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Improved healing rates for chronic venous leg ulcers: Pilot study results from a randomized controlled trial of a community nursing intervention

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Helen Edwards PhD1
Mary Courtney PhD2
Kathleen Finlayson MN3
Caroline Lewis MN4
Ellie Lindsay BSc(Hons)5
Jean Dumble RN6

Venous leg ulcers are a frequent source of chronic ill-health and a considerable cost to health-care systems. This paper reports pilot study results from a randomized controlled trial to determine the effectiveness of a community-based 'Leg Club' environment on improving healing rates of venous leg ulcers. Leg Clubs offer a setting where people with similar problems can socialize in a supportive, information-sharing environment. A sample of 33 clients with a below-knee venous leg ulcer were randomized to treatment, either in their own homes or in a community Leg Club. Treatment was provided to all participants, whether in the control group or intervention group, by a team of trained wound-care nurses following evidence-based assessment and treatment guidelines. Data were collected on admission to the study and at 12 weeks from admission. Results showed a significant improvement in healing in the intervention group compared to the control group, as measured by ulcer area size and Pressure Ulcer Scale for Healing scores. These results suggest that a community Leg Club environment provides benefits additional to wound care expertise and evidence-based care. Knowledge gained from this study provides evidence to guide service delivery and improve client outcomes.

Venous leg ulcers are a frequent source of chronic ill health, poor quality of life and considerable cost to the health-care system. The ulcers are notoriously difficult to heal and tend to recur, becoming a long-term, chronic health problem for many sufferers. The estimated prevalence in Australia is 1% of the over-60 years age group,¹ or 13/1000 of the general population,^{2,3} similar to figures from the United Kingdom (UK), Europe and the United States of America.^{1,4} These numbers translate to a cost of \$A400500 million/year to the Australian health-care system.⁵

Over the last decade, numerous articles have been published on the effectiveness of treatment for chronic venous leg ulcers. Interest has been sparked by poor healing rates, inconsistent and uncoordinated care, the emergence of the evidence-based practice movement, and new treatments and technologies enabling more efficient diagnosis of ulcer aetiology. The results of a systematic review of compression treatment for venous leg ulcers found the use of compression treatment increased healing rates compared to no compression treatment, and that multilayered bandaging systems were more effective than single layered systems.⁶ Factors associated with poor healing of leg ulcers include larger ulcer size,⁷ (ulcer size > 10 cm²),⁸ longer ulcer duration,⁷ age,⁹ poor limb joint mobility and poor general mobility.⁸

In recent years, a number of community leg ulcer clinics have been established as an alternative to community nurse, home-based care for people with leg ulcers. Evaluations of the effectiveness of these clinics have demonstrated considerable improvements in ulcer healing rates. Clinical audits before and after the introduction of leg ulcer clinics have reported significantly higher healing rates, up to 4267% at 12 weeks following the introduction of the clinics.¹¹ Comparisons also have been made between health authority districts in the UK, where one district introduced a number of community leg ulcer clinics and a similar district continued previous ulcer care routines. Significantly higher healing rates were recorded in the districts with the new leg ulcer clinics.^{13,15}

In most of these trials, nurses treating people in the community clinics had training and access to multilayered compression bandaging, which was not always available to district nurses providing home-based care. The use of multilayered bandaging systems necessitates specialized staff training in both application techniques and assessment skills. The introduction of community leg ulcer clinics has generally been associated with nurse specialists who are skilled in these techniques.^{12,13,15,16} McGuckin et al. argue that experienced, well-trained district nurses following consistent treatment guidelines can obtain equally good healing rates (40% at 12 weeks) without investing in the resources needed to set up a community clinic.¹⁷ Therefore, a limitation of the previous evaluations is the absence of a study comparing the effectiveness of community leg ulcer clinics and alternative forms of care, where all health carers are using similar assessment and treatment guidelines.

Evaluations of community leg ulcer clinics have identified a number of important benefits apart from improvements in healing rates. The clinics provide social benefits, peer support and empathy.^{18,20} Improvements in levels of enthusiasm, motivation for treatment, knowledge and understanding of the condition have also been reported.^{18,19,21,22} Some authors have noted that community leg ulcer clinics, often being less formal than other types of care, encourage more people to attend for preventative care and/or treatment.^{20,23} For example, Moffatt and Oldroyd reported that 25% of the people who self-referred to a community clinic had received no previous nursing or medical intervention.²³ The influence of these benefits on ulcer healing rates is unknown.

The 'Leg Club' concept applies the philosophies of social and health belief models in a framework that addresses the individual's hierarchy of needs.^{19,24} The social model emphasizes wellness and maintenance of health, and places equal emphasis on social health, communication, prevention of depression, development of a community within the facility and the maintenance of social position in the surrounding community. The perception of the community-based clinic (Leg Clubs) is primarily aimed at integrating the members into an environment where they can socialize with others who are experiencing similar problems.

The core fundamentals of the Leg Club model differ from conventional leg ulcer clinics in four key respects:

1. Clinics are held in a non-medical environment, in partnership with clients and the local community.
2. Clients are treated collectively.
3. Clinics operate on a 'drop in' basis (no appointments necessary).
4. Clinics incorporate an integrated 'well leg' regime.¹⁹

Thurlby and Griffiths' 2002 review on studies comparing community leg ulcer clinics with home visits found an absence of studies comparing effectiveness of treatment in community clinics to community home nurse visits, where the same nurses and treatments are available in both settings.²⁵ A randomized controlled trial of the effectiveness of a community Leg Club intervention compared to home care, where all participants receive similar treatment by the same team of nurses, was selected for this study to address this gap.

The aim of this trial was to evaluate the effectiveness of an integrated, community-based nursing intervention for managing clients with venous leg ulcers. More specifically, the study aimed to examine the effectiveness of this intervention in improving: (i) healing rates; (ii) quality of life; (iii) health status; (iv) functional ability; and (v) levels of pain of clients with leg ulcers.

Hypothesis

This article reports pilot study results related to ulcer healing rates based on the following hypothesis: clients who receive the community Leg Club intervention will have improved ulcer healing rates compared to those clients who do not receive the intervention.

Study design

A randomized controlled trial was undertaken to evaluate the effectiveness of a community nursing intervention in improving healing rates of venous leg ulcers.

Sample

The pilot study sample consisted of 33 clients referred for ulcer care to St Luke's Nursing Service in the Brisbane and Gold Coast regions of Queensland, Australia. Sixteen clients were randomly allocated to the intervention group and 17 to the control group. The clients were referred from community nurses, medical practitioners or they self-referred in response to newspaper advertisements.

Clients were eligible for inclusion in the study if they had:

1. A venous ulcer below the knee.
2. An Ankle Brachial Pressure Index (ABPI) of > 0.8 and < 1.3 .

Clients were excluded from the study if they:

1. Had diabetes mellitus.
2. Had ulcers of non-venous origin.

3. Were too immobile to be transported to Leg Club (i.e. they were unable to sit up in a wheelchair for 12 h). Volunteer transport was offered to clients who needed assistance to come to the venue.

Procedure

Using a computer-generated random number table, all eligible clients who fitted the inclusion and exclusion criteria and provided informed consent to participate were randomly allocated to the control or the intervention group.

A core team of nurses undertook a series of education sessions, practical training, practice sessions and competency training in order to provide consistent, evidence-based treatment for all clients with venous leg ulcers. This core group of nurses provided care using the same treatment guidelines for both the control group and intervention group clients.

Clients who were allocated to the intervention group received weekly treatment in a community Leg Club. Clients who were allocated to the control group received weekly treatment in their own homes. If more frequent visits were required for either group, these were provided in their homes.

All clients, whether in the control or intervention group, received:

1. A comprehensive health assessment, including ABPI assessment.
2. Referral for more extensive circulatory assessment whenever indicated.
3. Venous ulcer treatment founded on evidence-based guidelines, primarily relying on a short-stretch compression bandaging system.
4. Advice and support about venous leg ulcers.
5. Follow-up management: once clients' venous leg ulcers were healed, they were reviewed and reassessed every 12 weeks for preventative care and management.

In addition, clients in the intervention group received two extra benefits. The first benefit related to peer support, social interaction and control over illness and treatment. Clients attending Leg Club were invited to drop in during the morning or afternoon and participate in morning tea and social activities with the other participants before and after their wound treatment. Peer support and information-sharing was also encouraged through collective treatment in a friendly, non-clinical environment. Strategies were utilized by the staff, volunteers and healed Leg Club members to encourage clients to gain more control of their illness and treatment in order to encourage wound healing.

The second benefit involved goal setting to assist in the management of functional and social activities and to support the adoption of coping strategies. Goal setting is commonly used to increase motivation, as well as improve self-esteem and control. Clients attending the community Leg Club were assisted to identify individualized strategies for modifying daily activities and setting goals to achieve improvements.

Ethical approval for the study was obtained from St Luke's Nursing Service and the Queensland University of Technology Human Research Ethics Committee, which conforms to the National Health and Medical Research Council National Statement on Ethical Conduct in Research Involving Humans.²⁶

Data collection

Clients in both the intervention and control groups received pre- and postassessments. The assessments were undertaken at recruitment time and prior to the intervention (Time 1) and at 12 weeks from the initial assessment (Time 2). Data were collected on demographic information, general health status, ulcer status, functional ability, levels of pain and quality of life.

Data related to ulcer healing were collected by the following methods:

1. Area size: the dot-point method²⁷ of measuring the area of ulcers was used from ulcer tracings.
2. Progress in ulcer healing was also measured using the Pressure Ulcer Scale for Healing (PUSH). The PUSH scale was developed in 1997 and revised by Stotts et al.,²⁸ and includes three dimensions of ulcer healing, providing a more sensitive measure of healing than examining changes in ulcer area alone. The three subscales cover the area of the ulcer, the amount of exudate (i.e. light, medium and heavy) and the type of tissue (i.e. epithelial, granulating, slough or necrotic), giving a total score ranging from 017. Validation and reliability information has been reported in Stotts et al.²⁸ and Pompeo.²⁹
3. The number and rate of ulcers totally healed at each time point was calculated.
4. Additional clinical data related to healing was also collected, such as the presence of oedema, venous eczema, infection, recurrence and the development of new ulcers at each time point.

Data analysis

Data were collated and entered into a SPSS database (SPSS, Chicago, USA) for analysis. Chi-squared and t-tests were conducted to examine any differences between the intervention group and control group data on admission to the study. As small numbers of participants were involved, a sequential analysis technique, the triangular test for difference between means, was used to test the hypothesis.³⁰ Chi-squared tests were used with nominal data variables.

Demographics

Approximately half of the participants were male (51.5%, n = 17) and 48.5% (n = 16) were female. The majority were aged > 70 years, with 9.1% aged < 60 years, 21.2% aged between 60 and 70 years, 33.3% aged between 71 and 80 years and 36.4% aged > 80 years. Seventy-three per cent of participants were from the Brisbane area and 27% were from the Gold Coast area. These participants came from a large number of Brisbane and Gold Coast suburbs (23 in total), covering many different socioeconomic areas, with some clients travelling > 15 km to attend Leg Club.

Baseline general health and ulcer status

On admission to the study (Time 1), information on general health and ulcer status was collected.

General health status: Comorbidities and mobility

Many participants were suffering from one or more major health problems in addition to their leg ulcers, such as arthritis (75.8%), asthma and/or chronic obstructive airways disease

(46.9%), cardiac disease (31.3%) or neuromuscular disorders (12.2%). Only 39.4% of participants were able to mobilize without aid, while the remaining 60.6% used a variety of walking aids and wheelchairs.

Venous history

Sixty-six per cent of participants had a history of varicose veins, 25% had experienced one or more deep vein thromboses, 6% had varicose vein injections and 28% had undergone previous venous surgery. Seventy-three percent of participants had a history of previous venous leg ulcers.

Ulcer status

The length of time the ulcers had already been present when participants were admitted to the study ranged from 4468 weeks, with a mean duration of 43.2 weeks (standard deviation, SD = 81.64). There were no clinically infected ulcers on admission. Lower limb oedema was present in 81.3% of participants and venous eczema was present in 76.8% of participants.

The mean ulcer area on admission = 9.90 cm² (SD = 13.12), ranging from 0.356 cm². The predominant tissue types of the ulcers were characterized as epithelial (6.1%), granulating (24.2%), slough (63.6%) and 6.1% had necrotic tissue.

There were no significant differences found between the intervention group and control group with regard to comorbidities (arthritis: $\chi^2 = 0.26$, $P = 0.61$; pulmonary disease: $\chi^2 = 0.03$, $P = 0.87$; cardiac disease: $\chi^2 = 2.56$, $P = 0.11$) and mobility ($\chi^2 = 1.46$, $P = 0.23$), venous history (varicose veins: $\chi^2 = 0.31$, $P = 0.58$; previous venous surgery: $\chi^2 = 0.67$, $P = 0.41$) or ulcer duration ($t = 0.57$, $P = 0.56$) and the presence of oedema ($\chi^2 = 0.73$, $P = 0.39$) on admission to the study.

Ulcer healing

Treatment

Individualized treatment plans were formed after the initial clinical assessment by the wound-care nurses, with medical consultation and client input. The majority of clients (87.8%) received compression, mostly via a multilayered, short-stretch bandaging system. Reasons for withholding compression at Time 1 were delays in obtaining specialized circulatory assessments and client preference. There were no significant differences between groups in either the type of compression or type of wound dressing applied, with the majority receiving a zinc-impregnated dressing (61%) or a hydrocolloid dressing (22%).

Decreased area size

At Time 2 (12 weeks from admission to the study), the mean ulcer area of the control group had decreased from 10.63 cm² (SD = 15.07) to 9.60 cm² (SD = 13.99). In comparison, the mean ulcer area of the intervention group had decreased from 9.12 cm² (SD = 11.13) to 2.82 cm² (SD = 4.70).

As large ulcer areas and variance were involved, logarithmic transformation of the data was performed. Using sequential analysis, with an effect size of 1 and the significance levels set at $P < 0.05$, the triangular test for difference between means showed a significant difference between groups ($z = 2.64$, $P = 0.004$). The mean ulcer areas for both groups at Time 1 and Time 2 are shown in Fig. 1.

Pressure Ulcer Scale for Healing scores

Ulcer healing was measured using PUSH scale scores. The range of scores from the scale is 017, where 17 = the worst score possible and 0 = a completely healed ulcer.

At Time 2, the PUSH scores for the control group had improved from the initial score of 10.18 (SD = 3.68) to 7.63 (SD = 5.51). In comparison, the PUSH scores for the intervention group had improved from 10.31 (SD = 3.30) at Time 1 to 4.75 (SD = 4.49) at Time 2. Figure 2 displays the changes in mean PUSH scores of both groups over the two time points.

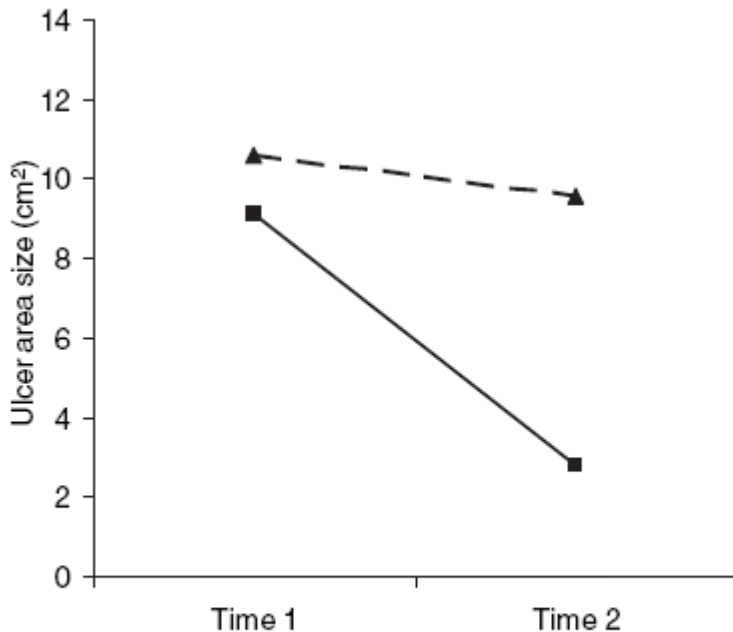


Figure 1. Changes in mean ulcer areas over time. ■, intervention; ▲, control.

Using sequential analysis, with an effect size of 1 and a significance level set at $P = 0.05$, the triangular test for difference between means showed a significant difference between groups ($z = 2.60$, $P = 0.005$).

Additional indicators of healing

At 12 weeks after admission to the study, 43.8% ($n = 7$) of the intervention group were completely healed, compared to 23.5% ($n = 4$) of the control group, although this was not a statistically significant difference. Significant differences were found regarding the presence of venous eczema at Time 2, which was found in 28.6% of the intervention group, compared to 64.7% of the control group ($z = 4.014$, $P = 0.045$), and of lower leg oedema, which was present in 21.4% of the intervention group and 70.6% of the control group ($z = 7.429$, $P = 0.006$).

One wound infection occurred during the 12 weeks in a control-group patient, and one intervention group patient developed a new (additional) ulcer. A significant difference between groups was also seen in ulcer tissue type (of those who had not healed), with the intervention group recording lower levels of sloughy tissue and higher levels of epithelial and granulation tissue than the control group ($z = 8.529$, $P = 0.036$).

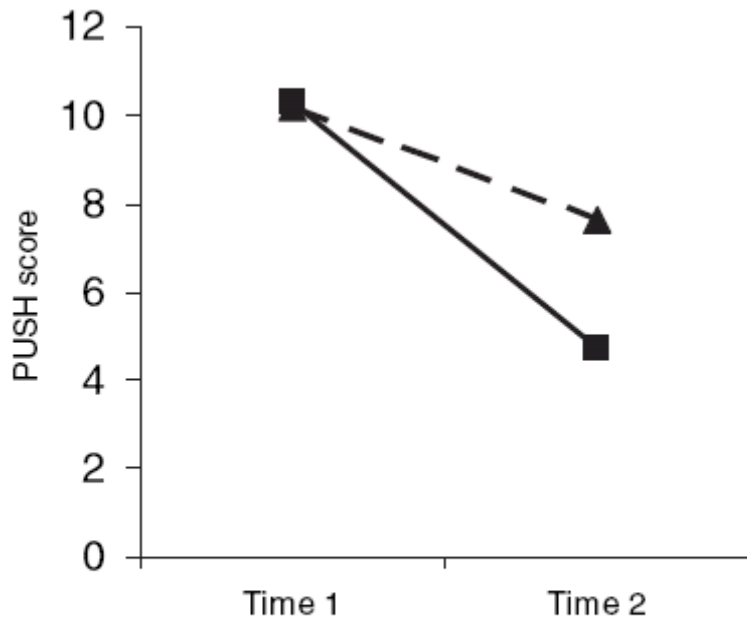


Figure 2. Changes in mean Pressure Ulcer Scale for Healing (PUSH) scores over time. The range =0–17, where 0 = completely healed and 17 = worst possible score. ■, intervention; ▲, control.

Demographics and general health

The participants in this sample were an elderly group, with 69.7% aged > 70 years and over one-third (36.4%) aged > 80 years. This is consistent with the findings of Lindholm et al.,³¹ who found the incidence of leg ulcers increased with age. The high number of participants with multiple, coexisting chronic health problems was also representative of this age group. Although previous studies have found chronic leg ulcers to be more common in women,^{10,31} our sample had almost equal numbers of men and women.

The majority of the participants had coexisting chronic health problems, the most common being arthritis, respiratory disease and cardiac disease. There was only one participant without any diagnosed comorbidities, and 54.6% of the participants had three or more chronic diseases. These health problems and, in particular, the very limited mobility of 61% of the participants, placed restrictions on their ability to care adequately for their leg ulcers (e.g. an inability to pull on compression hosiery or to elevate legs during rest times). The multiple comorbidities also presented a challenge for the nurses to develop detailed, individualized care plans to suit each participant's particular needs.

As so many of the participants had similar chronic health problems, participants who attended the Leg Club had the advantage of a weekly opportunity to share information and tips with 'fellow sufferers', not only about leg ulcer care, but also on other health issues. It was observed by the nurses that a large amount of discussion among participants took place on these subjects, especially the exchange of practical hints or helpful contacts.

Ulcer status and healing

There was a significant improvement in healing in the intervention group compared to the control group, as measured by a reduction in ulcer area and PUSH scores. These results support the findings of Moffatt et al., Musgrove et al., Ghauri et al. and Simon et al., who

demonstrated higher rates of healing within community leg ulcer clinics in comparison to home care.^{11,13,15} The design of this study has the additional strength of including consistent treatment regimes in the home and community Leg Club setting, providing further support for the positive effect of community Leg Clubs on ulcer healing.

Possible reasons for improved healing rates in the intervention group include the beneficial effects of social interaction and peer support and opportunities for sharing of helpful information in a community Leg Club setting. Social interaction and peer support might indirectly improve healing rates in a number of ways. The Leg Club environment is likely to encourage improved motivation for compliance to treatment, as participants are able to see the positive results of effective treatment in their Leg Club peers. In a hot, humid, Queensland climate, a considerable amount of motivation is necessary to tolerate the wearing of compression garments. Sharing information could also contribute to improved healing rates as participants were offered information and strategies from a number of health professionals, volunteers and peers on how to overcome practical difficulties and care effectively for their ulcer. Edwards explored the perceptions of 'non-compliant' leg ulcer clients and found one contributing factor was the lack of understanding of their condition and treatment.³² A community Leg Club environment might be more conducive to learning and understanding of their health issues.

The proportion of healed ulcers at 12 weeks in the intervention group (43.8%) is consistent with the healing rates reported by Ghauri et al.¹³ and Simon et al.¹⁵ within a community leg ulcer clinic setting, although not as high as the figures reported by Musgrove et al.,¹² Franks and Moffat¹⁴ and Moffatt et al.¹¹ Poor ulcer healing has been found to be associated with larger ulcer size in general,⁷ an ulcer size of > 10 cm,²⁸ and with longer ulcer duration (e.g. > 6 months).^{7,10} Margolis et al. found a synergistic effect, or significant interaction, between the two risk factors of ulcer size and duration, indicating that the larger ulcers of long duration were particularly difficult to heal.⁷ The average ulcer area of this sample on admission to the study was 9.9 cm². Although there was a large variation in size, 33.3% of the ulcers were > 10 cm². Also, the ulcers were mostly of long duration, with the mean at 43.2 weeks and 57% of the ulcers present for longer than 20 weeks. These factors might have impeded the ulcer healing rate of our sample.

Other factors associated with poor healing include poor limb joint mobility and poor general mobility,⁸ previous venous surgery or hip/knee replacement surgery⁷ and age.⁹ Again, our sample had a high proportion of participants with these problems, which might have slowed overall healing rates. The lower healing rates at 12 weeks of the control group (23.5%) and the total combined group rate (33.3%) is consistent with the findings by Morrell et al. (24% of their control group treated in the home)³³ and the findings by Brown et al. from a large study in Scotland.¹⁰ After providing intensive training in ulcer care to community nurses in the intervention areas and recording data from 3949 patients, Brown et al. found no change in the overall healing rate of 28% in both the intervention and control areas providing community nursing care in patients' homes.

Limitations

The small number in our pilot sample limit the generalizability of the findings. Higher than usual staff turnover occurred in the initial stages of the project, which might have limited consistency; however, this has since been overcome, resulting in greater continuity and staff input to the project. The sample was also limited by excluding participants (prior to randomization) for consideration of inclusion in the study who were unable to travel to Leg

Club, either because they were too physically disabled to travel by car or because they lived too far away to access the volunteer transport service (> 15 km away).

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Results from this pilot study indicate that healing rates of chronic venous leg ulcers might be improved through client participation in a community Leg Club environment and further evaluation with a larger sample is justified. Nursing knowledge gained from this evaluation will generate evidence that can be used to guide nursing service delivery in the future. This research has the potential to make a substantial contribution to improving the quality of life and health status for a wider population of patients with venous leg ulcers.

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