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## Cost effectiveness of community leg ulcer clinics: randomised controlled trial

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### Abstract

**Objectives:** To establish the relative cost effectiveness of community leg ulcer clinics that use four layer compression bandaging versus usual care provided by district nurses.

**Design:** Randomised controlled trial with 1 year of follow up.

**Setting:** Eight community based research clinics in four trusts in Trent.

**Subjects:** 233 patients with venous leg ulcers allocated at random to intervention (120) or control (113) group.

**Interventions:** Weekly treatment with four layer bandaging in a leg ulcer clinic (clinic group) or usual care at home by the district nursing service (control group).

**Main outcome measures:** Time to complete ulcer healing, patient health status, and recurrence of ulcers. Satisfaction with care, use of services, and personal costs were also monitored.

**Results:** The ulcers of patients in the clinic group tended to heal sooner than those in the control group over the whole 12 month follow up (log rank  $P=0.03$ ). At 12 weeks, 34% of patients in the clinic group were healed compared with 24% in the control. The crude initial healing rate of ulcers in intervention compared with control patients was 1.45 (95% confidence interval 1.04 to 2.03). No significant differences were found between the groups in health status. Mean total NHS costs were £878.06 per year for the clinic group and £859.34 for the control ( $P=0.89$ ).

**Conclusions:** Community based leg ulcer clinics with trained nurses using four layer bandaging is more effective than traditional home based treatment. This benefit is achieved at a small additional cost and could

be delivered at reduced cost if certain service configurations were used.

### Introduction

Complete healing of venous leg ulcers can take years and recurrence is a problem.<sup>1</sup> Patients experience pain, affecting sleep, mobility, and quality of life.<sup>2-4</sup> The financial cost of venous disease in Britain has been estimated at between £294m and £650m a year.<sup>5-6</sup> Most care for people with leg ulcers has been provided by community nurses,<sup>7</sup> who use numerous treatments, although adequate information about their effect on complete healing or quality of life is not available.<sup>6-8</sup>

A unique graduated four layer compression bandaging system was pioneered at Charing Cross Hospital<sup>9</sup> and clinics in Riverside that used this system achieved a healing rate of 69% of venous ulcers in 12 weeks.<sup>10</sup> Estimates indicated that costs for clinics were lower than for the previous care system.<sup>11</sup> The effectiveness, however, remained uncertain, and concern was expressed that this uncontrolled study provided the basis for the introduction of a new leg ulcer service.<sup>12</sup>

A randomised controlled trial was undertaken to compare the effect of four layer bandaging in a clinic setting on healing of venous leg ulcers and health status against the usual home based care provided by district nursing services. The relative cost effectiveness of the two interventions was also evaluated.

### Patients and methods

#### Recruitment

The study was approved by appropriate ethics committees. Recruitment was from September 1994 to May 1995 in eight clinics (four urban, two suburban, two semirural) in four community trusts in Trent. The

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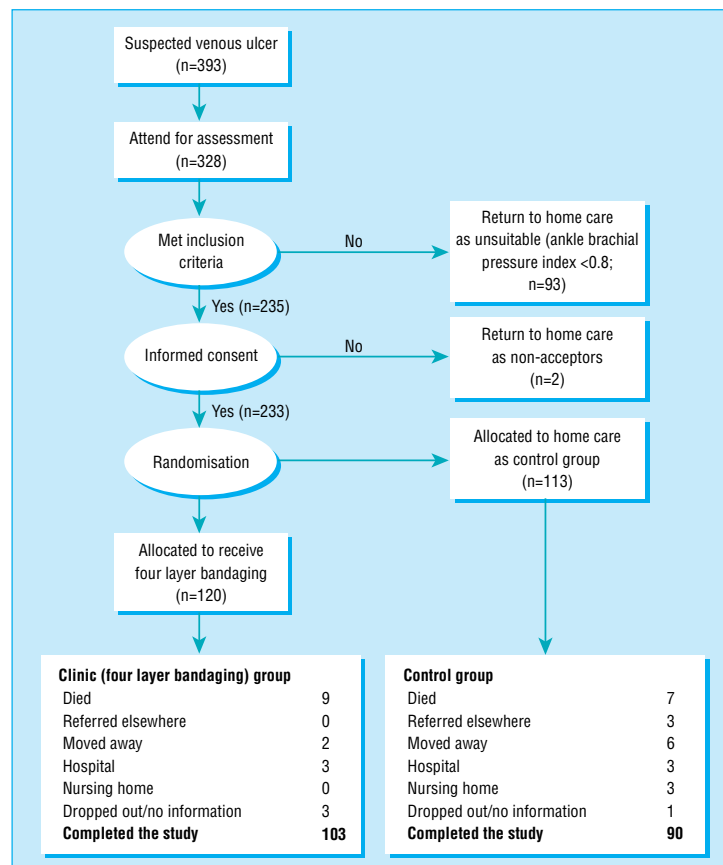


Fig 1 Diagrammatic representation of sample size

inclusion criteria were a venous ulcer below the knee to the foot that was present for at least 3 months and ability to travel to the clinic. Patients were assessed by clinic coordinators using Doppler ultrasound. Those with an ankle brachial pressure index  $<0.8$  were excluded. The nurses all adhered to the standardised clinic protocol. A total of 233 patients provided written informed consent (fig 1). A random assignment schedule and serially numbered, sealed, opaque allocation envelopes were prepared in advance for each of the eight clinic sites.

### Intervention

The intervention was weekly treatment in a leg ulcer clinic. Clinic coordinators all completed a course on management of leg ulcers (ENB N18) and additional training days to practice applying four layer bandaging (supervised by experienced practitioners). Treatment adhered as closely as possible to the Charing Cross bandaging technique.<sup>9</sup> After healing, patients were prescribed class 2 compression stockings and were reviewed by the clinic coordinators every 3 months. For the control group, as it was a pragmatic trial, nurses in the home provided the patients' usual treatment.

### Outcomes and follow up

The primary clinical end point was time to complete healing of all ulcers within the 12 month follow up period. The nurses recorded the date of healing, defined as re-epithelialisation of all ulcers. Secondary end points were health status, time to first recurrence of a healed ulcer, and the number of weeks the patients were free from ulcers.

In the absence of disease specific measures,<sup>13</sup> four measures of self perceived health status were used to cover all relevant dimensions of health: the 36 item short form health survey (SF-36),<sup>14</sup> the EuroQol (EQ),<sup>15</sup> the McGill short form pain questionnaire (SF-MPQ),<sup>16</sup> and the Frenchay activities index.<sup>17</sup>

Questionnaires were posted 12 weeks and 12 months after recruitment to collect data on health status and satisfaction. Reminder questionnaires and telephone calls were used for non-responders or missing responses.

### Economic evaluation and analysis

The economic analysis was undertaken from an NHS perspective. Total estimated NHS costs per patient were calculated by estimating the cost of treatment for leg ulcers (staff time, materials, transport, and overheads) and the cost of use of other health services (general practitioner contacts and hospital). For the control group data were collected for individual home visits to produce a mean cost per home visit. For the clinic group data on use of resources were available for each clinic session but not on an individual basis. The mean cost per attendance per patient was derived from the total cost per session.

Data on the use of health services related to care of leg ulcers were also collected by the postal follow up questionnaires. Data on resources not related to patients—for example, overheads—were collected from service managers. All resources were valued at 1995 prices. Unit costs were taken, when possible, from the local service providers or national data sources.<sup>18 19</sup> Because of the skewed distributions of the cost data, mean costs per patient for both groups were compared by permutation tests and confidence intervals were calculated by bootstrap methods,<sup>20</sup> which work by resampling from the observed data and thus make no assumptions on distribution.

### Statistical analysis

Sample sizes were calculated based on the expected difference in rate of healing between the groups after

Table 1 Baseline characteristics of patients recruited. Values are numbers (percentages) of patients unless stated otherwise

Characteristic	Clinic group (n=120)*	Home group (n=113)†
Mean (SD) age (years)	73.8 (10.9)	73.2 (11.6)
Mean (SD) area of ulcer (cm <sup>2</sup> )	16.2 (28.9)	16.9 (40.8)
Mean (SD) occurrence of first ulcer (years)	14.2 (14.9)	12.9 (15.9)
Mean (SD) maximum duration of current ulcer (months)	27.5 (53.8)	29.7 (82.3)
Mean (SD) body mass index (kg/m <sup>2</sup> )	27.0 (6.7)	27.1 (6.0)
Mean (SD) systolic brachial pressure (mm Hg)	154.8 (28.7)	153.9 (24.9)
Mean (SD) ankle brachial pressure index	1.08 (0.17)	1.10 (0.18)
Women	77 (64)	78 (69)
Married	56 (47)	52 (46)
Living alone	30 (25)	33 (29)
Walking with aid	66 (55)	57 (50)
Family history of leg ulcers	82 (28)	25 (22)
History of deep vein thrombosis	28 (23)	25 (22)
Varicose veins	77 (64)	76 (67)
Rheumatoid arthritis	14 (12)	18 (16)
Heart problems	13 (11)	8 (7)
Osteoarthritis	47 (39)	40 (35)
Diabetes mellitus	8 (7)	10 (9)

\*Mean values measured in at least 110 patients.

†Mean values measured in at least 100 patients.

**Table 2** Mean (SD) scores on measures of health status at baseline by allocation to treatment in clinic or at home

Measure (range of scores)*	Clinic group (n=120)†	Control group (n=113)‡
<b>SF-36 (0-100)</b>		
Physical function	41.8 (30.0)	45.0 (31.5)
Role limitation—physical	51.7 (42.5)	50.0 (40.1)
Pain	58.9 (28.9)	53.3 (28.4)
General health perception	66.8 (21.5)	62.4 (23.1)
Vitality	55.7 (19.3)	50.8 (23.8)
Social function	68.2 (30.0)	65.2 (31.2)
Role limitation—emotional	62.5 (43.1)	70.5 (40.3)
Mental health	71.7 (20.4)	67.6 (22.1)
<b>EuroQol</b>		
Derived single index (0-100)	58.1 (16.7)	55.4 (19.0)
<b>Frenchay</b>		
Frenchay activities index (15-60)	36.4 (9.9)	36.8 (10.4)
<b>SF-MPQ</b>		
Pain rating index—sensory (0-33)	8.5 (7.2)	9.0 (6.7)
Pain rating index—affective (0-12)	2.0 (3.0)	1.9 (2.6)
No of words chosen (0-15)	5.4 (3.8)	5.6 (3.7)
Visual analogue scale:		
Pain now (0-10)	3.1 (2.8)	3.1 (2.9)
Pain during day (0-10)	3.8 (2.8)	4.1 (3.0)
Pain at night (0-10)	4.2 (3.1)	4.3 (3.4)

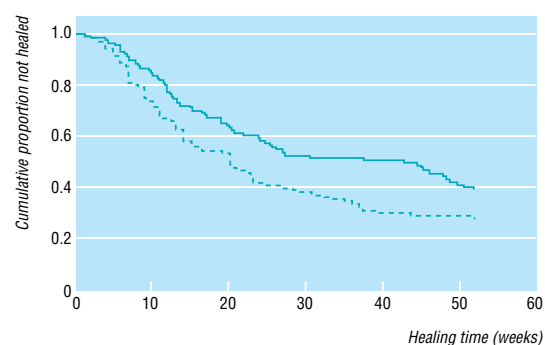
\*For SF-36, EuroQol, and Frenchay index high score indicates good health; for SF-MPQ high score indicates greater pain.

†For SF-36 general health perception and vitality n=119.

‡For SF-MPQ pain rating index (sensory) and No of words chosen n=112.

12 weeks. To have an 80% chance of detecting as significant (at the 5% level) an increase in healing from 50% to 70%, 206 patients were required.

All the data analysis was by intention to treat. We used *t* tests or Mann-Whitney tests for continuous measurements,  $\chi^2$  tests for categorical data, the Kaplan-Meier method to calculate the time from recruitment for the initial leg ulcer to heal, and the log rank test to compare the healing times of both groups. Previous work suggested that age, ulcer area, ulcer duration, and history of deep vein involvement were important factors in predicting time to healing.<sup>21</sup> Cox proportional hazards regression analysis was used to adjust healing times for these variables.<sup>22-23</sup> For each dimension of the four measures of health status, we calculated a summary measure of average health gain per month for all patients as the area under the response curve over the 12 months of follow up, measured with respect to the baseline score.<sup>24</sup>



**Fig 2** Healing times of initial leg ulcers by treatment group (solid line=control group, n=113; dotted line=clinic group; n=120). Log rank test statistic 4.90; df=1; P=0.03

## Results

The patients in the two groups were well matched at randomisation with respect to baseline clinical, demographic, and health status measurements (tables 1 and 2). Various treatments were used in the control group (table 3). Access to four layer bandaging for patients in the control group was minimal as all components were not available on prescription.<sup>25</sup>

There was evidence of a difference in the initial healing times for leg ulcers between the groups over the whole follow up (fig 2) with the clinic group tending to heal sooner (P = 0.03). The median healing times were 20 and 43 weeks for patients in the clinic and control groups, respectively. At 12 weeks the Kaplan-Meier estimates of the cumulative percentages healed at 12 weeks were 34% in the clinic group and 24% in the control (difference 10%, 95% confidence interval -2% to 22%).

According to the Cox model the initial ulcer was 1.45 times more likely to heal in the clinic group than in the control group (1.04 to 2.03). After adjustment

**Table 3** Range of treatments used by district nurses per visit in control group

Treatment	No of visits	No (%) of times used
Wound preparation:		
Normal saline	2114	1310 (62)
Water	381	42 (11)
Aqueous solution	243	17 (7)
Nothing	197	12 (6)
Normal saline and other	163	8 (5)
Aqueous solution and other	155	8 (5)
Other combination	158	8 (5)
Ulcer applications:		
Non-adherent dressings	548	88 (16)
Alginate sheets	487	68 (14)
Non-adherent dressings and other	469	66 (14)
Hydrocolloid dressings	337	34 (10)
Hydrogel dressings	290	26 (9)
Paste bandages	184	9 (5)
Nothing	140	6 (4)
Paraffin gauze	115	3 (3)
Alginate sheets and other	99	3 (3)
Hydrocolloid or hydrogel dressings and other	92	3 (3)
Other combinations	650	124 (19)
Skin applications:		
Nothing	1440	605 (42)
Liquid or soft white paraffin	512	77 (15)
Steroid cream	387	43 (11)
Aqueous cream	363	40 (11)
Lanolin free emulsifier	309	28 (9)
Other combinations	399	48 (12)
Securing agents:		
Gauze padding	1007	302 (30)
Nothing	701	147 (21)
Simple tape	544	87 (16)
Gauze padding and simple tape	416	50 (12)
Crêpe or crêpe and other	415	50 (12)
Other combinations	328	33 (10)
Bandages:		
Compression	1445	607 (42)
Tubigrip or Tubigrip and other	599	108 (18)
Compression and other	410	49 (12)
Light support or light support and other	334	33 (10)
None	270	22 (8)
Other combinations	352	35 (10)

**Table 4** Mean (SD) costs (£) per patient for use of all NHS services by group

Service	Clinic group	Home group	P value for permutation test
Leg ulcer treatment/year	804.03 (535.92)	681.04 (391.70)	0.05
GP services/year	18.33 (67.14)	29.82 (102.62)	0.31
Hospital services/year	55.24 (319.71)	152.22 (680.96)	0.17
Total costs	877.60 (674.30)	863.09 (865.32)	0.90
Total costs (with increased overheads for home visits)*	877.60	913.89	
Total costs (with other treatments excluded from home visits costs)†	877.60	788.17	
Total costs (with 10% increase in home visit costs)‡	877.60	931.19	
Total costs (with 10% reduction in home visit costs)‡	877.60	794.98	
Total costs (with 10% increase in clinic attendance costs)‡	958.00	863.09	
Total costs (with 10% reduction in clinic attendance costs)‡	797.20	863.09	

\*In baseline analysis no overheads were attributable to home visits as new working practices meant they were expected to be small. Overheads from other work,<sup>18</sup> believed to be much greater than for nurses in this study, were used to estimate costs.

†Other treatments are sometimes given within home visits. To estimate cost of this work non-treatment time was excluded from home treatment costs.

‡Mean cost estimates for home and clinic visits may be systematically biased because of missing data. Possible effects of any bias investigated by adjustment of visit costs by +/-10%.

for the prognostic variables the initial healing rate of clinic versus control patients was 1.65 (1.15 to 2.35).

In the clinic group, 35% (27/78) of patients who initially healed had a recurrence against 23% (14/62) in the control group. Some patients had several episodes of recurrences and re-healing over follow up. There was no evidence of a difference in the time to first recurrence between the groups (log rank test 0.78;  $df=1$ ;  $P=0.38$ ).

The mean time (in weeks) that each patient was free from ulcers during follow up was 20.1 and 14.2 in the clinic and control groups, respectively. On average, patients in the clinic group had 5.9 more ulcer free weeks (1.2 to 10.5) than control patients.

### Health status and satisfaction

For most dimensions of the SF-36 and EuroQol, health status deteriorated over time, with no difference between the groups. For three dimensions of the SF-MPQ there was evidence that the patients in the clinic group were more likely to experience a reduction in leg ulcer pain per month than control patients. Satisfaction was high in both groups, but there were no significant differences between the groups.<sup>26</sup>

### Economic evaluation

Complete data on resource use were available for 66% (214/323) of clinics and 62% (2110/3429) of recorded home visits. From these data, the mean (SD) cost per clinic attendance was estimated at £29.90 (£14.18), while the mean (SD) cost per home visit was estimated at £10.60 (£3.79).

The annual treatment cost was estimated for each patient by using the mean cost per treatment, the mean frequency of treatment, and patient specific data on weeks with an active ulcer. The mean annual treatment costs were £804.03 and £681.04 for the clinic group and the control, respectively; a difference of £122.99 (£1.56 to £234.84). The control group reported greater use of general practitioner and hospital services (table 4). When these NHS costs were combined with treatment costs, treatment for the clinic group

remained £14.51 more expensive (-£201.94 to £214.25).

One way sensitivity analysis<sup>27</sup> was undertaken to investigate the effect that different assumptions might have on mean costs. Changes in assumptions relating to treatment costs and overheads in the control group did not significantly affect the magnitude of costs (see table 4). Weeks free from ulcers was the most appropriate measure available for the cost effectiveness analysis. The additional cost for the clinic group treatment (£14.51) for achieving the benefit of 5.9 ulcer free weeks gave an incremental cost effectiveness ratio of £2.46 (-£31.94 to £99.12) per ulcer free week.

## Discussion

This subject is of economic importance, given the reported high annual cost to the health service for leg ulcer care.<sup>6, 28</sup> Although it was impossible to separate the effect of four layer bandaging or of the specially trained nurses from the clinic setting, the present study pragmatically tested the "package" of care which was already being used elsewhere.

The age distribution of the patients recruited was similar to those reported elsewhere.<sup>9, 10, 29, 30</sup> The baseline distributions of ulcer area and duration of ulcers, however, were much greater than those reported in other studies.<sup>10, 29, 30</sup> Within the context of other evidence on four layer bandaging the healing rate in the clinic group (34%) was lower than the rates reported as 74% and 69% in 12 weeks in dedicated clinics.<sup>9, 10</sup> This probably reflects the larger areas and longer duration of ulcers at baseline in this trial. The nearest comparisons were described in two observational studies as 40% (of leg ulcers) in 12 weeks<sup>31</sup> and 42% (of limbs) of people attending a leg ulcer clinic.<sup>32</sup> The limitations for use of four layer bandaging in a community clinic include the fact that some people are unable to leave their home and cannot tolerate or do not like the treatment.<sup>33</sup> Patients have to accept the additional time they must spend travelling and waiting for and having treatment.

The outcomes of the SF-36 and EuroQol seemed to show an overall deterioration in health status in both groups and no improvement in the clinic group associated with the superior healing rate. This could be because the sample size was based on the expected difference in healing rates between the groups and not in health status scores. Other possible explanations are that the measures of health status were not sensitive enough to detect the changes in health specific to the condition or that the time points for follow up did not coincide with the time when the patients improved. The patients did have health problems apart from their leg ulcer and some even died during the trial. Possibly the impact of their leg ulcer was less than the impact of their other health conditions and the tools were accurately describing a deteriorating health status.

### Economic evaluation

We undertook a modelling exercise to make the cost results more applicable to the real world. Clinic coordinators indicated that it was not necessary to use G or H grade nurses for the service. Reanalysis of the data with E grade salary costs gave a mean cost per clinic attendance of £27.61 and an annual NHS cost of around

## Key messages

- Leg ulcer clinics based in the community using four layer compression bandaging can be more clinically effective than usual care provided by the district nursing service
- Community based leg ulcer clinics could be provided more cost effectively than usual home based care for venous leg ulcers
- Recurrence of venous leg ulcers is an important variable that should be measured in future trials of venous leg ulcer care
- It is difficult to measure improvements in health related quality of life among people with venous leg ulcers

£740 per patient. The restrictions on throughput imposed by the trial produced an artificially high mean cost per attendance at the start and end of the trial. We estimated that by increasing throughput to more than 10 patients the mean cost per attendance could be reduced to £24.87 and the annual NHS costs to around £670 per patient. Altering both grade mix and throughput produced a mean cost per attendance of £23.37 and mean annual NHS costs of around £630 per patient (compared with £681 for traditional home treatment). With either scenario, the clinic treatment with four layer bandaging would dominate the home based treatments, being both cheaper and more clinically effective.

The mean cost per clinic attendance (£29.92) was slightly more than the cost reported in Riverside (£22.10 at 1995-6 prices).<sup>11</sup> The modelling work showed that small changes in the running of the clinics gave a similar cost (£23.37 per attendance). The mean cost per patient per year for clinic group patients in this trial (£804.03) was more than the cost identified in Riverside (£422 at 1995-6 prices). This difference could be explained by the healing rates in the Riverside study (80% of ulcers within 12 weeks).

Although the perspective of the economic evaluation was the NHS, a societal perspective would have included an account of patients' time and personal costs and loss of production due to treatment and poor health. The relative costs may have changed with this perspective as there were greater time costs for the patients in the clinic group.

This trial did not show the impressive healing effects reported in the early studies with four layer bandaging,<sup>9, 10</sup> but overall the clinic healing rates improved on care provided by the district nursing service. The improved clinical outcomes were achieved at a small incremental cost to the NHS. If the conditions of nurse grade and throughput per session were optimised, the clinic treatment with four layer bandaging would be more clinically effective and less costly for community trusts than treatment in the home.

We are grateful for the support of the former Trent Regional Health Authority (now NHS Executive Trent). We thank all the participating trusts, clinic coordinators, and the patients who took part in the trial.

Contributors: CJM was involved in the design of the research protocol, coordinated the setting up of the study, and participated in the data collection, management, analysis, and interpretation of

the data and the writing of the paper. SJW contributed to the statistical analysis and interpretation of the data and drafting and revising the paper. SD contributed to the economic analysis and interpretation of the data and drafting and revising the paper. KC and LB participated in preparing databases, data collection, management and analysis, and editing of the paper. JP was involved in setting up the study, preparing databases, data collection, management and analysis, and editing of the paper. CB initiated the formulation of the study hypothesis, secured the funding for the trial, and was involved in the conception and design of the study protocol and the editing of the paper.

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Conflict of interest: None.

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