (CIVIC)⁴⁶. As this tool focuses on patients with venous insufficiency, and not solely on having an ulcer, the QoL during ulceration can be compared with that after ulcer healing. It claims to be well validated and reliable.

Finally, so far the factors influencing QoL have not been clearly distinguished. These factors should be studied with a view developing better predictors of QoL.

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Ulcer related problems and health care needs in patients with venous leg ulceration: a descriptive, cross-sectional study

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Abstract

Background. Patients with leg ulceration often have long lasting and recurrent wounds. The treatment exists mainly of wound-care and compression therapy. International literature shows several indications of problems in relation to leg ulceration but no studies were performed to give a comprehensive overview of all problems identified and care received related to these problems

Objectives. The aim of the study was to describe leg ulcer related problems in patients with leg ulcers based on venous insufficiency or a mixed aetiology. Furthermore, an inventory of current care and care deficits in the care for leg ulcer patients was made.

Methods. The study had a descriptive, cross-sectional design. A sample of 141 patients was taken from the population of outpatient clinics of seven hospitals in the Netherlands. Data were collected through patient interviews, questionnaires and wound-observations. Medical information was provided by the dermatologist or derived from the patients' medical file.

Results. The study identified a number of serious problems. Main problems were pain (85%), outdoor mobility (47%) and problems in finding appropriate footwear (60%). Statistical analysis showed no differences between patients with ulcers based on a venous aetiology and ulcers based on mixed aetiology. Fifty to seventy percent of the patients did not receive any care in relation to these problems. Only a rather small proportion of the patients however regarded the help as insufficient.

Conclusion. Care at outpatient clinics is mainly focussed on wound care and compression therapy. Pain treatment and care related to problems encountered by patients appears to be insufficient. This is not only affecting the patient's quality of life, but is likely to affect also the healing process and prevention of leg ulcers. Nurses and dermatologist should take their responsibilities in this matter.

Introduction

Leg ulceration is often a chronic condition caused by venous or arterial insufficiency or a combination of both. This study focuses on patients with leg ulcers, resulting from venous insufficiency or a mixed aetiology of venous and arterial insufficiency.

The prevalence of leg ulcers in the Netherlands is estimated at 3.5 per 1000 inhabitants¹. The prevalence of Chronic Venous Insufficiency (CVI) is estimated at 5 to 15% in males and 15 to 30% in females^{1,2}. The typical patient is an elderly female with a low social economic status³. Van der Velden et al.⁴ reported a prevalence of 12 per 1000 for women over the age of 75 in the Netherlands.

Patients with recurring or more severe leg ulcers are referred to outpatient clinics for dermatology. Patients are often receiving wound care and compression therapy at the outpatient clinics for a long period of time.

In a systematic literature review on the impact of leg ulcers on daily life³ it was concluded that leg ulcers pose a substantial threat to physical functioning. Also, a negative impact on psychological functioning and, to a lesser degree, on social functioning is reported⁵. Major limitations are pain and immobility⁶⁻⁸, followed by sleep disturbance, lack of energy, limitations in work and leisure activities, worries, frustrations and a lack of self-esteem⁹⁻¹¹. Patients have a significantly poorer quality of life compared with healthy people. Finally, patients report problems with regard to follow-up treatment. The international studies in this review³ showed a wide variety on design and sample size. Most studies however only addressed some aspects of patients' functioning, thus making it difficult to draw up valid and comprehensive conclusions on problems and functioning with leg ulcers. What was missing from the international literature was a sound quantitative study on the total scale of ulcer related problems, in relation with professional provided care to address these problems.

Aim

This study aimed at describing the problems encountered by patients with leg ulcers based on a venous insufficiency or a mixed aetiology of venous and arterial problems. Furthermore, an inventory of current care provided in relation to these problems and an inventory of care deficits were made.

Methods

Design

The study used a descriptive, cross-sectional design. Patients were included at seven outpatient clinics for dermatology. These outpatient clinics were based at Dutch general (n=5) and university (n=2) hospitals. The inclusion of patients was restricted to patients who fulfilled the following criteria: leg ulcer based on a venous insufficiency or a mixed aetiology of venous and arterial insufficiency; open wound at the time of the study; capable of understanding and answering questions in the Dutch language.

Sample

Eventually 141 patients were included in this study in a period of eight months (May 2001 till January 2002). During this period 180 patients were asked to participate. This was the total number of eligible patients at these seven clinics. One hundred and fifty eight patients agreed to participate. Seventeen patients however, were excluded because their wound had healed in the days between informed consent and the moment of interviewing. Eighteen patients did not agree to participate in the study; twelve of them did not give a specific reason, and six patients decided that it was too aggravating for them to participate. Four patients failed to participate due to organisational difficulties concerning transport to the hospital and appointment planning.

Data collection

A combination of methods was used: a written questionnaire, an interview, screening of medical files and observation of the wound. If patients agreed to participate they had to sign an informed consent. The patients subsequently filled out a questionnaire at home and brought the completed questionnaire along at the time of the next visit (within a ten day period). Interviews and wound observations were scheduled for this next visit. Also, additional medical information was obtained from the dermatologist or the medical file at the time of this visit.

Set of written questionnaires - Health related functional status was measured using the shortened Sickness Impact Profile, SIP68¹². This is a list of 68 items on 6 categories of functional health. Patients had to mark all items that they agreed on in regard to their situation. A higher number of marked items, indicates a higher dependency of the patient. The maximum score is 68. The number of items on the separate categories varies from 6 to 17. Cantril's ladder of life¹³ was used as a quality of life measurement tool. This

is a ten-point scale (represented as a ladder) in which ten is the best possible quality of life. As the review of the literature identified activities of daily living, sleeping and pain as potentially relevant problem areas³, validated scales for these topics were selected. The Barthel index¹⁴ was used to collect data on basic self-care. The Subjective Sleep Quality Scale¹⁵ was used for the assessment of sleeping problems. Pain was measured using a Visual Analogue Scale.

Interviews - In the interviews, a pre-structured interview scheme was used to identify further problems and to explore current care and care deficits. Patients were asked if they experienced one or more of 12 specified problems in relation to their leg ulcer. The topics questioned were again derived from the review of the literature, and addressed pain, sleeping, mobility in- and outdoors, basic self-care, daily activities, wound-care, compression therapy, footwear, social activity and several emotional aspects (feelings of shame, fear, loneliness, powerlessness, dependency and grief). Patients were also asked if they experienced any other problems related to their leg ulcers. All problem related questions could be answered with "yes", "somewhat" or "no". Only when patients answered the question with "yes" or "somewhat", six questions followed concerning the nature of the problem and the nature of received and desired care. Finally, they were asked to indicate which of these problems had the largest impact on their daily life. A top three of problems could be given.

Wound observation- At the end of the interview wound characteristics were observed and registered by trained nurses. For wound surface measurement a plastic wound foil with a raster of square centimetre cells was used. Furthermore, wound colour and exudate were assessed.

Medical data - Dermatologists were asked for or medical files were screened to obtain data on wound aetiology and comorbidity Patients were asked about the time since their first ulcer and duration of the current ulcer.

Analysis

Analysis took place by means of descriptive statistics. Sub-group analyses were conducted for aetiology (venous or mixed) and wound recurrence (first or recurrent). As the subgroups for first wounds were relatively small for both venous and mixed wound aetiology, testing differences for these subgroups was not feasible and formal statistical comparison was restricted to the two groups with recurrent wounds. In comparing

means of continuous variables the independent t-test was used. Cross tabulation with a chi-square test was conducted for all nominal variables.

Results

Patient and wound characteristics

General characteristics of the patient sample are given in table 1. A majority of the sample were females (63%) and patients with lower educational levels (63%). A wide age range was found and age was skewed towards the older ages (mean=69). In 50% of the patients, the aetiology of the wound was strictly related to venous insufficiency. Patients with a mixed aetiology were relatively older (75 versus 69 years; $p=0.002$). Two-thirds of the patients were overweight and 50% of these patients were obese (body mass index >30). Only eighteen percent of the patients had a professional occupation at the time of this study. About one-third of the patients were living alone. The mean score on Cantrill's quality of life ladder was 6.4, on a ten-point scale. The mean score on the SIP68 was 13 indicating moderate, but clear functional limitations.

The limitations related to the areas of motoric control (4.4) and social behaviour (3.9). These scores are about equal to the SIP68 scores of patients on hemodialysis (13) and patients with a muscular disease (12). Two-thirds of the patients judged their mobility as insufficient and 22% went out of the house on only one day per week at best. Outdoor mobility was significantly more restricted in patients with a mixed aetiology ($p=0.003$).

Three quarters of all patients suffered from recurrent wounds. In one out of three patients, more than one wound was found. Most of the wounds were relatively small, 42% was equal to or smaller than 2 cm².

Table 1 Patient and wound characteristics (n=141)

Patient-characteristics	
Gender	63% female
Age	mean=69 years sd=14.8, range=29-92
Body Mass Index	mean = 27.6, sd=5.1, range=17-44 32% 25-30 (overweight) 33% >30 (obesity)
Smoking	11% smokes cigarettes
Living arrangement	34% living alone 60% living with family 6% other
Education	40% only primary school 23% lower professional education 37% moderate or higher level
Occupation	18% current occupation 48% no longer occupied 34% never had an occupation outdoors
SIP68	mean: 13 sd=10.5, range=0-44, scale=0-68
Cantril (quality of life)	mean=6.4 sd=1.7, range=1-10, scale=0-10
Barthell index	mean=18.2 sd=2.5, range=7-20, scale=0-20
Mobility	65% judges amount of mobility as insufficient 22% goes outdoors on 1 day per week or less
Wound-characteristics	
Aetiology & wound recurrence	39% venous recurrent 11% venous first wound 37% mixed aetiology recurrent 13% mixed aetiology first wound
Patients with one wound	68%
Wound surface in cm ²	mean=8.5, median=2.0, range=0.1-213.0
Wounds < 10 cm ²	82%
Wounds <= 2 cm ²	42%
Duration of the wound in months	mean=23.3, median=4.0 range=0.3-720.0
Wound duration <= 4 months	56%

Comorbidity

An overview of comorbidity is given in Table 2. Forty-five patients (32%) did not report any comorbidity. Fifty-five patients reported just one comorbidity. Two comorbidities were reported by thirty-three patients, seven patients reported three, and one patient reported five comorbidities. Oedema, varicose veins and other circulation related complaints can occur without leg ulceration. However, when patients have a history of leg ulceration these complaints will be related to the occurrence and healing of leg ulcers. Oedema and varicose veins were therefore not counted as comorbidities to venous leg ulceration. Oedema can be merely seen as a symptom of CVI and is often causally related

to leg ulceration. Varicose veins and DVT (in the past) are main causes of CVI. Erysipelas and trauma (both in the past) can be causally related to leg ulceration but were no actual comorbidities at the moment of interviewing. Other comorbidities such as CVA, lung diseases, ischias, rheuma and osteoporosis can be of influence on patient mobility.

Table 2 Comorbidity

Comorbidity	n=141 (%)
No comorbidity	45 (32)
Oedema*	57 (40)
Varicose veins*	46 (33)
Deep Venous Thrombosis in past (DVT)*	23 (16)
Hypertension	33 (23)
Diabetes	23 (16)
Erysipelas in past*	18 (13)
Trauma or fracture in past*	16 (11)
Angina pectoris	15 (11)
Arthritis / Arthrosis / Reuma	13 (9)
Allergies	11 (8)
Claudicatio	7 (5)

Other: CVA/TIA (3), lung-disease (3), hip surgery, carcinoma (3; skin/face, brain and prostate), meniscus defect, ischias, lymfoedema, Besnier Boeck, mixed connected tissue disease, cardiac valve replacement, cardiac arrhythmia, sclerodermie, Necrolions lipoiden, Budd Chiari syndrome (protein deficiency), Klinefelter syndrome (2), epilepsy, stomach bleeding, osteoporosis, psoriasis, migraine, spasticity, visual handicap, abdominal aneurysma, aorta sclerosa, cataract surgery.

*Not included in counting number of comorbidities

Ulcer related problems

Table 3 gives an overview of experienced problems, related to leg ulceration based on venous insufficiency or a mixed aetiology with a venous component. Also presented are the problems with the largest impact on daily life.

Table 3 Ulcer related problems and impact on daily life (n=141)

Problem	"Yes" or "Somewhat"	Problem with the largest impact on daily life	Problem in "top 3" of problems with the largest impact on daily life
Pain	120 (85%)	55 (39%)	73 (52%)
Mobility outdoor	66 (47%)	8 (6%)	35 (25%)
Footwear	85 (60%)	8 (6%)	31 (22%)
Daily activity	67 (48%)	8 (6%)	27 (19%)
Wound (-care)	53 (38%)	6 (4%)	27 (19%)
Sleep	56 (40%)	8 (6%)	25 (18%)
Mobility indoor	35 (25%)	7 (5%)	18 (13%)
Compression	51 (36%)	7 (5%)	18 (13%)
Social activity	37 (26%)	1 (1%)	16 (11%)
Negative emotions:	105 (74%)	1 (1%)	13 (9%)
Basic self-care	49 (35%)	3 (2%)	6 (4%)
Other problems	3 (2%)	3 (2%)	3 (2%)
No problems	4 (3%)	20 (14%)	20 (14%)

Problems with a substantial negative impact were found in 86% of the patients.

Pain - Large groups of patients reported pain as a problem (85%), a top three problem (52%), and even as the number one problem (39%). Forty percent of the 120 patients with pain reported the pain to be superficial as well as deep. The mean pain-score at the moment of interviewing was 4.6 on a 0 to 10 range. The mean pain-score over the previous week was 4.2 during the day and 3.6 during the night. One out of four patients with pain did not use any pain medication and another twenty five percent used pain medication only occasionally. Of the patients who indicated that they used some pain medication (n=94) 16% reported insufficient pain relief, whereas 70% indicated to experience tenable pain after taking pain medication.

Mobility - Nearly half of the patients reported limitations in outdoor mobility and a quarter reported limitations indoors as well. Impaired outdoor mobility comes second in the top three of problems. Patients reported mobility limitations as a result of pain, fear of falling, fear of hurting their leg and the need to sit and rest their legs.

Footwear - A majority of the patients (60%) reported problems with footwear. All of these patients addressed difficulties in finding well fitting shoes, because of the volume of the bandages. Also, new and often non-standard shoes were considered to be too expensive. Many patients (44%) wore slippers and mules inside the house and 20% wore them outdoors as well.

Daily activity - Many patients (48%) referred to limitations activities such as in housekeeping, shopping, a slower pace in all activities, being dependent of others, the need to adjust activities at work, and limitations in standing, walking or swimming.

Wound and wound-care - Patients experienced problems in relation to the wound or wound care (38%), such as leakage of the wound, odour, itching, pain, the timing and the time needed or available for wound care.

Sleep - In 45% of the patients with a sleeping problem, pain is the main cause. Furthermore, 38% reported itching of the wound, and 12% reported wound leakage as a main reason. The mean sleep quality score of all patients on the SSQS was 9.4 on a 0-15 scale, where 15 stands for excellent sleep. The mean score of the patients who had a sleeping problem was 6.7.

Compression therapy - Compression therapy was problematic (36% of the patients) due to difficulties in putting-on and taking-off elastic stockings, stockings or bandages being painful, too tight or coming loose, warm and itching legs on hot days, and bandages causing problems in wearing shoes.

Social activities – The reasons reported for a limitation in social activities (26%) were limited mobility, pain, not being able to stand for a longer period of time, leakage of the wound, shame, not being able to wear “nice clothes or shoes”, and fear of hurting their legs.

Emotional aspects - Patients reported feelings of powerlessness (37%), dependency (48%) or grief (41%). They described thoughts as “why me?”, not having any influence on the ulceration and feelings of dependence. Few patients with negative emotions however rated them in the top three of problems.

Basic self care- Scores on the Barthell index showed that 41% of the patients were completely independent. Fifty-three percent of the patients were considerably independent and only 3% of the patients needed considerable help.

Other problems – Only three patients reported “other problems” in relation to their leg ulceration. Other problems that were reported were; having to wait for a knee operation until the ulcer had healed, a backache caused by an altered walking pattern and the leg ulcer contributing to nursing home admission.

Patient characteristics and problems in relation to aetiology and wound recurrence

The patient group was divided into subgroups based on aetiology of the wound and wound recurrence. Four groups were distinguished; a venous recurrent group (n=55), a venous first wound group (n=16), a mixed aetiology recurrent group (n=53) and a mixed aetiology first wound group (n=17). Due to inequality in group sizes, only the venous recurrent and the mixed recurrent subgroups could be compared in statistical analyses.

When comparing the venous recurrent group and the mixed recurrent group, as previously described in the paragraph on data analysis, we found statistically significant differences for age ($p=0.001$), total SIP68 score ($p=0.027$), SIP68 mobility range ($p=0.015$), SIP68 social behaviour ($p=0.048$) and Barthel index scores ($p=0.008$). Patients with a mixed aetiology are older and have more limitations in basic self-care and functional capability. There was no difference however, in pain scores, wound size, duration of the wound, quality of life scores and other SIP68 subscales. With regard to the ulcer related problems in table 4, subgroup analyses did not show any significant difference between the venous and mixed recurrent group.

Table 4 Patient and wound characteristics combined with aetiology and recurrence

		Venous - recurrent wound n=55	Mixed - recurrent wound n=53	p-value
Age	mean	62.8 (29.0-92.1)	72.2 (50.9-91.1)	0.001*
Body Mass Index	mean	27.3 (17.0-39.0)	28.7 (20.5-43.85)	0.172
Quality of life	mean	6.8 (1.0-9.0)	6.2 (2.0-9.0)	0.543
Barthel (0-20)	mean	18.9 (15-20)	17.7 (7-20)	0.008*
Mobility, 1 day or less outdoors (%)□		13.3	37.7	0.003*
Judges own mobility as insufficient (%)□		29.6	35.8	0.493
SIP68 (0-68)	mean	9.9 (0-30)	14.2 (0-44)	0.028*
SIP-Mobility range (0-10)	mean	1.35 (0-7)	2.45 (0-10)	0.015*
SIP- Social behaviour (0-12)	mean	2.96 (0-10)	4.15 (0-11)	0.048*
SIP- Emotional stability (0-6)	mean	0.75 (0-5)	0.60 (0-5)	0.543
SIP- Psychic autonomy and communication (0-11)	mean	0.67 (0-7)	1.15 (0-8)	0.158
SIP- Mobility control (0-12)	mean	3.6 (0-11)	4.5 (0-10)	0.168
SIP- Somatic autonomy (0-17)	mean	0.60 (0-6)	1.32 (0-16)	0.096
Wound surface, in cm ²	mean	5.5 (0.1-82)	5.6 (0.2-43.0)	0.824
	median	2.0	1.8	
Wounds <= 2cm ² □	number	31 (56%)	31 (59%)	0.447
Pain score	mean	4.3 (0-9.5)	4.8 (0-10)	0.392
Wound duration in months	mean	13.6 (0.3-108)	19.6 (0.8-480)	0.550
	median	3.8	3.0	
Wound duration <= 4 months□	number	29 (53%)	36 (68%)	0.132

*Significant difference at $p < .05$ between the venous recurrent group and the mixed recurrent group.

□chi-square (cross-tabs) all others tested with independent t-test

Current care and unaddressed needs

This paragraph describes the care patients received in relation to their wounds and wound related problems, as well as suggestions made by patients to improve care.

Wound-care - All patients in this study received wound care at an outpatient clinic for dermatology. A quarter of the patients (27%) is also treated by community nurses.

The mean frequency of wound-care was three times a week. With 27% of the patients the wound was cared for once a week, with 45% this was two to three times a week and with 28% this was more than three times a week. Wound-care was conducted at the outpatient clinic for dermatology, by the home healthcare or by the patient or the partner. Seventy nine percent of the patients had short-stretched bandages, 10% had a long stretched bandages and about 9% wore elastic stockings. Two patients wore a bandage without compression.

Care and care- deficits in relation to reported problems - Table 5 shows the help patients indicated to receive. Many patients reported not receiving any help with their problems. Percentages vary from 25 to 73% for the various problems. Main unaddressed problems concerned sleep (73%), footwear (70%) and coping with the negative effects of compression (71%). Only 12-17% of the patients however judged the help in these three

areas as insufficient. The highest percentage of insufficient help was reported with problems related to the wound (care) (32%).

Table 5 Care in relation to ulcer related problems

Problem	Number of patients	Out-patient clinic	Home health care	GP	Family	Others	No help	Insufficient help
Pain	N=120	46 (38%)	5 (4%)	10 (8%)	16 (13%)	6 (5%)	61 (51%)	19 (16%)
Mobility outdoor	N=66	-	-	1 (2%)	21 (32%)	14 (21%)	40 (61%)	6 (9%)
Footwear	N=85	5 (6%)	1 (1%)	1 (1%)	9 (11%)	13 (15%)	60 (70%)	14 (17%)
Daily activity	N=67	2 (3%)	3 (4%)	-	32 (48%)	42 (63%)	17 (25%)	12 (17%)
Wound (-care)	N=53	12 (23%)	8 (15%)	-	8 (15%)	8 (15%)	30 (57%)	17 (32%)
Sleep	N=56	6 (11%)	1 (2%)	6 (11%)	5 (9%)	-	41 (73%)	7 (12%)
Mobility indoor	N=35	1 (3%)	1 (3%)	-	9 (26%)	6 (17%)	24 (69%)	7 (20%)
Compression	N=51	4 (8%)	9 (18%)	-	1 (2%)	2 (4%)	36 (71%)	7 (14%)
Social activity	N=37	1 (3%)	1 (3%)	-	13 (35%)	9 (24%)	19 (51%)	4 (11%)
Negative emotions	N=105	6 (6%)	5 (5%)	-	46 (44%)	7 (7%)	59 (56%)	8 (8%)
Basic self care	N=49	1 (2%)	8 (16%)	-	9 (18%)	8 (16%)	27 (55%)	6 (12%)

Suggestions for more help - All patients found it difficult to indicate what kind of help they would like to receive related to their problem. This section gives an overview of suggestions made by patients. These suggestions were made by small numbers of patients. At each topic one to eight patients gave suggestions for more or better care.

Concerning the wound or wound care, patients wanted their bandages changed more often, wished for relief of itching and pain, desired treatment closer to the home, hoped for more home health care hours and hoped for more attention from their medical doctor. They wished for less time spent waiting. Patients also indicated the need for more comfortable elastic stockings. Concerning problems in daily activities, patients indicated the need for more help regarding domestic tasks, daily shopping and daily activities in general. For sleeping problems, patients wanted medication. On the subject of social activities patients indicated the need for more pain relief. Some patients also wished for some kind of aid that would allow them to swim while having a leg ulcer, and more help with transport. Concerning negative emotions patients wanted more attention from people within their own network, clear information on leg ulcer etiology from dermatologists, more attention for their worries and more attention for prevention of new wounds.

Discussion

Many patients in this study experienced a substantial negative influence related to one or more ulcer related problems. Pain, impaired mobility and difficulties in finding proper

footwear are three problems with the largest impact on daily life. However, other problems such as problems related to sleep, wound care and daily activities are very common in these patients. Furthermore, a majority of the patient's reports negative emotions in relation to their leg ulceration. These findings are in line with the findings in a literature review on quality of life related to leg ulceration³. In this review pain is reported in all studies with a variety of 50 to 100% of patients that experience pain in relation to their leg ulcer, in our study this was 85%. Although we specifically asked patients to report problems related to their leg ulceration, it is possible that comorbidity had some influence on the severity of reported ulcer related problems. There seems to be little difference between patients with leg ulceration based on different aetiology concerning ulcer related problems and patient characteristics. Patients with a mixed aetiology seem to be somewhat more fragile, with an older age, higher scores on the SIP68 and lower scores on the Barthell-index, indicating a more dependent group.

Reported problems are likely to be closely related. Literature shows that pain has a severe impact on mobility, social activity, and quality of life³. Patients have pain and are therefore limited in their mobility. Proper footwear is important to enhance physical mobility and to promote an effective way of walking in which patients enrol their feet so they will stimulate their calf muscle.

Care received by patients at outpatient clinics mainly exists of wound-care and compression therapy. There is no structural attention for leg ulcer related problems. Pain medication for example is prescribed, but insufficiently evaluated. Large percentages of patients received no or insufficient help with other problems but only a small amount of patients judge the help as insufficient. Krassner⁷ found that patients consider pain to be a normal aspect of having a leg ulcer. This was also found in a study by Haram¹⁶. Patients had confidence in the treatment they received despite a number of problems regarding the care they received. This confidence could be due to the helpers' manners and attitude^{16,17}.

This study succeeded in giving insight into the amount and nature of problems experienced by leg ulcer patients treated in outpatient clinics for dermatology, and the lack of care in relation to some of these problems. The results of the study also showed that there is little difference between patients with venous or mixed aetiology in leg ulcer related problems and wound characteristics. In daily practice it is often assumed that venous leg ulcers are less painful and are less of a burden to the patient in contrast to leg ulcers with a mixed aetiology.

The study is limited to patients treated at outpatient clinics for dermatology. Many leg ulcer patients are treated by general practitioners and home health care. Problems might be less prevalent in these patient groups, assuming that these patients have less complicated leg ulcers. Another limitation of the study is the fact that subgroups of patients with first wounds were relatively small and could not be used in subgroup analyses. For patients treated at outpatient clinics, the study is likely to be valid, because of the participation of seven different hospitals.

Conclusion

Patients with leg ulceration encounter several serious problems. Leg ulcer patients receive insufficient care with ulcer related problems and can be seen as an 'underserved population'.

Structural, systematic attention and appropriate action concerning ulcer related problems are a necessity in the treatment of leg ulceration. Patients need to adhere to the main principle of treatment, the ambulant compression therapy. This means that they have to wear elastic stockings each day for the rest of their life, combined with a sufficient amount of walking. Nurses and dermatologists should take their responsibility in this by focussing care more at necessary conditions for adherence.

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Venous leg ulcer patients: a review of the literature on lifestyle and pain-related interventions

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4

Abstract

Background. Having a leg ulcer has a major impact on daily life. Lifestyle is mentioned in most leg ulcer guidelines but mostly without much emphasis on the subject.

Aims and objectives. Evidence for the effect of nutrition, leg elevation and exercise on the healing of leg ulcers was reconsidered. Furthermore, the evidence for effective pain-related interventions was investigated.

Design. Systematic literature review.

Methods. Medline, Cinahl, Psychinfo and Cochrane were searched for studies on pain related interventions, and the effectiveness of leg elevation, leg exercise and nutritional interventions in patients with venous leg ulceration.

Results. Some evidence was found to support a positive effect of leg exercises on the endurance and power of the calf muscle and on the haemodynamic status of the limb. There is also evidence for a positive effect of leg elevation during bed rest without compression. No hard evidence was found concerning the effect of enriched or altered nutrition on wound healing. However, there is some evidence of nutritional deficits in this patient group. The use of eutectic mixture of local anaesthetic cream is effective for reducing pain in wound debridement, but pain relief in daily life is insufficiently treated.

Conclusion. There is no real evidence of effectiveness of the investigated lifestyle interventions but there are indications that lifestyle interventions might contribute to healing or prevention of venous leg ulceration.

Relevance to clinical practice. Although there is no hard evidence, it can be expected that interventions such as nutritional monitoring, guided exercise and leg elevation will have a substantial impact on wound healing in patients with venous leg ulceration. The use of eutectic mixture of local anaesthetic cream can be advised for pain relief with wound debridement. The current lack of effective pain treatment with venous leg ulceration emphasizes the need for effective pain treatment.

Background

Chronic leg ulcers are common in the older population. The point prevalence for active leg ulcers in a study by Nélzen et al.¹ was found to be 3.0 /1000 total population. A prevalence of 12 per 1000 has been reported in a study of women above the age of 75 ². Margolis et al.³ found a prevalence rate of 1.69% in the older population, aged 65 years and older. The occurrence of leg ulcers appears to be related to both age and sex. In a study by Lindholm et al.⁴ the predominance of women was even 3:1 and 88% of leg and foot ulcer patients were over 75 years or more.

This review concerns leg ulcer patients with an aetiology of the ulcer based on venous insufficiency or a combination of venous and arterial insufficiency. Patients with leg ulcers in the Netherlands are treated by nurses from home health care services, by general practitioners, by dermatologists and by nurses at outpatient clinics. When the ulcer requires intensified care, patients are admitted to a clinical dermatology ward. The ulcers sometimes exist for a very long period: in a study by Harrison et al.⁵, 40% of the patients had an ulcer for 1 year or longer. In a study by Price and Harding⁶, 20% of the patients had a leg ulcer for 5 years or more. The ulcer recurs after healing in 45–50% of the patients ^{5,7}.

First line treatment is based on compression therapy and wound care. Many studies of leg ulcer patients address the issues of compression therapy and wound dressings. Compression therapy is effective in wound healing and prevention of leg ulcers^{8,9}. Various types of bandages are used for compression: multilayered systems, elastic and non-elastic bandages, singlelayered systems and compression hosiery. Evidence also indicates that high compression is more effective than low compression⁸.

Lifestyle is another important factor in the treatment of leg ulceration and chronic venous insufficiency (CVI). Most guidelines¹⁰ for venous leg ulcer care mention lifestyle in connection with leg ulceration and CVI, but there is little emphasis on this topic. Relevant lifestyle topics are healthy nutrition and weight, exercise, leg elevation and stop smoking¹¹.

To improve lifestyle, it is essential to deal with the problems encountered by patients in their daily lives. One of the major problems leg ulcer patients encounter is the pain caused by their ulcer. There is some indication that pain is undertreated¹². A consequence of undertreatment of pain is that it can become a disturbing factor in wound healing.

Aims and objectives

In this literature review, we looked for evidence for the effects of healthy nutrition, nutritional supplements, leg elevation and exercise on the healing of leg ulcers. We also reviewed pain-related interventions for leg ulcer patients. Our central research questions were:

- 1 What is the evidence for the effect of nutritional interventions, leg elevation and leg exercises on healing or prevention of leg ulceration in venous leg ulcer patients?
- 2 What are the evidence-based interventions for pain relief in leg ulcer patients that appear in the literature?

Methods

Search strategy

We searched the Medline, Cinahl, Psychinfo and Cochrane databases for literature published in the period from 1991 to 2002. We also looked in references and grey literature, and one industrial request was made. There was no restriction in language.

The following search terms were used: leg ulcer* OR venous ulcer* OR varicose ulcer* OR ulcus cruris OR ulcus venos* in title. These terms were combined with the following terms in abstracts: nutrition*, nutritional* supplement*, zinc*, zink*, vitamin*, ascorb* acid*, exercis*, leg exercis*, leg elevation, weight*, overweight, pain*, pain management.

Selection of studies

Two reviewers independently made a selection of all literature using the following inclusion and exclusion criteria.

TYPES OF STUDIES

Studies on therapeutic effect and studies on risk factors for leg ulceration, including clinical trials (randomized and nonrandomized), case control studies, cohort studies and pilot studies.

PARTICIPANTS

Patients with venous leg ulceration or patients with a mixed aetiology of venous and arterial insufficiency. Studies involving patients who had venous insufficiency without leg ulceration at the time of the study were also included. Studies on patients with diabetic ulcers were excluded.

INTERVENTIONS

Exercise, leg exercise, leg elevation, nutrition, nutritional supplements and interventions related to pain management. Studies on wound dressings as a pain related intervention were excluded from this review.

OUTCOME CRITERIA

1 Effects on wound healing or prevention of leg ulceration;

2 Pain reduction;

3 Ejection fraction and residual fraction (leg exercises);

4 TcPO₂ value, laser Doppler flux and limb volume (leg elevation).

The outcome criteria number 3 and 4 were specifically added for the subjects of leg elevation and leg exercises. These criteria are essential haemodynamic parameters for wound healing.

Results: number of studies

The first search resulted in 168 hits. Two reviewers made a selection of papers based on criteria for inclusion and exclusion. On quality we looked at basic criteria: did the study make clear what patients were included, what and how the intervention was executed and on what data the conclusions were based? Finally, 23 papers were included in the literature review.

All studies listed in Table 1 are on the use of eutectic mixture of local anaesthetic cream (EMLA) for pain management. The two reviews on the use of EMLA included a total of amount of 12 studies. Table 2 lists all studies on the use of oral zinc. Table 3 concerns all descriptive studies on nutrition. Table 4 presents two studies on exercise and Table 5 contains four studies on leg elevation.

Results

Pain alleviation

The only pain-related intervention that was reported in the literature for patients with painful chronic venous leg ulceration was the use of EMLA cream, a mixture of prilocaine and lignocaine/lidocaine. The use of EMLA cream was restricted to reducing pain during and after debridement. There were two reviews^{13,14} about the use and effectiveness of EMLA cream in debridement of venous types of leg ulcers. In the updated version of the systematic review by Briggs & Nelson¹⁴ six randomized controlled trials of EMLA vs. 'placebo' or 'no anaesthesia' were included¹⁵⁻²⁰. Two further randomized trials studied

dose response, length of cream application and plasma concentration^{15,18}. Vanscheidt et al.¹³ reviewed 12 studies, including all eight studies reviewed by Briggs. Vanscheidt also included three open, uncontrolled studies on the use of EMLA^{21,23}, and a study on lidocaine/prilocaine plasma levels after application of EMLA cream²⁴. Four of the studies (Table 1; 4, 5, 6, 7) reviewed by Vanscheidt et al.¹³ and Briggs & Nelson¹⁴ were also included in our search. In the latest update Briggs & Nelson¹⁴ excluded the study by Peschen et al.²⁵ because it appeared not to be a randomized controlled trial. Both reviews were very thorough in nature, the review by Briggs & Nelson¹⁴ was restricted to controlled trials, Vanscheidt et al.¹³ also included uncontrolled studies.

Table 1 Studies on Pain Intervention

Author	Methods	Participants	Intervention	Main outcomes
1. Briggs ¹⁴	Systematic review (4,5,6)		EMLA cream for sharp debridement	Pain relief for leg ulcer debridement.
2. Stymne ²⁷	Clinical trial	10 patients with leg ulcers of arterial, venous or mixed origin	A 24-hour application of EMLA cream	Peak plasma concentrations are less than one-fifth of those associated with toxic reactions.
3. Vanscheidt ¹³	Review article (4,5,6,7)	Leg ulcer patients, 12 clinical investigations	EMLA cream for sharp debridement	EMLA significantly reduces pain EMLA decreases incidence of post-debridement pain. EMLA reduces the time needed for debridement
4. Holst ¹⁸	Single blind, three-armed parallel group study, random allocation	59 patients stratified for leg ulcer type, 19 arterial, 39 venous and 1 diabetic	Treatment with EMLA prior to debridement 10, 20, 60 minutes prior to debridement	A minimum of 20 minutes application time gives substantial pain relief in the majority of patients.
5. Hansson ⁵⁸	A controlled study, random allocation	22 patients experimental, control group 21 patients, venous ulcers	EMLA cream against no cream	Treatment with EMLA for 30 minutes significantly decreased the pain from cleansing leg ulcers and the frequency of post-cleaning pain No significant differences in local reactions or adverse effects on granulation tissue, ulcer area or bacterial flora
6. Lok ²⁶	A randomised, double-blind, placebo-controlled study	36 patients, control group of 33 patients, 52 venous and 17 mixed art / venous	EMLA cream against placebo	EMLA decreased the number of debridements required for a clean ulcer and decreased pain by 50% Plasma levels of lidocaine/prilocaine were low without any apparent accumulation
7. Peschen ²⁵	Open comparison	15 patients in experimental group, 7 patients in control group	EMLA-cream against no cream, using a CO ² laser as a tool for debridement	The mean VAS score was 12.8 in the EMLA group and 52 in the control group. EMLA was effective in reducing pain from debridement

The following conclusions were drawn from both reviews and the separate studies in our review. EMLA cream applied to the ulcer for 30–45 minutes under occlusion significantly reduced the pain experienced during sharp debridement. It decreased the incidence of postdebridement pain and reduced the time needed to achieve a clean ulcer. The number of treatments needed to obtain a clean ulcer also decreased with the use of EMLA. Applications of up to 10 g EMLA resulted in plasma levels of lidocaine and prilocaine well below toxic levels^{16,26,27}. Briggs & Nelson¹⁴ recommend that research is required to determine whether debridement of venous leg ulcers aids healing and what impact local anaesthetics have on leg ulcer healing.

Nutrition

INTERVENTIONAL STUDIES ON NUTRITION

The only trials that were found in our search for evidence on the effect of nutrition or nutritional supplements on wound healing were on the use of oral zinc. There were two reviews on this topic: one systematic review²⁸ and one narrative review²⁹. Both reviews were based on relatively old studies (1966–77). Malone²⁹ included one recent study by Haggard et al.³⁰. However, this study was conducted on patients with pressure ulcers. There is a clear difference in quality of both reviews. The review by Wilkinson has a clear systematic approach according to existing guidelines³¹. The review by Malone has a narrative approach and does not give insight into search strategy or selection of studies. The main outcome of both reviews was that no real evidence was found for a beneficial effect of zinc sulphate treatment on wound healing. There is some evidence that oral zinc may have a beneficial effect on the healing of venous ulcers in people with a low baseline serum zinc level.

Only one of the studies included in the review conducted by Malone²⁹ is a study involving leg ulcer patients³². In this study by Hallbrook & Lanner³², a double blind trial, zinc supplementation was beneficial for patients whose zinc status was below normal. Twenty-seven patients were given daily zinc sulphate or a placebo three times daily for 18 weeks. Where patients had initially low serum zinc levels, the healing frequency was higher in those treated with zinc than in those given placebo ($P=0.02$).

Author	Methods	Participants	Intervention	Main outcomes
1. Malone ²⁹	Review article	20 young men with granulating wounds. 14 pressure ulcer patients. 27 patients with chronic venous ulcers. 26 zinc, 44 no zinc, pressure ulcer patients.	1. Randomised daily zinc sulphate or no medication; 2. and 3. Daily zinc sulphate or a placebo; 4. Daily zinc sulphate; retrospective pilot review.	No consistent beneficial effect of zinc on wound healing. Zinc supplementation is beneficial for patients whose zinc status was below normal. All studies, except one, are relatively old: 1966, 1971, 1972, 1999.
2. Wilkinson & Hawke ²⁸	Systematic review	Patients with chronic leg ulcers. 5 studies of venous leg ulcer patients, 1 study of patients with arterial ulcers.	Oral zinc against placebo (5) or oral zinc against no treatment (1).	No real evidence of a beneficial effect of treatment with zinc sulphate. Some evidence that oral zinc might have a beneficial effect on healing of venous ulcers in people with low baseline serum zinc levels. Relatively small studies, 10-42 patients Only 1 trial mentioned the time that the blood samples were taken. Relatively old trials: 1972, 1974, 1977.
3. Wissing et al. ³⁸	Pilot study	6 patients, with venous ulcer for more than 1 year.	An individually designed programme of nutritional support.	With 4 out of 6 patients, the ulcers were healed or nearly healed after nine months.

Wilkinson & Hawke²⁸ included five relatively smallscale trials on the effect of oral zinc supplementation on wound healing with venous leg ulcer patients³²⁻³⁶ and one study in patients with arterial ulcers³⁷. In all studies except this study by Haeger & Lanner³⁷ a placebo treatment was used. In all studies the number of participants was rather small and varied between 10 and 42. Only one of the trials included by Wilkinson stated when the blood samples were taken³⁵. Wilkinson & Hawke²⁸ concluded that interpretation of the results was difficult due to the variation in length of treatment and follow up and whether or not the zinc serum was measured initially.

One pilot study on the effect of nutrition was included in our search. This study³⁸ was the only study on the effect of a nutritional intervention. Wissing et al. ³⁸ conducted a pilot study in which she used an individually designed programme of nutritional support. This study indicates that some effects might be expected from nutritional support. In four out of six patients with longlasting leg ulcers (ulceration for more than 1 year), the leg ulcers were healed or nearly healed after a period of 9 months.

STUDIES ON NUTRITIONAL DEFICIENCY

Six observational studies on nutrition were included in our study. These studies used various methods for measuring nutritional status. Rojas & Phillips³⁹ and Balajj & Mosley⁴⁰ primarily used blood samples. Both studies show deficiencies in biochemical indices, lower levels of vitamin A, zinc and carotenes were found.

Wipke-Tevis & Stotts^{41,42} used blood samples in both studies along with an assessment instrument of daily nutritional intake. In both studies Wipke-Tevis found that 70–80% of the patients were at moderate or high nutritional risk. However, no statistically significant relationship was found between biochemical and nutritional indices and wound healing. In the second study by Wipke-Tevis & Stotts⁴² more than 50% of the patients were obese. However, both studies had a small sample size: the first was a pilot study including seven patients⁴¹ and the second was a prospective study of 25 patients⁴². In this prospective study patients were followed for only a short period of time, there were two moments in time when wound measurement was conducted, the time between the two measurements was 4 weeks.

Wissing et al.⁴³ and Wissing & Unosson⁴⁴ and Van Rijswijk⁴⁵ did not take blood samples in their studies on nutrition and leg ulceration. Wissing et al.⁴³ and Wissing & Unosson⁴⁴ conducted two descriptive studies: one pilot study of nine patients and one study of 70 patients. These studies showed that intakes of energy and key nutrients for wound healing, such as protein, vitamin C and zinc, were not optimal and that about 50% of the patients were classified as being at risk of malnutrition. The mean body mass index (BMI) value in the risk group did not indicate underweight; in fact, many of the patients were found to be obese. BMI in patients with venous leg ulcers was higher than in patients with ulcers from other causes. In this study, however, there were no significant differences between the well-nourished patients and those classified as being at risk of malnutrition or those who were actually malnourished regarding the number and the duration of open ulcers.

Van Rijswijk⁴⁵ analysed a sample of 61 patients with full-thickness leg ulcers in relation to their demographics and predictors of healing and compared them with a group of 120 patients with partial-thickness ulcers. She found that patients with full-thickness ulcers were more likely to be overweight ($P < 0.001$) and not fully mobile ($P = 0.016$).

Table 3 Nutrition - Descriptive

Author	Methods	Participants	Intervention	Main outcomes
1. Balajj & Mosley ⁴⁰	Observational	50 pat. with large leg ulcers, 25 venous, 17 arterial, 8 pat. with no evidence of art. or venous insufficiency.	Fasting blood samples, various biochemical nutritional indices	Metabolic deficiency was common in all patients 60% had vitamin C deficiency. In the group of eight patients there were several nutritional deficiencies, especially of vitamin C and zinc.
2 Rojas & Philips ³⁹	Observational	17 patients with chronic leg ulcers, 14 venous, two arterial and one mixed.	Fasting blood samples	Significantly ($p < 0.001$) lower levels of vitamin A, zinc and carotenes were found in chronic ulcer patients. The study data were compared with data obtained from the nutritional status survey in the greater Boston area
3 van Rijswijk ⁴⁵	Controlled clinical study	61 patients with full thickness leg ulcers (41 venous, 11 mixed origin, 3 trauma, 6 others), control; 124 patients with partial-thickness ulcers	Identification of patient and wound characteristics	Patient with full thickness leg ulcers are more likely to be overweight ($p < 0.01$), and not fully mobile ($p = 0.016$) Odour at baseline ($p = 0.005$) and advanced age ($p = 0.017$) are associated with increased time for healing
4. Wipke-Tevis & Stotts ⁴¹	Observational pilot study	7 patients with venous ulcers	Public awareness checklist for nutritional risk, biochemical indicators of nutritional status	Nutritional risk for 5 of 7 patients Inadequate intake for caloric needs in 5 of 7 patients Abnormalities in biochemical indicators in 4 patients, including zinc in 3 patients.
5. Wipke-Tevis & Stotts ⁴²	Prospective	25 patients with venous ulcers	Nutritional risk Anthropometric measures Biochemical indices Two 3-day dietary records Transcutaneous tissue oxygen levels Wound surface area was evaluated 2 times 4 weeks apart.	Inadequate protein intake in 2 patients. 84% at nutritional risk >50% obese 17 out of 25 pat. had one or more abnormal biochemical nutritional indices Caloric intake (17 out of 20), protein intake (15 out of 20) and zinc intake (17 out of 20) were inadequate to meet the needs for healing. No statistically significant relationships were found between biochemical nutritional indices, tissue oxygenation and healing.
6 Wissing et al. ⁴³	Descriptive	9 patients with venous leg ulcers	Body Mass index, Swedish nutritional recommendations	Intake of energy, protein, vitamin C and zinc were not optimal.

Table 3 Nutrition - Descriptive

Author	Methods	Participants	Intervention	Main outcomes
7 Wissing & Unosson ⁴⁴	Descriptive correlational	70 patients with leg and foot ulcers, of which 18 venous, 4 mixed venous / arterial, 1 arterial and 13 others	Patient interviews, using the Mini Nutritional Assessment Individual self-reported data	46% classified as being at risk of malnutrition, 2 patients were malnourished Many patients were obese BMI in patients with venous ulcers was higher than in patients with ulcers from other causes No significant differences between well-nourished patients and those classified as malnourished or at risk of malnutrition regarding number and duration of open ulcers

Exercise

During the search we found two studies on leg exercise: Yang et al.⁴⁶ and Kan & Delis⁴⁷. In both studies, the outcome criterion was not wound healing, but the improvement of parameters for venous circulation. Both studies showed that exercise is beneficial to calf muscle pump function. In previous studies by Araki et al.⁴⁸ and Back et al.⁴⁹ it was shown that the capacity of the calf muscle pump function is crucial to venous leg ulceration.

The first study was conducted by Yang et al.⁴⁶; this was a single-armed experimental pilot study of 20 patients with CVI and recently healed venous ulceration. They were given a 6-week exercise programme that was specifically tailored for each patient. The exercise programme comprised heel rises (tip-toe exercise) on alternate days. The results showed significant improvement in calf muscle pump function with increased venous ejection fraction (EF) ($P=0.001$) and decreased residual fraction (RF) ($P=0.001$). There was no significant change in venous refilling (VFI) ($P=0.351$) or venous volume ($P=0.279$). Venous reflux was not altered. Calf muscle strength and endurance parameters all increased, but not significantly ($P > 0.05$). Yang concluded that poor calf muscle pump function in patients with chronic venous ulceration can be improved by physical exercise.

The second study on exercise was conducted by Kan & Delis⁴⁷. This was a prospective controlled study involving 21 patients: an experimental group of 10 patients with venous ulceration and a control group of 11 patients who were matched with the experimental group for age, sex, ulcer size and ulcer duration. The aim of the study was to evaluate the effects of short-term supervised calf exercise on calf muscle pump function and venous haemodynamics in limbs with venous ulceration. The intervention consisted of 7 days of supervised daily exercise where the subjects completed three sets of flexions of 6 minutes each. A 5-minute rest period was allowed between consecutive sets. The control group received standard care. The results showed that ejected volume, EF and residual volume

fraction all improved in the experimental group. Calf muscular endurance in the exercise group increased by 135% from a median of 153 plantar flexions at baseline to 360 on day seven. Kan concluded that isotonic exercise improves ejection ability and global haemodynamic status in limbs with venous ulceration by increasing the muscular endurance, efficacy and power of the calf muscle.

Table 4 Studies on Exercise

Author	Methods	Participants	Intervention	Main outcomes
1. Kan & Delis ⁴⁷	Prospective controlled study	10 patients with venous ulceration. Control group, 11 patients matched with the control group for age	7 days of exercise; 4 kg. Control group; no intervention	Ejected venous volume, ejection fraction, residual venous volume and residual volume fraction all improved in comparison to the control group.
2. Yang et al. ⁴⁶	Single-armed experimental pilot study	20 patients with CVI and recently healed venous ulceration	Six-week exercise programme	Significant improvement in calf muscle function. Venous reflux was not altered. Calf muscle strength and endurance parameters all increased, but not significantly.

Leg elevation

Four out of the five studies in this area used partial pressure of transcutaneous tissue oxygen (TcPO₂) as an indicator of perfusion, which is important in wound healing and prevention. One of these studies showed that TcPO₂ is lower in venous leg ulcer patients than in healthy adults⁵⁰. In the following section, the results of each study will be presented followed by a brief summary.

Abu Own et al.⁵⁰ studied 15 patients with lipodermatosclerosis (caused by chronic venous insufficiency) and 15 control subjects. The intervention consisted of a change in position: lying in the supine position and elevating the foot 30 cm above heart level. The conclusion of this study was that limb elevation enhanced the microcirculatory flow velocity in liposclerotic skin of patients with chronic venous insufficiency.

Wipke-Tevis et al.⁵¹ conducted an experiment with a convenience sample of 20 patients with venous ulcers. TcPO₂ was measured in four positions, with and without inspired oxygen: leg elevation, sitting, standing and lying supine. The results of this study showed that lower extremity resting TcPO₂ levels were lower in patients with venous ulcers than in healthy adults. Minimal changes in TcPO₂ occurred with position changes when subjects breathed room air. When arterial oxygen saturation was increased using inspired oxygen, TcPO₂ was lower during leg elevation, sitting and standing compared with lying supine. Wipke-Tevis concluded that leg elevation, sitting and standing decrease wound

perfusion and may not be beneficial to individuals with venous insufficiency and ulceration. She stated that 'the findings from my study substantiate a basic treatment for venous ulcers, which is to have patients stay off their feet as much as possible,' and 'clearly a higher TcPO₂ while laying than while standing explains the clinical observation that patients experience increased healing with bedrest.' She recommended further research to explore relationships between tissue oxygenation, blood perfusion, compression, positioning and venous ulcer healing.

Table 5 Studies on leg elevation

Author	Methods	Participants	Intervention	Main outcomes
1. Abu Own et al. ⁵⁰	Experiment	15 patients with chronic venous insufficiency, 15 control subjects	Change in position: lying supine and elevating the foot 30 cm above heart level.	Limb elevation enhanced the microcirculatory flow velocity in liposclerotic skin of patients with chronic venous insufficiency
2. Barnes et al. ⁵²	Prospective	13 patients with venous leg ulceration	Measurement of TcPO ₂ and Laser Doppler Flow (LDF) after 24 hours of lying supine with the leg elevated at 10°.	Significant change in LDF after elevation at 10° for 24 hours (p=0.002). Changes in the means of TcPO ₂ were not significant despite an increasing trend (p=0.05). Significant decrease in limb volume and circumference
3. Johnson ¹⁷	Descriptive correlational	156 patients with venous and mixed aetiology leg ulcers	Descriptive, 1-month follow up.	Increased pain when mobilising and increased time with limbs horizontal to the torso were associated with poorer healing rates.
4. Wipke-Tevis et al. ⁵¹	Experiment	20 patients with venous ulcers	Measurement of TcPO ₂ (indicator of perfusion) in four positions with and without inspired oxygen. Positions: leg elevation, sitting, standing and lying supine.	Lower extremity resting TcPO ₂ levels were lower in patients with venous ulcers than in healthy adults. Minimal changes in TcPO ₂ occurred with position changes when subjects breathed room air. When arterial oxygen saturation was increased using inspired oxygen, TcPO ₂ was lower during leg elevation, sitting and standing compared to lying supine (p<0.05).

Johnson¹⁷ studied healing determinants in older people with leg ulcers. In a correlational study she found that increased time spent with limbs horizontal to the torso (i.e. not elevated), in combination with compression, was one of the factors associated with poorer healing rates for leg ulceration. High compression reduces TcPO₂ when limbs are horizontal. High compression therapy is more appropriate for ambulant patients. Bandages that provide high compression when ambulant and low compression when

resting may be beneficial. However, low compression, as received by patients in Johnson's study, was not associated with healing.

Barnes et al.⁵² reported that limb elevation (10 degrees above horizontal for 24 hours) resulted in a decrease in limb volume and an increase in laser Doppler flux without a corresponding change in TcPO₂. Barnes concluded that admission to hospital with elevation of the limb for patients with venous ulceration results in microcirculatory changes which are probably attributable to reduced lower limb oedema.

The conclusions of the above studies can be summarized as follows. Compression therapy while in a standing position has a positive effect on the TcPO₂ of the lower legs. Without compression therapy, lying supine gives the highest TcPO₂ rates in comparison with leg elevation, standing or sitting. This effect, however, was only found when patients received inspired oxygen. When they breathed room air, there was no difference in TcPO₂. Leg elevation at 10 degrees resulted in a decrease in limb volume and an increase in laser Doppler flux without a corresponding change in TcPO₂. Consequently, leg elevation may not positively affect TcPO₂, but does have a positive effect on the volume of the leg.

Abu Own et al.⁵⁰ did not use TcPO₂ as an outcome measure; the results showed a positive effect of leg elevation (30 cm above heart level) on the microcirculatory flow velocity in liposclerotic skin of patients with chronic venous insufficiency.

Conclusion

Pain

Several studies emphasized the need for assessment and treatment of pain in venous leg ulcer patients. Adequate pain control results in better compliance with treatment, and pain relief promotes a better quality of life⁵³. Venous ulcers are painful and pain is often treated inadequately. Lower limbs Effect of interventions on healing⁵⁴; many patients take mild analgesia or no analgesia at all. Pain seems to be under-treated with venous leg ulcer¹². Pain relief is important for several reasons. It leads to a substantial improvement in quality of life, enables patients to mobilize and improves patients' appetites; their nutritional status may also be improved. To treat pain adequately, it is essential to emphasize the importance of pain relief to patients and health care workers.

Little research has been conducted into effective treatment of pain with leg ulcer patients. Only one evidence-based intervention with pain management was found in the literature. This intervention is the use of EMLA cream with debridement of wounds on

leg ulcer patients. EMLA cream is effective in relieving pain related to debridement of the wound. The use of EMLA should be recommended for this purpose. It should be part of a total package of pain treatment, beginning with assessment of pain and aiming at total pain relief.

Nutrition

The studies on nutrition included in this review showed that many leg ulcer patients have low levels of vitamin A, C, zinc and carotenes. With respect to chronic wounds, studies indicate that malnutrition is a risk factor for pressure ulcer formation⁵⁵ and that malnutrition slows down healing in pressure ulcers⁵⁶. Metabolic deficiency seems to be relatively common in leg ulcer patients. The mean daily intake in many leg ulcer patients is inadequate to meet their caloric needs, and a high percentage of leg ulcer patients are at moderate or high nutritional risk. Nutritional status and nutritional intake is often insufficient according to existing guidelines. Furthermore, obesity is common in patients with leg ulcers caused by venous insufficiency. However, current literature provides no solid evidence of a direct relationship between nutrition or the use of nutritional supplements and the healing or nonhealing of venous leg ulcers. Only for the use of zinc supplements is there some evidence that this might be effective when baseline zinc serum levels are low.

More research should be conducted into the effect of nutrition and nutritional supplements on the healing and prevention of leg ulcers. In the meantime, nutritional status should be assessed so that possible nutritional deficiency can be revealed and treated. Patients should also be encouraged and guided to achieve normal, healthy weight. Overweight and obesity can be regarded as risk factors for venous leg ulceration. Part of the problem caused by obesity is a limitation in exercise. Obese people have more difficulty walking and doing their exercises than those with normal weight.

Exercise

There is some evidence for a positive effect of leg exercise on the conditions for wound healing. Both of the experimental studies on exercise in our review show that exercise improves calf muscle pump function, calf muscle endurance, efficacy and power. Guidance from an occupational therapist in learning how to do these exercises is recommended. With guidance, exercises can be tailored to the capability of each patient.

Leg elevation

Leg elevation is advised in brochures for patients with venous leg ulcers. However, it is not always clear what exactly is meant by leg elevation. In the studies included in this review, leg elevation means elevating the leg above the level of the heart by 10–30_ without compression. These studies show that elevating the leg under these conditions has a beneficial impact. However, high compression combined with leg elevation appears to have a negative impact on TcPO₂ and on wound healing. This was also concluded by Gaylard et al.⁵⁷ who studied the effect of compression on venous stasis with healthy people. Further research should be conducted on the effect of leg elevation with compression while patients are in a sitting position. In the meantime, patients should receive instructions on leg elevation in accordance with the kind of compression they use. The compression they receive should be appropriate to their ability to mobilize.

Limitations and relevance of this review

The limitations of this review are mainly the result of a lack of controlled intervention studies on the relevant topics. Firstly, we found very few studies about the effect of nutrition on wound healing in leg ulcer patients. We decided not to extend our search to related topics like the effect of nutrition on surgical wounds. Secondly, we included observational studies in our review of the literature on the topics of pain and nutrition. We included these studies for the reason that they do give some direction for possible interventions. Thirdly, we found no studies on the effect of leg exercises on the healing of leg ulcers. On this topic, we included studies with outcome measures aiming at the improvement of parameters for venous circulation instead of wound healing.

This review however is most relevant because it presents the latest research concerning venous leg ulceration and leg elevation, leg exercises, nutrition and pain management. Although our review shows that only limited research has been conducted in this area during the past 10 years, it does provide some serious indications for future research and changes in current daily practice.

The lifestyle aspects addressed in this review can make a difference to the lives of leg ulcer patients, in the healing of their leg ulcers and through adequate pain relief. Professional care for leg ulcer patients should focus much more on lifestyle. Patients should be assessed and treated for pain and nutritional deficiencies. Appropriate guidelines for leg elevation should be given to each patient, and leg exercises should be adapted to the needs and abilities of each patient. Assistance from an occupational

therapist can be beneficial to guide patients with their exercises to individualize the intervention. Further research should be carried out on nutrition, leg elevation and exercise in relation to healing and prevention of leg ulceration. In the meantime, assessment and effective treatment of pain and nutritional status, the initiation of guided exercise and individual advice concerning mobilization and leg elevation can and should begin.

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Physical activity and adherence with compression therapy in patients with venous leg ulcers

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5

Abstract

Background. Ambulant compression therapy is essential in the treatment of venous leg ulceration. In addition it is vital that leg ulcer patients adhere to compression therapy and remain physically active in order to stimulate the calf muscle pump function by walking and conducting lower leg exercises. To date, little is known about patient health behaviour with respect to these activities.

Aim. The aim of this study is to assess levels of physical activity, particularly walking and leg exercises, among venous leg ulcer patients and the extent to which patients adhere to compression therapy.

Methods. The sample included 150 patients at 12 outpatient clinics for dermatology with a leg ulcer at that time or at some point in time in the month prior. Patients were contacted for an interview and were asked to wear an accelerometer during the week prior to the interview.

Results. In this study, 39% of the patients interviewed displayed adherence to compression therapy. Self reported data validated by the use of an accelerometer indicated that the amount of moderate strenuous activity was low in comparison to the general Dutch population. 35% of the patients did not have a 10-minute walk on any day of the week.

Conclusions. Low levels of physical activity were established in a group of 150 venous leg ulcer patients. Full adherence to compression therapy was reported in about 40% of the patients. As a result, patients should be educated and stimulated to a) enhance physical activity through walking and leg exercises; and b) increase adherence to compression therapy.

Background

In 70% of all leg ulcer patients, ulceration is caused by venous insufficiency¹. The main causes of venous insufficiency are: a) varicose veins (reflux); b) deep venous thrombosis (obstruction); and c) diminished calf muscle pump function. Physical activity and adherence to compression therapy are two vital factors with respect to decreasing wound healing time and preventing wound recurrence. Leg exercises and physical activity stimulate the calf muscle pump which supports venous circulation. Walking is particularly relevant as it causes the calf muscles to contract and expand. This results in increased pumping of blood from the lower leg upwards towards the heart^{1,2}. A diminished pump function, or absence of the calf muscle pump, can contribute significantly to the development of oedema in the lower legs and other chronic venous insufficiency (CVI) symptoms. Leg ulcer patients should therefore be encouraged to enhance calf muscle activity through walking³.

Leg exercises for the lower legs efficiently supplement daily physical activities and walking, especially when the opportunities to walk or engage in other physical activity is limited. Several studies show positive effects of leg exercises on the calf muscle pump function^{4,6}. The tip toe exercise in the standing position, as well as the flexing and stretching of the feet in the sitting position, effectively stimulate the calf muscle and enhance venous return^{5,7}.

To effectively treat venous leg ulceration, compression therapy of the lower legs is essential. Patient adherence to compression therapy improves the effectiveness of the calf muscle pump, reduces venous volume, lowers venous pressure (only with high external pressure), and improves the microcirculation¹. It also prevents the occurrence of oedema and reduces the development of skin changes, especially after deep venous thrombosis⁸. Additionally, activation of the calf muscle in patients with CVI is less effective when compression is not used⁹. Compression therapy is applied by means of bandages or therapeutic elastic stockings. Bandages are applied when a wound or oedema of the lower legs is present. Patients with leg ulcers should wear short stretch bandages for 24 hours a day over the course of seven days. Once or twice a week, the bandages are changed by trained medical staff from the outpatient dermatology clinic or home health care organisation. When the wound has healed and there is no oedema left in the lower legs, patients should then wear properly fitting therapeutic elastic stockings from the moment they rise in the morning to the moment they go to bed at night. It is important that therapeutic elastic stockings be replaced regularly to ensure adequate compression.

Evidently, inadequate compression or poor adherence to compression therapy can result in the recurrence of venous leg ulcers¹⁰⁻¹³. Reduced adherence, reported in a review from Serup et al.¹⁴, to dermatological treatment is noted in 34-45% of patients, this concerned mostly patients with psoriasis or eczema. Adherence to long term therapy is defined by the World Health Organisation¹⁵ as the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.

In sum physical activity through walking and leg exercises, combined with an adequate use of compression therapy, is essential in the treatment of venous leg ulcers. However, little is known about a) the levels of physical activity, walking and leg exercises among venous leg ulcer patients; and b) their adherence to compression therapy.

The aim of this study is to assess physical activity levels in venous leg ulcer patients, with a specific focus on walking and lower leg exercises and to establish levels of patient adherence to compression therapy. The following research questions were formulated: 1a) How much time do leg ulcer patients spend on moderately intensive physical activities? 1b) How much time do patients spend walking during a seven day period? 1c) To what extent do patients conduct lower leg exercises? 2) To what extent do leg ulcer patients adhere with compression therapy by means of therapeutic elastic stockings or bandages?

Methods

Patients and procedure

Interviews were conducted with 150 patients by a team of three trained interviewers. Patients were included at 12 hospital based outpatient dermatology clinics in the Netherlands. The study was approved by the medical ethical committee of all participating hospitals.

Patients receiving treatment at outpatient dermatology clinics with a leg ulcer at the time of the study or in the month prior were asked to participate in this study. Only patients with leg ulceration based on venous aetiology or a mixed aetiology of venous and arterial or venous and arteriolar insufficiency were invited to participate. In order to be included in the study, patients had to be able to speak and understand the Dutch language. Additionally, participants were required to provide informed consent. Exclusion criteria included arterial insufficiency with an ankle/brachial pressure index of < 0.8 or full immobility.

Patients were interviewed at the outpatient dermatology clinic where they were being treated. All participants were initially approached by dermatology nurses and/or dermatologists and asked if they would be willing to participate in this study. Participants were contacted by one of the interviewers and patients were informed that the interview would last approximately one hour. Patients were also asked to wear an accelerometer in the week prior to interview and were given instructions for its use. The accelerometers were then sent by post.

Assessments

Data on wound characteristics and aetiology were provided by the dermatologist or dermatology nurses. Patients, as well as nurses from the outpatient clinics for dermatology, were asked to report on comorbidity, the duration of the current wound and the date of the first wound. Questions relating to patient characteristics such as age, occupation and education were then posed and followed by an enquiry about therapy and care of their leg ulcers. Information was compiled on the kind of compression the patient was currently using, how often their wound was cared for and by whom care was provided.

Additionally, patients were asked to report on whether or not they conducted leg exercises. Also the kinds and frequency of exercises was established. On adherence to compression therapy six questions were presented to determine actual treatment adherence behaviour. Answers were registered in pre-structured categories. The questions and categories are displayed in box 1. Additional remarks from the patient concerning their experience with compression therapy were reported at the end of the interview.

Observations

Footwear was observed by the interviewer and patients were questioned as to whether or not their footwear on that day was the footwear they usually wear. If this was not the case, patients were asked what kind of footwear they usually wear. The interviewer judged the quality of the footwear and paid special attention to the height of the heels (< 4 cm) and the supportive capacity of the shoe. The interviewer also observed whether or not the patient's shoes fit properly and were suitable for walking. Subsequently, the weight and height of the patient were registered. Dermatology nurses were asked to

report if they had an indication for non adherence with treatment regimen through observation of the bandages or stockings or the amount of oedema in the lower legs.

Box 1 Questions and scoring list to determine adherence with compression therapy

Instruction for the interviewer and questions to determine adherence with compression

Instruction Ask the following questions to learn about the actual behaviour of the patient Ask about a period of six months prior to the interview Be sure not to judge or correct the answers of the patient Make sure that you give the patients the impression that nobody is perfect and that it is all right to talk about non-adherence Try to determine precisely when the patient does not wear the stockings or bandages

- 1 When do you normally put on your therapeutic elastic stockings and when you take them off again? (Let the patient describe the day and try to find out at what moment the patient puts on and takes off the therapeutic elastic stocking)
- 2 We all forget thing sometimes Do you sometimes forget to put on your stockings in the morning?
- 3 Do you sometimes take off your stockings early, perhaps because they are hindering you?
- 4 Do you have the same routine every day or do week days differ from weekends?
- 5 Does it ever happen that you do not wear your stockings for a whole day?
- 6 Do you find it difficult to wear your stockings on special days? (think of holidays, very warm days, a day on which you are going to swim or sit in the sun)

The interviewer was instructed to translate the given answers to the questions above into pre-structured compliance categories The following categories were used

Scoring categories, adherence with therapeutic elastic stockings and/or bandages

The patient did wear the therapeutic elastic stockings/bandages

- always, all day
- occasionally somewhat shorter, <2 hours shorter, less than once a week
- regularly somewhat shorter, <2 hours shorter, \geq once a week
- occasionally, considerably shorter, >2 hours, < once a week
- regularly, considerably shorter, >2 hours shorter, \geq once a week
- occasionally not, for one day, less than once a month
- not, on a regular base, more than once a month
- not, in the last 6 months, more than one day at a time
- no experience (yet) with therapeutic elastic stockings

Questionnaires

All patients completed the Seven Days Physical Activity Recall questionnaire (PAR)^{16 17}. The PAR asks respondents to recall and report all physical activity engaged in over the previous seven days. A distinction was made between week days and weekends. The PAR requires respondents to report on any moderately strenuous activities in the week prior and the amount of time spent on these activities. To increase understanding of what kinds of activities are considered moderately strenuous, examples were provided on the back of the questionnaire. These examples were explicitly shown to the patient by the interviewee. Patients were also asked to report on strenuous and very strenuous activities

in the same time frame of a week. Furthermore, the amount of walking in the week prior to the interview was investigated using a question derived from the International Physical Activity Questionnaire (IPAQ)¹⁸. This question asked patients how often they, in the previous week, had walked for a minimum of 10 minutes. In cases where patients had taken at least a 10 minute walk on at least one day, further questions relating to the average time spent on walking were posed. In addition, patients were also asked whether or not they believed that walking enhances wound-healing and if they thought that walking helps to prevent recurrent wounds.

Accelerometer

To measure actual physical activity, an accelerometer (PAM for physical activity monitor) was used¹⁹⁻²¹. The PAM is a small device that can be attached to the waistband of a trouser or skirt containing a display that shows two different scores of physical activity, namely a day-score and a mean week-score. The PAM was used as a control device for over-reporting of physical activity. The accelerometer was sent to the patients by mail. Patients were instructed to wear the meter everyday from the moment they got out of bed in the morning until the moment they went to bed at night.

Analyses

Descriptive analysis was used for data analysis in this study. Scores for self-reported physical activity were combined with PAM-scores to validate self-reported activity. Self report on adherence with compression was combined with dermatology nurses observations.

Results

In total, 227 patients were invited to participate in our study. Of the 227 patients, 77 (34%) choose not to participate for the following reasons: a) For 29 patients, participation in this study was considered to be too much trouble (many of these patients were dependent on others for transportation to the hospital); b) For an additional 16 patients, participation was not possible due to the fact that the patient or his/her partner was unwell; c) four patients indicated that they did not have time to participate due to work commitments; d) seven patients stated that they did not have sufficient time as a result of other activities; and e) a final 21 patients did not provide a specific reason for not participating.

Patient characteristics

Table 1 presents patient characteristics, wound characteristics and comorbidity. The mean age of the patients in our study was 66 years and two thirds of the patients were female. Most patients had a lower educational level. For 60% of the patients, the leg ulcer was the result of a mixed aetiology of venous and arterial or arteriolar insufficiency. All patients with diabetes, heart-failure, hypertension or intermittent claudication were also classified as patients with a mixed aetiology.

Table 1 Patient characteristics, wound characteristics and comorbidity (n=150)

Patient characteristics		
age (mean, median (range))		67, 68 (27-91)
female		93 (62%)
education (highest completed level)	- elementary school	37 (25%)
	- lower secondary school	72 (48%)
	- vocational education	18 (12%)
	- higher educational level	21 (14%)
paid occupation outdoors		30 (20%)
BMI (mean, median, (range))		30, 29, (20-53)
	- 19-25 normal	34 (23%)
	- 25-30 overweight	57 (38%)
	- >30 obesity	59 (39%)
Wound characteristics		
Aetiology	- venous	60 (40%)
	- mixed	90 (60%)
Oedema	- much	49 (32%)
Duration in months (mean, median, (range))		7.9, 4.0, (0.5-60.0)
First wound in years ago, (mean, median (range))		23, 20, (1-76)**
Frequency	- first wound	41 (27%)
	- second wound	27 (18%)
	- 3 rd -10 th wound	53 (35%)
	- > 10 th wound	29 (20%)
Professional wound-care, frequency per month (mean, (range))		8 (1-29)
Compression*	- Bandages short stretch	69 (46%)
	- Bandages long stretch	6 (4%)
	- Therapeutic Elastic Stocking(s)	89 (59%)
	- Other	23 (15%)
Comorbidity		
	- varicose veins	106 (71%)
	- hypertension	59 (39%)
	- deep venous thrombosis (in past)	53 (35%)
	- cardiac problem	29 (19%)
	- diabetes	30 (20%)
	- intermittent claudication	12 (8%)
	- erysipelas in past	26 (17%)
	- eczema	10 (6%)
	- arthritis/arthrosis	35 (23%)
	- hip / back / knee	24 (16%)

* patients can have both, a stocking on one leg and bandages on the other

** n=109, patients with previous wound(s)

Patients that had a leg ulcer based on a pure venous aetiology comprised 40% of the sample. Almost three-quarters of the patients (71%) had varicose veins and more than one third had deep venous thrombosis in the past. At the time of interview, 103 patients (69%) had a wound. The other patients had a wound in the month prior to the interview. Less than one-third of the patients had their first wound at the moment of, or in the month prior to, inclusion while almost one fifth of the patients had had wounds on more than 10 occasions. The median duration of the wound was 4 months with a range of two weeks to five years. All patients received professional wound care with a mean frequency of twice a week. Compression therapy was applied by short stretch bandages or therapeutic elastic stockings. Some patients had both because they had different types of compression when both legs were affected.

Physical activity

In table two, the figures for physical activity, walking and leg exercises are displayed. Results of the physical activity recall questionnaire (PAR), corrected for over reporting, showed that less than half (44%) of the patients had a minimum of 2.5 hours of moderate strenuous activity a week. Thus 56% of the patients had less than 2.5 hours of physical activity a week.

Table 2 Amount of moderate strenuous physical activity, walking and leg exercises (n=150)

Physical activity-PAR	
≥ 2.5 hours of moderate strenuous activity	66 (44%)*
no moderate strenuous activity	39 (26%)
Walking	
≥30 minutes of walking on ≥ 5 days	19 (13%)*
<10 minutes of walking on all days	52 (35%)
Don't know	11 (7%)
Leg exercises	
Patients conducting leg exercises	53 (35%)
-Flexing and stretching the feet	30 (20%)
-Rotating (or circling) the feet	35 (23%)
-Tip-toe	11 (7%)

* Self reported data corrected for pam scores. PAM- corrections explained: ≥30 minutes of walking on ≥ 5 days of the week or ≥ 2.5 hours of moderate strenuous activity is not possible when the average daily PAM-score is 9 or less

** 26 patients with self reported >2.5 hours msa /week, had a mean week-score on the PAM <10, but 9 patients reported cycling as moderate strenuous activity, so only 17 patients were corrected for PAM in their physical activity score, as pam scores are known to underestimate activity during cycling.

About half of these patients (26%) did not have any moderate strenuous physical activity in the week prior to the interview. Seventeen patients (11%) were corrected for PAM scores on the amount of physical activity a week, twelve patients (8%) were corrected for

the amount of walking in the week previous to the interview. Patients who reported more than 2.5 hours on the PAR and had a score of >9 on the PAM were categorized in the >2.5 hours activity group.

Only 13% of the patients were likely to walk for 30 minutes on at least 5 days of the week. The percentage of patients that did not walk for 10 minutes on any day in the week prior to the interview was 35%.

With respect to leg exercises, only 35% of the patients conducted exercises for the lower legs. Flexing and stretching the feet was done by 20% of the patients. Circling the feet to loosen up the ankle was conducted by about a quarter of the patients. Tip-toe exercises were done by only eleven of the patients interviewed.

Adherence compression Therapy

In table 3, adherence to compression therapy figures are displayed. Of the sample, 119 patients had stockings at the moment of the interview or had experience with stockings in the past six months. Ninety-seven patients had bandages or experience with bandages in the past six months. With respect to treatment adherence, 39% of all patients (n=150) were fully adherent to the use of therapeutic elastic stockings as well as bandages. Of the patients who had experience with therapeutic elastic stockings (n=119), 33% reported wearing their stockings on all days from the waking until they went to bed at night. With respect to the use of bandages, 80% of the patients who had experience with bandages (n=97) reported being completely adherent.

Table 3 Adherence to compression therapy using bandages and/or stockings

Adherence	Stockings or bandages	
Full adherence with bandages and stockings (n=150)	(59) 39%	
Adherence	Stockings n=119	Bandages n=97
<i>Fully adherent</i>		
-on a daily basis (according to guidelines)	39 (33%)	78 (80%)
<i>Moderately adherent</i>		
- occasionally to regularly somewhat shorter	45 (38%)	14 (15%)
<i>Non-adherent</i>		
- occasionally, considerably shorter to more than one day at a time	35 (29%)	5 (5%)

Only a small number of patients reported wearing the stockings or bandages for a somewhat shorter period of time on occasion. This was the case with ten patients wearing stockings and two patients wearing bandages. The number of patients that wore their stockings or bandages for a shorter period of time on a regular basis was considerably

higher. Of the patients with stockings, 23% reported regularly decreasing the time they wore their bandage or stocking. With patients using bandages, this was 12%. Non-adherence was reported in 35 patients that had experience with wearing elastic stockings and in 5 patients who had experience with bandages.

Discussion

Activation of the calf muscle pump function combined with compression therapy is the most effective non-invasive component of venous leg ulceration treatment^{22,23}. This study provides insight into levels of physical activity among venous leg ulcer patients and in particular on walking and leg exercises, and patient adherence to compression therapy. The results of this study show that moderate strenuous activity levels in venous leg ulcer patients are low. A substantial number of patients do not even engage in 10 minutes of walking per week. Additionally, this study showed that only one-third of the patients conducted leg exercises. Adherence to compression therapy was also low, with less than half of the patients reporting full adherence to therapy.

There are no studies in the international literature that report on the physical activity and walking behaviour of venous leg ulcer patients. There is, however, a study in the Netherlands (where our patient sample was obtained) in which 8000 members of the general population were questioned with regard to their physical activity²⁴. The patients in our sample show lower physical activity levels compared to the sample in the survey among the general Dutch population thereby indicating that our sample is comparatively more inactive. In the Dutch adult population more than 50% is sufficiently physically active compared to 44% of the patients in our sample. Furthermore, in the Dutch study only 8% of the sample was completely inactive compared to 26% of the patients in our sample. In the large scale study with the general population, subgroup characteristics for individuals showing low levels of physical activity were identified. In our study, the sample selected shared certain characteristics with the large scale study's low activity subgroups. The coinciding characteristics include lower levels of education, age of over 65 years, and the existence of chronic medical conditions.

Clearly, venous leg ulcer patients have low levels of physical activity and spend little time walking despite the fact that walking activates the calf muscle pump and reduces venous hypertension when combined with compression therapy. There are, however, no

guidelines that indicate the amount of walking necessary to improve venous insufficiency. In the study reported here, the actual amount of walking done by patients was assessed using reports of 10 minute walking periods, as 10 minute walking periods ensure that the calf muscle is sufficiently activated. A study by Van Uden et al.⁴ established that walking faster is more effective in promoting venous circulation of the lower legs. To determine the amount of walking to achieve beneficial effects with respect to decreasing venous leg ulceration needs to be further established by future research. Recommendation with respect to the amount of physical activity most appropriate, should be related to the capabilities of the individual patient.

Most patients in this study were categorized as moderately adherent with compression therapy. A smaller group were categorized as non-adherent. In a study by Mayberry and colleagues¹² non-compliance was established for only 9.7% of the patients. At follow-up, this number had increased to 20.5%. Erickson et al.¹⁰ have shown that strict compliance was established in 32% of the cases in their study which is more on par with the results of our study. Obviously, compliance or adherence rates are influenced by the methods used to obtain results. The patients in the study by Mayberry et al. or Erickson et al.^{10,12} were considered compliant when they did not consistently refuse to use ambulatory elastic compression or when they kept 100% of their appointments, adhered completely with prescribed compression therapy, and followed all instructions for wound and extremity care. Kjaer et al.¹³ have stated that the indicator used to determine compliance is susceptible to bias. In our study, compliance was assessed by questioning the patients on their daily habits concerning compression therapy. Patients were invited and stimulated to tell the interviewer about their experiences with their bandages and medical stockings. In many cases, when the interviewer asked patients specifically about their habits concerning compression therapy, many reported lower adherence level than what they had initially reported. Evidently, by discussing experiences and habits concerning compression in a non-judgemental way, the provision of socially desirable answers was diminished.

Several studies have concluded that patients who display strict compliance with their treatment regimen show significant faster healing rates and fewer recurrences in comparison to patients that are less compliant or non-compliant¹⁰⁻¹³. High adherence is, according to the WHO review on adherence to long-term therapies²⁵ associated with

more severe symptoms or illness, knowledge about and belief in efficacy of treatment, adequate social support and trust in the clinician¹⁴. In a study of Renzi²⁶ in dermatologic patients it was concluded that dissatisfaction with care was associated with poor treatment compliance. Unfortunately, few studies report on the determinants of non-adherence with compression therapy. A study by Edwards²⁷ concluded that many patients do not have a clear understanding of their condition or the treatment regimes prescribed. Additionally, Edwards has indicated that concurrent problems associated with compression bandaging, such as pain, leakage of exudates and skin irritation, contribute to non-compliance. In a study by Kiev et al.²⁸, socio-economic factors, cosmetic reasons, complaints of discomfort and difficulty in putting on the stockings were identified as primary reasons for non-compliance.

Moreover bandagers, who supply therapeutic elastic stockings once the wound has healed, need to provide patients with the best fitting stockings possible for each and every patient. When non-adherence is caused by poorly fitting or irritating stockings, the bandager also needs to be consulted. Furthermore, patients should be educated about the importance of full compliance with compression therapy. Consequently, we recommend more research on the determinants of adherence to compression therapy. Identified behavioural determinants should be taken into account in educating and stimulating patients to fully adhere with compression therapy.

A limitation of our study is the fact that a relatively large number of patients declined participation. It is possible that this created a selection bias. Another limitation is related to the fact that the sample of venous leg ulcer patients in our study was obtained from outpatient dermatology clinics. In the Netherlands, most patients with uncomplicated venous leg ulceration are treated by general practitioners and/or nurses from home health care organisations. Patients with poorly healing wounds, recurrent wounds or a wounds related to more complicated aetiology are referred to outpatient dermatology clinics. As a result, the generalisability of our findings is probably limited to patients with more severe complaints of venous leg ulceration. On the other hand, generalisability of our results is likely enlarged as the patients included were recruited from a large number of outpatient dermatology clinics in both academic and general hospitals in the Netherlands.

It is important to note that the validity of this study was strengthened by the use of several methods like self reported data, validated questionnaires, data from the medical files, observational data from dermatology nurses and interviewers and the use of an accelerometer. Using an accelerometer allowed us to objectively measure actual physical activity alongside self-reported physical activity. In our study, the accelerometer was used specifically to control for over-reporting of physical activity by the patients rather than to measure the total amount of physical activity.

Conclusions

Venous leg ulcer patients with ambulant compression therapy have low levels of physical activity and spend little time walking. Levels of full adherence with compression therapy are low. Most patients are, however, moderately compliant with compression therapy. Physical activity, in the form of walking, and compression therapy are the two most important non-invasive elements of leg ulceration treatment where the ulceration is a result of venous insufficiency. Patients should be stimulated to enhance physical activity that aims to activate the calf muscle pump. This can best be done by walking and by doing lower leg exercises. Patients should receive professional support to increase adherence to treatment with compression bandages or stockings. Determinants for enhancing adherence and physical activity levels need to be further explored. Nurses from outpatient clinics for dermatology, in a multidisciplinary setting with dermatologists, physiotherapist and bandagers, can play an essential role in the provision of information, education and support if they are given sufficient time and training on how to motivate and educate patients.

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The sedentary leg ulcer patient: Bio-psychosocial determinants of physical activity

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Abstract

Aims. The aim of this study was to identify determinants of physical activity in venous leg ulcer patients in order to develop recommendations for health-related behavioural interventions, aimed at enhancing physical activity in these patients.

Background. Physical activity promotes wound-healing and prevents the recurrence of wounds in venous leg ulcer patients. Many leg ulcer patients, however, have a sedentary lifestyle.

Methods. Twenty-five patients were interviewed using a combination of pre-structured questions and more qualitative open-ended questions. All patients included in this study were treated at an outpatient clinic for dermatology and had a leg ulcer with a venous or mixed aetiology at the time of the interview or in the month prior to the interview.

Results. Only 9 of the 25 patients (36%) reported sufficient levels of moderate strenuous physical activity, defined as 30 minutes a day on at least five days a week. The results show limited knowledge about the relationship between physical activity and leg ulceration and low self-efficacy for increasing physical activity. In addition, multi-morbidity, pain and social support were identified as main determinants of physical activity.

Conclusions. The results indicate that there is a broad range of bio-psycho-social determinants of physical activity in leg ulcer patients. Suggestions for improving physical activity levels include influencing knowledge, beliefs and self-efficacy through active learning and goal setting. In doing this, individual physical limitations, pain, adequate footwear and social support should be taken into account. Programs to stimulate physical activity by specialised dermatology nurses might fulfil patient needs and help patients enhance physical activity levels.

Introduction

Physical activity has a positive effect on health in the general population and in particular in leg ulcer patients. Physical activity supports lower leg circulation, and thus has a beneficial effect on wound healing as well as to preventing recurrent wounds^{1,2,3}. Previous studies^{4,5} however show that leg ulcer patients have low levels of physical activity. Understanding determinants of physical activity in these patients is essential to address the sedentary lifestyles and to develop tailored health interventions that can meet the specific needs of leg ulcer patients. So far, little research has been done on the ways in which physical activity in leg ulcer patients can be stimulated. For these reasons, a pilot study that explores the hindering and facilitating determinants of physical activity in patients with venous leg ulceration was conducted.

Background

Although multiple factors can contribute to the occurrence of leg ulcers, most leg ulcers in Western society are caused by venous insufficiency (70%)¹. Common causes of venous insufficiency are post thrombotic syndrome and varicose veins. Regular elements of non-invasive treatment and the prevention of venous leg ulcers are ambulant compression therapy and physical activity to activate and improve the functioning of the calf muscle pump^{3,6,7}. When ulcers are present, compression therapy is applied by using short stretch bandages. These bandages should be worn 24 hours a day and should be changed once or twice a week. When the wound has healed, patients are encouraged to wear therapeutic elastic stockings or long stretch bandages on a daily basis. In general, wound care and compression therapy is done by community health nurses or nurses at outpatient clinics for dermatology.

Activation of the calf muscle is essential to improving the blood flow upwards. With respect to walking, adequate footwear and an adequate push-off phase are necessary for an effective calf muscle pump function^{1,3}. Lower leg exercises can also activate the calf muscle pump function. Lifting and lowering the heels in slow tempo while in a standing position, strengthen the calf muscles and consequently stimulate the blood flow back to the heart. Tip-toe exercises also yield the same kind of effects^{8,9}.

Impaired mobility is a major problem for leg ulcer patients¹⁰. In a study on ulcer related problems and health care needs in 141 leg ulcer patients, one-third of all patients judged

their own physical activity level as insufficient. Approximately, one quarter of all patients engaged in walking outdoors only once a week or less⁴. In a study of 150 patients leg exercises were conducted by only one-third of the patients⁵. Evidently, physical activity and leg exercise levels in leg ulcer patients need to be stimulated.

In order to promote behaviour change in a specific group it is necessary to identify relevant determinants for this group. Health behaviour theories like social cognitive theory¹¹, theory of planned behaviour¹² and the health belief model¹³ are useful to understand and select relevant determinants of behaviour¹⁴.

From these theories and related research on behaviour change a number of individual and environmental determinants of health behaviours can be identified. Individual factors include knowledge and beliefs about the relation between the behaviour and health outcomes, motivation for behaviour change and self-efficacy to perform the activity^{11,14-17}.

Environmental factors refer to the objective factors that can affect a person's behaviour but that are physically external to that person as well as the person's perception of these environmental factors¹⁸. Environmental factors can refer to interpersonal as well as organizational factors that hinder or facilitate the performance of the behaviour, e.g social support, accessibility of health care systems or personal aids.

To learn about health behaviours in leg ulcer patients, generic as well as population-specific determinants of health behaviour have to be explored to facilitate the development of therapeutic possibilities to stimulate health behaviour changes by professionals.

The study

Aim

The objective of this study was to identify determinants of physical activity in patients with leg ulcers resulting from a venous or combined aetiology of venous and arterial or arteriolar insufficiency.

Design

A cross-sectional study with a triangulated design¹⁹ was conducted to explore determinants of physical activity in leg ulcer patients. Determinants of behaviour change in the literature on behaviour change in general, and health behaviour in particular, were used as the basis for the development of the semi-structured questions used in this study.

In addition, a more qualitative approach using open-ended questions about the determinants of physical activity in this specific population was applied.

Participants

Twenty-five leg ulcer patients with a venous or mixed aetiology of venous and arterial or arteriolar insufficiency were randomly selected and interviewed at two outpatient clinics for dermatology where these patients were being treated for leg ulceration. All patients provided informed consent. Non-response was not encountered.

Data collection

Data were collected using interviews that combined both semi-structured and open-ended questions. Interviews were conducted at the outpatient clinics for dermatology and were performed by the first author and a research assistant.

Interview part 1: general health- The first part of the interview addressed general patient, disease and wound characteristics. Data were gathered on age, gender, education, occupation, social situation and comorbidity. Additionally, data were collected on current wound status, wound duration, frequency of past wounds, and the time that has transpired since the first wound.

Interview part 2: physical activity- Physical activity was addressed in the second part of the interview. This part aimed to acquire information on the nature and amount of physical activity patients engaged in at that time. Additionally, questions about the patients' experience with physical activity were included. Patients were asked whether they performed housekeeping activities and participated in sports or other types of physical activity like walking or cycling. The amount of time spent on these activities and the amount of time spent on leg exercises was also explored. Both present and past physical activity, were explored.

Interview part 3: determinants of physical activity- In this part, patients were asked pre-structured questions on their physical activity. These questions were based on determinants of behaviour change relevant in the general population. The questions focused on the following: a) the patient's judgement of current level of physical activity; b) beliefs and knowledge with respect to the beneficial effects of physical activity on healing and preventing leg ulcers; c) self-efficacy and motivation to change behaviour

related to physical activity; d) physical limitations; and e) environmental factors, such as the patient's need for professional support. In addition, adherence to and satisfaction with compression therapy were discussed. The use and effectiveness of pain medication was also addressed and pain levels were measured using a 0 to 10 visual analogue scale. Furthermore, patients were asked whether or not they were satisfied with their footwear and if they were able to unroll their feet while walking. Topics like experience with therapeutic elastic stockings, pain, footwear and the ability to unroll the feet were included in the interview as these factors are expected to influence physical activity levels in this population. Open-ended questions were then used to further explore individual determinants of physical activity. Patients were asked to convey their opinions on the causes of leg ulceration and the factors enhancing or hindering wound healing. With regard to environmental determinants of physical activity, patients were asked about hindering and facilitating factors in the interpersonal domain and with respect to facilities such as health care services.

Ethical considerations

As this study did not intervene with usual care and the interviews were not burdensome to patients, the local medical ethics committee waived the need for formal approval. All patients provided an informed consent and all relevant aspects of the Helsinki Declaration were taken into account in collecting, processing and reporting the data.

Data analyses

Descriptive and content analyses were used to analyse data. Data derived from the open-ended questions were analysed using Atlas.ti²⁰, a program for qualitative analysis of textual, graphical, audio and video data. A categorization scheme was constructed by the first author and the content analyses of the answers to open-ended questions were confirmed by two of the authors (MMH, TvA). Physical activity determinants mentioned by only one or two patients were not reported in the results section of this article.

In addition to analysing the data for the whole sample, data from patient subgroups classified as those with sufficient or insufficient current physical activity levels were analysed with regard to physical activity determinants. The categorization was based on national and international guidelines that considered a minimum of 30 minutes of moderate strenuous exercise a day for five days a week to be sufficient physical activity²¹.

²².

Results

Patient characteristics

Patient characteristics are displayed in Table 1. The patients included had a median age of 75 years. The majority of the patients were female and had a lower educational level. Half of the patients were living alone at the time this study was conducted. A number of comorbidities were reported and are displayed in Table 1. Hypertension was found in half of the patients, whereas a third of the patients suffered from heart failure. Other comorbidities, reported by one or two patients, included kidney-disease, liver-disease, cancer, alcohol dependency, psoriasis, migraine, weak-sightedness, CVA, polycythaemie, stomach-bowel problems.

Table 1 Patient and wound characteristics

Patient characteristics (n=25)		
Age in years, median (range)		75 (50-85)
Gender female		21 (84%)
Education	* primary school	7 (28%)
	* lower advanced	14 (56%)
	* moderate/higher advanced	4 (16%)
Living alone		12 (48%)
Body Mass Index median (range)		29 (22-41)
Comorbidity	- Hypertension	12 (48%)
	- Heart failure	8 (32%)
	- Diabetes	4 (16%)
	- Lung-disease	4 (16%)
	- Other	20 (80%)
Wound characteristics (n=25)		
Open wound at time of interview		19 (76%)
Aetiology pure venous		8 (32%)
Time since first wound in years, median (range)		11 (0-49)
Frequency of wound	-first wound	5 (20%)
	-2 to 5 times	9 (36%)
	->5 times	11 (44%)
Duration of previous wounds in months (n=20), median (range)		4 (2-13)

At the time of the interviews, six patients (24%) reported that their leg ulcer had healed in past month. Only eight patients (32%) had a leg ulcer that was based on a pure venous aetiology. The other 17 patients (68%) had a mixed aetiology based on a combination of venous insufficiency and arterial or arteriolair problems. In many patients, leg ulcers were a recurrent problem. Only five patients interviewed reported that their current wound was their first, while eleven patients did have five or more wound episodes in the past. The median duration of previous wounds was four months, with a range from two to thirteen months.

Physical activity

Table 2 provides an overview of the current levels of physical activity for all patients. Only nine patients (36%) met the general population norm of a minimum of 30 minutes of moderate strenuous physical activity a day for five days a week. Physical activity as a result of housekeeping or going from one place to another was most commonly reported. Unfortunately, most of these activities lack the intensity (e.g. washing the dishes) or duration (e.g. 5 minute walk to bus stop) necessary to meet the general physical activity norms and were therefore not reported as moderate strenuous activity. More than half of the patients (n=15) performed specific leg exercises to some extent. The patients who did not perform these exercises were generally unaware of the existence of specific exercises for leg ulcer patients.

Table 2 Current physical activity in leg ulcer patients (n=25)

General level of physical activity	
Type of physical activity reported:	
- housekeeping independently	13 (52%)
- walking or cycling as transportation	20 (80%)
- sports	6 (24%)
Sufficient physical activity (30 min on 5 days/week)	9 (36%)
Leg exercises	
Performing (some) leg exercises	15 (60%)

Determinants of physical activity

Table 3 summarizes the results of the both the pre-structured and open-ended questions on knowledge and determinants of physical activity for all patients. This table also displays the results for the subgroups possessing sufficient and insufficient levels of current physical activity.

Only a little more than half of the patients (14) knew what caused their leg ulceration and even less than fifty percent (10) had some knowledge about what made the ulceration better or worse. The results also show that several partially incorrect beliefs about leg ulcers existed among this group. For example, four patients said that only rest in general and bed rest during admission to the hospital would make the wound better. Patients only incidentally reported a number of correct influencing factors such as standing too long, heat in the summertime, failure to wear elastic stockings, oedema, kinds of bandages and ointments, and quality of care. Two-thirds of all patients - ten in the low physical activity-group (PA-group) and six in the group with sufficient physical activity levels - believed that an inverse relationship exists between exercise and leg ulceration. Three patients did not expect a positive influence of physical activity on

wound healing or the prevention of recurrent wounds. This was due to incorrect beliefs or a lack of knowledge about the relationship between physical activity and leg ulceration healing.

Table 3 Individual and environmental determinants of physical activity and leg exercises

Determinants	Total (n=25)	*pa<30/5 (n=16)	*pa≥30/5 (n=9)
Individual factors			
<i>Knowledge and beliefs about</i>			
-causes of leg ulceration stated ^o	14 (56%)	9 (56%)	5 (56%)
-physical activity influences leg ulceration	16 (64%)	10 (63%)	6 (67%)
-physical activity negatively influences leg ulceration ^o	3 (12%)	2 (13%)	1 (11%)
-other factors influencing leg ulceration stated ^o	10 (40%)	7 (44%)	3 (33%)
<i>Motivation</i>			
-dissatisfied with current level of physical activity	8 (32%)	8 (50%)	0 (0%)
-motivated for leg exercises if positive influence leg ulcer	21 (84%)	14 (88%)	7 (78%)
-motivated for enhancing physical activity if positive influence leg ulcer	19 (76%)	12 (75%)	7 (78%)
<i>Self-Efficacy</i>			
-SE to enhance leg exercises	19 (76%)	13 (81%)	6 (67%)
-SE to enhance physical activity	9 (36%)	5 (31%)	4 (44%)
<i>Physical impairments</i>			
-pain	15 (60%)	11 (69%)	4 (44%)
-difficulties in unrolling the feet while walking	6 (24%)	5 (31%)	1 (11%)
-Impairment in mobility ^o	18 (72%)	14 (88%)	4 (44%)
Environmental factors			
<i>Hindering</i>			
-current footwear ^o	6 (24%)	4 (25%)	2 (22%)
-therapeutic Elastic Stockings ^o	3 (12%)	1 (6%)	2 (22%)
<i>Facilitating</i>			
-support from partner, family, friends, etc ^o	5 (20%)	5 (31%)	-
-support from physiotherapist with leg exercises or physical activity	17 (68%)	12 (75%)	5 (56%)

* pa= physical activity less than 30 minutes a day for at least 5 days a week or more than/equal to 30 minutes a day for at least five days a week

^o determinants identified from open-ended questions

Motivation with regard to behaviour change would be positively influenced through the belief that increasing physical activity or conducting leg exercises has a positive influence on leg ulceration healing and prevention in 19 respectively 21 patients. Only eight patients however, all with low activity levels, were dissatisfied with their current level of physical activity, which implies some motivation for behaviour change.

Self-efficacy for increasing levels of physical activity was rather low. Only nine patients were confident about being able to engage in more physical activity in the next two months if they wanted to. This was found in only one-third of the low physical activity group and less than half of the sufficient physical activity group. With respect to leg exercises, self-efficacy was much higher. Nineteen patients were confident that they could do more exercises in the next two months if they wanted to.

Pain and physical limitations are of great influence on physical activity levels. Fifteen patients experienced pain related to their leg ulcer. This was the case for eleven out of sixteen patients (69%) in the low exercise group and four out of nine patients (44%) in the sufficient exercise group. The median pain score of patients with pain was 5.3 on a scale of 0-10. Eleven patients indicated that the pain has a substantial impact on their daily life. Twelve patients took pain medication but, for eight of the twelve, pain medication provided insufficient pain relief. Fear of side effects, allergic reactions or a general aversion to taking pills were some of the reasons provided for not taking pain medication. With respect to unrolling the feet, six patients had some difficulties. Five of these patients were categorized in the low-level physical activity group. The open-ended questions also revealed that almost three quarters of the patients (72%) interviewed reported pain combined with mobility-related comorbidity as a hindering determinant of physical activity levels.

Regarding environmental factors, more than half of the patients thought that help from a physiotherapist would facilitate higher levels of physical activity. Most of these patients (11) were in the low level physical activity group. The interviews also revealed that support from a physiotherapist would motivate seventeen patients to conduct leg-exercises. Twelve of these patients were in the low level physical activity group. Additionally, for five of the patients, social support from family or friends would function as a facilitating determinant of physical activity. Furthermore, six patients had difficulties with respect to finding appropriate footwear and five patients reported difficulties with footwear as problematic in the open-ended questions. Only three patients were dissatisfied with their therapeutic elastic stockings and perceived them as hindering physical activity.

Discussion

Although physical activity in venous leg ulcer patients has a direct effect on their health status, determinants of physical activity in this patient group had not been addressed prior to this study. Our study offers a first exploratory look at a broad set of biopsychosocial determinants of physical activity in leg ulcer patients using pre-structured and open-ended interviews. Theories of health behaviours and determinants of physical activity in the general population²³⁻²⁵ were used as the bases of this study. Pre-structured questions were developed using general theories of health behaviour regarding physical

activity, while open-ended questions focused on the perspective of this specific group of leg ulcer patients. Several individual and environmental determinants of physical activity among leg ulcer patients were identified. These include knowledge and beliefs about the influence of physical activity on health, self-efficacy beliefs, physical impairments and social support.

Patients in our study reported several factors that function as barriers to increasing physical activity levels. A substantial number of patients had insufficient knowledge with respect to the causes of leg ulceration and the relationship between physical activity and wound healing and prevention. Patients were often not conscious about the potential effects of their individual lifestyle on leg ulceration. For example, patients are often told that it is beneficial for them to walk because it stimulates the calf muscle pump. However, when the wound fails to heal, patients are hospitalised with bed rest. As a result, patients believe that rest, rather than walking and being physically active, enhances wound healing.

A substantial number of patients also reported that knowledge of the positive effect of physical activity on wound healing could function as a motivation for increased physical activity. Dissatisfaction with current levels of physical activity can enhance motivation to change this behaviour. Only half of the patients in the low level exercise group however were dissatisfied with their level of physical activity.

Self-efficacy for enhancing levels of physical activity was low. Regarding leg exercises self-efficacy was clearly higher. Self-efficacy is a strong element in enhancing physical activity in combination with other social cognitive variables like, self regulation, outcome expectancies and social support Bandura¹⁵. In a study of Anderson et al.¹⁷ it was found that self-regulation, which is regarded as the key to social-cognitive approaches to changing health behaviour, was the most influential social cognitive variable in the model, as well as social support. Self-efficacy on the other hand is an important precursor to self regulation. In the same study¹⁷ it was also found that age contributed to the participants' physical activity levels. Anderson et al.¹⁷ suggested that the confidence of older adults in the ability to self regulate physical activity might have less to do with their perceived abilities to be consistent than with their perceived physical limitations, which might as well be the case with the sample in the current study.

Pain and comorbidity related to mobility were frequently reported as hindering determinants of physical activity. Both are physical aspects influencing behavioural

capability and self-efficacy. The pain experienced by patients seems to be underestimated by professional workers. Pain medication is prescribed but is not evaluated on a consistent basis. When patients feel that the pain medication they are receiving is ineffective, they often discontinue their use of the medication and accept the pain as a mere fact of life. Additionally, general practitioners and specialists might be too reluctant about providing additional prescriptions for pain medication to patients who find their medication ineffective.

Patients in this study also indicated that problems related to footwear and a lack of social support, were (environmental) factors that hindered their ability to increase physical activity levels. Support from a physiotherapist was reported as a factor that can enhance the patient's motivation to increase physical activity levels and to conduct leg exercises. This was especially the case among patients in the low-level physical activity group. Therapeutic elastic stockings and compression bandages were seldom reported as hindering determinants related to physical activity.

As with any study, several limitations have to be taken into account. The sample size (25 patients) in this study was relatively small. This sample size decreases generalizability but does allow for descriptive analyses. The limited sample size made it impossible to statistically test differences in determinants between patients with high levels of physical activity and patients with low levels of physical activity. An additional limitation is linked to the fact that patients included in this study were selected at outpatient dermatology clinics. In general, patients that are treated at outpatient clinics tend to have wounds that heal slower and recur more often than patients that are treated by community health nurses under the supervision of general practitioners. The aetiology often differs as well. For a large number of patients being treated at outpatient clinics, the aetiology is mixed. We therefore advise caution in generalizing the results of this study to leg ulcer patients treated in general practice. Nonetheless, the patient characteristics in our study are very similar to those in several international studies on patients with leg ulceration or chronic venous insufficiency (CVI)^{26,27}, thus supporting some generalizability of our findings.

In spite of the limitations several recommendations seem to be relevant for clinical practice. Knowledge and consciousness of the potential effects of their lifestyle would significantly increase the effect of outcome expectancies of patients^{28,35}. It is thus important that patients receive structured, information, tailored to their current knowledge and beliefs³⁰⁻³⁴. Information should be provided in accordance with the

principles of active learning^{28,35}. Feedback of current physical activity levels and the support of significant others can influence one's motivation to change behaviour. Furthermore, modelling can be used as a method to enlarge self-efficacy for increasing physical activity levels¹⁶.

Self-efficacy and behavioural capability are also prerequisites for changing behaviour. Behaviour change however has to be approached in small goal directed steps if it is to be successful. It is also necessary to be as specific and concrete as possible about the intended change^{16,36}. In trying to enhance physical activity levels, patients' individual limitations need to be taken into account and support in making changes should be provided. Self-regulation in enhancing physical activity and goal setting are essential to succeed¹⁷. Furthermore, pain associated with leg ulcers should be optimally treated to increase physical activity levels and improve patients' quality of life.

Conclusion

A set of bio-psychosocial factors, including knowledge and beliefs about the effect of physical activity on leg ulcers, self-efficacy to conduct physical activities, multi-morbidity, pain and social support, are identified as the main determinants of physical activity levels among leg ulcer patients in this study. Currently, regular consultations at outpatient clinics for dermatology lack time and attention to elaborate on the importance of physical activity. Feasibility of increasing physical activity levels and patient limitations are either shortly discussed or neglected. The present study suggests that increasing physical activity could be accomplished through the provision of an individual approach by trained dermatology nurses in which active learning, goal setting, guided practice and enhancing social support are the main components.

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Supporting adherence and healthy lifestyles in leg ulcer patients: Systematic development of the Lively Legs program for dermatology outpatient clinics

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7

Abstract

Objectives. The objective of our project was to develop a lifestyle program for leg ulcer patients at outpatient clinics for dermatology.

Methods. We used the intervention-mapping (IM) framework for systematically developing theory and evidence based health promotion programs. We started with a needs-assessment. A multidisciplinary project group of health care workers and patients was involved in all five IM steps; formulating proximal program objectives, selecting methods and strategies, producing program components, planning for adoption and implementation and planning for evaluation. Several systematic literature reviews and original studies were performed to support this process.

Results. Social cognitive theory was selected as the main theory behind the program 'Lively Legs' and was combined with elements of goal-setting theory, the precaution adoption model and motivational interviewing. The program is conducted through health counseling by dermatology nurses and was successfully pre-tested. Also, an implementation and evaluation plan were made.

Conclusion. Intervention mapping helped us to succeed in developing a lifestyle program with clear goals and methods, operational strategies and materials and clear procedures.

Practice implications. Coaching leg ulcer patients towards adherence with compression therapy and healthy lifestyles should be taken on without delay. Systematic development of lifestyle programs for other patient groups should be encouraged.

1. Introduction

The most common cause of leg ulceration is a chronic venous insufficiency (CVI)¹. Venous obstruction, venous reflux and failure of the calf muscle pump are generally considered to be the main causes of CVI². As in other circulation disorders, health behaviours such as exercise, smoking, nutrition and weight maintenance can influence CVI prognosis³⁻⁵. Programmes to improve these behaviours may have a positive impact on functional status and quality of life. Life style change however is difficult, so a health education program should be carefully targeted at the most crucial determinants of health behaviours and well implemented in clinical settings. This paper reports on the development of a program for behaviour change in patients with a leg ulcer, which was implemented in outpatient dermatology clinics.

Leg ulcers can heal within one week, but often become a chronic problem to patients. Harrison et al.⁶ found that 60% of all ulcers lasted for more than 6 months, and 33% of the ulcers did not heal within a 1-year period. Cornwall et al.⁷ estimated leg ulcer prevalence at 1.8 per 1000 in the United Kingdom population. In the Netherlands, the prevalence was estimated at 3.5 per 1000⁸. The typical patient is an elderly, low SES female. A study by Van der Velden et al.⁹ reported a prevalence of 12 per 1000 for women over the age of 75. After healing, 45% of all patients suffer from recurrent ulcers^{6,10}.

In the Netherlands, many leg ulcer patients are treated by family physicians and community nurses. Patients with wounds that are large, recurrent, healing insufficiently or of mixed aetiologies are often referred to outpatient dermatologic clinics. Dermatologists and dermatology nurses focus on wound care and compression therapy. After the leg ulcer has healed, patients are instructed to continue compression therapy using elastic stockings. However, adherence is not always monitored or discussed. Also, relevant lifestyle behaviours¹¹ such as smoking, physical inactivity, overeating or unbalanced diets are not often addressed. Furthermore, coaching to support lifestyle adjustment and adherence with compression therapy is not provided³.

Our aim was to develop an effective program for behaviour change in leg ulcer patients, which could be effectively implemented in dermatology outpatient clinics (Lively Legs program).

2. Methods

For designing the Lively Legs program, we used the intervention-mapping (IM) framework for systematically developing theory and evidence based health promotion programs^{12,13}. IM was previously used to develop health promotion programs for smoking cessation¹⁴, asthma management¹⁵⁻¹⁷, HIV prevention¹⁸ nutrition^{19,20}, sexual risk taking²¹, sun protection²² and violence prevention²³. IM guides the identification of health promoting behaviours and their determinants, development of intervention objectives, selection of methods and strategies for inducing change, and planning of program implementation, and evaluation of its impact. This section describes how we operationalized each IM step. An overview of the methods and results is given in Table 1.

2.1. Step 0: needs assessment

The start of intervention mapping is preceded by a needs assessment, a thorough problem analysis, structured by the PRECEDE-PROCEED model²⁴. Key elements are identification of a population at risk, description of relevant health and quality of life problems, retrieval of relevant behavioural and environmental factors and reviewing key determinants of these factors. Our needs assessment comprised four studies.

The first study was a systematic literature review. We searched the Medline and Cinahl databases for publications on quality of life issues for venous leg ulcer patients from the period 1985–2002²⁶. The second study was a crosssectional description of health and quality of life in a sample of 141 leg ulcer patients at eight outpatient clinics (mean age = 69; 63% females; median ulcer duration = 4 months)²⁷. Thirdly, another systematic review of the literature was performed, focused on the evidence for effects of adherence with compression therapy, physical activity, smoking behaviour, nutrition and weight management on leg ulcer healing and recurrence³. Finally, an in-depth fourth study explored the actual leg ulcer-related health behaviours of patients and key determinants of these behaviours with a new sample of 25 patients at two outpatient clinics (mean age = 72; 84% females; median ulcer duration = 6 months).

2.2. Step 1: matrices of proximal program objectives

In the first step of IM, we developed proximal program objectives with a multidisciplinary panel of 15 participants; three leg ulcer patients, two dermatology nurses, a community nurse, two dermatologists, a medical psychologist, a physiotherapist, a dietician, a nurse manager, an outpatient clinic supportive staff

member, a researcher (MMH) and the project leader (TvA). The researcher provided the project group with evidence from the needs assessment. In five successive meetings the panel defined desired changes for the target population, proposed determinants of these objectives and completed the matrix of proximal program objectives. In addition, desired change objectives for nurses as key persons in health care delivery were proposed.

2.3. Step 2: selecting methods and strategies

Once proximal program objectives were defined, the next step was to select theoretical methods and practical strategies based on evidence for alternative methods. Using this information, the project group decided on a final selection of methods and strategies in two further meetings.

2.4. Step 3: producing program components

The third step of the program development comprised of creatively composing program materials and pre-testing these materials with a third sample of patients (n=15) at three outpatient clinics (mean age = 61; 73% females; mean ulcer duration = 9 months). Each patient had two meetings with a health counsellor and one contact by telephone. The actual use of materials was evaluated from this pilot and from interviews with nurse health counsellors (n=3) and patients (n=15).

2.5. Step 4: planning for adoption, implementation and sustainability

We integrated step 4 in the development of the program from step 1 onwards. By involving the future program facilitators (health care workers at outpatient clinics) a linkage system was foreseen.

Step 4 furthermore consisted of an intervention-mapping cycle itself, aiming at implementation of the program. Two panels (each n=7) completed the selection of implementation objectives, methods and strategies. The panels for these sessions included four health managers or health policy makers each. Furthermore, the researcher, the project leader and an additional expert in health care innovation and implementation were present at both panel sessions. The health managers and health policy makers represented a patient organization (n=1), professional organizations of nurses (n=1), dieticians (n=1) and physiotherapists (n=1), outpatient clinic management (n=1), hospital policy staff (n=1) and clinical nurse specialists (n=2).

2.6. Step 5: planning for evaluation

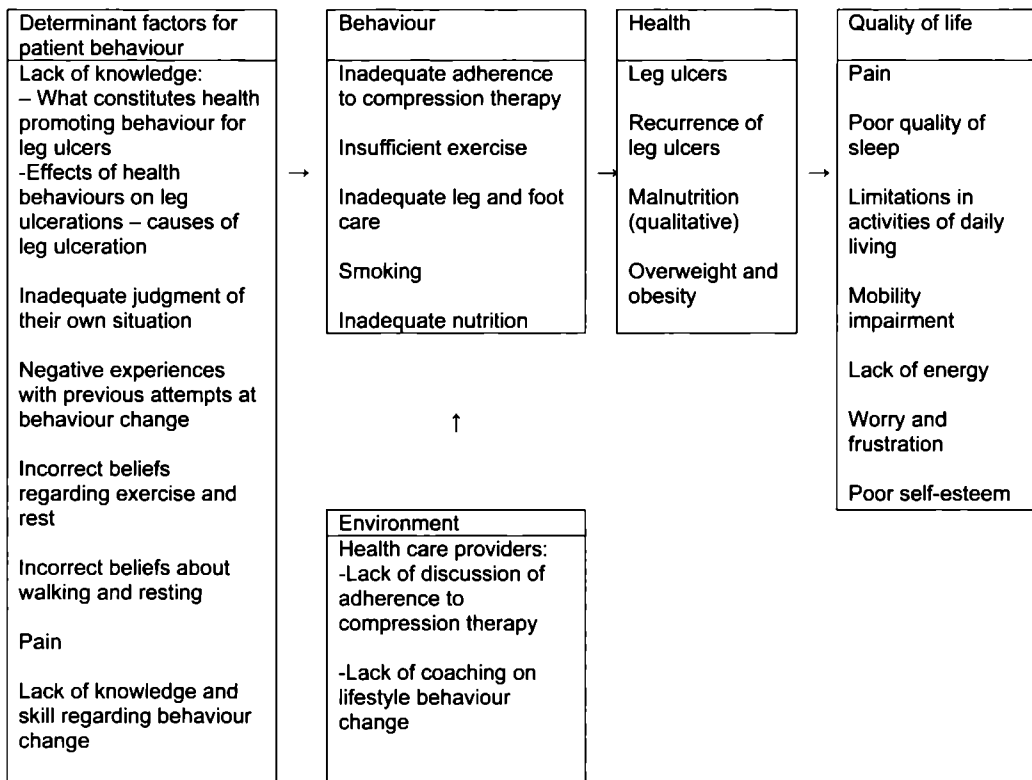
The final step in the IM protocol was the preparation of the program evaluation. The ‘evaluation map’ included health and quality of life targets as identified in the needs assessment. The matrices of proximal program objectives from step 1 describe which changes in behaviour and the environment should be accomplished after implementation. Process evaluation criteria were also defined in this last phase. A protocol for evaluating the cost effectiveness of the program was written.

3. Results

3.1. Step 0: needs assessment

The results of the needs assessment are presented in Fig. 1 and are briefly summarized; more comprehensive reports have been published elsewhere^{26,27}.

Figure 1 Needs Assessment



3.1.1. HEALTH PROBLEMS AND QUALITY OF LIFE

The review of health problems and quality of life issues included 37 studies of both quantitative and qualitative designs²⁶. All studies reported pain as a primary problem. Also, mobility impairments were reported in all but one study and often found to be pain-related. The studies reported a negative impact of leg ulceration on psychological functioning and social functioning. Other common problems in the lives of patients were disturbed sleep, lack of energy, limitations in work and leisure activities, worries, frustrations and lack of self-esteem. Quantitative studies in the review reported lower quality of life scores in leg ulcer patients as compared to healthy comparison or norm groups.

Patients in the descriptive study (n=141)²⁷ reported pain (85%), impaired outdoor mobility (47%) and difficulties in finding appropriate footwear (60%). Many patients (varying from 25% to 74%) experienced problems in daily activities, wound or wound care, sleep, indoor mobility, compression therapy, social activities, negative emotions and basic self-care. Over two-thirds of the patients were overweight and half of the overweight patients had a body mass index (BMI) of over 30, indicating obesity. In the indepth interview study (n=25), half of the patients were obese.

3.1.2. HEALTH BEHAVIOURS

With 16% of the patients in the descriptive study, feet and toes were cared for less than once a week. One-third of the patients themselves reported insufficient exercise, two-thirds were not familiar with leg exercises and did not perform them regularly, and a quarter smoked.

Before retaining health behaviours as targets for intervention, we wanted to consider the evidence for their relation to leg ulcers and recurrence. A relationship between adherence with compression therapy and recurrence of leg ulcers was identified in a Cochrane review of two trials²⁵. Both Harper et al.²⁸ and Franks et al.²⁹ found that not wearing compression hosiery was associated with higher leg ulcer recurrence rates.

A review by our project group described the effects of physical exercise, nutrition, weight and smoking³. Only two studies addressed the effects of physical exercise in leg ulcer patients. Both studies^{30,31} showed a significant improvement in calf muscle pump function after exercise, as indicated by increased venous ejection fraction, decreased residual fraction and increased calf muscle endurance.

The systematic review revealed no experimental studies that described the effects of smoking, nutrition and weight on leg ulcer healing or leg ulcer recurrence. However,

experts in our project group agreed on the relevance of these lifestyle behaviours, and this was in accordance with the consensus based National Guideline Diagnosis and Treatment of the Ulcus Cruris Venosum³². Recommendations from this guideline and our expert group are supported by ‘circumstantial evidence’, such as studies that (1) demonstrate negative effects of smoking on circulation and wound healing^{4,5}; (2) describe the importance of vitamin C in basic metabolism^{33,34}; (3) demonstrate vitamin A and C deficiencies as well as low level of zinc in leg ulcer patients³⁵⁻³⁸; (4) provide evidence for additional risk of cardiovascular conditions in overweight persons³⁹; (5) demonstrate high prevalence of overweight and obesity in leg ulcer patients³.

3.1.3. ENVIRONMENTAL FACTORS

In the descriptive study (n=141), 50–70% of the patients reported not receiving any care in relation to the problems they experienced. Also, more than two-thirds of the patients were not, or only somewhat, informed about necessary lifestyle adjustments.

In the in-depth interviews (n=25), six patients reported negative interactions with health care providers. Inadequate attention by health care providers to either adherence, or lifestyle behaviours was considered to be an important environmental factor.

3.1.4. DETERMINANTS OF PATIENT BEHAVIOUR

In the in-depth study (n=25) patients reported a lack of knowledge of the effects of health behaviours on leg ulcerations, overestimation of their own health behaviours, negative experiences with previous attempts at behaviour change, incorrect beliefs regarding exercise and rest, and contradictory information on walking and resting in relation to leg ulceration. Furthermore, they described pain and other physical inconveniences as making it difficult to accomplish lifestyle changes. Patients also reported not knowing how to change their behaviour, what effects of behaviour change would be, and whether to expect to be successful in changing their behaviour.

3.2. *Step 1: matrices of proximal program objectives*

The project group decided on seven general patient behaviour change objectives, based on the needs assessment, the available evidence and their expertise (Table 1).

Table 1 Overview of the Intervention Mapping stages, methods and results

	Methods	Results
Step 0 Needs assessment	Problem analysis using PRECEDE PROCEED model, analysis based on Systematic review Study on patient problems (n=141) Systematic review on evidence for lifestyle impact Study on determinants (n=25)	See summary of results in figure 1 Serious quality of life issues Relevant behaviours identified Relevant determinants identified
Step 1 Matrices of proximal program objectives	Systematic review on evidence for lifestyle impact Five meetings of expert panel (n=15) of patients and relevant health disciplines	Seven program objectives (1) healthy weight, (2) balanced nutrition, (3) no smoking, (4) sufficient exercise and leg exercises, (5) adequate leg and foot-care, (6) adherence to compression therapy and (7) taking prescribed pain medication Matrices of proximal program objectives and determinants of behaviour (tables 2 and 4)
Step 2 Selecting methods and strategies	Use of evidence on effectiveness of methods in the literature Matching methods with determinants from step 0 Two further meetings of the expert panel (n=15) to decide on methods and strategies	Social Cognitive Theory adopted as the main theory for the program Elements of Goal Setting Theory and the Precaution Adoption Model are adopted Motivational Interviewing and tailoring are integrated to increase the potential effectiveness of methods and strategies
Step 3 Producing program components	Use of evidence on program delivery methods in the literature Two expert panel (n=15) meetings on project materials Pre-testing the program procedures and materials (n=15)	Key features of the program are Health counselling by nurses Target group patients with ulcers, or patients within a month after healing Setting outpatient clinics for dermatology Duration six visits in six months Sequence (1) assessment of health behaviours and exploring motivation and obstacles for change, (2) setting feasible goals for behaviour change, (3-6) follow up, monitoring progress, providing feedback, offering alternative strategies, extending goals, maintenance Materials, process protocol, assessment form, overview form, goal setting forms, generic brochure on leg ulceration, specific brochures for different lifestyle behaviours
Step 4 Planning for adoption, implementation and sustainability	Linkage system by involving future program facilitators in the panel for development of the program Policy group (n=14) to reflect on program development Selection of implementation objectives with two panels (2x n=7) of health care managers and health policy makers	Program tailored to future facilitators Identification of interventions to promote implementation (table 6) striving for adoption by significant institutions, training nurses, publicity, developing tools for exchange between disciplines, organizing requirements at clinics, evaluating cost effectiveness, policy campaign
Step 5 Planning for evaluation	Identification of outcomes from the objectives in step 1 Writing a protocol for the evaluation	Outcomes for the evaluation are, Generic quality of life, leg ulcer recurrence, duration of leg ulcer healing and leg ulcer free months Behavioural outcomes (table 1) Performance objectives for nurses (table 3)

Specific performance objectives for patients were formulated for all general program objectives (Table 2). Behavioural determinants were identified, again based on experience and information from the needs assessment. Patients' knowledge, skills, beliefs and self-efficacy and social support provided by significant others were identified as the most important behavioural determinants.

Performance objectives and determinants of patient behaviour were crossed in matrices, in order to create proximal objectives (selected examples are given in Table 3).

Table 2 Patient performance objectives

Weight management

- 1a If BMI=20-25: maintain BMI of 20-25
- 1b If BMI=25-30: lower weight to BMI=25
- 1c If BMI=30 or higher: reduce weight with 10%

Nutrition

- 2 Consumes two fruits or fruit juices daily
- 3 Consumes 200 grams of vegetables daily
- 4a If patient under the age of 65: daily intake of >1500ml of fluids
- 4b If patient 65 or older: daily intake of >1700ml of fluids
- 5a If patient under the age of 65: daily intake of 5-7 slices of bread
- 5b If patient 65 or older: daily intake of 4-6 slices of bread
- 6a If patient under the age of 65: 150-250gr pasta/rice or 3-5 potatoes daily
- 6b If patient 65 or older: 150-250gr pasta/rice or 2-4 potatoes daily
- 7 Uses 50-75 grams of meat, fish, egg, tahoe or tempe daily
- 8 Uses 2-3 glasses of milk or dairy products daily (300-450ml)

Physical exercise

- 9 Walks for 30 minutes a day on at least five days of the week
- 10 Performs tip-toe exercises according to instructions
- 11 Elevates feet while sitting
- 12 Enrolls feet while walking

Smoking

- 13 Does not smoke

Leg and foot care

- 14 Performs skin care on legs and feet as prescribed

Compliance with compression therapy

- 15 Wears compression hosiery whenever out of bed

Pain

- 16 Takes pain medication at prescribed dose and times
-

Table 3 Matrix of proximal program objectives for patients (selected examples)

Determinants of patient behaviour	Knowledge		Beliefs	Self efficacy	Support from significant others
Performance objectives					
2. Patient consumes two fruits or fruit juices daily	<p>K2.1 Describes relation vitamin consumption and health</p> <p>K2.2 Describes relation vitamin consumption and wound healing</p> <p>K2.3 Describes vitamin C in fruits and fruit drinks</p> <p>K2.4 Describes two fruits or fruit juices a day as the prescribed intake</p>	S2.1 Demonstrates skills in planning for obtaining and selecting fruits to ones own taste	B2.1 Expresses to be convinced of importance of consuming two fruits or fruit juices a day	<p>SE2 1 Says to be able to incorporate fruit or fruit juice consumption in daily life</p> <p>SE1.1 Says to be able to maintain fruit or fruit juice consumption over longer periods of time</p>	SSO2 1 Describes significant others as supporting fruit or fruit juice consumption
3. Patient consumes 200 g of vegetables daily	<p>K3.1 Describes relation vitamin intake and health</p> <p>K3 2 Describes re Table 5 Matrix of proximal program objectives for nurses: adherence with compression therapy example (selected)litation vitamin intake and wound healing</p> <p>K3.3 Describes vitamins in vegetables</p> <p>K3.4 Describes 200 grams of vegetables as the desired daily intake</p>	S3 1 Demonstrates skills in planning for vegetable consumption during regular meals	B3.1 Expresses to be convinced of importance of consuming 200 grams of vegetables a day	<p>SE3 1 Says to be able to incorporate vegetable consumption in daily life</p> <p>SE3 1 Says to be able to maintain vegetable consumption over longer periods of time</p>	SSO3 1 Describes significant others as supporting vegetable consumption
9. Patient walks for 30 min a day on 5-7 days a week	<p>K9.1 Describes beneficial effects exercise on health</p> <p>K9.2 Describes beneficial effects exercise on circulation, ulcer healing, recurrence prevention</p> <p>K9.3 Describes how walking especially stimulates calf muscle pump</p>	<p>S9.1 Demonstrates skills in planning daily walks</p> <p>S9 2 Names relevant barriers</p> <p>S9.3 Demonstrates ability to find ways to handle barriers</p> <p>S9.4 Demonstrates ability to set intermediate goals towards 30 minutes of daily walking</p>	<p>B9 1 Expresses to be convinced of the importance of exercise in general and walking in particular</p> <p>B9 2 Expresses to belief that pain during walking is not an indication of negative effects of exercise</p>	<p>SE9 1 Expresses confidence in accomplishing 30 minutes of walking on a daily basis, or intermediate goals</p>	<p>SSO9 1 Significant others express to be convinced of the im-portance of daily walks</p> <p>SSO9.2 Patient is able to find walking partners if desired</p> <p>SSO9.3 Significant others provide reminders</p>

Table 3 Matrix of proximal program objectives for patients (selected examples)

Determinants of patient behaviour	Knowledge		Beliefs	Self efficacy	Support from significant others
15. Patient wears compression hosiery whenever out of bed	<p>K15.1 Describes how compression prevents edema</p> <p>K15.2 Describes the etiology of ulcers</p> <p>K15.3 Describes when to wear hosiery</p> <p>K15.4 Describes reasons to contact outpatient clinic</p>	<p>S15.1 Demonstrates ability to tell when hosiery is too tight or loose</p> <p>S15.2 Demonstrates how to put on and take off hosiery</p> <p>S15.3 Demonstrates the use of tools in putting on and taking off hosiery</p>	<p>B15.1 Expresses to be convinced of the effects of wearing hosiery</p> <p>B15.2 Expresses to be convinced of individual need to wear hosiery</p>	<p>SE15.1 Expresses own ability to use compression hosiery as prescribed</p>	<p>SSO15.1 Significant others express to be convinced of the importance of wearing hosiery</p> <p>SSO15.1 Significant others provide assistance in putting on and taking off hosiery when needed</p>

To target the environmental factors, the team developed matrices for nurse behaviour. Nursing objectives for each patient behaviour change domain followed the same patient education pattern (Table 4).

1	Assess current adherence with compression therapy	adherent	
		non adherent	→ 2
2	Discuss & set general adherence goals		→ 3
3	Assess readiness for change	motivated	→ 6
		not motivated	→ 4
4	Assess knowledge of circulation and effects of compression	understood	→ 6
		not understood	→ 5
5	Inform on circulation and effects of compression & check understanding		→ 6
6	Assess skills in using compression hosiery	adequate	→ 8
		inadequate	→ 7
7	Demonstrate and practice skills in using compression hosiery (with tools)	mastered	→ 8
		not mastered	→ 15
8	Re-assess readiness for change	motivated	→ 11
		not motivated	→ 9
9	Elicit change statement		→ 10
10	Elicit barriers & ways to overcome		→ 11
11	Assess self efficacy	high	→ 14
		low	→ 12
12	Elicit change statements		→ 13
13	Elicit barriers & ways to overcome		→ 14
14	Specify goals		→ 17
15	Explore potential for assistance by significant others	possible	→ 17
		not possible	→ 16
16	Arrange for professional help to assist in compression therapy		→ 17
17	Re-asses adherence at follow-up visit	adherent	
		non adherent	→ 2

*Nurse performance objectives are similar for other elements of the Lively Legs program

The behavioural determinants identified for the nurses were: knowledge, skills, materials (tools) and organization. Identical to the procedure for patient performance objectives, matrices of proximal program objectives for nurses were developed (example in Table 5).

Table 5 Matrix of proximal program objectives for nurses: adherence with compression therapy example (selected)

Determinants nurse behaviour	Knowledge	Skills	Tools & materials	Organisational requirements
Performance objectives				
1. Assess current adherence with compression therapy	K1.1 Describe good adherence with compression therapy K1.2 Name key question in assessing adherence K1.3 Describe signs of lack of adherence to be observed	S1.1 Demonstrate general interviewing & assessment skills S1.2 Demonstrate recognition of correct hosiery use S1.3 Demonstrate edema recognition	TM1.3 Possibility for structured description of adherence in patient files	OR1.1 Patient education planned at visits to outpatient clinics OR1.2 Adherence follow up planned at outpatient clinic
5. Inform on circulation and effects of compression	K5.1 Describes etiology of leg ulcers K5.2 Describes circulation functioning K5.3 Describes calf muscle pump functioning	S5.1 Demonstrates general skills in patient education S5.2 Demonstrates ability to tailor information to individual needs	TM5.1 General brochure on leg ulcers available at outpatient clinic	OR5.1 Patient education planned at visits to outpatient clinics OR5.2 Consensus on basics in leg ulcer information at outpatient clinic
9. Elicit change statement	K9.1 Describes principles of motivational interviewing	S9.1 Demonstrates open ended questions S9.2 Demonstrates affirmations S9.3 Demonstrates reflective listening S9.4 Demonstrates summaries	--	OR1.1 Provision of motivational interviewing training

3.3. Step 2: selection of methods and strategies

Members of the project group stressed the importance of providing advice that was both tailored to the needs of the patient and practical, giving accurate information, involving the partner, exhibiting a positive attitude towards patients (non judgmental, no fear arousal), connecting with the patient perspective, persuasive, giving both professional and personal attention, coordinating tasks between disciplines, enhancing motivation, training skills, repeating information (by nurses and dermatologists), involving the patient to participate actively, setting goals with the patient, encouraging intermediate goals, setting priorities (most significant behavioural changes first) and using role-models.

Based on this brainstorm, evidence to support theories on behavioural determinants and the selection of determinants from step 1, we chose Social Cognitive Theory (SCT)⁴⁰ as the main theory behind the program interventions. The main methods within SCT are active learning, reinforcement, modelling, guided practice and persuasion. For changing beliefs, we also used the construct of consciousness raising⁴¹, as we found patients are

often unaware of the potential effects of their individual lifestyle. Furthermore, we used Goal-Setting Theory to improve self-efficacy in patients. Goal-Setting Theory describes how goals should address specific behaviour rather than health outcomes and be measurable or observable⁴². Locke and Latham⁴³ demonstrated that setting challenging goals with moderate complexity leads to better results than easily attainable goals or no goals at all.

In addition, both tailoring and motivational interviewing⁴⁴ were selected to increase the potential effectiveness of methods and strategies within the program.

Table 6 Determinants, methods and strategies (step 2)

Determinant	Method	Strategy	Materials / tools
Knowledge (Behavioural capability*)	Active learning	Invite patient to demonstrate knowledge Help patient to identify knowledge deficits Provide written and verbal information Encourage to ask questions and check understanding Invite to demonstrate knowledge in follow-up visits	General brochure on leg ulcer etiology and treatment Specific brochures on leg ulcers in relation to weight, nutrition, smoking, exercise
Skills (Behavioural capability*)	Guided practice	Invite patient to demonstrate skills Model skills Invite to practice skills Provide feedback	Written instructions Information materials on specific tools (e.g. hosiery application aids, nicotine replacement products)
Beliefs (Outcome expectations*)	Consciousness raising Motivational interviewing	Ask the patient to judge own leg ulcer-related health behaviour Discuss actual behaviour in relation to guideline Invite to express own thoughts about behaviour and leg ulceration Provide feedback Elicit change statements	Assessment form on leg ulcer related health behaviours Specific brochures on leg ulcers in relation to weight, nutrition, smoking, exercise
Self efficacy*	Goal setting Motivational interviewing	Discuss previous experiences with behaviour change Discuss barriers for behaviour change and ways to overcome Elicit change statements Set challenging, realistic goals & specify goals, what, when, how, how often Identify and choose practical strategies	Patient workbook barrier form and goal setting form
Support from significant others (Environment*)	Involvement of partner	Partner present at counselling Discuss what social support is meaningful Set support goals When necessary referral to other discipline, dietician or physiotherapist	

*SCT terminology for determinants

The methods for the Lively Legs program were operationalized into practical strategies and materials. Table 6 gives an overview of the methods, strategies and materials.

3.4. Step 3: producing program components

The primary delivery method of the Lively Legs intervention was nurse counseling. We developed a process protocol and other materials to facilitate counseling. In the protocol, nurses are instructed to always address potential for improvement regarding pain, adherence with compression, general physical exercise, leg exercises and hygiene. As the evidence for the effects of smoking cessation, balanced nutrition and weight maintenance was less strong, the instructions present these as optional elements of the program.

Our project group decided there was a need for a general leg ulcer and compression therapy brochure and four separate brochures for the different leg ulcer-related health behaviours, as the latter brochures would not apply to all patients and information should be tailored to individual needs. We first explored the availability of existing materials in Dutch. We collaborated, at this point, with the Netherlands Heart Foundation (NHF). The NHF felt the need for a general brochure on leg ulcers and leg ulcer treatment, which our project group could develop, while the NHF could publish and distribute these brochures. For the leg ulcer-related health behaviours, existing NHF brochures could be modified. Information in these brochures was already clear and complete. Also, these brochures already used important methods such as modelling and active learning. However, the brochures were developed for the general public and addressed general circulation disorder risks. Our modifications included addressing leg ulcer patients, explaining the effects of leg ulcer-related health behaviours, rewriting modelling cases to represent the leg ulcer population and using a larger font size. Furthermore, illustrations were replaced in order to be more appealing and to better represent characteristics of the population.

The program was pre-tested in four male and eleven female patients at three outpatient clinics (median age = 71 years, age range = 18–79). Problematic health behaviours in these patients were adherence to compression therapy (n=3), pain management (n=2), walking (n=4), performing leg exercises (n=4), weight management (n=10), balanced nutrition (n=4), smoking (n=3) and leg and foot care (n=2).

Nurses (n=3) and patients (n=15) commented that the program was useful and meaningful, but some materials and aspects of training could be improved. In the assessment medical data were missed, and the part on exercise led to confusion, partly

because the guideline for patients was not clear to all nurses. Whereas general guidelines recommend 30 min of moderate exercise, the guideline for leg ulcer patients is 30 min of walking. The examples on goal setting on the forms needed to be adapted, as too many examples of old and impaired patients were given, thus not representing younger patients.

The nurse-subjects thought that thoroughly educating future nurses was essential in relation to each health behaviour subject and regarding general motivational interviewing skills in particular. Furthermore, instructions could be more precise and clarify which materials are to be given to the patient at what time, the exact timing of goal setting, the role definitions for nurse and patient in this process, when to inform other disciplines and the exact criteria for referral to other disciplines.

Finally, the pilot results indicated that the Lively Legs program could apply to all leg ulcer patients at outpatient clinics, and should always be offered.

3.5. Step 4: planning for adoption, implementation and sustainability

As already described in the methods section, a linkage system was foreseen from the beginning of the project by involving the future users of the program in the project group.

A second group reflected on the program development and implementation from a policy perspective, thus easing the development of a feasible program. In addition to the researcher and project leader, this group included 14 representatives: 2 dermatologists, 3 staff nurses, 2 hospital policy staff members, staff of the Netherlands Heart Foundation, and representatives of organizations for patients, nurses, physiotherapists, dieticians and general practitioners.

Members of two implementation panels were asked to think of obstacles and conditions with regard to the implementation of the program. They then met twice to make suggestions at four levels: the individual nurses and patients; cooperation with other disciplines; and the hospital organization, insurance and health policy (Table 7).

At the individual level, the objectives were to encourage availability of two trained nurse health counsellors at all outpatient clinics and to have all outpatient clinic nurses trained in the basics of leg ulcer-related health behaviours; the training for nurses is being developed with the society of dermatology nurses. Another performance objective at the individual level is that patients perceive the program as a certified, good quality program. As strategies for this objective, adoption by the significant institutions (e.g.

Netherlands Heart Foundation, professional organizations), information at outpatient clinics, and publications in both popular and serious mediawere decided on as main strategies.

Table 7 Changeable and relevant aspects, objectives and interventions for the implementation of the Lively Legs program

Ecological level	Promoting or hindering factors	Objective	Intervention
Patient	Motivation, effects of program must be visible	Patients perceive the program as a certified, good quality program	Adoption by significant institutions, information at outpatient clinics, and publications in both popular and professional media
Nurses	Competence of nurses, education is needed; is hindering as well as promoting	Encourage availability of two trained nurse health counselors at all outpatient clinics	Nurse education on health counselling will be developed based on the strategies chosen for in step 2
Cooperation with dermatologists and other professionals	The willingness and commitment dermatologists and other professionals of	More than 90% of the dermatologists and their management are convinced of the importance of the program	Spread knowledge using <ul style="list-style-type: none"> - guidelines - lobbying - congresses - publications - involve organisations for dermatologists
		The lifestyle assessment, goals and outcomes are discussed in multi-disciplinary meetings	Include instructions for informing other disciplines in the program
Organisation	The availability of a consulting room and nursing time	Providing a private room and time for counseling	Requirements are discussed and arranged before starting the program
Structure	The financing system	The health counselling must be funded within the health insurance system and patient pathways at outpatient clinics.	Evaluate cost effectiveness of the program A national approach of influencing health policy through contacting organizations for dermatologists, assurance companies and hospital management.

At the level of cooperation with other disciplines, the panels chose two objectives The first objective was to convince more than 90% of the dermatologists and their management of the importance of the program. As the most important strategy for physicians, the group decided that key figures, for example, within the union for dermatologists, need to play a role in the adoption of the program. This was already partially foreseen with the involvement of two dermatologists in the program

development and the involvement of two dermatologists, who are active within their professional peer group in the policy group. The second objective was that the assessment, goals and outcomes of the leg ulcer related health counseling are discussed in multidisciplinary meetings. For this purpose, it was decided to include informing other disciplines in the nurses' instructions for the program.

At the organizational level the panels formulated two performance objectives: providing a separate consultation room and time for counseling. These objectives imply the need for additional nursing staff at outpatient clinics, which brings us up to the level of hospital organization and health policy. At this level, only one performance objective was formulated: leg ulcer related health counseling must be funded within the health insurance system and patient pathways at the outpatient clinics. This asks for a national approach of influencing health policy through contacting organizations for dermatologists, assurance companies and hospital management. This strategy was preliminary prepared within the program, also creating evidence for the effects of the program by experimentally testing the program in the future was chosen as an important strategy with these objectives.

3.6. Step 5: planning for evaluation

In planning for the evaluation, our project group identified health and quality of life outcomes for the target group. We decided on generic quality of life, leg ulcer recurrence, duration of leg ulcer healing and number of leg ulcer free months as the primary outcomes to be evaluated in a further study. In health promotion interventions however, behavioural outcomes should always be identified. For patients, these targets were already identified (Table 2). The previously defined performance objectives for nurses (Table 4) can be used as process outcomes in the evaluation of program delivery.

From a research perspective, evaluating the program in a randomized clinical trial is the design to be preferred. Our project group also recommended evaluation in everyday care practice. For these purposes, it was decided that a continuous registration of a quality of life visual analogue score, leg ulcer recurrence and duration, and patient behaviour for the 16 patient performance objectives would be both worthwhile and feasible. Furthermore, it was decided to evaluate nurses' performance using the nurse performance objectives during site visits at regular intervals.

4. Discussion and conclusion

4.1. Discussion

The nursing discipline does not have a strong tradition of systematic intervention development. The wellaccepted nursing process including assessment, diagnosis, planning, interventions and evaluation, provides a general framework for selecting and applying interventions.⁴⁵ However, development of interventions is often characterized by ad hoc use of theories and empirical evidence and is often not tailored to specific target groups. Our project provides an illustration of how systematic development of a theory and evidence informed intervention program is possible.

A potential limitation of our approach is that although we identified ‘support from significant others’ as a relevant determinant of patient behaviour, significant others were not directly involved in the program development. Although the perspective of significant others was often addressed by patients and health care workers in our expert panel, direct involvement could have improved our program.

It should be noted that a limitation of IM and probably of all systematic intervention development are its requirements: the need for scientific staff, establishing networks with target group members and key actors and sufficient budgets and time for project staff. Possibly, these requirements cannot be fulfilled for all relevant interventions in patient care. In these cases, thoroughness might be reduced. Furthermore the relation between determinants, goals and intervention is partially still based on subjective and creative factors. However, staying with the IM essentials seems crucial, as unfocussed interventions are likely to be ineffective and inefficient.

4.2. Conclusion

Promotion of health behaviours in leg ulcer patients is important. Our needs assessment clearly identified the need to address health behaviours in leg ulcer patients. Furthermore, the needs assessment successfully identified determinants with regard to the health behaviours. Based on the needs assessment results, our project set out to systematically develop a health promotion program for the outpatient population of leg ulcer patients.

The process of IM was successfully completed. IM was of great value in the development of clear goals and methods, operational strategies and materials and clear procedures for the Lively Legs program. Whereas the thoroughness of the needs assessment and the development of matrices in the first steps of the development process

were sometimes perceived as tiresome, these proved to be essential in operationalizing the program and preparing the implementation and evaluation. In a previous IM project, it was concluded that IM guarantees a program based on empirical evidence, theory and relevant practice perspectives.⁴⁶ Our experiences with IM in this project were in line with these conclusions. The framework of IM can therefore help taking future development of nursing interventions to a higher level.

4.3. Practice implications

Although implementation of the Lively Legs program might be hindered by the initial need for some investment on organization and nursing time, chances of implementation at outpatient clinics are good. At a national level, important organizations such as the professional organization of dermatology nurses, the professional organization of nurses in circulation disorders, the organization of patients with circulation disorders and the Netherlands Heart Foundation adopted the program. Therefore, we believe the program holds a promise for current outpatient care. Coaching leg ulcer patients towards adherence with compression therapy and healthy lifestyles can improve health and quality of life in patients and should be taken on without delay.

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Discussion

8

The aim of this thesis was to gain insight in leg ulcer related problems and health behaviours in venous leg ulcer patients and to enable the development of an evidence-based lifestyle program aimed at improved quality of care, wound healing and decreased wound recurrence.

Principal findings

The principal findings of the studies in this thesis are categorized in three sections; ulcer related findings (1), lifestyle related findings (2) and a section on the development of Lively Legs a lifestyle program for leg ulcer patients (3). Ulcer related findings were studied in chapters 2 & 3 by means of a literature review and a descriptive study in 141 venous leg ulcer patients on ulcer related problems and health care needs. Lifestyle related findings were studied in chapters 4, 5 & 6; which subsequently address; a review on lifestyle and pain-related interventions, a descriptive study on physical activity levels and adherence in 150 venous leg ulcer patients, and a study on determinants of physical activity in 25 leg ulcer patients. The development of Lively Legs is described in chapter 7.

1. Ulcer related findings

One of the principal findings of our systematic literature review on the impact of leg ulceration on daily life (chapter 2), is that pain is the perceived dominant effect of having a leg ulcer. Other major problems identified in this review were immobility, sleep disturbance, lack of energy, limitations in work and leisure activities, worries, frustrations and lack of self-esteem. There was a good correspondence between results from studies based on quantitative and qualitative methods supporting validity of findings.

The findings of the review were confirmed in our study in 141 leg ulcer patients on patient characteristics and ulcer related problems (chapter 3). Pain, impaired mobility and problems concerning footwear were identified as ulcer related problems with the largest impact on daily life. Hardly any differences in patient characteristics and ulcer related problems were observed between patients with a purely venous aetiology and patients with a mixed aetiology of venous and arteriolar insufficiency. This study on ulcer related problems and health care needs, gave a thorough insight in the nature and amount of leg ulcer related patient problems and health care needs in relation to these problems.

2. Health behaviour related findings

Our review on interventions related to pain and leg ulcer related health behaviours (chapter 4) showed that there was little evidence on lifestyle and pain related interventions in venous leg ulcer patients. With regard to pain, only one evidence based intervention concerning pain management in leg ulcer patients could be identified. This intervention concerns the use of EMLA cream with debridement of wounds in leg ulcer patients^{1,2}, but leaves the questions on treatment of long lasting pain unanswered. Regarding the relationship between leg ulceration and food intake, the studies in this review on leg ulcer related health behaviours showed that many leg ulcer patients have low levels of vitamins, zinc and carotenes, indicating malnutrition^{3,9}. On the other hand obesity is common. Current literature however provided no solid evidence of a direct relationship between nutrition and the healing or non-healing of venous leg ulcers. A complete nutrition however, is regarded as essential in tissue repair and wound healing¹⁰⁻¹³. With regard to specific leg exercises, there is evidence from two experimental studies^{14,15} for a positive effect on the conditions for wound healing.

Although there were few studies on lifestyle and pain related interventions, our review summarized the state of the art concerning studies on lifestyle and pain in venous leg ulcer patients, resulting in indications for future research and challenges for implications in current care.

In our study on determining levels of physical activity and adherence with compression therapy (chapter 5) only one-third of the patients appeared to conduct leg exercises. Also a substantial number of patients had low physical activity levels or did not have a 10-minute walk ever. This study was a first study reporting on physical activity and adherence with compression therapy. Furthermore physical activity in this study was not only determined through self report (using a validated questionnaire, PAR)^{16,17}, validity was further enhanced through the use of an accelerometer to control on over-reporting of physical activity^{18,19}. The patients in our sample show lower physical activity levels compared to the sample in a Dutch survey of 8000 people in the general population²⁰. Our sample shared certain characteristics with the large-scale studies low activity subgroups including lower levels of education, age of over 65 years, and the existence of chronic medical conditions.

Multi-morbidity, pain, knowledge, self-efficacy and social support were identified as main determinants of physical activity in our study on determinants of physical activity (chapter 6).

The combination of pre-structured and open-ended questions in patient interviews in this study made it possible to achieve a more complete and in-depth picture of physical activity determinants. Pre-structured questions were developed based on theories on health behaviour and open-ended questions focussed more on the patient's perspective.

Adherence rates with compression therapy reported in this study were also rather low, 39% of the patients in our study in 150 leg ulcer patients (chapter 5), reported to be fully adherent. In a study of Mayberry et al.²¹ full compliance was determined in 91% of the patients and in the follow up this was 80%. In a study of Erickson et al.²² strict compliance was established in 32% of the cases. Adherence rates in literature, however, are not easy to compare because figures on adherence are influenced by the methods for obtaining these data. In our study compliance was assessed by questioning the patients on their daily habits concerning compression therapy. Patients were invited and stimulated to tell about their experiences with their bandages and medical stockings. When the interviewer asked them more specifically about their habits concerning compression therapy patients often reported, to be less adherent than they initially said. Social desirable answering was avoided through discussing experiences and habits concerning compression in a non-judgemental way.

3. Development of the Lively Legs program

In order to improve adherence with compression therapy and leg ulcer related health behaviours, an evidence-based lifestyle program, Lively Legs, was developed. Intervention Mapping²³ was used as a method for the development of the program. By following this method we thoroughly worked through all relevant aspects concerning content, design and implementation of our program. Intervention Mapping was previously used to develop several health promotion programs, varying from smoking cessation²⁴ to asthma management^{25,26}, HIV prevention²⁷, nutrition^{28,29}, sexual risk taking³⁰, sun protection³¹ and violence prevention³². The method of Intervention Mapping appeared to be thorough but time consuming. A possible pitfall might be taking too much time before choices are made and decisions are taken. IM is furthermore rather detailed in planning the development of a program, for example in step 1 when matrixes of proximal program objectives for each level of intervention planning have to be created by crossing performance objectives with determinants and learning and change objectives have to be written. Eventually however this appeared to be very useful. It made the process of program development more transparent for all participants.

As a main theory for the program we chose Social Cognitive Theory from Bandura^{33,34}. Furthermore, elements from goal setting theory^{35,36}, the precaution adoption model³⁷ and Motivational Interviewing³⁸ were used. Social cognitive theory has proven to be useful in identifying behavioural determinants as well as choosing strategies for behaviour change^{39,40}.

Strengths and weaknesses of the study

1. Representativeness of study groups

Patient characteristics in our studies (chapters 3, 5 & 6) are very similar to those in several international studies on patients with venous leg ulcers or chronic venous insufficiency (CVI)⁴¹⁻⁴³. In addition, all studies are multi-centre studies, in which outpatient clinics of general as well as university hospitals participated, supporting the generalisability of the study results for leg ulcer patients being treated at outpatient clinics in the Netherlands.

However, the fact that only patients from outpatient clinics are included also means that the samples used in our studies are not representative for all leg ulcer patients in the Netherlands. Generally, patients treated at outpatient clinics have a more complex aetiology or slower healing wounds compared to the population of patients treated by family physicians and home health care nurses. Furthermore, generalisability of our study on behavioural determinants of physical activity is limited because of a rather small sample size (chapter 6).

2. Selection of reviewed studies

A limitation of our literature study on the impact of leg ulceration on daily life (chapter 2) was the fact that various types of studies were included which made it more difficult to draw firm conclusions. Alternatively, selection of both qualitative and quantitative studies could be seen as data triangulation in this review and results from the two types of studies rendered similar results. Our review on lifestyle interventions and pain management (chapter 4) was limited through a lack of randomized controlled intervention studies. Observational studies on nutrition and pain were also included to give some direction for possible treatment. Furthermore studies on leg exercises had outcome measures directed at the improvement of parameters for venous circulation instead of wound healing. The level of evidence from these studies could be debated.

3. Confounders

In our study on ulcer related problems and health care needs (chapter 3) we specifically asked patients to report problems in relation to their leg ulcers. However reported problems might be influenced or even caused by comorbidity, health related problems or other unmeasured variables e.g. medication or psychosocial problems.

4. Selection bias

A possible cause for selection bias of our study on determining levels of physical activity and adherence with compression therapy (chapter 5) is due to refuses of patients to participate or to exclusion criteria. A rather large number of patients did not want to participate (34%) in this study. From the reasons for refusal however, it could be expected that this group is an equally or even more fragile group of patients. Only a few patients refused participation because of occupation or other activities. Patients were excluded when their leg ulcer was caused by other than chronic venous insufficiency, when they were fully immobile or when they were insufficiently able to answer questions due to language or mental capability.

5. Treatment development

The Lively Legs program clearly needs to be tested for its effectiveness and efficiency, although development of the program was based on theory and empirical research. The pilot study conducted during the development of the program was conducted with a small sample of 15 patients at two outpatient dermatology clinics. The aim of this pilot was testing the program and its materials and to evaluate first experiences of nurses and patients on applicability and efficiency. Patients as well as nurses were interviewed after three consultations (one by telephone) on their experiences and expectations of the program. No outcomes on behaviour change were measured at that time.

A potential limitation in the development of Lively Legs, our lifestyle-program (chapter 7), is that although we identified 'support from significant others' as a relevant determinant of patient behaviour, significant others were not directly involved in the program development.

Implications for Nursing Care

From the studies of this thesis it can be concluded that interventions aiming at adequate pain treatment, improving nutritional status, maintaining or achieving a healthy weight,

stimulating physical activity and adherence with compression therapy would most likely be beneficial for a substantial part of leg ulcer patients treated at outpatient dermatology clinics. Enhancing health behaviours and effective pain treatment will support quality of life as well as wound healing and prevention. Lifestyle coaching at dermatology outpatient clinics might be a solution to enhance leg ulcer related health behaviours including adherence with compression therapy. Implementation of the program at outpatient dermatology clinics is supported and adopted by professional organizations of dermatology nurses, nurses in circulation disorders, the organization of patients with circulation disorders and the Netherlands Heart Foundation, suggesting that the program holds a promise for current outpatient care. Professional organizations can play an important role in the implementation and achievement of evidence-based practice as such associations aim to develop and further educate nurses professionally, build professional networks representing the interests of nurses and the nursing profession and influence the government and policymakers⁴⁴. Actual practice knowledge derived from scientific research is however, rarely used by nurses⁴⁴, in spite of the fact that in a meta-analysis of Heater et al.⁴⁵ it is shown that patients receiving care based on research have better health outcomes than those receiving care based on tradition.

Implementation and adoption of the Lively Legs program will be further facilitated when its cost-effectiveness has been established through further research. Implementation of the program should be aiming at embedding the program in daily care and financing through existing financial systems.

Expanding the Lively Legs program to the home health care system is a possibility for further development. By doing so more patients can be reached, in, most likely, earlier phases of leg ulceration or chronic venous insufficiency. Our project provides a general framework of the systematic development of a theory and evidence informed intervention program.

Future research

The Lively Legs program needs to be further tested on cost-effectiveness in a randomized controlled trial with outcome measures aiming at behaviour change as well as wound healing and time to recurrent wounds. Furthermore, diagnostic screening criteria and instrument development to identify patients at risk and to offer tailored treatment need to be investigated.

Also, determinants with a direct effect on wound healing need to be further investigated through experimental and prospective studies; e.g. the amount of walking and frequency of daily walks that is beneficial for wound healing and prevention, the actual nutritional status in venous leg ulcer patients, the effectiveness of nutritional and pain related interventions.

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Summary

Ulcer related problems and health behaviours in venous leg ulcer patients were studied in this thesis. This resulted in the development of a program aiming at enhancing health behaviours in leg ulcer patients at dermatology outpatient clinics.

Chapter 1

In Chapter 1 the rationale for this thesis is given. The aim of this thesis was to study leg ulcer related patient problems and the possible need for and content of interventions directed at improving nursing care at outpatient dermatology clinics. Ulcus cruris or leg ulcer is defined as a wound on the lower legs caused by a disturbance in the venous or arterial circulation the microcirculation or a combination of these. Most ulcers are caused by venous insufficiency, which is the patient group subject to this thesis. Non-invasive treatment of venous leg ulcers beholds ambulant compression therapy and activation of the calf muscle pump next to wound care. Ambulant compression therapy is conducted by means of bandages or stockings. When the wound is closed patients have to wear therapeutic elastic stockings for the rest of their lives. Patients' adherence to this treatment is essential for the effectiveness of the treatment. Dermatology nurses observed several ulcer related patient problems, unhealthy lifestyles and non-adherence with compression therapy in venous leg ulcer patients, but did not have the time and the means to respond adequately to these observations. Addressing ulcer related problems and lifestyles would not only improve the patient's quality of life but would also be beneficial to the healing and prevention of recurrent wounds.

In chapter 1 background information is given on pathology, epidemiology, treatment and nursing care of patients with venous leg ulceration, followed by what is known about ulcer related patient problems, health behaviours, adherence with compression therapy and behaviour change. Also a brief introduction is given on program development and implementation.

Chapter 2

This chapter forms the base for all further studies in this thesis. The aim of the study described in chapter 2 was to gather information about the impact of leg ulcers on patient's daily life as described in quantitative and qualitative studies. Therefore a

systematic literature review was conducted in which Medline and Cinahl databases were searched for venous leg ulcer studies up to 2002. A total of 37 studies were included. All studies reported that leg ulcers pose a threat to physical functioning. Furthermore, a negative impact on psychological functioning is reported and, to a lesser degree, on social functioning. Major patient problems and limitations are pain and immobility, followed by sleep disturbance, lack of energy, limitations in work and leisure activities, worries and frustrations and a lack of self-esteem. Patients have a significantly poorer quality of life compared with healthy people. Finally, patients report problems with regard to follow-up treatment. In this study it was concluded that having a leg ulcer has a major impact on a patient's life and there are indications of under-treatment of pain. Keeping in mind that leg ulceration is notorious for its chronic character the negative impact on patient's life implies that many patients suffer over longer periods of time. This emphasizes the need to focus on quality of life aspects in patient care. There is much to gain, especially concerning pain and mobility. The development of comprehensive care programmes is essential.

Chapter 3

International literature shows several indications of problems in relation to leg ulceration but no studies were performed to give a comprehensive overview of all problems identified and care received related to these problems. The aim of our study reported on in chapter 3 was to describe leg ulcer related problems in patients with leg ulcers based on venous insufficiency or a mixed aetiology. Furthermore, an inventory of current care and care deficits with regard to identified patient problems was made. The study had a descriptive, cross-sectional design. A sample of 141 patients was taken from the population of outpatient clinics of seven hospitals in the Netherlands. Data were collected through patient interviews, questionnaires and wound-observations. Medical information was provided by the dermatologist or derived from the patients' medical file. The study identified a number of serious problems. Main problems were pain (85%), outdoor mobility (47%) and problems in finding appropriate footwear (60%). Statistical analysis showed no differences in ulcer related problems between patients with ulcers based on a venous aetiology and patients with ulcers based on mixed aetiology. Fifty to seventy percent of the patients did not receive any care in relation to these problems. Only a rather small proportion of the patients however regarded the help as insufficient. Care at outpatient clinics is mainly focused on wound care and compression therapy.

Pain treatment and care related to problems encountered by patients appears to be insufficient. This is not only affecting the patient's quality of life, but is likely to also affect the healing process and prevention of leg ulcers. Nurses and dermatologist should take their responsibilities in this matter.

Chapter 4

In chapter 4 the literature on lifestyle and pain-related interventions in venous leg ulcer patients was systematically reviewed. Lifestyle is mentioned in leg ulcer guidelines but mostly without much emphasis on the subject. The aim of this study was to review the evidence for the effect of nutrition, leg elevation and exercise on the healing of venous leg ulcers. Furthermore, the evidence for effective pain-related interventions was investigated.

Medline, Cinahl, Psychinfo and Cochrane databases were searched. Evidence was found to support a positive effect of leg exercises on the endurance and power of the calf muscle and on the haemodynamic status of the limb. There was also evidence for a positive effect of leg elevation during bed rest without compression. There were no experimental studies found concerning the effect of enriched or altered nutrition on wound healing in venous leg ulcer patients. There is some evidence, however, of nutritional deficits in this patient group. The use of Eutectic Mixture of Local Anaesthetic (EMLA) cream is effective for reducing pain in wound debridement. There are no studies on effective interventions concerning pain relief in daily life. Although there is limited evidence from experimental studies, it can be expected that interventions such as nutritional monitoring, guided exercise and leg elevation will have a substantial impact on wound healing in patients with venous leg ulceration. The importance of a qualitative complete nutrition in wound healing is generally accepted. Several experimental studies in among other surgical patients support the relevance of a qualitative complete nutrition on wound healing. Walking is known to have a positive influence on the haemodynamic status of the lower leg through stimulation of the calf muscle pump. The use of EMLA cream can be advised for pain relief with wound debridement. The current lack of effective pain treatment with venous leg ulceration emphasizes the need for effective pain treatment.

Chapter 5

Ambulant compression therapy is essential in the treatment of patients with venous leg ulcerations. It is vital that leg ulcer patients are physically active to stimulate the calf muscle pump function, in combination with compression therapy. For stimulation of the calf muscle pump, walking is the most effective form of physical activity next to exercises of the lower legs. Little is known about patient behaviour in respect to physical activity and adherence to compression therapy. The aim of our study described in chapter 5 was to assess the amount of physical activity, walking and leg exercises in venous leg ulcer patients, and to assess patients' adherence to compression therapy. A descriptive cross sectional study was conducted in which 150 patients from twelve outpatient clinics for dermatology participated. A team of three interviewers interviewed all patients. Patients were also asked to wear an accelerometer in the week prior to the interview. Patients were included when they had a leg ulcer at the moment of the interview or in the month prior to the interview. Thirty-nine percent of the patients appeared to be fully adherent to compression therapy, most patients were only moderately adherent and a small group was identified as being non-adherent with compression therapy. The amount of moderate strenuous activity is low, also when compared to the general Dutch population. Thirty-four percent of the patients did not have a 10 minute walk on any day, only 35% of the patients conducted leg exercises. Patients should be educated and stimulated to enhance physical activity through walking and leg exercises, and to increase their adherence to compression therapy.

Chapter 6

The aim of the study described in chapter 6 was to identify physical activity determinants in venous leg ulcer patients. Identification of determinants was needed to develop recommendations for the focus of health related behaviour interventions aimed at enhancing physical activity in leg ulcer patients. Physical activity promotes wound healing and prevention of wounds in venous leg ulcer patients. Many leg ulcer patients however have a sedentary lifestyle. Twenty-five patients were interviewed by means of a pre-structured interview combined with a more qualitative approach through open-ended questions. All patients were treated at an outpatient clinic for dermatology and had a leg ulcer with a venous or mixed aetiology at the moment of interviewing or had their ulcer closed in the month before the interview. Only nine of twenty-five patients (36%) had a sufficient level of moderate strenuous physical activity (30 minutes for at

least 5 days a week). There was a lack of knowledge about the relation between physical activity and leg ulceration, self-efficacy for increasing physical activity was low. In addition, multi-morbidity, pain and lack of social support were identified as main determinants of (less) physical activity.

The results of this study indicate a broad range of bio-psychosocial determinants of physical activity in leg ulcer patients. Suggestions for improvement of physical activity include influencing knowledge, beliefs and self-efficacy through active learning and goal setting, taking into account individual physical limitations. Pain, adequate footwear and social support should be addressed. Increasing physical activity could be accomplished through the provision of an individual approach, by trained dermatology nurses, in which active learning, goal setting, guided practice and enhancing social support should be the main components.

Chapter 7

As a method for the development of a lifestyle program for leg ulcer patients, Lively Legs, the Intervention-Mapping (IM) framework for systematically developing theory and evidence based health promotion programs was used. A multidisciplinary project group of health care workers and patients was involved in all five IM steps; formulating proximal program objectives, selecting methods and strategies, producing program components, planning for adoption and implementation and planning for evaluation. All studies reported on in chapters 2 to 6 contributed to this process. Social Cognitive Theory was selected as the main theory for Lively Legs, combined with elements of Goal-Setting Theory, the Precaution Adoption model and Motivational Interviewing. The program is pre-tested in fifteen patients with the purpose to test the program and its materials and to evaluate first experiences of nurses and patients on applicability and efficiency. Patients as well as nurses were interviewed after three consultations on their experiences and expectations of the program. Individual coaching of venous leg ulcer patients aiming at enhancement of health behaviours should be started on short notice. Systematic development of nursing interventions for other patient groups should be encouraged.

Chapter 8

In chapter 8 the findings of the studies in this thesis and the development of Lively Legs, a lifestyle program for leg ulcer patients, as well as implications for nursing care and future research are discussed.

The studies presented in this thesis as well as our program on lifestyle coaching in leg ulcer patients, Lively Legs, are restricted to patients visiting outpatient dermatology clinics for their leg ulcers. This implicates a probably more complex patient group compared to leg ulcer patients treated by general practitioners. The findings of our studies therefore might not be representative for all leg ulcer patients. Not all studies had an equally large sample size, especially the study on physical determinants was rather small. This could be cause for a limited generalisability of our findings. On the other hand generalisability is supported through the fact that patient characteristics in all studies were very similar, also in comparison with patient characteristics in international studies.

Lively Legs might be expanded to the home health care organizations in order to also reach leg ulcer patients that are not attending outpatient clinics for dermatology. In that case the program will need some adaptations, at least concerning organizational aspects of the program.

In the future, the Lively Legs program will be tested on cost effectiveness in a randomized controlled trial with outcome measures aiming at behaviour change as well as wound healing and time to recurrent wounds. Furthermore, diagnostic screening criteria and instrument development to identify patients at risk, in order to offer tailored treatment, need to be investigated. Also, determinants with a direct effect on wound healing should be studied through experimental and prospective studies; e.g. the amount of walking and frequency of daily walks that is beneficial for wound healing and prevention, and the effectiveness of nutritional and pain related interventions.

From the results of the studies in this thesis it can be concluded that interventions aiming at adequate pain treatment, improving nutritional status, maintaining or achieving a healthy weight, stimulating physical activity and adherence with compression therapy would most likely be beneficial for a substantial part of leg ulcer patients treated at outpatient dermatology clinics. Enhancing health behaviours and effective pain treatment will support quality of life as well as wound healing and prevention. Lifestyle coaching at dermatology outpatient clinics might be a solution to enhance leg ulcer related health behaviours including adherence with compression therapy. Furthermore the development of Lively Legs sets an example of how evidence based nursing interventions can be developed by the use of a systematic method like Intervention Mapping.

Samenvatting

Ulcus gerelateerde problemen en gezondheidsgedrag van patiënten met een ulcus cruris op basis van veneuze insufficiëntie vormen het onderwerp van dit proefschrift. Dit onderzoek heeft geresulteerd in de ontwikkeling van een programma gericht het bevorderen van gezond gedrag bij ulcus cruris patiënten op de polikliniek dermatologie.

Hoofdstuk 1

In hoofdstuk 1 worden de achtergronden voor dit proefschrift beschreven. Het doel van het onderzoek was het beschrijven van ulcus gerelateerde patiëntproblemen en het verkennen van de mogelijke behoefte voor en inhoud van interventies gericht op verbetering van de verpleegkundige zorg op de poliklinieken dermatologie.

Ulcus cruris ofwel het open been wordt gedefinieerd als een wond aan het onderbeen veroorzaakt door een verstoorde bloedcirculatie in het veneuze of arteriële systeem, de microcirculatie of een combinatie van meerdere van deze factoren. De meeste ulcera worden veroorzaakt door veneuze insufficiëntie.

Niet invasieve behandeling van veneuze ulcera bestaat uit ambulante compressietherapie, het activeren van de kuitspierpomp en wondbehandeling. Ambulante compressietherapie wordt toegepast door middel van zwachtels of therapeutisch elastische kousen. Wanneer er een wond is of wanneer er veel vocht in de benen zit worden de benen gezwachteld. Wanneer de wond gesloten is krijgen de patiënten therapeutisch elastische kousen voorgeschreven. De mate waarin patiënten deze kousen volgens voorschrift dragen is essentieel voor de effectiviteit van deze behandeling.

Dermatologieverpleegkundigen observeren bij patiënten ulcus gerelateerde problemen, maar ook overgewicht, onvoldoende passend en steunend schoeisel en therapie-ontrouw met betrekking tot de compressietherapie. Verpleegkundigen hebben echter in de huidige organisatie niet de tijd en de middelen om hier adequaat op te reageren. Behandeling van ulcus gerelateerde patiëntproblemen en bevordering van een gezonde leefstijl komen niet alleen ten goede aan de kwaliteit van leven van de patiënt maar hebben ook een gunstige invloed op de genezing van wonden en de preventie van recidive wonden.

In hoofdstuk 1 wordt achtergrondinformatie gegeven betreffende de pathologie,

epidemiologie, behandeling en verpleegkundige zorg voor patiënten met een veneus ulcus cruris, gevolgd door een korte beschrijving van wat bekend is met betrekking tot patiëntproblemen, gezondheidsgedrag, therapietrouw met compressietherapie en gedragsverandering. Ook wordt een korte introductie gegeven met betrekking tot programma ontwikkeling en implementatie.

Hoofdstuk 2

Hoofdstuk 2 vormt de basis voor alle verdere studies in dit proefschrift. Het doel van de studie beschreven in hoofdstuk 2 was het verkrijgen van informatie betreffende de impact van het ulcus cruris zoals beschreven in kwantitatieve en kwalitatieve studies. Hiervoor werd een literatuurstudie gedaan waarbij in CINAHL en Medline databases is gezocht naar studies betreffende patiënten met een ulcus cruris op basis van veneuze insufficiëntie, tot het jaar 2002. In totaal werden 37 studies geïncludeerd. Alle studies rapporteerden dat beenwonden een bedreiging vormen voor het lichamenlijk functioneren. Ook werd er een negatieve impact op het psychologisch functioneren en in mindere mate op het sociale functioneren gerapporteerd. De grootste problemen en beperkingen waren pijn en immobiliteit, gevolgd door slaapstoornissen, gebrek aan energie, beperkingen in werk en vrijetijdsbesteding, zorgen en frustraties, en een negatieve invloed op het gevoel van eigenwaarde. Ulcus cruris patiënten hadden een significant lagere kwaliteit van leven in vergelijking met gezonde mensen. In deze studie werd geconcludeerd dat het hebben van een ulcus cruris een substantiële invloed heeft op het leven van de patiënt en dat er signalen zijn van onvoldoende behandeling van pijnklachten. Gezien het chronische karakter van veneuze ulcera kan geconcludeerd worden dat veel patiënten over een lange periode de negatieve gevolgen van het hebben van een beenwond ondervinden. Dit benadrukt de behoefte aan aandacht voor kwaliteit van leven aspecten in de patiëntenzorg. Er is veel te winnen, met name betreffende pijn en mobiliteit. De ontwikkeling van allesomvattende zorgprogramma's is essentieel.

Hoofdstuk 3

Het doel van de studie beschreven in hoofdstuk 3 was het geven van een zo volledig mogelijke beschrijving van ulcus gerelateerde problemen, zorgbehoeften en ervaren zorgtekorten bij patiënten met een ulcus cruris op basis van veneuze insufficiëntie of een gemengde etiologie. De studie had een beschrijvend, cross-sectioneel design. Een steekproef van 141 patiënten werd genomen uit de populatie van de poliklinieken

dermatologie van zeven verschillende ziekenhuizen in Nederland. Gegevens werden verzameld door middel van interviews met patiënten, vragenlijsten en wondobservaties. Medische informatie werd verkregen via de dermatoloog en de medische status. In deze studie werden een aantal serieuze problemen geïdentificeerd. De belangrijkste problemen waren pijn (85%), mobiliteit buitenshuis (47%) en problemen met het vinden van geschikt schoeisel (60%). Statistische analyses lieten geen verschil zien in de mate waarin ulcus gerelateerde problemen werden gerapporteerd tussen patiënten met een veneus ulcus of een ulcus op basis van een gemengde etiologie. Vijftig tot zeventig procent van de patiënten kreeg geen hulp in relatie tot de geconstateerde problemen. Echter maar een klein deel van de patiënten beschouwde de hulp als onvoldoende. Verpleegkundige zorg op de polikliniek dermatologie is voornamelijk gericht op wondzorg en compressietherapie. Behandeling van pijnklachten en zorg gericht op de door patiënten ervaren problemen bleek in onvoldoende mate gegeven te worden. Dit heeft niet alleen invloed op de kwaliteit van leven van de patiënt maar heeft ook effect op het genezingsproces en de preventie van recidive beenwonden. Verpleegkundigen en dermatologen zouden hierin hun verantwoordelijkheid moeten nemen.

Hoofdstuk 4

In hoofdstuk 4 worden de resultaten beschreven van een systematische review van de literatuur betreffende leefstijl en pijngerelateerde interventies bij patiënten met een ulcus cruris op basis van veneuze insufficiëntie. Leefstijl wordt genoemd in verschillende richtlijnen betreffende de behandeling en verzorging van het ulcus cruris, meestal wordt het onderwerp echter weinig benadrukt. Het doel van de studie beschreven in hoofdstuk 4 was om een overzicht te geven van de evidence voor het effect van voedingsinterventies, het hoog leggen van het been en het doen van oefeningen op de genezing van het ulcus cruris op basis van veneuze insufficiëntie. Ook werd gezocht naar effectieve interventies gericht op pijnbestrijding. Hiervoor werd een systematische review gedaan waarbij gezocht werd in de Medline, CINAHL en Cochrane databases. Evidence werd gevonden voor een positief effect van het doen van beoefeningen op de sterkte van de kuitspier en de hemodynamische status van het been. Ook was er evidence voor een positief effect van het hoog leggen van het been tijdens bedrust zonder compressietherapie op de perfusie van de huid uitgedrukt in TcPO₂. Betreffende de effectiviteit van verrijkte of veranderde voeding op de genezing van de beenwonden bij patiënten met een veneus ulcus cruris werden geen experimentele studies gevonden, wel

zijn er aanwijzingen gevonden voor voedingstekorten bij deze patiëntengroep. Het gebruik van Eutectic Mixture of Local Anaesthetic (EMLA) cream is effectief voor het reduceren van pijn bij debridement van de wond, pijnbestrijding in het dagelijkse leven wordt echter niet beschreven.

Ondanks het beperkte aantal experimentele studies gericht op leefstijl bij patiënten met een veneus ulcus cruris, is het waarschijnlijk dat interventies zoals monitoring van de voeding, het doen van beenoefeningen en het hoogleggen van het been een positieve invloed zullen hebben op wondgenezing bij deze patiëntengroep. Een kwalitatief volledige voeding is een algemeen geaccepteerde voorwaarde voor wondgenezing. Dit wordt bevestigd door verschillende experimentele studies bij onder andere chirurgische patiënten. Van de loopbeweging is bekend dat deze een positieve invloed heeft op de hemodynamische status van het onderbeen door stimulatie van de kuitspierpomp. Het gebruik van EMLA crème kan geadviseerd worden voor pijnbestrijding bij het debridement van de wond. Het huidige gebrek aan pijnbestrijding benadrukt de noodzaak om te komen tot een effectieve pijnbehandeling.

Hoofdstuk 5

Ambulante compressie therapie in combinatie met voldoende lichaamsbeweging is essentieel in de behandeling van patiënten met een veneus ulcus cruris. Lopen is, naast specifieke beenoefeningen, de meest effectieve vorm van bewegen om de kuitspierpomp optimaal te stimuleren. Er is echter weinig bekend over de mate van lichamelijke activiteit en therapietrouw met betrekking tot het dragen van compressietherapie bij patiënten met veneuze ulcera. Het doel van de studie beschreven in hoofdstuk 5 was om de mate van lichamelijke activiteit, het lopen en het doen van beenoefeningen alsmede de therapietrouw met betrekking tot de compressietherapie vast te stellen. Een beschrijvende cross-sectionele studie werd uitgevoerd met de medewerking van de poliklinieken dermatologie van 12 verschillende ziekenhuizen. In totaal werden 150 patiënten geïncludeerd. De patiënten zijn geïnterviewd door een team van 3 interviewers. Aan de patiënten werd gevraagd om de week voorafgaand aan het onderzoek een bewegingsmeter te dragen. Patiënten werden geïncludeerd wanneer zij een beenwond hadden op het moment van interviewen of wanneer de wond in de maand voor het interview gesloten was. Slechts negenendertig procent van de patiënten bleek volledig therapietrouw te zijn met compressietherapie. De meeste patiënten waren matig therapietrouw en een kleine groep werd geïdentificeerd als therapie-ontrouw. De

hoeveelheid matig inspannende lichamelijke activiteit was laag, ook in vergelijking met de Nederlandse populatie. Zesentwintig procent had geen enkele matig inspannende activiteit in de week voorafgaand aan het onderzoek. Vierendertig procent van de patiënten had in de week voor het interview geen enkele dag waarop zij een wandeling van 10 minuten maakten. Slechts 35% van de patiënten deed beoefeningen. Patiënten zouden gestimuleerd moeten worden met betrekking tot therapietrouw en lichamelijke activiteit, met name in de vorm van lopen en het doen van beoefeningen.

Hoofdstuk 6

Het doel van de studie beschreven in hoofdstuk 6 was om determinanten van lichamelijke activiteit bij patiënten met een ulcus cruris op basis van veneuze insufficiëntie te identificeren. Identificatie van determinanten was nodig om aanbevelingen te formuleren voor de focus van gezondheidsgerelateerde gedragsinterventies gericht op het verhogen van lichamelijke activiteit van deze patiënten. Lichamelijke activiteit bevordert de wondgenezing en de preventie van wonden bij ulcus-cruispatiënten. Veel van deze patiënten hebben een weinig actieve leefstijl. Vijfentwintig patiënten zijn geïnterviewd met behulp van een voorgestructureerde vragenlijst gecombineerd met een meer kwalitatieve benadering door middel van open vragen. Alle patiënten waren onder behandeling op een polikliniek dermatologie en hadden een beenwond met een veneuze of gemengde etiologie op het moment van interviewen of hadden een wond in de maand voorafgaand aan het interview. Slechts negen van de vijfentwintig patiënten (36%) hadden voldoende matig intensieve beweging volgens de Nederlandse norm gezond bewegen (30 minuten op minstens 5 dagen in de week). Er was een tekort aan kennis betreffende de relatie tussen lichamelijke activiteit en het ulcus cruris en de eigen-effectiviteit voor het verhogen van de hoeveelheid lichamelijke activiteit was laag. Verder werden multimorbiditeit, pijn en een tekort aan sociale ondersteuning geïdentificeerd als determinanten van lichamelijke activiteit.

De resultaten van deze studie laten een brede range van bio-psychosociale determinanten met betrekking tot lichamelijke activiteit zien. Suggesties voor verhoging van de lichamelijke activiteit behelzen het beïnvloeden van kennis en beliefs, en de eigen-effectiviteit door middel van actief leren en het stellen van doelen, waarbij rekening wordt gehouden met individuele lichamelijke beperkingen. Voorwaarde voor gedragsverandering is dat professionele zorg zich richt op pijnbehandeling, het vinden

van goed passend en ondersteunend schoeisel en het mobiliseren van sociale steun. Het doen toenemen van de lichamelijke activiteit zou bereikt kunnen worden door een individuele benadering door getrainde dermatologie verpleegkundigen, waarbij actief leren, het stellen van doelen, begeleide oefening en het bevorderen van sociale steun de belangrijkste componenten zijn.

Hoofdstuk 7

Voor de ontwikkeling van Lively Legs, een leefstijlprogramma voor ulcus cruris patiënten, is gebruik gemaakt van Intervention Mapping (IM). Dit is een methode voor het systematisch ontwikkelen van op theorie en evidence gebaseerde gezondheidspromotie programma's. Een multidisciplinaire projectgroep van patiënten en professionals in de gezondheidszorg was betrokken bij alle IM stappen; het formuleren van proximale programmadoelen, het selecteren van methoden en strategieën, het produceren van de programma-onderdelen, de planning voor adoptie en implementatie en het plannen van de evaluatie. Alle studies beschreven in de hoofdstukken 2 tot en met 6 hebben bijgedragen aan dit proces. In het volgens IM ontwikkelde programma werd Social Cognitive Theory van Bandura gekozen als basis voor de leefstijlbegeleiding. Deze theorie werd gecombineerd met elementen van Goal setting Theory van Locke & Latham, Precaution Adoption Model van Weinstein en Motivational Interviewing van Miller & Rollnick. Het leefstijlprogramma is gepretest bij 15 patiënten waarbij de materialen en de eerste ervaringen van verpleegkundigen en patiënten op de toepasbaarheid en efficiëntie geëvalueerd zijn. Patiënten en verpleegkundigen zijn geïnterviewd betreffende hun ervaringen en verwachtingen na drie consulten. Individuele coaching van ulcus cruris patiënten met als doel het bevorderen van gezondheidsgedrag zou op korte termijn kunnen en moeten starten. Systematische ontwikkeling van verpleegkundige interventies voor andere patiëntengroepen zou aangemoedigd moeten worden.

Hoofdstuk 8

In hoofdstuk 8 worden de bevindingen van de studies in dit proefschrift en de ontwikkeling van Lively Legs alsook de implicaties voor de verpleegkundige zorg bediscussieerd.

Zowel de studies in dit proefschrift als het ontwikkelde leefstijlprogramma Lively Legs zijn beperkt tot ulcus cruris patiënten die onder behandeling zijn op de polikliniek

dermatologie. Over het algemeen betreft dit een meer gecompliceerde groep van patiënten dan de patiënten die onder behandeling zijn van de huisarts. De bevindingen van deze studies zijn daarom niet zonder meer representatief voor alle patiënten met een ulcus cruris. In de toekomst zou Lively Legs uitgebreid kunnen worden naar de thuiszorg om ook de patiënten die daar onder behandeling zijn te kunnen bereiken. In dat geval zal het programma een aantal aanpassingen behoeven, minimaal op het niveau van organisatorische aspecten.

Niet alle studies waren gebaseerd op een steekproef van even grote omvang (met name de studie naar determinanten van lichamelijke activiteit was hierin beperkt) waardoor representativiteit enigszins gelimiteerd is. Anderzijds wordt de representativiteit ondersteund door het gegeven dat patiëntkenmerken in de verschillende studies sterk overeen komen en vergelijkbaar zijn met kenmerken beschreven in internationale studies.

In de toekomst zal Lively Legs getest worden op kosteneffectiviteit door middel van een randomized controlled trial met uitkomstmaten gericht op zowel gedragsverandering als op wondgenezing en op de duur van wondvrije periodes. Ook zouden diagnostische screeningscriteria opgesteld en instrumenten ontwikkeld moeten worden om risico patiënten te kunnen identificeren, waarmee zorg op maat geleverd kan worden. Determinanten met een direct of indirect effect op wondgenezing zouden verder onderzocht moeten worden door middel van experimentele en prospectieve studies. Hierbij valt te denken aan onderzoek naar de frequentie en tijdsduur van looperperiodes die de wondgenezing gunstig beïnvloeden, het effect van specifieke voedingsinterventies en effectieve pijn gerelateerde interventies.

Uit de resultaten van de studies in dit proefschrift kan geconcludeerd worden dat pijnbehandeling en interventies gericht op gezondheidsgedrag, waaronder therapietrouw met compressietherapie en lichamelijke activiteit, van nut kunnen zijn voor een aanzienlijk deel van de ulcus cruris patiënten die onder behandeling zijn op de polikliniek dermatologie. Het bevorderen van gezond gedrag en therapietrouw, en een effectieve pijnbehandeling kan zowel de kwaliteit van leven, de wondgenezing en de preventie van recidive wonden gunstig beïnvloeden. Leefstijl-coaching op de polikliniek dermatologie zou hiertoe een middel kunnen zijn. Daarnaast is de ontwikkeling van Lively Legs een voorbeeld van hoe evidence based verpleegkundige interventies ontwikkeld kunnen worden door gebruik te maken van een systematische methode zoals Intervention Mapping.

Dankwoord

Graag wil ik iedereen bedanken die heeft meegewerkt aan het tot stand komen van dit proefschrift. Een aantal mensen wil ik in het bijzonder noemen.

Allereerst wil ik Theo van Achterberg bedanken voor zijn enorme steun en vertrouwen in de afgelopen jaren. In 2001 ben ik gestart met het onderzoek naar patiëntkenmerken, problemen en zorg. Carla Frederiks was in oktober 2000 net met emeritaat gegaan en Theo nam de zaken waar. Carla Frederiks had een stevige basis gelegd voor Verplegingswetenschap Nijmegen waar zij een bijzondere leerstoel had. De afdeling Verplegingswetenschap bestond toen nog uit twee kamers in een zijgang van de prekliniek. In februari 2002 werd Theo benoemd tot hoogleraar Verplegingswetenschap. Verplegingswetenschap groeide gestaag en werd op 1 januari 2003 onderdeel van de afdeling Kwaliteit van Zorg. Inmiddels is Verplegingswetenschap onder de leiding van Theo uitgegroeid tot een gezonde (sub)afdeling met een groot aantal promovendi in het UMC St Radboud en daarbuiten. De twee kamers zijn uitgebreid tot een drukbezette gang.

Als promotor en projectleider heeft Theo een belangrijke rol gespeeld in de hier beschreven studies en de totstandkoming van dit proefschrift. Ik heb veel geleerd de afgelopen jaren op het gebied van onderzoek, zowel op het inhoudelijke als het voorwaardenscheppende vlak. Theo heeft veel kwaliteiten die ik bewonder, zijn interesse in anderen, zijn humor en zijn relativeringsvermogen zijn eigenschappen die ik de afgelopen jaren zeer gewaardeerd heb en die naar mijn idee ook zeer waardevol zijn om goed leiding te kunnen geven aan een onderzoeksgroep als de onze. Ik prijs me gelukkig dat ik hier terecht gekomen ben en zoveel heb kunnen leren. Theo bedankt voor alles, je bent de beste.

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Curriculum Vitae

Maud Heinen, werd geboren op 13 september 1966 te Nijmegen. Zij groeide op in Oss waar zij in 1984 haar Atheneum-B diploma behaalde aan het Maaslandcollege. Na de middelbare school moest een keuze gemaakt worden voor een vervolgopleiding. Medicijnen studeren, biologie of toch de verpleging? Er bleek een HBO-opleiding verpleegkunde te bestaan. Het werd de HBO-V te Nijmegen, waar Maud in 1988 haar diploma behaalde. Na vervolgens twee jaar als verpleegkundige te hebben gewerkt in het Groot Ziekengasthuis te Den Bosch op de afdeling algemene, vaat en plastische chirurgie werd besloten tot een vervolgstudie. Zij verhuisde naar Maastricht om Gezondheidswetenschappen, studierichting Verplegingswetenschap, te gaan studeren. In februari 1994 werd ook deze studie met goed resultaat afgesloten. Infuusbehandeling thuis was het afstudeeronderwerp.

Na deze studie verhuisde Maud terug naar Oss en ging weer aan het werk als verpleegkundige, ditmaal in het UMC St Radboud op de afdeling vaatchirurgie en traumatologie.

Na een eerste start gemaakt te hebben met onderzoek betreffende verpleegkundige diagnostiek bij traumapatiënten en een tweede verkenning in het onderzoek, betreffende het gebruik van de ICDH (ICF) in de verpleging, volgde in 2001 het eerste onderzoek met betrekking tot de ulcus cruris patiënt. Maud heeft zich de afgelopen jaren met name bezig gehouden met dit onderzoek en de ontwikkeling van een leefstijlprogramma voor ulcus cruris patiënten. Naast het onderzoekswerk is zij enkele jaren penningmeester van de werkgroep Vasculaire Verpleegkunde geweest en voor een kortere tijd tevens lid van de werkgroep Congressen van de Nederlandse Vereniging voor Hart en Vaat Verpleegkundigen. Verder geeft zij onderwijs aan verpleegkundigen van de opleiding dermatologie in het UMCU. Momenteel is zij betrokken bij de intergratie van het verplegingswetenschappelijk onderzoek in de opleiding verpleegkunde van de Hogeschool Arnhem Nijmegen. Maud is werkzaam bij de sectie Verplegingswetenschap en Paramedische wetenschappen van de afdeling Kwaliteit van Zorg van het UMC St Radboud waar zij op dit moment onderzoek doet naar de doelmatigheid van leefstijlbegeleiding bij ulcus cruris patiënten.

