Community Leg Ulcer Bandaging Study: Lessons Learned in a Pilot, Randomized Controlled Trial

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Abstract
Compression is the cornerstone of venous leg ulcer (VLU) care but comparative effectiveness evidence is limited, especially regarding home care. In preparation for a large, community-based randomized controlled clinical trial (RCT), the “Canadian Bandaging Trial” (CBT), a pilot study was conducted to assess the practicality of the CBT study protocol. Nurses who provided home care also performed the research intervention and outcome measurements. All trial procedures were implemented to examine the following aspects of the study protocol: 1) eligibility screening, recruitment, enrollment, and randomization procedures; 2) integration of intervention protocol with usual clinical routines; 3) data collection and management and outcome measures; and 4) database creation and testing. Guided by a Pilot Research Process Framework (PReP), this 6-month pilot RCT was conducted at two community-based sites in Ontario, Canada. Participants included 12 persons with VLUs, 40 nurses providing leg ulcer care, and two site investigators. Individuals with a VLU were randomized to a four-layer or short-stretch compression bandage. Eligibility screening and randomization procedures were found to be efficient but the ratio of screened (49) versus enrolled (12) patients was low and suggested the need for nine additional clinical sites, a change in ulcer size eligibility, and research to evaluate how to incorporate persons with diabetes in leg ulcer trials. Screening practices, data collection form concerns, and wound photo assessment outcomes issues were addressed. The results of this study improved and streamlined the large RCT quality and processes and confirm the value of pilot studies. Research to test the usefulness of the PReP framework for other pilot studies is needed.

Key Words: venous ulcers, home health care, randomized controlled clinical study methods, pilot study, study framework

Potential Conflicts of Interest: The authors disclose they have no competing interests.
elastic systems that compress the leg during standing, sitting, or walking (short-stretch). The short-stretch bandage technology provides high pressure with muscle contraction against a fixed resistance and lower pressure at rest and is made from relatively inextensible materials such as cotton applied over a layer of padding. The four-layer bandage (elastic system) can provide high pressure at rest and less pressure with muscle contraction. This four-layer system has five components (a wound contact layer and four bandages); the precise components used depend on the circumference of the ankle. Four-layer compression (elastic) has high initial supply costs, requires special training for nurses, and can remain in place for up to 7 days. Short-stretch compression bandages can be washed and reused, reducing supply costs, but they might require more frequent reaplication. Other factors include individual preferences, social circumstance (eg, ability and willingness to wash bandages at home), and comfort. To date, substantive clinical, practical, and economic differences can be found among the classes of compression technology, with no clear evidence to indicate which system is the most effective and efficient choice for use in the community management of leg ulcers. At the beginning of this study, the only two randomized controlled trials (RCTs),\textsuperscript{14,15} conducted in the UK, that compared these two technologies were underpowered.

To answer the question about bandaging effectiveness, a sample size of 414 participants would be needed to achieve 80% power at 0.05 level of significance, based on time to healing (MCT-110636)\textsuperscript{17}; thereby, necessitating a multisite trial.

The research team and clinical partners agreed a pilot study would be necessary before conducting the large trial. Before the pilot trial, routine practices for leg ulcer care, nurse education needs, and preferred communication and liaison strategies were assessed and study orientation and training sessions were conducted at pilot study sites.\textsuperscript{18}

The pilot RCT study conducted in preparation for the large-scale “Canadian Bandaging Trial” (CBT) is described. The CBT was designed to compare four-layer to short-stretch technology. The purpose of the pilot was to assess the practicability of the CBT study protocol and determine protocol revisions that might be required before launching the CBT.

Methods

This pilot study was guided by a Pilot Research Process Framework (PReP)\textsuperscript{19} and the following working definition of pilot study — ie, a smaller version conducted in preparation for a proposed study in order to develop and/or refine the research plan and methodology, or to assess its feasibility. The PReP framework in conjunction with the specific procedures and requirements for the larger CBT trial guided methodological planning for the pilot study.

Study design. This was a pilot RCT with patients allocated to one of two treatment arms: short-stretch or four-layer bandage technology. It was a pragmatic trial, whereby nurses who normally deliver care in the community would be involved in the intervention, outcome measurements, and initial and ongoing assessments, as outlined in Figure 1.

To examine all trial procedures, a 6-month time frame was chosen to enable a 3-month recruitment time frame and 3 months’ follow-up with a reasonable number of participants.

All trial procedures (see Figure 1) were implemented to examine practicality of their integration into usual clinical care routines: 1) eligibility screening, recruitment, enrollment, and randomization procedures and study retention; 2) intervention protocol; 3) data collection and management and outcome measures — ie, quality, completeness, and ease of use; and 4) database creation and testing.

Settings and participants. The pilot RCT was conducted at two community-based sites that represented different service delivery models. One site was a large not-for-profit nursing agency providing service in an urban-rural area with care delivered to the leg ulcer population through nurse clinics or traditional home care visits. The second site was a small community-based company of nurses dedicated to wound care and responsible for performing all initial assessments for wound referrals and providing ongoing care for complex wounds such as leg ulcers. This site had at least five enterostomal therapists, a category of nurses specially trained in wound and ostomy care. The site investigators were clinical experts and champions for best practices with wound care within their organizations; they would be instrumental in assisting with the nuances of operationalizing the protocol in their settings. Researchers and site investigators agreed on a sample size of 12 study participants with leg ulcers to meet the objectives of this study.

Ethics approval for this study was obtained from the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board and through administrative review as required from each site.

Data collection. One of the authors (LJS) maintained a log to track issues arising and actions taken related to the trial protocol and procedures. She also took field notes during teleconferences, meetings, and home visits to clients with their assigned nurse, emailed correspondence, and held informal interviews.
with site investigators and nurses providing leg ulcer care. Data related to screening, recruitment, retention, and errors or missing information on data collection tools were summarized and distributed to site investigators for discussion at monthly teleconferences.

Trial procedures examined (see Figure 1).

Eligibility screening, recruitment, enrollment, and randomization procedures and study retention. The procedures for eligibility screening and recruitment were implemented by nurses during routine clinical care. Clinical nurses used standard initial assessment and screening forms considered as part of normal intake to home care to determine if a person was eligible for the study (see Table 1 for eligibility criteria). The initial screening included an ankle-brachial pressure index (ABPI) performed by experienced nurses to rule out significant arterial disease. Once eligibility was determined, the nurse introduced and explained the project, providing a detailed verbal and written explanation. Individuals were given 24 hours or until their next visit to consider the information in order to decide about participating and signing the consent form. Site investigators documented the reasons for ineligibility or declining to participate and forwarded this information to the research center. A flowchart was created to track recruitment and retention over the course of the pilot study to determine the number of sites required for the larger
Once consent was obtained, the nurse identified the reference ulcer and proceeded to randomize the participant to the intervention. The nurse called a research assistant at the research center using a toll-free number to obtain the client’s research number and bandaging system to be used and recorded this information on the client’s file as required. A computer-generated schedule of randomization was used to allocate participants to short-stretch or four-layer bandaging treatment. Participant allocation was kept in sealed, opaque, serially numbered envelopes for each site. Based on the Margolis’ Prognostic Model,20 participants were stratified by re-

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<tbody>
<tr>
<td>• Leg ulcer ≥1 cm in any one dimension</td>
<td>• Diagnosed with diabetes mellitus — insulin-dependent or using oral hypoglycemics</td>
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<tr>
<td>• Ulcer a minimum duration of 1 week</td>
<td>• Participant failed to improve over a 3-month period with either trial bandage before the study</td>
</tr>
<tr>
<td>• Ankle-brachial pressure index (ABPI) ≥ 0.80</td>
<td>• Symptoms of cognitive impairment noted</td>
</tr>
<tr>
<td>• Participant can provide written informed consent</td>
<td>• Participants previously enrolled in the study but now have ulcer recurrence or a new ulcer</td>
</tr>
<tr>
<td>• Participant can communicate in English or translation available</td>
<td>• Age less than 18 years</td>
</tr>
<tr>
<td>• Participant 18 years of age or older</td>
<td>• History of all types of malignancy (except for non-melanoma skin cancer)</td>
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Note: Inclusion criteria later revised to add “Clinical presentation of venous insufficiency” and “Leg ulcer larger than 0.7 cm in any one dimension”

Once consent was obtained, the nurse identified the reference ulcer and proceeded to randomize the participant to the intervention. The nurse called a research assistant at the research center using a toll-free number to obtain the client’s research number and bandaging system to be used and recorded this information on the client’s file as required. A computer-generated schedule of randomization was used to allocate participants to short-stretch or four-layer bandaging treatment. Participant allocation was kept in sealed, opaque, serially numbered envelopes for each site. Based on the Margolis’ Prognostic Model,20 participants were stratified by research site, ulcer duration (less or greater than 6 months), ulcer size (less or greater than 5 cm²), and ulcer status (new versus recurrent ulcer). When an individual presented with multiple ulcers (either on one leg or both) the largest ulcer was designated the reference ulcer and followed during the trial.

Intervention protocol: integration with usual clinical routines. As a pragmatic trial, the CBT question is whether the application of different compression systems, as applied by trained community nurses, results in different healing times. Nurses in the community applied the allocated bandage (four-layer or short-stretch) according to standard protocols developed in a preliminary trial.18 The primary dressing of choice to be used with either compression system was a low-adherent dressing with a low potential to cause skin sensitivity. Normal practice at the clinical sites was maintained — eg, progression to other dressing types if clinically indicated. Each center had trained compression experts who accompanied nurses on clinical visits during the early period of the study and when necessary to identify problems with bandage application. Author LJS gathered field notes and nurse feedback to examine the ease with which the protocol was integrated with routine clinical care.

Data collection and management, outcome measures: quality, completeness, ease of use. The data management center prepared sets of pre-packaged, labeled forms for each measurement time period and mailed them to the research sites. Data collection forms were color-coded to more easily differentiate among various data and collection time points. Data were collected by nurses at baseline (initial assessment) and at regular measurement time points (see Figure 1). Baseline data collected by the RN included a complete initial assessment and pain and quality-of-life measures (ie, McGill Pain Scale, Short Form 12-Item Health Survey [SF-12], EuroQOL EQ-5D). The research center and site agencies used tracking databases to set up reminders for pending data collection. Site-specific administrative processes were developed to communicate to front-line nurses when data collection measurements were due. For example, at one site a checklist was kept in the clients’ charts with details of when the data collection was due and what forms to complete for the nurse to initial when documentation was complete. Other methods included computer print-outs of scheduled visits, flagged to indicate the assessment was due. Tracking logs were used to identify issues arising including missing data and error rates on trial data collection tools and for nurse feedback.

Outcome measures (area of the reference ulcer, ulcer photographs) were collected using pre-established protocols. Each site could use a product of their choice for ulcer tracings but the tracings 1) could not have been in contact with the surface area of the wound, 2) had to be labeled with the date and research ID, and 3) had to be stapled or taped to the assessment tool or the monthly status report and forwarded to the research assistant who calculated an accurate ulcer area using computerized planimetry.21 This method measures volume by creating a two-dimensional or planar image from the wound tracing. A transparent sheet of graph paper was laid over the wound tracing using a computer. The number of complete graph squares within the boundaries of the wound were summed to produce a scale area calculation, which was stored in the research database.

Because attending nurses could not be blinded to the intervention they were applying, a dated digital photograph of the reference ulcer was taken at baseline to provide a visual record of ulcer size and condition at enrollment as described by Houghton et al.22 A photograph also was taken of skin status at time of healing. Both baseline and healed photos were forwarded by email to an International Expert from the UK, masked to allocation, for verification of healing.

Data analysis. Data were analyzed to examine issues regarding implementation of the trial procedures to determine
Figure 2. Study flowchart for pilot randomized control trial.
how the CBT study protocol might need to be revised. Qualitative data from field notes and tracking logs (nurse feedback) were transcribed and sorted into major themes at each stage of the research process to guide improvements in ongoing pilot processes and to further develop the study protocol for the larger CBT. Quantitative data regarding errors and missing information on data collection instruments were entered into an Excel database and descriptive statistics were calculated (sum, percents).

All other quantitative patient data were entered into the Statistical Package for Social Sciences, Version 11.0 (SPSS, Chicago, IL), with the exception of data on a “visit treatment and supply” form, which were entered into an Excel database. Statistical analysis of the data was performed to identify any issues related to the quality of the data.

Results

Pilot cohort. Participants included 12 individuals with leg ulcers; 40 nurses with advanced education, skills, and training in the assessment and management of leg ulcers; and two site investigators. The majority of the patient participants with ulcers were women (67%), older than 75 years (67%), and had a previous history of ulcers (67%). Of those who reported having a previous ulcer history, four (50%) had used compression in the past. Of the 83% who reported having leg ulcer pain, 60% were receiving pain medication. Seven persons (58%) had an ulcer >5 cm² and two (17%) had an ulcer duration >6 months. The mean summary scores on the SF-12 were 39 (physical component) and 52 (mental health component) (see Table 2).

VLU population. The VLU population was similar at both study sites. Site investigators estimated that approximately 95 of the 373 persons with VLUs to whom they provide services per year were without diabetes and, therefore, eligible for high compression (see Table 3).

During the 3-month pilot recruitment period, 49 people were screened to recruit 12 participants (see Figure 2). Of the 15 people eligible to participate, three (20%) declined because they refused compression bandages or for other reasons. No one withdrew from the pilot study or was lost to fol-
Table 3. Venous leg ulcer population at study sites

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>SITE 1</th>
<th>SITE 2</th>
<th>TOTAL</th>
</tr>
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<tbody>
<tr>
<td>Number of patients serviced/year</td>
<td>203</td>
<td>170</td>
<td>373</td>
</tr>
<tr>
<td>Number of new referrals/year</td>
<td>188</td>
<td>123</td>
<td>311</td>
</tr>
<tr>
<td>Number of patients serviced/week</td>
<td>40</td>
<td>13</td>
<td>53</td>
</tr>
<tr>
<td>Number of patients eligible for high compression (HC)</td>
<td>56</td>
<td>66</td>
<td>122</td>
</tr>
<tr>
<td>Number of patients with diabetes eligible for HC</td>
<td>10</td>
<td>17</td>
<td>27</td>
</tr>
<tr>
<td>Percent who would normally be eligible for HC but ineligible for study due to diabetes</td>
<td>18%</td>
<td>26%</td>
<td>22%</td>
</tr>
<tr>
<td>Number of nondiabetic patients eligible for HC - not diabetic (per year)</td>
<td>46/year</td>
<td>49/year</td>
<td>95</td>
</tr>
</tbody>
</table>

Recruitment, enrollment, randomization, and study retention issues.

Inconsistent screening practices, including screening for diabetes. Discussions held between researchers and site investigators revealed that screening practices were inconsistent because some nurses were not completing the screening process if they thought the person with a leg ulcer would not be eligible (ie, persons with diabetes). For example, initial screening of the venous ulcer population at these sites via site navigators revealed that persons ineligible for high compression due to diabetes represented 22% of the combined populations (18% Site 1, 26% Site 2) (see Table 3). In contrast, during the screening for this pilot study by the community nurse, the number of persons found to be ineligible due to diabetes only represented 10% (n = 5 persons with diabetes of 49 screened) (see Figure 2). As a solution, nurses were instructed to screen all persons with a leg ulcer so an accurate profile of the statistics for factors rendering persons ineligible for the study, including diabetes could be captured.

Exclusion of persons with diabetes. Excluding persons with diabetes reduced the number of participants potentially eligible for this study. Research colleagues in Canada and the UK and the clinical site investigators were consulted about the possibility of including persons with diabetes. As a solution, the research team decided that as a safety precaution, persons requiring treatment for diabetes would remain ineligible if they were on oral hypoglycemic drugs or taking insulin. Persons managed with diet and exercise would be eligible.

Screening tool deficiency: flag lacking for venous insufficiency. Nurses pointed out that the screening tool lacked a “flag” for clinical presentations of venous insufficiency. As a result, some people appeared to be eligible on the screening tool although they had no clinical presentation of venous insufficiency (for example, a pressure ulcer on the heel). The solution was to add the phrase “clinical presentation of venous insufficiency” to the screening tool to ensure persons were flagged as ineligible for compression and the study. The phrase also was added to the inclusion criteria list to avoid confusion.

Ulcer size of 1.0 cm and exclusion of participants. Nurse feedback indicated that in many cases (n = 12, 25% of those screened) people were not eligible because their ulcers were <1 cm. However, many had recognizable ulcers larger than 7 mm. This issue was addressed by modifying eligibility criteria to a minimum of 7 mm in any one dimension because the intent of the criteria was to include only ulcers, not eczema erosion. The clinical group felt confident that ulceration could be differentiated with this size.

Treatment provision pending decision to enroll. Nurses were unclear about what treatment to provide while waiting for a client to decide about study enrollment. The nurses suggested applying tensor bandages (elasticized bandages to hold tension and provide support). The researchers and clinical experts decided that usual practice would be maintained but carefully recorded and to ensure the start date of the actual trial intervention was documented.

Intervention protocol — integration with clinical care issues.

Bandage layers. Important practical questions not detailed in the original intervention protocol were raised — eg, whether additional bandage layers could be applied over the short-stretch bandage if necessary for retention or if a third short-stretch bandage could be used for a larger leg. The clinical and research team consulted with an international expert on compression technology (E.A. Nelson) and it was decided that nurses should continue their usual clinical practice of intervention application with clear documentation and that if extra retention layers were necessary, the product should be consistent across sites.
DO NOT DUPLICATE

2). The experience was that data could be successfully compiled and returned to the research center for each client at each repeated measure time point. Overall, the streamlined data collection measures, end-of-treatment measures, and post-healing follow-up measures. Healing rates relevant to the CBT stratification are shown in Table 4.

Data collection, management, and outcome measures issues. Participants were followed for 3 months, which enabled a reasonable field test of all instruments. Before the end of the pilot study, the ulcers of eight people healed and two people discontinued the intervention (see Figure 2), enabling researchers to evaluate the practicality of the healed wound data collection measures, end-of-treatment measures, and post-healing follow-up measures. Healing rates relevant to the CBT stratification are shown in Table 4.

Form completion. According to plan, no “pending” data collection measures were noted in this small study (see Figure 2). The experience was that data could be successfully compiled and returned to the research center for each client at each repeated measure time point. Overall, the streamlined data management flow procedures worked well on the pilot sites.

With “post-healing follow-up” data collection, site investigators reported inconsistencies in the timing of post-healing follow-up and difficulty contacting these people, indicating that more consistent tracking mechanisms would be necessary. Thus, the research team developed scheduling logs for sites to track when these calls were due, procedures with time frames for repeated contact efforts by phone, and a pro forma letter before it was finally determined someone was lost to follow-up.

Missing data. Initially, there were some issues with the quality and completeness of data collected, which nurses and site investigators often attributed to issues of acceptance and ease of use of trial data collection tools and case record. The most frequent errors (reported as a percent of missing data on all forms) included missing dates of ulcer onset (42%), adverse events (25%), visit time (17%), supply size (17%), supply number (10%), and inaccurate completion of many areas in the medication section (17% to 25%). To address relevant concerns, issues of data quality and completeness were examined with site investigators through monthly teleconferences. Problems with the tools were identified and potential solutions and improvements offered. In particular, the monthly debriefing was determined to be ongoing with the full scale trial to deal with data issues as they arose.

Form revisions. Substantive feedback from nurses was written directly on the tools. This led to suggestions for form changes — eg, include additional reasons for bandage changes and additional supplies used. Visiting nurses and patients offered suggestions during home visits regarding a “participant monthly expense” form, noting it did not capture cost data related to their purchase of larger shoes to wear over the bandage and that some items needed rewording for ease of use and understanding. In response, key questions were highlighted and re-formatted and site-specific, easier to complete supply forms were developed. These revised data collection tools were perceived to be clearer, easier to use, and enabled a more acceptable fit with usual practice. Subsequent revisions were made to the trial database — eg, the addition of variables and values, congruent with the new forms.

Ulcer tracings (outcome measure). Nurses integrated the ulcer tracing protocol with their usual clinical routines with little difficulty. While each site used different tracing materials, tracings did not come in contact with the surface of the open wounds and were returned to the research center according to protocol. Nurses reported that during home visits they oc-

| Table 4. Time to healing by stratification (Total healed, N = 8) |
|-----------------|----------------|------|------|------|------|
| Stratification type | Frequency (n) | Mean time to heal (weeks) | SD | T-test df | Significance (two-tailed) |
| Ulcer duration | | | | | |
| < 6 months | 8 | 5.75 | 3.73 | N/A N/A N/A |
| ≥ 6 months | 0 | N/A | N/A | | |
| Ulcer size | | | | | |
| < 5 cm² | 2 | 3.50 | 0.71 | -0.98 6 | 0.36 |
| ≥ 5 cm² | 6 | 6.50 | 4.09 | | |
| Previous ulcer | | | | | |
| Yes | 4 | 6.25 | 5.19 | 0.35 6 | 0.74 |
| No | 4 | 5.25 | 2.22 | | |
| Research site | | | | | |
| Site One | 5 | 5.6 | 4.72 | -0.14 6 | 0.90 |
| Site Two | 3 | 6.0 | 2.00 | | |

Patient or family application of bandage. Nurses were asked whether clients or their family members could be taught to apply the bandages. The clinical and research team again consulted an international expert on compression technology (E.A. Nelson) and the decision was that if the client or family would normally be taught to do periodic bandage changes, this practice would continue. Trial forms were modified so this practice could be documented and flagged for analysis.

These intervention decisions reflect the key ingredient to a pragmatic trial — ie, to compare interventions as they are used in real life practice. The intent is not to answer the question, Is there a difference between short-stretch (inelastic) and four-layer (elastic) bandages for healing venous ulcers? Instead, the intervention protocol for the CBT reflects this approach and rather than controlling aspects of care, the focus is on acceptable fit with usual practice. Subsequent revisions were made to the trial database — eg, the addition of variables and values, congruent with the new forms.
 occasionally forgot to take the ulcer tracing before applying the compression bandage. This measure was obtained during their next visit to avoid an unnecessary dressing change. However, with increased familiarity with the process, this occurred less frequently.

**Wound photos (outcome measure).** Concerns regarding the blind assessment of wound healing were raised by the international expert who examined the wound photos. The way the pictures were taken posed photo quality problems and in some cases exposed the treatment arm and blinding was lost. Issues included: 1) light reflection from creams made it hard to see the wound, 2) photos showed the bandage on the leg and blinding was lost, 3) not all relevant parts of the leg could be seen, 4) an anatomical reference point was needed to know if it was the same ulcer from the same leg, 5) leg length was not always on the widest part of the photo, and 6) a standard format and resolution were needed for all photos to improve imaging. Because time-to-healing would be the primary outcome measure of the larger trial, it was essential that these issues be fully resolved. To rectify the problems, an international expert on compression technology (E.A. Nelson) was consulted and subsequently revisions were made to the wound photo protocol, including taking two photos (one of the leg and one of the wound) to provide an anatomical reference point. Samples of the required type and quality of photos were sent to all site investigators to review with nurses responsible for obtaining this outcome measure.

Overall, providing nurses with this opportunity to gain experience with the data collection and management protocols resulted in streamlined forms and processes, which improved data quality and completeness. It was clearly beneficial for the site investigators to serve as a primary point of contact for site nurses locally and the research center, to facilitate the collection and transmission of data.

**Analysis procedures.** It should be noted that no significant issues arose throughout the analysis procedures. Form revisions were followed by relevant database revisions.

**Discussion**

The purpose of this pilot study was to examine and refine the procedures to be utilized in a large-scale CBT. Results presented relate to the practicality and planning information for the research protocol and important adjustments were made to the final trial protocol. The pilot study was not intended to enable statistical comparisons between the two compression technology interventions and therefore was not powered to do so. No similar pilot studies of large-scale community bandaging RCTs could be found in order to compare findings. Interesting results warrant further discussion.

**Study sites.** The participating pilot sites represented delivery systems in one Canadian province serving both urban and rural home environments. However, the necessity of an additional nine sites for the larger CBT would mean more varied community service delivery of leg ulcer care, including services under different provincial health jurisdictions with different organizational mechanisms and possibly providing only urban or only rural services. Careful consideration will need to be made when recruiting new sites, including communication across various time zones, accessibility to the bandaging technologies, site and nurse learning needs, and whether service delivery environments are conducive to the required 1.5- to 2-hour initial nursing assessment. Both participating sites had experience doing research, but more issues may arise in new sites that may be unfamiliar or inexperienced with managing research protocols. Lastly, differences in policies, procedures, and practices across numerous community agencies will mean that standard template protocols will need to be complemented by site-specific processes (eg, site-specific supply and treatment records, tracing materials, processes to alert nurses of pending data collection, and various service delivery system processes to carry out the intervention and outcomes data collection).

**Nurse experience with intervention.** The clinical effectiveness of any compression system might be influenced by nurses’ familiarity with it. Before this pilot study, a full assessment of site and nurse learning needs was conducted, including previous experience with both treatment interventions. Special training was provided regarding the application of both short-stretch and four-layer technologies, including written protocols and ongoing support from the research team and clinical experts. Little staff turnover occurred, eliminating the need for education of new staff during the pilot.

One large bandaging trial provided a retrospective assessment of patterns of bandage use at participating study sites. For the CBT, it will be important to continue the ongoing needs assessments and training, especially as new sites are recruited and staff turns over, to ensure bandaging skill and other bandage-related decisions are optimal throughout the trial. In the event a patient is instructed on the bandaging technique, it will be imperative to examine any differences in outcome related to this flagged variable.

**Allocation concealment.** As with any trial, it will be important to ensure the attending nurse who recruits participants does not have foreknowledge of the treatment group to which the person will be allocated in order to avoid patient selection bias. This allocation concealment was achieved in the current study by using a remote telephone randomization system where the allocation was revealed only after the recruiting nurse provided the individual’s enrollment information. This process is similar to that used in the VenUS I Trial; few other studies reported using this concealment process (six out of 26 trials in the literature).

**Outcome assessment blinding.** Ideally, the person measuring trial outcomes should be unaware of the allocation. However, patients in this pilot trial (and forthcoming CBT) are treated in community settings where it would be logistically impossible and entirely impractical to provide an additional blinded provider during a visit to assess the ulcer after
removal of bandages. Neither the patient nor the nurse applying the bandages could be blinded to the treatment and the system does not have the capacity to supply additional nurses even with compensation. However, measures were taken to reduce the potential bias (eg, sending wound photos to an independent international expert to verify healing).

**Pain and quality-of-life issues.** Living with chronic leg ulcer pain is a recurring theme in many studies.\textsuperscript{24-28} Quality of life is one of the outcomes in the CBT and will be explored further. It would be useful to examine in the large-scale CBT whether changes in the condition of the ulcer had an impact on the levels of pain reported or if the pain may be associated with other health conditions common to this population.

**Short-stretch bandage and four-layer bandage technology.** Since the start of this pilot study, a large UK study\textsuperscript{16} (VenUS 1) has been published; it concluded that the four-layer bandage was more clinically and cost effective than the short-stretch bandage — ie, the four-layer bandage was associated with a higher healing rate, a reduced median time to healing, and lower costs.\textsuperscript{16} Persons with diabetes were excluded from the VenUS 1 trial because they were regarded as at higher risk for compression damage due to increased microvascular disease.\textsuperscript{16}

The CBT (Canadian RCT) was funded and initiated in 2004 and recently completed. It evaluated the effectiveness of these two compression technologies widely used in Canada. The overall planning process and preliminary work for the CBT is detailed elsewhere.\textsuperscript{18} There is no experience with a large-scale bandaging trial in these settings in the Canadian context, which is different from the UK with respect to healthcare delivery, scopes of practice, system organization, and climate. It will be exciting to compare the results of the CBT to those of the UK trial, and hopefully eventually pool the data in a meta-analysis with other similar trials to conclusively answer questions about the effectiveness of these two classes of compression technology.

**Conclusion**

This study demonstrated the value of piloting the process, procedures, and measures contemplated for use in a large RCT. The pilot was instrumental in gaining experience with the protocol and the hands-on experience provided data to make protocol revisions in preparation for the large-scale trial. Additional sites were recruited as a result of this pilot study. Lessons learned improved the efficiency and start-up of the larger trial and provide implications for others implementing large-scale community trials. This is an important area in wound research because delivery of care occurs largely in the community and remains a relatively new research frontier. Piloting also can be a way of introducing a larger study to the site in a nonthreatening way — ie, there is not as much pressure because the purpose of the pilot is to learn about the site and process and not “study” them per se.

This study has implications for future research. First, this study adds to the literature on pilot studies. There is a lack of published studies meeting recognized pilot study aims, as well as a lack of pragmatic multicenter community pilot study designs whereby the research protocol is interfaced with routine clinical care.\textsuperscript{19} Pilot studies need to be published that meet recognized pilot study aims and processes in preparation for larger trials. Second, research is needed to evaluate how one can monitor and incorporate the population with diabetes in leg ulcer trials. Practice guidelines\textsuperscript{9,10,13} recommend that compression be used with caution in persons with diabetes and a specialist referral is advised. This recommendation is based on Level C evidence (ie, evidence from expert committee reports or opinion, and/or clinical experience or respected authorities). It indicates the absence of directly applicable studies of good quality. As such, research is needed to provide guidance for the development of best leg ulcer practice for persons with diabetes. Lastly, research to test the PReP Framework\textsuperscript{19} in future pilot studies in various settings would contribute to knowledge on pilot study methodologies. The framework was useful to guide planning of this community leg ulcer RCT pilot, but its usefulness in other settings (hospital or other health sectors), different health/illness populations, or for different research designs has not been studied. Research to further develop and validate the framework or to modify it as a useful tool for planning and conducting pilot studies is needed.

**Acknowledgment**

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