

Chronic venous leg ulcers: effect of a community nursing intervention on pain and healing

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Abstract

Aim To investigate the effectiveness of a new community nursing model of care for clients with chronic leg ulcers in terms of levels of pain and ulcer healing.

Method A randomised controlled trial comparing the new model of care with standard community nursing care was conducted with a sample of 56 clients with chronic venous leg ulcers, 28 clients in the intervention group and 28 in the control group. Data were collected on admission to the study and at 12 weeks from admission.

Results Significant improvements in levels of pain and ulcer healing were found in the intervention group receiving the new model of care.

Conclusion Results from this study have implications for health professionals providing care for clients with chronic leg ulcers.

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Keywords

Community care; District nursing; Leg ulcers; Primary nursing

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estimated that up to 50 per cent of community nurses' time is spent on caring for this client group (Simon *et al* 2004).

Although the majority of leg ulcers are venous in origin and the standard treatment of compression is known to be effective (Cullum *et al* 2004), barriers to its successful implementation and maintenance commonly occur. These include poor client tolerance, and a lack of understanding of, and agreement with, the need for long-term compression therapy (Lindsay 2000). The incidence of chronic leg ulcers increases with age (Cullum *et al* 2004), and consequently the implementation of treatment plans for this group is likely to be complicated by a number of co-morbidities and physical limitations. In addition, the pain and limited mobility associated with leg ulcers frequently result in social isolation (Walshe 1995, Ebbeskog and Ekman 2001), which may in turn contribute to poor motivation and concordance with treatment.

The multitude of long-term problems present in this group of clients poses a challenge for health professionals involved in their treatment. Community nurses have traditionally cared for people with leg ulcers in the person's own home and are sometimes the only social contact that the person receives. Lindsay (2000) felt that isolated individual visits to homes by community nurses did not meet the clients' needs for peer support, information exchange and empathy, factors that assist in the effective management of chronic conditions. She realised there was a need to establish an alternative model of care that would provide social interaction and support, leg care maintenance, education and ulcer treatment and thereby promote healing and self-management of the condition.

The hypothesis was generated that leg ulcer management could be improved by delivering care within a social setting as opposed to the

CHRONIC LEG ULCERS are associated with significant levels of pain, reduced mobility and the high costs of long-term healthcare treatment (Ryan *et al* 2003, Nemeth *et al* 2004). Clients with this condition often endure prolonged healing and frequent recurrence and it is

conventional models of healthcare delivery. This led to the establishment of a leg ulcer clinic in an informal community setting in which clients can develop a sense of ownership and empowerment. Named to reflect its non-threatening, welcoming approach, and conceived as a partnership between the district nurses, the clients (members) and the local community, the first Leg Club™ opened in 1995 in the rural Suffolk village of Debenham, UK. Inspired by the Lindsay Leg Club™ model, St Luke's Nursing Service in south-east Queensland, Australia, opened two Leg Clubs™ in 2002 and formed a partnership with Queensland University of Technology to commence a study to determine the effectiveness of the model.

Aims

The aims of this study were to determine the effectiveness of a new community nursing model of care on healing rates, levels of pain, quality of life and the functional ability of clients with chronic venous leg ulcers. Of these aims this article reports results on levels of pain and healing rates of clients with chronic venous leg ulcers at 12 weeks from commencement of the study.

Literature review

Chronic leg ulcers occur in approximately 1-2 per cent of the over 60 years' population in the US, UK, Europe and Australia (Lees and Lambert 1992, Baker and Stacey 1994, Johnson 1995, Margolis *et al* 2002). Prevalence increases with age (Cullum *et al* 2004) and as the number of people aged over 65 years is expected to double in the next few decades, this problem will become increasingly significant to healthcare systems.

People with chronic leg ulcers have reported pain, restricted mobility, discomfort and embarrassment from wound exudate and odour, significant cost, inconvenience and social isolation (Baker and Stacey 1994, Charles 1995, Walshe 1995, Chase *et al* 2000). As many as 17-65 per cent of people with venous leg ulcers have reported severe or continuous pain associated with their leg ulcer (Briggs and Nelson 2003). Reviews of the effect of leg ulcers on lifestyle have found that pain is one of the major limitations for these clients and may be inadequately managed (Heinen *et al* 2004, Nemeth *et al* 2004, Persoon *et al* 2004, Wilson 2004).

Although various methods of alleviating pain during dressing changes and topical treatments have been investigated (Holm *et al* 1990, Hansson *et al* 1993, Back and Finlay 1995, Lok *et al* 1999, Agrifoglio *et al* 2000, Rosenthal *et al* 2001), a review of interventions for the persistent pain associated with venous leg ulcers between dressing changes found no studies addressing this problem (Briggs and Nelson 2003).

The pain, exudate and extensive bandaging associated with chronic leg ulcers result frequently in limited mobilisation, embarrassment and subsequent social isolation for many of these clients. One Australian study found that 45 per cent of the study participants were housebound because of their ulcers (Baker and Stacey 1994). In addition, Ebbeskog and Ekman (2001) found the pain from chronic leg ulcers interrupted sleep and left participants feeling tired and lacking in energy which affected their ability to socialise or undertake usual activities.

Improved healing rates for chronic venous leg ulcers have been reported by studies evaluating community leg ulcer clinics (Moffatt *et al* 1992, Simon *et al* 1996, Musgrove *et al* 1998), along with additional benefits of peer support and empathy (Chaloner and Noirit 1997, Lindsay 2000). These studies, however, have generally compared: the healing progress of participants receiving evidence-based treatment with access to specialist equipment and practitioners skilled in compression techniques in the leg ulcer clinics with healing progress of participants receiving a variety of treatments during home-based care in the community.

There is little evidence available to determine the effectiveness of community leg ulcer clinics with regard to healing in comparison to traditional community nursing care when all clients, regardless of the model of care, are receiving consistent, evidence-based treatment. As the studies above did not involve randomisation, it is possible that the participant groups attending leg ulcer clinics were more motivated to obtain the best treatment to heal their ulcers, or more mobile and healthy than the comparison groups receiving home care. In addition, there is little evidence available to demonstrate benefits other than healing from community leg ulcer clinics, such as improvements in pain control and the impact of this on clients' lives.

A randomised controlled trial was therefore chosen by the investigators of this study to determine the effectiveness of a community Leg Club™ model of care on pain and healing, in comparison to the traditional community

nursing model of care for clients with chronic venous leg ulcers. Consistent evidence-based treatment was available to both groups of clients.

Hypotheses

1. Clients with chronic venous leg ulcers receiving care in a community Leg Club™ will report lower levels of pain than clients receiving home-based community nursing care.
2. Clients with chronic venous leg ulcers receiving care in a community Leg Club™ will demonstrate improved ulcer healing in comparison to clients receiving home-based community nursing care.

Methods

Design A sequential randomised controlled trial was conducted to investigate the effectiveness of a Leg Club™ model of care on the levels of pain and healing rates of clients with chronic venous leg ulcers.

Sample The sample consisted of 56 clients (28 in the intervention group, 28 in the control group) with venous leg ulcers referred for care to St Luke's Nursing Service in the South Brisbane and Gold Coast regions of Queensland, Australia. As a sequential clinical trial design was chosen to collect and analyse data, sample size was determined when the plotted data coordinates during sequential analysis with a triangular test design crossed the statistical significant border (Whitehead 1997). The borders were determined before commencing the trial with the following specified parameters: significance level $P < 0.05$, power=0.9 and an anticipated effect size of 1.

Clients were eligible for inclusion in the study if they had a venous leg ulcer and an ankle brachial pressure index (ABPI) > 0.8 and < 1.3 , and were excluded if they had diabetes, ulcers of non-venous aetiology, or were too immobile to be transported to the Leg Club™ via volunteer transport.

Procedure Clients who provided consent and fitted the inclusion criteria were randomised via a computer randomisation programme to receive treatment either during individual home visits from community nurses (the control group), or from the community nurses during a weekly visit to a Leg Club™ (the intervention group). Evidence-based assessment and treatment guidelines (Royal College of Nursing 1998, Australian Wound Management Association 2002) for clients with venous leg ulcers were followed for study participants in both groups, with the addition of study protocols specifying dressing and compression type to promote consistency in treatment. These were primarily

based on a short-stretch compression bandaging system.

A small team of 10 community nurses with an interest and skills in wound care were updated and educated on the assessment and treatment guidelines and research project protocols before commencing the trial. The education involved a series of seminars and interactive learning sessions from specialists in the field, assisted practice sessions and attainment of competencies in leg ulcer management. St Luke's Nursing Service provided regular training sessions for all staff to maintain clinical skills. This group of nurses provided care for both the intervention group at the Leg Club™ and for the control group in the home.

Intervention Clients randomised to the intervention group visited a Leg Club™ weekly, where they received: comprehensive health assessment including ABPI and referral for further circulatory assessment as indicated; venous ulcer treatment based on the guidelines above; advice and support about venous leg ulcers; follow-up management and preventive care; peer support and social interaction; and goal setting to assist in the management of functional and social activities. The Lindsay Leg Club™ model is based on the provision of an informal, 'drop-in', relaxed environment that is conducive to social interaction and leg ulcer management and preventive care, with community involvement and ownership of the clubs.

The St Luke's Nursing Service Leg Clubs™ opened weekly for a morning or afternoon, and clients were invited to drop in and socialise before and after their ulcer treatment at the Club. Members of the Leg Clubs™ were encouraged to direct and manage the social and fund-raising activities of the Clubs, and once healed were encouraged to continue to attend regularly to provide volunteer and peer support for members with active ulcers. Volunteer transport was provided for clients unable to travel independently to the Leg Club™ venue. Collective treatment was provided in an informal environment to promote the destigmatisation of the condition and encourage information exchange and educational opportunities for both clients and staff.

Clients randomised to the control group were visited by the community nurses in their own homes, where they received a comprehensive health assessment including: ABPI and referral for further circulatory assessment as indicated; venous ulcer treatment based on the guidelines above; advice and support about venous leg ulcers; and follow-up management and preventive care.

Data were collected using questionnaires and clinical wound assessments on admission to the

study (time 1) and at 12 weeks from admission (time 2).

Instruments and measures Levels of pain were measured using the Rand Medical Outcomes Study Pain Measures (Sherbourne 1992), consisting of 12 items covering the amount, frequency and duration of pain and how it affects clients' lives.

Progress in healing was measured by: tracing the ulcers monthly and using the dot-point method of calculating area (Bahmer 1999); recording clinical variables related to healing, for example, tissue type, presence of oedema, eczema or inflammation; and calculating Pressure Ulcer Scale for Healing (PUSH) (Stotts *et al* 2001) scores. PUSH has three components measuring ulcer area, the type of tissue, and level of exudate. This forms a combined total score, from 0-17, where 17 = worst score possible, and 0 = a completely healed ulcer. The scale provides a more comprehensive measure of healing than considering area alone.

Data analysis Data were analysed using a sequential analysis technique to determine differences in levels of pain and progress in healing between the intervention group and the control group after 12 weeks of treatment. Sequential analysis is a statistical method originally devised for quality control, where a confident statistical decision needs to be made when the statistical nature of the data is uncertain, and where practical or ethical reasons require that a study be terminated when the null hypothesis can reasonably be accepted or rejected (Whitehead 1997). The probability assumptions underlying statistical tests are adjusted to enable continuous or periodic inspection of the data, and instead of defining a fixed sample size, statistical borders are drawn to decide whether the null hypothesis should be accepted or rejected, or whether data collection should continue (Whitehead 1997).

Sequential analysis was first used in the quality control of munitions during the second world war, and became an important tool in the testing of new drugs in the pharmaceutical industry during the second half of the last century (Whitehead 1997). A large array of sequential analyses are now available to suit a wide range of research conditions, and the group sequential methods were popularised by Whitehead in the 1990s to analyse clinical trials.

The group sequential methods have advantages over the older methods in that they do not require pairing of the data, and have a flexible and adjustable frequency of data

inspection. Not requiring pairing of the data allows clinical trials to be designed according to conventional models, and the use of random numbers to allocate cases to different groups. Having adjustable frequency of data inspection allows less frequent inspection with greater power in the early stages of the trial, and more frequent inspections to terminate the trial earlier when the data available suggest that the null hypothesis is close to being accepted or rejected.

The triangular test is one of the group sequential methods. Although this test is limited to comparison of two groups, it has the advantages of simplicity, is intuitively easy to understand, and close ended in that the maximum number of required cases can be known at the planning stage.

The design of the triangular test requires the same information as that in sample size determination. The probability of type I and type II errors needs to be nominated, and in this trial these are 0.05 and 0.1 (power of 90 per cent) respectively. The effect size for measurements is the difference between the two groups that will be clinically meaningful, divided by the anticipated within group standard deviations (SDs). Where either effect size criteria are not known, as was so in this case, the effect size of 0.3 or less is designated as small, 0.3-0.7 as moderate, and more than 0.7 as large. We have nominated an effect size of 1.0, because we were only interested in a large and obvious effect, given the cost and difficulties involved in the treatment.

Ethical approval for this study was received from St Luke's Nursing Service and Queensland University of Technology Human Research Ethics Committee.

Results

Demographics Demographic characteristics of the sample are displayed in Table 1.

Levels of pain Pain levels were measured using the Rand Medical Outcomes Study Pain Measures (Sherbourne 1992), consisting of 12 items covering the amount, frequency and duration of pain and how it affects daily lives. Analysis of equality of means for all pain measures found no significant differences between the intervention and control groups at the commencement of the study. Sequential analysis showed that the intervention group had significantly reduced pain levels across several items by time 2 (12 weeks), for example, the amount of pain experienced, and the degree to which pain affected mood, sleep and normal work.

Significant reductions were found in the intervention group in the following items:

- ▶ Amount of pain experienced ($Z=3.02$,

$P=0.001$). Mean pain scores are shown in Table 2.

- ▶ Degree to which pain affected mood ($Z=2.65$, $P=0.004$). Mean scores are shown in Table 2.
- ▶ Degree to which pain affected sleep ($Z=2.71$, $P=0.003$). Mean scores are shown in Table 2.
- ▶ Degree to which pain interfered with normal work ($Z=1.94$, $P=0.026$). Mean scores are shown in Table 2.

Healing results

Ulcer area On admission to the study, the average duration of the ulcers was 47.4 weeks (as shown in Table 3), and average area was

8.97cm² (SD 14.9). Analysis of equality of means and equality of variances for ulcer size and duration found no significant differences between the intervention and control groups at the commencement of the study. As large variations in ulcer size were involved, logarithmic transformation of the data was performed. The border criteria for the triangular test are based on an assumption that the data have a normal distribution. The distribution of the data used here was exponential, in that the variance among the higher values was greater than the lower one. The log transformation was used so that the data better conformed to the normal distribution.

A significant reduction in size for the

TABLE 1

Demographic characteristics (n=56)				
Characteristic		Intervention group % (n)	Control group % (n)	Total % (n)
Sex	Female	50.0 (14)	42.9 (12)	46.4 (26)
	Male	50.0 (14)	57.1 (16)	53.6 (30)
Age	≤60 years	7.1 (2)	14.3 (4)	10.7 (6)
	61-70 years	21.4 (6)	21.4 (6)	21.4 (12)
	71-80 years	39.3 (11)	28.6 (8)	33.9 (19)
	81-90 years	28.6 (8)	35.7 (10)	32.1 (18)
	>90 years	3.6 (1)	0	1.8 (1)
Marital status*	Married/de facto†	22.2 (6)	32.1 (9)	27.3 (15)
	Single	37.0 (10)	21.4 (6)	29.1 (16)
	Widowed	40.7 (11)	46.4 (13)	43.6 (24)
	Lives alone	53.6 (15)	60.7 (17)	57.1 (32)
Is the primary carer for another		17.9 (5)	17.9 (5)	17.9 (10)
Requires aid to mobilise		53.6 (15)	57.1 (16)	55.4 (31)
Source of referral††	Self	56.0 (14)	42.9 (12)	49.1 (26)
	Family/friends	8.0 (2)	10.7 (3)	9.4 (5)
	Nurse	24.0 (6)	39.3 (11)	32.1 (17)
	GP/medical	8.0 (2)	3.6 (1)	5.7 (3)
	Hospital	4.0 (1)	3.6 (1)	3.8 (2)

*One participant's data was missing for this variable; †de facto = a legal, long-term relationship; ††Three participants' data were missing for this variable

TABLE 2

Mean scores on amount of pain and impact of pain on mood, sleep and normal work (n=56)				
Sequential analysis showed the intervention group had significantly reduced pain levels at time 2 (12 weeks), for example, the degree to which pain affected mood ($Z=2.65$, $P=0.004$), sleep ($Z=2.71$, $P=0.003$) and normal work ($Z=1.94$, $P=0.026$)				
Pain measure	Intervention group mean (SD)		Control group mean (SD)	
	Time 1	Time 2	Time 1	Time 2
Amount of pain	4.04 (0.94)	3.09 (1.38)	3.39 (1.57)	3.29 (1.52)
Impact of pain on:	▶ Mood	2.44 (1.25)	1.65 (0.89)	2.00 (1.22)
	▶ Sleep	2.44 (1.12)	1.80 (1.04)	2.21 (1.17)
	▶ Normal work	2.81 (1.18)	2.04 (1.17)	2.61 (1.67)

Note: Rand Medical Outcomes Study Pain Measures 1-5, where 1=not at all, 2=a little, 3=moderately, 4=quite a lot, 5=extremely. SD=standard deviation

FIGURE 1

Mean ulcer area (cm²) at time 1 (on admission) and time 2 (12 weeks)

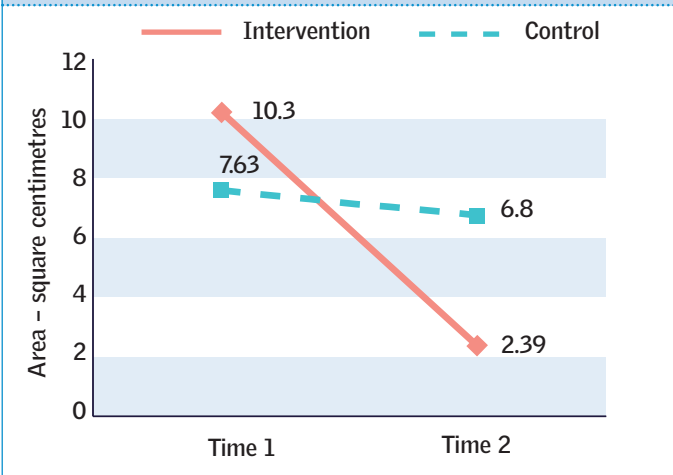
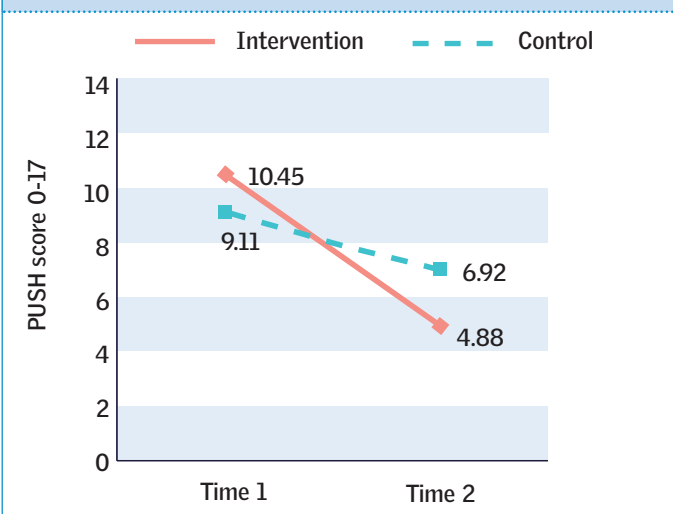


FIGURE 2

Mean Pressure Ulcer Scale for Healing (PUSH) scores at time 1 (on admission) and time 2 (12 weeks)



intervention group as compared to the control group was found ($Z=2.64, P=0.004$). Mean ulcer areas from the intervention and control groups on admission to the study (time 1) and after 12 weeks (time 2) are shown in Figure 1.

Rates of ulcer healing At 12 weeks from admission to the study, 46.2 per cent ($n=12$) of the intervention group were completely healed, compared to 25.9 per cent ($n=7$) of the control group, although this was not a statistically significant difference ($\chi^2=2.36, P=0.125$).

When examining per cent reduction in ulcer size, the intervention group was found to have a significantly greater per cent reduction in size, with 74.2 per cent ($n=20$ (data for one participant missing)) and 59.1 per cent ($n=16$ (data for one participant missing)) of the control group recording greater than 50 per cent reduction in size ($\chi^2=11.11, P=0.025$).

PUSH score As stated earlier, PUSH scores range from 0-17, where 0=completely healed and 17=worst possible score. A significant difference between groups was found, with the intervention group's reduction in mean PUSH scores being significantly greater than the changes in the control group's mean PUSH scores ($Z=2.93, P=0.002$). Mean PUSH scale scores at time 1 (on admission to the study) and time 2 (12 weeks from admission) are displayed in Figure 2.

Discussion

Current results indicate that the intervention group receiving care at a community Leg Club™ had significantly improved outcomes in levels of pain and ulcer healing as measured by area reduction and PUSH scores in comparison to clients receiving individual home visits for treatment.

Demographics When examining the demographic profile of this (total) sample, it is noteworthy that more than three quarters of the participants were either living alone (57.1 per cent), or were themselves the primary caregiver for another household member who was more disabled than themselves (17.9 per

TABLE 3

Duration of ulcers on admission to study ($n=51, t=0.42, P=0.68$)

Ulcer duration on admission	Intervention group % (n)	Control group % (n)	Intervention group mean (SD)	Control group mean (SD)	Total group mean (SD)
≤12 weeks	38.5 (10)	28.0 (7)	-	-	-
12-24 weeks	7.7 (2)	24.0 (6)	52.5 (87.6)	42.1 (90.1)	47.4 (88.0)
24-52 weeks	34.6 (9)	36.0 (9)	-	-	-
>52 weeks	19.2 (5)	12.0 (3)	-	-	-

Note: Data missing for five participants

cent). As two-thirds of the participants were aged over 70 years (one third over 80 years) and half (55.4 per cent) required physical aids to walk, it is clear that many participants had very limited social support to help them manage their leg ulcer care. Without the support of St Luke's Nursing Service to provide vehicles and volunteer drivers, many of these clients were unable to leave their homes.

Levels of pain On admission to this study the mean amount of pain was rated as moderate by most participants, and affected their daily work, mood, mobility, sleep and recreation to varying degrees ranging from 'a little' to an 'extreme' amount. These findings are consistent with the review results from Briggs and Nelson (2003), Heinen *et al* (2004), Persoon *et al* (2004) and Wilson (2004), where pain from chronic leg ulcers was reported as one of the most significant factors influencing quality of life, affecting energy levels, sleep, mobility and socialisation.

This study illustrates the influence of factors such as peer support and empathy on healing and pain. Significant reductions in the amount of pain and the degree to which pain affected mood, sleep and normal work activities were found in the intervention group in comparison to the control group. Nemeth *et al* (2003) found participants who reported pain that was associated with venous leg ulcers were more likely to have osteoarthritis and poorer mental health, demonstrating the multiple needs of this group of clients. It was observed by the nurses in this study that many Leg Club™ members had

similar multiple general health difficulties and were able to exchange helpful tips and information among themselves during the social activities held at Leg Clubs™ to improve the effective management of their problems.

Nemeth *et al* (2003) suggest that a large prospective repeated measures study is required to increase understanding of factors related to experiencing leg ulcer pain to develop improved pain management strategies. The results from this study present an imperative to develop a framework for research into future assessment and management of leg ulcer pain which encompasses a holistic view of the multiple aspects involved in experiencing and managing chronic leg ulcer pain.

Healing The significantly improved results on ulcer healing as shown in area reduction and PUSH score changes in the intervention group suggest a community Leg Club™ model of care provides additional benefits to promote healing apart from the provision of consistent, evidence-based clinical treatment. These results support the improved rates of healing reported from previous studies on community leg ulcer clinics (Moffatt *et al* 1992, Simon *et al* 1996, Musgrove *et al* 1998, Ghauri *et al* 2000), with the added strength of a randomised controlled trial design. Although the difference in numbers of clients totally healed at 12 weeks was not statistically significant (46.2 per cent of intervention group, 25.9 per cent of control group), the results suggest further study with a larger sample size may provide additional significant results in this area.

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The Leg Club™ model of care aims to provide opportunities to improve understanding of the condition and increase motivation to manage the symptoms and treatment effectively to promote healing and general wellbeing. Clients are treated collectively and are able to follow their peers' progress in healing each week and to communicate freely with members whose ulcers are now healed. The results from this study suggest that further investigation of the contribution of these factors to improved healing rates and levels of pain is warranted.

Conclusion

The provision of a Leg Club™ model of care for clients with chronic venous leg ulcers promotes improved ulcer healing and decreased levels of pain. The model provides a focal point for further examination of factors that influence healing and pain in chronic conditions such as venous leg ulcers **NS**

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IMPLICATIONS FOR PRACTICE

- ▶ The Leg Club™ concept provides a model to address many factors likely to influence the healing of chronic leg ulcers. Such factors include loneliness, decreased sense of control and morale, lack of knowledge, motivation and non-adherence to compression therapy.
- ▶ The model provides an excellent opportunity for staff development as nurses can examine and exchange information or discuss practice in a group environment.
- ▶ Many community nurses are attracted to community care because it enables them to work with community groups to provide holistic care. As the Leg Club™ concept is underpinned with support from volunteers, support agencies and local health professionals, it provides a dynamic model for community care.
- ▶ In addition to the benefits of improved client care and staff development opportunities for nurses, the model has the potential to reduce healthcare costs. Therefore, community nursing organisations should consider the establishment of a Leg Club™ model of care for clients with chronic leg ulcers.

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