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Edwards, Helen E., Courtney, Mary D., Finlayson, Kathleen J., Shuter, Patricia E., & Lindsay, Ellie (2009) A randomised controlled trial of a community nursing intervention : improved quality of life and healing for clients with chronic leg ulcers. *Journal of Clinical Nursing*, *18*(11), pp. 1541-1549.

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http://dx.doi.org/10.1111/j.1365-2702.2008.02648.x

Title

Improved quality of life and healing for clients with chronic leg ulcers: A randomised controlled trial of a community nursing intervention.

Concise Title

Improved quality of life for clients with chronic leg ulcers

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Source of Support

This project was supported by a grant from the Queensland Nursing Council, Australia. The views expressed do not necessarily represent the views of the Council or the members, Executive Officer or staff of the Council.

TITLE

Improved quality of life and healing for clients with chronic leg ulcers: A randomised controlled trial of a community nursing intervention.

ABSTRACT

Aims and Objective:

The negative impact of chronic leg ulcers on quality of life is well documented. The aim of this study was to determine the effectiveness of a new community nursing model of care on quality of life, morale, depression, self-esteem, social support, healing, pain and functional ability of clients with chronic venous leg ulcers.

Background:

Venous leg ulcers are slow to heal, frequently recur and are associated with pain, restricted mobility and decreased quality of life. Although chronic wound care consumes a large proportion of community nursing time and health care resources, there is little evidence available on the effectiveness of differing models of community care for this population.

Design:

Randomised controlled trial.

Methods:

We recruited a sample of 67 participants with venous leg ulcers referred for care to a community nursing organisation in Queensland, Australia after obtaining informed consent. Participants were randomised to either the Lindsay Leg Club® model of care (n=34), emphasising socialisation and peer support; or the traditional community nursing model (n=33) consisting of individual home visits by a Registered Nurse. Participants in both groups were treated by a core team of nurses using identical research protocols based on short-stretch compression bandage treatment. Data were collected at baseline, 12 and 24 weeks from commencement.

Results:

Participants who received care under the Leg Club model demonstrated significantly improved outcomes in quality of life (p=0.014), morale (p<0.001), self-esteem (p=0.006), healing (p=0.004), pain (p=0.003) and functional ability (p=0.044).

Conclusion:

In this sample, the evaluation of the Leg Club model of care shows potential to improve the health and well-being of clients who have chronic leg ulcers.

Relevance to clinical practice:

These results suggest further evaluation and implementation of this model is warranted by community health organisations involved in the care of this population.

KEYWORDS:

Wound Care, Venous Leg Ulcer, Chronic Illness, Community Care, Randomised Design.

INTRODUCTION

Chronic leg ulcers are associated with decreased quality of life, restricted mobility, anxiety and depression (Price & Harding 1996, Franks & Moffatt 1999, Franks *et al*. 2003, Charles 2004, Persoon *et al*. 2004, Jones *et al*. 2006). Severe or continuous pain is reported by 17–65% of those with the condition (Briggs & Nelson 2003) and social isolation often ensues as a result of restricted mobility, pain and the psychological impact of unsightly wounds and bandages (Persoon *et al*. 2004). Negative impacts on psychological health have been reported and encompass negative emotions (Phillips *et al*. 1994, Ebbeskog & Ekman 2001), sleep disturbances (Persoon *et al*. 2004, Hareendran 2005) and depression and anxiety (Phillips *et al*. 1994, Jones *et al*. 2006).

The majority of chronic leg ulcers occur as a consequence of chronic venous insufficiency, caused by venous reflux and/or valve incompetence or obstruction (Brem *et al*. 2004). A diagnosis of venous insufficiency indicates a life-long plan of chronic disease management and preventive care is required. The ulcers are difficult to heal, frequently recur (Barwell *et al*. 2004) and draw on up to 50% of community nursing time (Simon *et al*. 2004). Prevalence is estimated at 0.63–1.9% in the adult populations of the UK, the USA, Europe and Australia (Briggs & Closs 2003) and increases with age (Margolis *et al*. 2002, Moffatt *et al*. 2004). As populations continue to age (Parker 2005), the demand for effective interventions for this condition will continue to increase.

Health professionals caring for this population recognise the need to address pain and quality of life issues along with clinical wound healing outcomes from local treatments (Franks & Moffatt 1999, Charles 2004). Many clients with chronic leg ulcers are cared for individually in their homes by community nurses. However, this traditional model of care cannot always provide the social and psychological support necessary to enhance effective chronic disease management and quality of life (Lindsay 2000). Observation and anecdotal evidence suggests the community Leg Club model of care—established in the UK in 1995 for chronic leg ulcer sufferers—can overcome many of these challenges (Lindsay 2000). Based on community involvement and ownership, the Leg Club model provides social activity and peer support for leg ulcer sufferers. However, there is a lack of research that demonstrates evidence of improved client outcomes at Leg Clubs compared with usual community care. Previous studies have compared wound healing outcomes from a variety of specialist community leg ulcer clinics with those from individual community care and reported promising results, but the studies have been limited by lack of randomisation, inconsistent treatment protocols between groups and a limited range of outcome measures (Moffatt *et al*. 1992, Simon *et al*. 1996, Morrell 1998, Ghauri *et al*. 2000).

Aim

The aim of this study was to determine the effectiveness of a Leg Club model of care in improving quality of life, morale, depression, social support, self esteem, healing rates, pain and functional ability of clients with chronic venous leg ulcers.

Hypothesis

We hypothesised that participants receiving care under the Leg Club model would show improved quality of life, morale, social support, self esteem, healing rates and functional ability; and decreased levels of depression and pain in comparison to participants receiving individual home care.

Early results on the effectiveness of the model on healing rates and levels of pain following 12 weeks of care have been previously reported (Edwards *et al*. 2005). This paper reports results on outcomes of quality of life, morale, depression, social support, self-esteem, healing rates, pain and functional ability of clients following 24 weeks of care.

METHODS

Design

A randomised controlled trial was conducted to determine the effectiveness of the new community nursing model of care for clients with chronic venous leg ulcers. Ethical approval to conduct the study was obtained from Spiritus (formerly St Luke’s Nursing Service) Human Research Ethics Committee and the Queensland University of Technology Human Research Ethics Committee and complied with the Declaration of Helsinki rules for human experimentation.

Participants

We recruited a sample of 67 clients (34 intervention; 33 control) who were referred to a community nursing service for care of venous leg ulcers within the Brisbane and Gold Coast regions of Queensland, Australia. Informed consent was obtained, where clients were informed that although the wound care in both control and intervention groups was the same, they would be randomised to receive this care in either their own homes or at the Leg Club location. Clients thus had to be willing to receive care in either location. If they had a preference for care in either of these locations, they were excluded from participation in the trial and received care at the preferred location. All consenting participants were offered care in the alternative location at the end of the trial.

Consenting clients were eligible if they had a venous ulcer below the knee and an Ankle Brachial Pressure Index (ABPI) of over 0.8 and less than 1.3. Clients with any of the following were ineligible for recruitment: ulcers of non–venous origin; clinical signs of a wound infection on admission; or the clients were unable to sit upright for one or two hours to be transported and attend a Leg Club. Sample size was determined using a group sequential analysis method, the triangular test of difference between means (Whitehead 1997, Edwards *et al*. 2005), to assess the sample size needed to cross the statistical significance border. Parameters were specified at a significance level of $p<0.05$, power of 0.9 and an effect size of 1.

Procedure

After we collected baseline data on clients who met the selection criteria and provided informed consent, we randomised the participants using a computer randomisation program to receive treatment either via individual home visits (control group) or during a weekly visit to a Leg Club (intervention group). Assessment and treatment of clients in both the intervention and control groups followed evidence-based research protocols that were developed for the study based on best practice guidelines (Australian Wound Management Association 2002, Royal College of Nursing 2006). Compression treatment was based on a short-stretch bandaging system. A small team of community nurses with expertise in wound care were trained to implement the research protocols; they then provided care to clients in both groups, i.e. in the home and the Leg Club settings.

Clients randomised to the control group received individual home nursing care consisting of: 1) a comprehensive health assessment including ABPI; 2) referral for further circulatory assessment as indicated; 3) venous ulcer treatment based on research protocols; 4) advice and support about venous leg ulcers; and 5) follow-up management and preventive care. Clients randomised to the intervention group visited a Leg Club weekly where they received the same five care items as the control group. In addition, they were provided with opportunities for peer support, assistance with goal setting and social interaction. The Leg Club settings entailed a room or space for social activities and refreshments and separate areas where wound care was provided at two or three ‘dressing stations’, where clients were still able to communicate with each other. Trained volunteers provided transport for those clients in the intervention group who were unable to travel independently to a Leg Club site. The Leg Clubs were developed in accordance with the *Lindsay Leg Club*® model, which proposes that wound care occur in an informal, community-owned environment that encourages social interaction, peer support, information sharing and long-term involvement, including preventive care after healing (Lindsay 2000).

Data collection

Following recruitment to the study and prior to commencement of the intervention, baseline medical, venous and demographic data were obtained from clients’ medical charts and baseline data on health and ulcer status were acquired during clinical assessment. Data on quality of life, pain, functional ability, depression, morale, self esteem and social support were collected using self-report questionnaires at baseline (Time 1), then at 12 and 24 weeks after the commencement of the intervention (Time 2 and Time 3). The questionnaires contained a total of 80 short answer (tick the box) items, using instruments (as described below) which were designed for older people. Short Form versions of each tool were used wherever available. Participants had the choice of filling in the questionnaire during their visit with the assistance of a nurse, or keeping or taking the questionnaire home to fill in at their leisure to return at the next visit. On average participants were able to complete the questionnaire in 10–15 minutes. Data on progress in ulcer healing were collected at baseline, 12 and 24 weeks.

Instruments and measures

Quality of life, functional and psychosocial outcomes were measured using Spitzer's Quality of Life Index (Spitzer *et al*. 1981), the Geriatric Depression Scale (Yesavage *et al*. 1983), Philadelphia Geriatric Centre Morale Scale (Lawton 1972), Rosenberg's Self Esteem Scale (Bowling 1997), the Medical Outcomes Study (MOS) Pain Measures (Sherbourne 1992), MOS Social Support Scale (Sherbourne & Stewart 1991) and the Index of Activities of Daily Living (Katz & Akpom 1976). The Index of Activities of Daily Living (Katz & Akpom 1976) was designed to measure physical functioning of the elderly and chronically ill and has been widely used in community settings. The MOS Social Support Scale was designed for the chronically ill and contains 19 items measuring four dimensions of social support: tangible support, affectionate support, positive social interaction and emotional/informational support; while the MOS Pain Measures consist of seven items measuring the intensity, frequency and duration of pain and the impact of pain on daily living. Good evidence exists for reliability and validity (Sherbourne & Stewart 1991; McDowell & Newell 1996). The Rosenberg Self-Esteem Scale consists of 10 items and is widely used, with evidence confirming its suitability for older people, good reliability and construct validity (Bowling 1997).

The Philadelphia Geriatric Centre Morale Scale is applicable to older populations in both community and institutional settings. The scale consists of 17 items covering three areas: agitation, attitude towards own ageing and lonely dissatisfaction (Bowling 1997). The Geriatric Depression Scale was designed for the elderly in outpatient settings. The scale uses a yes/no answer format and an abbreviated 15-item scale avoids problems of fatigue. Studies have shown good reliability and high sensitivity and specificity in elderly people (McDowell & Newell 1996). The Quality of Life Index was developed for chronically ill patients and consists of 5 items measuring domains of activity, daily living, health, support and psychological outlook. Good validity, consistency and reliability has been reported from sevaral studies and countries (Spitzer *et al*. 1981; Bowling 1997).

Ulcer healing measures: A dot-point method (Bahmer 1999) was used to calculate ulcer area from ulcer tracings. Ulcer area, percentage reduction in area and the number of healed ulcers were recorded at each time point (fully healed was defined as full epithelialisation lasting for two weeks). The presence of any clinical signs of infection, venous eczema, oedema and wound bed tissue type were also recorded.

Data analysis

Due to the sequential nature of recruitment and small sample size, Group Sequential Analysis methods for use with clinical trials were used for analysis (Whitehead 1997, Edwards *et al*. 2005). Prior to commencing the trial, borders were set with the following parameters: significance level, $p<0.05$; power, 0.9; effect size, 1. The triangular test of difference between means was used to test the hypotheses (Whitehead 1997). Analyses were conducted using intention to treat principles.

RESULTS

Participant characteristics

Figure 1 shows the flow of the clients through the study. Fifteen participants were lost to follow-up (seven from the control group, eight from the intervention group). We found no significant differences between the participants lost to follow-up and the remaining participants with regard to demographic, medical, venous, ulcer characteristics or quality of life variables. The study sample contained slightly more males (53.7%, n = 36) than females (46.3%, n = 31). Only 10.4% of clients in the study sample were under 60 years, 22.2% were 60–70 years, 32.8% were 71–80 years and 32.8% were 81–90 years. Slightly more than a quarter (28.4%) of participants were married, 28.4% were single and 43.3% were widowed. Just over half of all participants (56.7%, n = 38) were living alone; another 16.4% (n = 11) of participants were the primary caregiver for another member of their household (i.e. a spouse or relative who was more disabled than themselves); and the remainder shared a household with a spouse, relative or friend (26.9%, n = 18). Many participants required a walking aid or wheelchair to mobilise (58.2%). Demographic characteristics did not differ significantly between the intervention and control groups.

The average number of co–morbidities present was 2.2 (Standard Deviation [SD] 1.4): these included cardiovascular disease (53.6%), osteoarthritis (42.9%) and rheumatoid arthritis (12.5%). A history of varicose veins was reported by 60.7% of participants, deep vein thrombosis by 23.2% and previous venous surgery by 25.0%. Intervention and control groups did not differ significantly on presence of co–morbidities; they also did not differ significantly with regard to measures of quality of life, pain, functional ability, morale, depression, self-esteem, social support, ulcer size (median area 7.5 cm^2, range 1.0 – 140.0 cm^2), duration (median 22 weeks, range 4 – 180 weeks), or history of previous ulcers (75.4%).

Quality of life and functional ability

Intervention and control group mean scores and standard deviations at baseline and at 24 weeks from baseline are displayed in Table 1. Using sequential analysis, the triangular test for difference between the intervention and control groups' Quality of Life Index means showed that the intervention group's mean score improved significantly more than the control group's mean score ($Z = 2.19$, $p = 0.014$, Fig. 2). Similarly, analysis showed a significant difference between the intervention and control groups' mean Index of Activities of Daily Living scores ($Z = 1.70$, $p = 0.044$), as seen in Table 1.

Morale, depression, self-esteem and social support

Intervention and control group mean scores and standard deviations at baseline and at 24 weeks from baseline are displayed in Table 1. Analysis of the mean Philadelphia Geriatric Centre Morale Scale scores revealed that the intervention group's mean morale score improved significantly more than the control group's mean score ($Z = 4.45$, $p < 0.001$, see Table 1); and analysis of Rosenberg's Self Esteem Scale scores also showed a significant improvement in the intervention group's mean scores in comparison to the control group ($Z = 2.51$, $p = 0.006$, see Table 1). However, analysis of mean Geriatric Depression Scale scores found no significant differences between the two groups (p = 0.227, see Table 1). Sequential analysis revealed no significant difference between the intervention and control groups' Total Index Social Support scores (p = 0.15, see Table 1). Separate analysis of each the four types of social support, however, yielded a significant difference between groups for the positive social interaction subscale ($Z = 2.01$, $p < 0.028$), but no significant differences between the groups for the remaining subscales.

Ulcer healing

Numbers healed: At 24 weeks from commencement of the study, 60% (n = 15) of the intervention group were completely healed, in comparison to 40% (n = 10) of the control group, although the difference was not statistically significant ($\chi^2 = 2.0$, p = 0.157).

Ulcer area: Intervention and control group mean scores and standard deviations at baseline and at 24 weeks from baseline are displayed in Table 1. Due to large differences in ulcer area and variance observed, logarithmic transformation of data was performed to examine differences in ulcer area over time. Using sequential analysis, the triangular test for difference between means showed a significant difference between groups, with the intervention group mean ulcer area significantly smaller than that of the control group ($Z = 2.64$, $p = 0.004$) by 24 weeks. Mean ulcer areas are shown in Table 1.

Percentage reduction in ulcer area: When looking at percentage reduction in ulcer area from baseline, the mean percentage reduction in area at 24 weeks in the intervention group was 77.65 (*SD* 46.23) and in the control group 56.81 (*SD* 66.89), Mann-Whitney U 238.5, p = 0.135.

Oedema, venous eczema and wound bed tissue type were also examined. At 24 weeks from baseline, lower leg oedema had significantly reduced from 74% (n = 21) to 12.0% (n = 3) of the intervention group and from 83% (n = 24) to 60.9% (n = 15) of the control group ($\chi^2 = 12.51$, $p < 0.001$). A significant difference between groups was also observed for venous eczema, which was present in 16.0% (n = 4) of clients in the intervention group compared with 56.5% (n=14) of clients in the control group ($\chi^2 = 8.6$, $p = 0.003$) at 24 weeks. Differences were found in the type of tissue present in unhealed ulcers, with the intervention group recording lower levels of sloughy tissue and higher levels of epithelial and granulation tissue than the control group at 24 weeks ($\chi^2 = 10.08$, $p = 0.018$).

Pain

The amount, frequency and duration of pain and its impact on daily life were measured using the Medical Outcomes Study Pain Measures (Sherbourne 1992), which yields an overall score and three subscale scores. Sequential analysis revealed that the intervention group mean scores had significantly greater decreases in the Severity of Pain subscale ($Z = 3.02$, $p = 0.001$, see Fig. 3), the Effect of Pain subscale, ($Z = 2.65$, $p = 0.004$) and the overall total pain score ($Z = 2.71$, $p = 0.003$) when compared with the control group, as shown in Table 1.

DISCUSSION

Our results indicate that the intervention group receiving care at a community Leg Club had significantly improved outcomes in comparison to the control group following 24 weeks of care in quality of life, pain levels, morale, self-esteem, independence in activities of daily living and ulcer healing. These results provide the first evidence from a randomised controlled trial of the effectiveness of a Leg Club model of care on a broad range of outcomes for clients with chronic leg ulcers. The improvements in ulcer healing found in the intervention group are consistent with results from previous trials evaluating dedicated leg ulcer clinics in comparison to usual care (Simon *et al*. 1996, Morrell 1998, Ghauri *et al*. 2000), with the addition of consistent treatment protocols provided to both intervention and control groups in this study and the unique aspects involved in a Leg Club model rather than a ‘clinic’. Previous discussion has focused on whether improved healing rates found in leg ulcer clinics in comparison to individual community care are due to the provision of consistent care by specialist health professionals and improved access to appropriate treatments, or whether the same results could be achieved by simply following consistent, evidence based guidelines whether in a clinic or in the home (McGuckin *et al*. 2002). However, results from this study suggest a group social environment may have advantages other than just the provision of consistent, evidence based care.

Studies of quality of life in patients with chronic leg ulcers have generally found significantly lower quality of life scores than in the general population (Franks *et al*. 1999, Brem *et al*. 2004, Jull *et al*. 2004, Persoon *et al*. 2004). Results from this study are consistent with previous reports of improvements in quality of life scores following healing (Franks *et al*. 1999) and worsening quality of life in patients with pain and non-healing ulcers (Hareendran *et al*. 2005). The improvements in morale and self-esteem found in the intervention group in this study may indicate the value of a social model of care for this group of clients in addressing some of these issues. No significant differences were seen in the Geriatric Depression Scale scores in this sample, however, the scores were generally all fairly low and below levels which indicate ‘mild depression’ (i.e. mean scores were below 5) (Yesavage *et al*. 1983). Although we may have expected significant improvements in social support, only one of the four subscales (the positive social interaction subscale) demonstrated a significant improvement in the intervention group in comparison to the control group. The remaining scales measuring tangible support, affectionate support and emotional/informational support failed to show a difference, possibly due to the limited time available for participants to get to know each other well, in addition to their limited physical ability to provide physical tangible support for each other.

Relevance to Clinical Practice

Although the small sample size limits generalisation of the findings, our data supports further introduction and evaluation of this model of care in the management of clients with leg ulcers. An economic evaluation of this study has demonstrated that the model is a cost effective option for health service providers (Gordon *et al*. 2006). The results of this trial suggest that health service managers and clinicians from community health organisations involved in the care of this population should consider the model as appropriate and effective in improving quality of life and healing in clients with chronic leg ulcers.

CONTRIBUTIONS

Study Design: HE, MC, KF, EL

Data Collection and Analysis: HE, MC, KF, PS,

Manuscript Preparation: HE, MC, KF, PS, EL

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FIGURE. 1 Flow of clients through the study

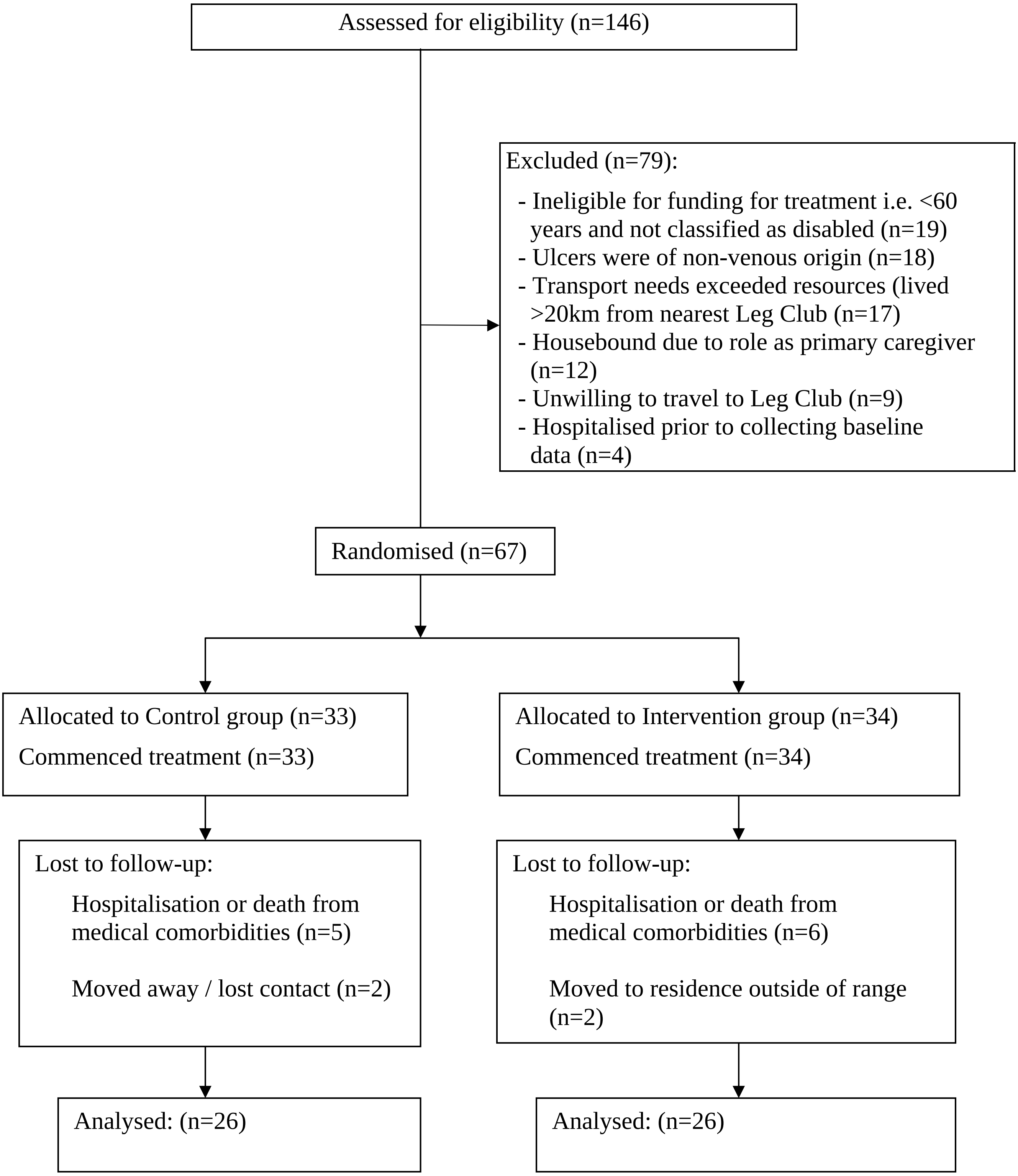

FIGURE 2. Mean Quality of Life Index scores

(range: 0 – 10, where 0 =very poor quality of life; 10 = high quality of life).

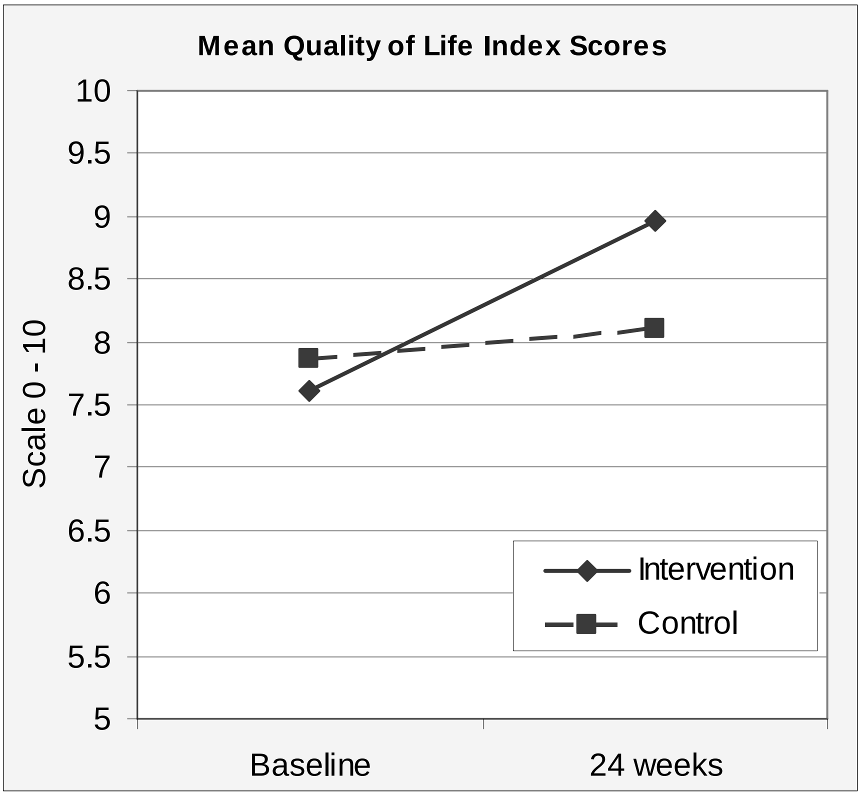

FIGURE 3. Mean severity of pain subscale scores

Scale: 0 – 100, where higher scores indicate more pain

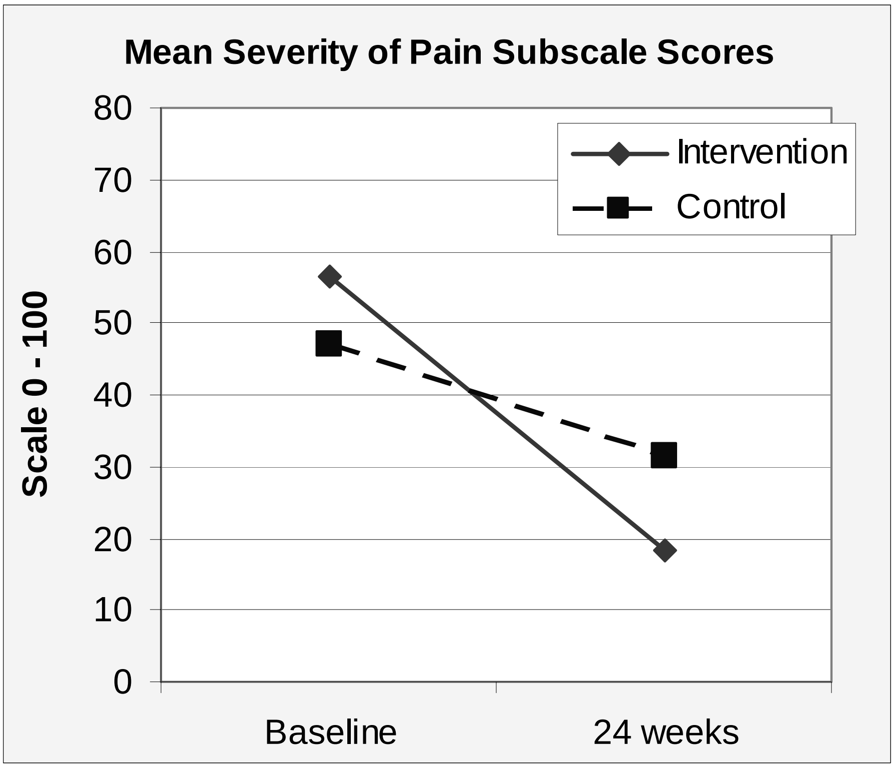

TABLE 1. Quality of life measures and ulcer healing outcomes at baseline and at 24 weeks from baseline.

	Mean (*SD*) at baseline		Mean (*SD*) at 24 weeks			
	Intervention	**Control**	**Intervention**	**Control**	***Z***	***p***
Quality of Life[1]	7.61 (1.65)	7.86 (2.27)	8.96 (1.43)	8.11 (2.10)	2.19	0.014
ADL[2]	0.54 (0.96)	0.60 (1.0)	0.08 (0.28)	0.67 (1.4)	1.70	0.044
PGC Morale[3]	10.61 (3.32)	11.64 (5.08)	14.18 (2.67)	11.91 (5.12)	4.45	<0.001
Depression[4]	4.43 (3.24)	4.11 (3.90)	3.50 (2.77)	3.33 (3.53)	1.26	0.227
Self Esteem[5]	31.93 (4.43)	32.14 (4.40)	33.44 (5.23)	31.52 (5.42)	2.51	0.006
Social Support[6]	60.71 (27.79)	66.82 (28.30)	72.64 (23.53)	76.54 (24.39)	1.43	0.150
Ulcer area (cm^2)	7.94 (10.21)	8.31 (11.82)	1.54 (5.26)	6.17 (9.24)	2.64	0.004
Pain Severity[7]	56.39 (21.63)	46.93 (23.14)	18.28 (22.31)	31.46 (25.01)	3.02	0.001
Effect of Pain[7]	46.03 (22.55)	39.55 (26.91)	20.17 (18.70)	33.89 (24.37)	2.65	0.004
Overall Pain[7]	53.02 (17.64)	42.03 (26.09)	21.54 (24.02)	34.29 (23.23)	2.71	0.003

[1] Range 0–10, where 0 = poor quality of life and 10 = excellent quality of life

[2] Activities of Daily Living Scale: 0–6, where 0 = fully independent and 6 = dependent

[3] Philadelphia Geriatric Centre Morale Scale: Range 0–17, where 0 = poor morale

[4] Geriatric Depression Scale: Range 0–15, where 0= no depression and 15 = high levels

[5] Rosenberg’s Self Esteem Scale: Range 10–40, where higher scores indicate greater self esteem.

[6] MOS Social Support Scale: range 0–100, where higher scores indicate greater available social support

[7] MOS Pain Measures, Range 0–100, where higher scores indicate higher levels of pain