CHAPTER 1

EXPERIMENTAL METHODS AND SIMPLE INTERVENTIONS: BANDAGES FOR LEG ULCERS

Wilkinson, I., Buttfield, S., Cooper, S. and Young, E. (1997) 'Trial of two bandaging systems for chronic venous leg ulcers', *Journal of Wound Care*, 6 (7): 339–40

What you need to understand in order to understand the exemplar
The basics of experimental design. *See Chapter 5, throughout but particularly sections 1 to 5, 9 and 12*
The table of results in the exemplar, how the data in it were tested for statistical significance and what this means. *See Chapter 7, sections 1 and 2*
The importance of blinding subjects and researchers to the treatments received and the problems of not doing so. *See Chapter 5, section 5*
The implications of randomising ulcers to treatments rather than individuals to treatments. *See Chapter 5, section 4*
Reporting by intention to treat. *See Chapter 5, section 8*
Odds ratios and confidence intervals. *See Chapter 7, section 10.4; see also sections 4 and 5*

Introduction

The treatment of leg ulcers is one of the largest single costs of medical and nursing care for older people. Even a small reduction in the cost of treatment, or a small increase in the rate of healing, would have a considerable impact on NHS costs when multiplied by the large number of people who suffer from the condition. This is to say nothing

of the pain, inconvenience and restriction caused to those who have ulcerated legs. The exemplar study for this chapter investigates the relative effectiveness of two compression bandaging systems. One of these is more expensive than the other. Thus, if they proved equally effective, and equally acceptable to patients, the way would be clear for deciding to use the cheaper system. The experiment is a randomised controlled trial (RCT), without blinding, and the topic is particularly suitable for investigation using the RCT design (see Chapter 5, sections 9, 11 and 12). There are unambiguous measures of success and the treatments are simple and easy to standardise. The key process is a physiological one, and it seems likely that what would facilitate wound healing under experimental conditions, would also do so in routine practice. However, there is other research which shows that rates of leg ulcer healing can be influenced by patients' beliefs and practitioners' faith in particular treatments. Hence the failure to blind subjects or practitioners is a design weakness, even though such blinding would have been impracticable (Chapter 5, section 5). Random allocation of ulcers to treatments probably ensured that practitioner/researcher bias could not influence who got which treatment.

As the authors themselves note, the sample for this trial was a little too small for confidence as to whether the two bandaging systems are indeed equally effective. The results are good enough, however, to be sure that if one treatment were more effective than the other the difference would not be very great. The experiment compared two treatments. Thus the finding that the treatments were 'equally effective' might mean that they were equally effective in promoting healing, or that they were equally ineffective in doing so. Healing might have occurred whether compression bandages were used or not. But this seems very unlikely since the research follows on from other published research comparing compression bandaging with other treatments and with no treatment at all, showing that compression bandages do increase healing rates. None the less, only some of the healing will be attributable to the use of compression bandages. Evidence from other research quoted in the text suggests that roughly 25 per cent of the ulcers would have healed had they been subjected to treatments other than compression bandaging.

TRIAL OF TWO BANDAGING SYSTEMS FOR CHRONIC VENOUS LEG ULCERS

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Summary

A four-layer bandaging system developed at Charing Cross Hospital has been found to be effective in healing chronic venous ulcers but is not available on the *Drug Tariff*. An alternative system was devised from bandages available on the *Drug Tariff* and a community-based randomised controlled trial was undertaken to compare the two systems. Twenty-nine patients with a total of 35 ulcerated legs were recruited.

Equal numbers of ulcerated legs healed using the two compression systems. Nineteen ulcerated legs did not heal, of which six were withdrawn from the trial – two in the trial system and four in the Charing Cross system. Of the 13 remaining ulcerated legs, for which treatment was completed, the mean reduction in ulcer area was 34% with the trial system and 39% with the Charing Cross system. The change in ulcer area was not statistically significant. However, a much larger trial is required in order to demonstrate definitively that the two bandaging systems are equivalent.

Introduction

Compression bandages have been advocated for the healing of leg ulcers since 1805.[1] Their two main functions are to control oedema and counteract the effects of venous hypertension. Physiological studies have shown that graduated compression (compression decreasing from the ankle to the knee) is most effective.[2] It has also been shown that compression bandages vary greatly in their characteristics,[3,4] with some losing 60% of the sub-bandage pressure exerted within four hours.

The four-layer bandaging system developed at Charing Cross Hospital[5] is widely used for applying compression.[6,7] It has the advantage of requiring changing only once a week as the bandages maintain the required degree of compression. In the Charing Cross study, healing rates of up to 69% were obtained at 12 weeks,[8] but the bandaging system has not previously been tested against a high-compression bandage in a randomised controlled trial. Other researchers have failed to reach these levels of healing, obtaining rates of 40%–50% at 12 weeks.[7,9] These are, nevertheless, a marked improvement on the 25% healing rate achieved with traditional treatments.[10]

However, as three of the component bandages for the Charing Cross system are not available on the *Drug Tariff*, they cannot be used in the community. We were uncertain whether other bandages available on the *Drug Tariff* could be used in a combination that would be as effective as the Charing Cross system. Such a treatment would then be available for use by nurses working in primary care.

Method

A four-layer bandaging system using bandages available on the *Durg Tariff* was designed to give a degree of compression (30–40 mmHg at the ankle) similar to that of the Charing Cross system. The system comprised a lightweight elasticated tubular bandage (Tubifast) over the dressing, lint applied in separate strips horizontally around the leg to absorb exudate and pad bony prominences, a high-compression bandage (Setopress) and a lightweight elasticated tubular bandage (Tubifast) to hold the high-compression bandage in position and prevent it from 'rucking up'.

The Charing Cross system was used as supplied in the package (Profore). This consists of orthopaedic wool (Soffban), a crêpe bandage, a light compression crêpe bandage (Litepress) and a cohesive bandage (Coplus). A knitted viscose primary dressing (Tricotex) was used under both systems and the cleansing solutions and emollients used were standardised.

Patients with an uncomplicated chronic venous ulcer on the lower leg who were being treated by a district or practice nurse were recruited with their GPs' permission. Exclusion criteria included a resting ankle brachial pressure index (ABPI) of <0.8, a known contact allergy to latex, evidence of cellulitis or an ankle circumference of <18 cm or >25 cm. Details of each patient's medical history and medications were noted.

When patients were considered suitable to enter the trial, informed consent was obtained and the patients' ulcerated legs allocated to one of two groups using numbers generated by random number tables. If there was more than one ulcer on a leg then the largest (<10 cm^2 and ≥ 10 cm^2) was included in the trial. Ulcer area is a strong predictor for healing. Ulcer size was calculated by multiplying the maximum length and width of the ulcer. All patients were reviewed by a dermatologist within two weeks of starting treatment to confirm that they had uncomplicated venous ulcers.

Nurses were taught to apply the bandages by the research nurse who continued to attend the surgery until agreement on competency was met. Measurements of sub-bandage pressure were not made under either regimen.

Patients were reviewed weekly when the bandages were changed. The ulcers were measured at four, eight and 12 weeks. The main outcome measure was healing of the ulcer, defined as a continuous layer of epithelial cells across the ulcer surface. This was assessed by the community nurse, who was not 'blind' to the bandaging system. When ulcers healed, the patients were supplied with Class 2 compression stockings.

Results

Twenty-nine patients with a total of 35 ulcerated legs were recruited. Recruitment was slow as fewer suitable patients than anticipated were willing to enter the trial. There were no significant differences between the groups in age, sex, duration or size of current ulcer, number of smokers or other medical conditions. Initial ulcer area was not significantly different – trial system mean 8.6 cm^2 (range 0.25–45 cm^2), Charing Cross system 11.2 cm^2 (0.25–49.6 cm^2).

The outcome of treatment for all ulcers is shown in Table 1. The odds ratio for healing with the Charing Cross system compared with the trial system is 1.11 (95% confidence interval 0.24–5.19). Nineteen ulcers did not heal. Of the 13 ulcers that completed the trial without healing, the mean reduction in area was 34% with the trial system and 39% with the Charing Cross system. This difference is not significant (*t*-test 1.4, df 5, $p = 0.89$). Six ulcers were withdrawn from the trial – four in the Charing Cross group and two in the trial group (Table 2). No patients were lost to follow-up. The results were analysed on the basis of intention to treat.

Table 1 Outcome of treatment at 12 weeks

Bandaging system	Healed	Not healed	Withdrawn
Charing Cross ($n = 17$)	8 (47%)	5 (29%)	4 (24%)
Trial system ($n = 18$)	8 (44%)	8 (44%)	2 (12%)

$\chi^2 = 1.3$; df $= 2$; $p = 0.51$

Table 2 Reasons for withdrawal from treatment

Bandaging system	No. of ulcerated legs	Reasons for withdrawal
Charing Cross	1	Developed cellulitis
	1	Bandage uncomfortable/slipped
	1	?Allergic to bandage
	1	Bandage too painful
Trial system	1	Leg painful, possibly infected
	1	Bandage too painful

Discussion

The healing rates obtained with both systems at 12 weeks are similar to other published rates using four-layer bandaging. This suggests that the bandaging technique is correct.

The trial system was better tolerated by patients than the Charing Cross system as shown by the smaller number of withdrawals from the trial group, but with the small numbers involved this may be due to chance.

There is no significant difference in the number of ulcers healed by the two systems but the 95% confidence interval for the odds ratio is very wide (0.24–5.19) because of the small number of participants. A much larger trial is needed to demonstrate definitively that the two bandaging systems are equivalent. This study has, however, highlighted the difficulty in recruiting a large number of patients with suitable ulcers into a trial.

The majority of patients with leg ulcers are managed in primary care. It is therefore important to have effective treatments that can be used without referral to hospital. Nurses applying the bandages must receive adequate training in the assessment of leg ulcers, including measurement of ABPI, and in applying compression bandages. Inappropriate application or excessive compression can cause considerable damage to the underlying skin.

The results of this trial show that the benefits of compression bandaging in the treatment of chronic venous leg ulcers can be available to all patients in the community as the bandages used are available on prescription.

References

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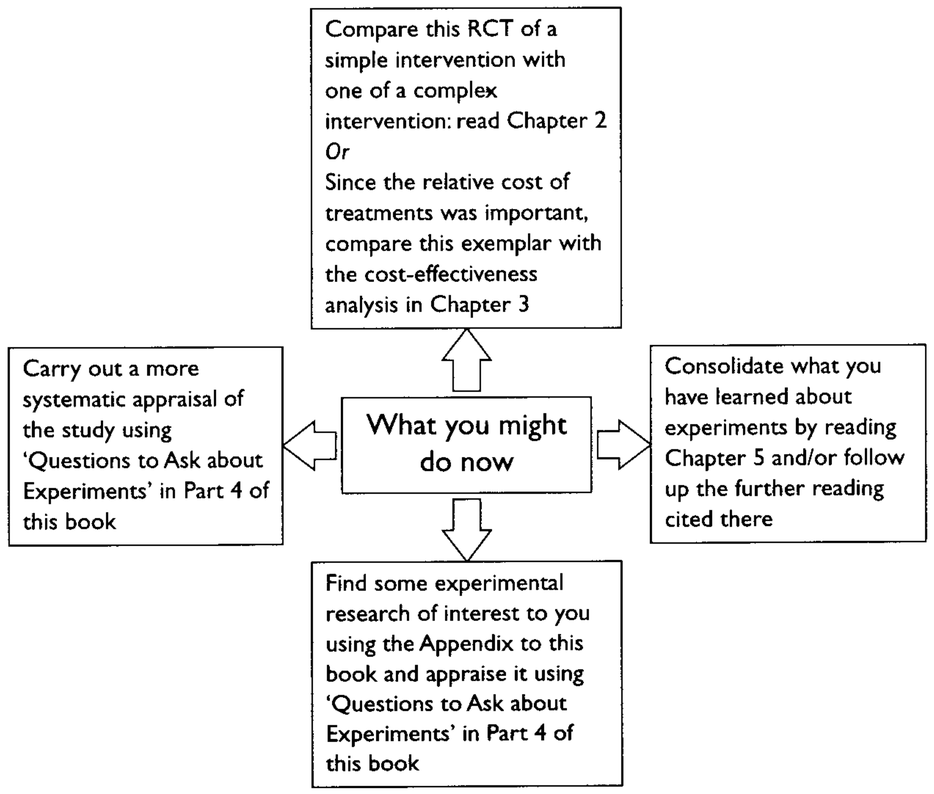
What you might do now



CHAPTER 2

EXPERIMENTAL METHODS AND COMPLEX INTERVENTIONS: CASE MANAGEMENT IN MENTAL HEALTH CARE

Marshall, M., Lockwood, A. and Gath, D. (1995) 'Social Services case-management for long-term mental disorders: a randomised controlled trial', *The Lancet*, 345: 409–12

EXEMPLAR

What you need to understand in order to understand the exemplar
The basics of experimental design. *See Chapter 5, throughout but particularly sections 1 to 3, 5 to 9 and 12*
'the data were first evaluated to ensure normality of sampling distributions, linearity and homogeneity of variance' *See Chapter 7, section 6*
The table of results (Table 3). *See Chapter 7, section 10.1*
Why the researchers used 'off-the-peg' instruments rather than inventing their own. *See Chapter 6, section 1*
The problems caused by subjects dropping out of experiments. *See Chapter 5, section 8*
That given the extreme scores of all subjects on entry, some of the improvement shown may be due to regression to the mean. *See Chapter 5, section 6*
The difficulties arising from non-standardised treatment of subjects within arms of an experiment. *See Chapter 5, section 7; Chapter 7, section 7*
The problem of conducting experiments about complex interventions. *See Introduction to this Chapter; Chapter 5, section 9*