Framework for Planning and Conducting Pilot Studies
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Abstract
Researchers working with partners in home care to plan a pragmatic multicenter community-based, randomized, controlled trial for leg ulcer compression treatment realized a smaller pilot study would be necessary. Because no framework for conducting pilot studies could be found, the authors developed a framework for pilot study methodology to inform the planning of such research. To this end, an integrative literature review was conducted, guided by an explicit search strategy, retrieval procedures, and appraisal process, to identify recognized pilot study aims, processes, and methodologies used in previously reported community pilot studies. Factors influencing study inclusion were recognized pilot study aims and purposes and a concise working definition of pilot study. Methodologies used in previously conducted community pilot studies were reviewed. Although relevant published research was limited, 11 pilot studies met the inclusion criteria for this review and contained suggestions to further develop or improve plans for larger definitive trials to enable a better fit of protocols within the delivery systems and scopes of practice. Pilot research processes could be divided into two stages: early planning and pilot trial. Direction for procedures and methods was gained relative to planning for an effective pilot study regarding eligibility, recruitment and data collection, management, and analysis. The results were used to develop an organizing framework for the authors’ pilot study and named the Pilot Research Process (PReP) Framework. The process was instrumental in working with the authors’ research team and clinical partners in the planning of their leg ulcer treatment pilot study. This framework may provide a foundation for others to analyze or develop a pilot study methodology in planning a large-scale study.

Key Words: pilot studies, leg ulcer, research design, community health, feasibility studies

Potential Conflicts of Interest: This work in preparing for a pilot study was supported in part by a Tendra Wound Care (Mölnlycke Health Care, Oakville, Ontario, Canada) educational grant through the Canadian Association of Wound Care.
Research has not provided specific recommendations on the use of compression bandages for venous ulcers in home care largely due to small, underpowered trials conducted to date.\(^1,2\) The lack of clear information on the effectiveness of bandaging technologies and substantial resource differences in terms of supply costs and nursing time are concerning for home care authorities. In planning a pragmatic, multicenter community-based randomized controlled trial (RCT), it became clear there would be numerous methodological and logistical challenges. The purpose of the study, the Canadian Bandaging Trial (CBT) is to determine the effectiveness and efficiency of two different compression technology systems (four-layer versus short-stretch) on venous leg ulcer healing. The purpose of this project was to develop a framework for pilot study methodology to inform the planning of a randomized, controlled, multicenter, community-based leg ulcer bandaging study.

**Background**

RCT experience is limited in community settings generally and even more so in the area of chronic wound care. Large-scale compression bandaging trials have been conducted internationally, but there is no published experience conducting such studies in Canada. Bandaging trials included in the Cochrane database were carried out in hospital clinic settings or community leg ulcer services in the UK.\(^3\)\(^-\)\(^7\) These trials were instrumental in providing data to calculate a sample size estimate based on time to healing (414 participants would be needed to achieve 80% power at 0.05 level of significance). However, important differences in delivery systems and scopes of practice would need to be considered in planning a Canadian study.

**The need for a pragmatic trial.** Given the size of the trial (414 participants), the fact that the majority of care is delivered in the home, and that the organization of home care is regionally based, the planned trial would need to be pragmatic. Pragmatic trials have been described as being in the domain of complex treatments, which often rely on the people providing the care and the setting of a study.\(^8\) According to Roland and Torgerson,\(^9\) a pragmatic trial measures effectiveness — ie, the benefit the treatment produces in routine clinical practice; therefore, the design of a pragmatic trial reflects variations between patients that occur in real clinical practice and aims to inform choices between treatments. Pragmatic trials differ from explanatory trials, which generally measure efficacy (ie, the comparative benefit a treatment produces under ideal conditions), often using carefully defined participants in a research clinic.\(^9\)\(^-\)\(^10\)

Utilizing a pragmatic approach for the CBT would enable a realistic evaluation of the two compression technologies (four-layer versus short-stretch) as delivered in routine clinical practice by community nurses. The nurses who normally would deliver care in the community would be involved in the screening, intervention, and outcome measurements. The nurses’ direct involvement in the intervention and data collection would be necessary to track healing rates in the community because the weekly or biweekly visits could not be duplicated with a separate research visit. Once bandages were applied, removal for outcome assessment would be inappropriate, prohibitively expensive, and unduly intrusive.

In planning a pragmatic large-scale multicenter community trial and given the nature and size of the CBT, along with the lack of experience conducting large-scale community wound care trials, the authors’ partners in home care and the nursing agencies agreed a pilot study would be necessary. The logistics of planning community trials is different from inpatient settings, particularly with respect to accessibility of data, data collection, and management. A Canadian pilot study would be conducted to prepare adequately for the larger trial by addressing feasibility issues, determining the practical and educational needs of research sites and nurses, and testing the fit of the research protocol with usual clinical practice.

Because the authors could not find a framework for conducting pilot studies, they developed a framework for pilot study methodology using guidance from previously reported community pilot studies. The first step was to conduct a literature review to identify recognized pilot study aims, processes, and methods used in previously reported community pilot studies in order to develop a framework to inform the planning of a multicenter, community-based leg ulcer treatment pilot study.

**Pilot study definitions in the literature.** First, the definitions of pilot study were examined to guide the development of study inclusion criteria for this review. The term pilot study has had a varied pattern of use in the literature since the 1960s. Common terms used to refer to pilot work are small-scale study, feasibility study, practice run or trial run, and preliminary trial.\(^11\) Four frequently cited sources\(^12\)\(^-\)\(^15\) define pilot studies as smaller versions of a proposed

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**Key Points**

- Limitations of currently available wound care research have been well documented but information about failed studies or studies that were terminated due to methodological or process problems remains largely anecdotal.
- The authors describe the need for, and processes used to develop, a framework for conducting pilot studies.
- Observations, recommendations, and the framework included in this paper are worth noting for all researchers interested in planning studies.
### Table 1. Pilot study definitions and purposes

<table>
<thead>
<tr>
<th>Definition</th>
<th>Reference</th>
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<tbody>
<tr>
<td>“A small-scale version, or trial run, done in preparation for a major study” The function of the pilot study is “to obtain information for improving the project or for assessing its feasibility”</td>
<td>Polit and Hungler(^{14})</td>
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<tr>
<td>“A smaller version of a proposed study conducted to develop and/or refine the methodology, such as the treatment, instrument, or data collection process”</td>
<td>Polit, Beck, and Hungler(^{13})</td>
</tr>
<tr>
<td>“…Pilot studies can provide small-scale tests of a complete study plan”</td>
<td>Burns and Grove(^{12})</td>
</tr>
<tr>
<td>“…Pilot work can be thought of as work (a) designed to answer a methodological question(s) and (b) conducted prior to or as part of the development of a research plan”</td>
<td>Prescott and Soeken(^{15})</td>
</tr>
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</table>

**Electronic Database Definitions (Scope Notes)**

- **Medline and Health/Star Ovid**
  - “Small-scale tests of methods and procedures to be used on a larger scale if the pilot study demonstrates that these methods and procedures can work”
  - Subject Heading: Pilot Projects
  - Database: Medline and Health/Star Ovid
- “Studies to determine the advantages or disadvantages, practicability, or capability of accomplishing a projected plan, study or project”
  - Subject Heading: Feasibility Studies
- “A small-scale version, or trial run, of a major study for the purpose of obtaining information to improve the project or assess its feasibility”
  - Subject Heading: Pilot Studies
  - Database: CINAHL®

**Note:** There is no separate subject heading for feasibility studies.

**No scope notes in Emtree under the subject headings “Pilot Study” and “Feasibility Study”**

**Subject Heading**
- Pilot Projects
- Feasibility Studies
- Pilot Studies
- CINAHL®
- Embase

**Purposes of Pilot Studies**

- Small-scale version, or trial run, done in preparation for a major study
- Assess feasibility of a proposed (full-scale) study. Determinants include: 1) timelines; 2) availability of study participants; 3) cooperation, support of others; 4) availability of necessary facilities and equipment; 5) financial resources required; 6) ethical considerations; 7) experience of researcher and staff skills to carry out the project, 8) staff relief to learn skills to implement the study
- Determine if research protocol is realistic and workable: develop treatment protocol; identify logistical problems and obtain information to improve/further develop the design of a research study; give all those involved in the research study experience with the research protocol
- Assess the effectiveness of proposed recruitment approaches and sampling technique; obtain population sample representation; estimate variability in outcomes to help determine sample size
- Assess adequacy of the data collection plan; develop, refine, and test data collection instruments (including reliability and validity); test and evaluate the proposed data analysis techniques
- Convince funding bodies and other stakeholders of research team competence, feasibility of main study, and that the main study is worth supporting
study using a combination of the following concepts and purposes: 1) to be a small-scale version of a proposed study, 2) to be a trial run, 3) to prepare for a major study, 4) to assess feasibility of a proposed research study, 5) to develop or refine the methodology, and 6) to develop a research plan. In a review of nursing texts and 212 studies published in three research journals from 1985 to 1987, Prescott and Soeken reported a similar understanding of pilot studies. These authors noted that except for proposed instrumentation reliability testing, discussion was scant regarding how pilots could be designed or implemented to achieve the intended purpose. Their search uncovered 18 reported pilot studies, of which 13 were related to instrumentation reliability testing. Methodological questions important to the development of a research plan were not addressed in these studies, leading Prescott and Soeken to conclude that pilot studies are under-discussed, under-used, and under-reported.

Pilot study definitions and their purposes have been compiled in Table 1 and include the “scope note” definitions of a term found in some electronic databases for health care/nursing journals (e.g., the Cumulative Index to Nursing and Allied Health Literature — CINAHL®). These scope notes contain information about the use of an index term or detailed instructions to an indexer on how to apply the term. Within the realm of these underlying definitions, the purposes of pilot studies reflect various aspects of the research process such as data collection and analysis and addressing practical issues such as convincing funding bodies of team competence and study feasibility. These definitions and purposes are supported by other sources that state a pilot study is related more to research process than to the research question. The purpose of a pilot study is to identify strengths and weaknesses in a research plan that could alter the design of the future study,11,16,17

The following definition of pilot study was developed by the authors of this article to guide study selection for the current review: “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.”

Methods used for pilot study selection for the current review were designed to answer the question, “What are the recognized pilot study aims, planning processes, and methods used in previously reported community pilot studies?” The answer to this question would help develop a framework to inform the planning of the authors’ multicenter, community-based leg ulcer treatment pilot study.

Methods

This integrative study in the form of a literature review was guided by an explicit search strategy of the electronic databases for medical/nursing journals and a pre-determined retrieval procedure and appraisal process.

Search strategy and retrieval process. The electronic databases and search strategy are summarized in Table 2. Article abstracts resulting from the search strategy were screened online using the pre-specified inclusion and exclusion criteria. These criteria were based on the concepts inherent in the established working definition of pilot study and community-based pilot work.

Inclusion criteria.
• Conducted in community or outpatient healthcare settings;
• Provides small-scale version or trial run of proposed study;
• Assesses feasibility of proposed research study;
• Conducted to develop or refine the research plan and/or methodology.

Exclusion criteria.
• Conducted solely in inpatient hospital settings;
• Represents completed research that piloted programs or projects (such as healthcare delivery initiative, education or support program) but not intended precursors to another study.

Research studies that met the inclusion criteria then were ordered and retrieved for an in-depth appraisal. Only

<table>
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<tr>
<th>Database</th>
<th>Search Terms</th>
<th>Total articles</th>
<th>Articles that met inclusion criteria</th>
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<tbody>
<tr>
<td>Medline 1966 – June 2004</td>
<td>Explode research design feasibility studies pilot projects; explode community health services</td>
<td>136</td>
<td>5</td>
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<tr>
<td>HealthSTAR/Ovid Healthstar</td>
<td>See Medline</td>
<td>148</td>
<td>4*</td>
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<tr>
<td>1975 – June 2004</td>
<td>*Pilot studies</td>
<td>59</td>
<td>4</td>
</tr>
<tr>
<td>CINAHL 1982 – June 2004</td>
<td>Pilot study feasibility study explode community care</td>
<td>109</td>
<td>2</td>
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<tr>
<td>EMBASE 1980 – June 2004</td>
<td>*also in Medline</td>
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<tr>
<td>Total abstracts screened = 452</td>
<td>Total unique pilot studies that met inclusion criteria = 11</td>
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### Table 3. Aims in relation to larger definitive trial (continues through page xx)

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<tr>
<td><strong>Evans et al</strong>19</td>
<td>Purpose: Prepared for large RCT of conservative treatment for acute neck pain</td>
<td>Tracked number of inquiries per recruitment source; number of patients disqualified, unwilling to participate, dropouts and reasons why; number of randomizations per month</td>
<td>Assessed “user friendliness” of instruments by calculating missing data rates, errors made</td>
<td>Evaluated protocols for checking and retrieving missing data — ie, verified records immediately after completion, follow-up on records with missing data</td>
<td>Study and treatment protocols: Patient and clinician compliance (measured by compliance rates, adherence to treatment); patient satisfaction (self-report questionnaires)</td>
</tr>
<tr>
<td>*Design: RCT; Setting: US chiropractic and medical clinics; *Sample: n=28 patients with neck pain, age 21-65; *Duration: 12-week intervention</td>
<td>Loss to follow-up estimates to factor in sample size calculations for full-scale RCT</td>
<td>Established test-retest reliability of applicable outcome measurements</td>
<td>Examined performance of chosen outcome measures in the target study population</td>
<td>Confirmed feasibility of a control group (examined self-report questionnaire; combined with visit and follow-up compliance rates)</td>
<td>Pragmatic trial, allowing physicians to treat with minimal restrictions but within the confines of a standardized protocol</td>
</tr>
<tr>
<td><strong>Gross et al</strong>22</td>
<td>Purpose: Evaluated feasibility of a larger trial per willingness to participate in study of HIV prophylaxis</td>
<td>Self-administered questionnaire to assess willingness to join studies of various hypothetical regimens for HIV prophylaxis</td>
<td>Interest in studies declined as the hypothetical regimen became more demanding</td>
<td>Based on pilot results, a proposal was developed and funding obtained</td>
<td>Developed strategies to prevent dropout and losses to follow-up (patient education, flexible scheduling, phone reminders)</td>
</tr>
<tr>
<td>*Design: Prospective cohort; Setting: US HIVNET VPS; *Sample: n=4,572 respondents at risk for HIV exposure; *Duration: 18 months</td>
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Note: *Sample = rationale stated for sample size; *Duration = rationale stated for study/intervention duration

Results of Literature Search

- The search strategy identified 452 citations, of which 11 (2%) met the criteria for this review (see Table 2). The manuscript abstracts consisted of treatment evaluations: instrument testing; education; treatment; patient satisfaction; study protocols. The study protocol was developed and optimized data collection processes. The pragmatic trial, allowing physicians to treat with minimal restrictions but within the confines of a standardized protocol. The developed strategies to prevent dropout and losses to follow-up (patient education, flexible scheduling, phone reminders).
Table 3. Aims in relation to larger definitive trial (continues through page xx)

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<tr>
<td>Joachim27</td>
<td></td>
<td>Designed and modified a data collection tool to improve data quality; test of tool validity and reliability</td>
<td>Selected appropriate hardware and software for larger study</td>
<td></td>
<td>Discovered benefits of adding two control groups, new data collection tool and computer technology changes to the study protocol</td>
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<td><strong>Purpose</strong>: Prepared for an epidemiology study of IBD in children</td>
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<td>Use of system analyst to design the data collection tool to maximize the use of computer technology</td>
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<tr>
<td><strong>Design</strong>: Descriptive Setting: Canada Pediatric GI Clinic; <strong>Sample</strong>: n=42 pediatric patients; <strong>Duration</strong>: unclear</td>
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<td>Keen et al26</td>
<td></td>
<td>Examined a record-based methodology for evaluation of children's outcomes. Suggested this method was successful for providing crude indicators of treatment success or failure, but recommended a questionnaire based component be used in future research study for more in-depth interpretation of data</td>
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<tr>
<td><strong>Purpose</strong>: Prepared for a larger study of an intervention on heroin-addicted parents and their children</td>
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<tr>
<td><strong>Design</strong>: Retrospective cohort; Setting: UK residential family center; <strong>Sample</strong>: 23 family groups (adults for drug rehab and their children/families); <strong>Duration</strong>: 13 months</td>
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<td>Marcus et al23</td>
<td>Surveys and phone interviews to determine feasibility of two assumptions: 1) if cancer patients willing to grant access to their first-degree relatives (FDRs), 2) if FDRs receptive to study intervention</td>
<td>Debriefing interviews with clinic staff regarding effect of integrating initial recruitment into routine clinic visits</td>
<td>Protocol for patient accrual into the main study changed to initial phone contact as a result of disruptions noted doing patient interviews during clinic appointments (initial contact will be made by mail)</td>
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<td><strong>Purpose</strong>: Prepared for two RCTs of cancer screening promotion</td>
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<td><strong>Design</strong>: Survey; Setting: US private and two hospital clinics; <strong>Sample</strong>: n=178 adult cancer patients; <strong>Duration</strong>: unclear</td>
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### Table 3. Aims in relation to larger definitive trial (continues through page xx)

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<tr>
<td><strong>MRC Working Party</strong></td>
<td><strong>Purpose:</strong> Assessed feasibility of definitive trial of treatment for mild hypertension</td>
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<tr>
<td><strong>Design:</strong> RCT; <strong>Setting:</strong> UK 25 clinics; <strong>Sample:</strong> n = 1,800 patients age 35–64 years with hypertension; <strong>Duration:</strong> 3 years+</td>
<td></td>
<td>Examined screening, recruitment, and drop-out rates and reasons why</td>
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<td></td>
<td></td>
<td>Confirmed sample size estimate for large trial</td>
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<td>Examined willingness of additional sites to participate</td>
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<td></td>
<td></td>
<td>Decisions per type of clinic recruitment (cost, efficiency)</td>
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<tr>
<td><strong>Mock et al</strong></td>
<td><strong>Purpose:</strong> Prepared for proposal of an exercise intervention study for fatigue in patients with cancer</td>
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<td><strong>Design:</strong> RCT; <strong>Setting:</strong> US outpatient departments, four sites; <strong>Sample:</strong> n = 50 adult women being treated for breast cancer; <strong>Duration:</strong> 1 year</td>
<td></td>
<td>Tracked recruitment and reasons for withdrawal</td>
<td>Selected, tested, and compared data collection instruments at different measurement periods</td>
<td>Established site-specific strategies for data management and analysis</td>
<td>Identified members of local teams and established regular multisite communications. When two or more participants entered at sites, site investigators met to evaluate progress, concerns, successes to formulate details of larger study</td>
<td>Research group met early in planning phase to make decisions about instruments, procedures, with advice from nationally known experts</td>
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<td></td>
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<td>Developed strategies to maximize participation and retention</td>
<td>Developed questionnaire to measure cost of care</td>
<td>Data transferred by regular or express mail to central site</td>
<td>Obtained ethics and institutional approval at all sites and institute procedure for monitoring scientific integrity</td>
<td>Developed and tested standardized protocols, interventions, teaching materials and training manuals for all sites</td>
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<td>Central site prepackaged labelled questionnaires by testing period</td>
<td>Developed computer database structural format</td>
<td>Evaluated adherence to treatment intervention (diaries, interviews)</td>
<td>Demonstrated future trial feasibility</td>
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<td>Suggested electronic data scanning of instruments into database due to large amounts of data</td>
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<td>Consulted with nationally known experts</td>
<td>Revised data collection timeline per patient feedback</td>
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<td>Instrument burden – participant feedback</td>
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<td>Developed project communications directory</td>
<td>Use of a conceptual framework related to fatigue to guide pilot</td>
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<td>Determined guidelines for use of data and authorship</td>
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Support, or healthcare delivery program evaluations; and disease etiology or illness recovery descriptions. The most common attributes of the 441 excluded articles (98%) were completed research, not intended precursors to a larger trial, not community-based, unrelated to pilot study, and opinion papers (not actual studies). Studies written in a foreign language (6%) also were excluded.

Characteristics of included studies.

The 11 pilot studies identified (see Table 3) were published between 1977 and 2004 and consisted of three RCTs, surveys, one retrospective cohort, and three descriptive studies. All focused on the preparation of a larger definitive trial and provided rationale for study purpose, design, and setting. Sample sizes and study durations also varied—ie, the RCT pilot samples ranged from 28 to 1,800 participants and study durations ranged from 12 weeks to 3 years. Studies were conducted through outpatient medical clinics, a community center, and one involved a combination of community midwife collaboration with five hospital maternity units in Canada and the rest took place in the US, UK, or the Netherlands. Two studies described conceptual frameworks that guided their pilot study planning. Others...
Table 3. Aims in relation to larger definitive trial (continued through page xx)

<table>
<thead>
<tr>
<th>Study/Purpose/Design/Setting</th>
<th>Sample/Duration</th>
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</table>
| Tulman et al.29 | Purpose: Prepared for a study of biobehavioral correlates of functional status in women with breast cancer.  
Design: Descriptive; Setting: US radiation and medical oncology practices; Sample: n = 18 female patients; Duration: 13 months. |
| van Teijlingen et al.25 | Purpose: Prepared for a large Scottish births survey.  
Design: Survey; Setting: UK, five hospital maternity units and community midwives; Sample: n = 52 completed questionnaires by women who delivered babies in Scotland in pre-specified time period; Duration: unclear. |

Aims of included pilot studies in relation to larger definitive trials. The most commonly discussed topics were recruitment and feasibility, data collection processes, and study protocol feasibility and operationalization (eight out of 11, 73%). Data management and analysis were addressed less frequently (four out of 11, 36%). Pilot studies typically noted “lessons learned” and provided suggestions to further develop or improve plans for the larger trials.

The pilot research processes reported in these studies can be divided into two phases: 1) Phase 1, Early Planning Phase and 2) Phase 2, Pilot Trial of Research Protocol. These processes also were used to develop a “Pilot Research Process (PrEP) Framework,” presented in Figure 1.

Phase 1: Early Planning Phase. Several studies described an early planning phase to formulate details of the pilot trial and larger trial initiative. Involving multiple research sites required establishing regular meetings to collaboratively develop and refine the research protocol.20 Preliminary work also included obtaining ethics approval and consulting with computer experts to maximize the use of computer technology and to develop and format instruments for ease of data entry and analysis.20,27,28 Decisions regarding pilot study sample sizes and/or study duration were typically handled through a consensus process among experienced investigators and clinicians.19,26,28 After the early planning phase, attention turned to the pilot research protocol implementation phase, describing methods throughout the various steps of the research process.
Phase 2: Pilot Trial of Research Protocol: Implementation, Operationalization, and Evaluation of Research Protocol/Feasibility. Issues related to study protocol feasibility, operationalization, evaluation, and ongoing development were addressed at each step of the research process, as well as issues pertaining to communication, future resource planning, and preparing for a funding proposal.

Protocol-related issues addressed included feasibility of study design, adherence to the study or treatment protocols, the impact of external policy, and practice directives challenging the research protocol. Through the pilot process, investigators found ways to further develop their protocols and enable a better fit within the delivery systems and scopes of practice. A recurring theme was the integration of the research protocol into the clinical routines.

Resource planning included the systematic tracking of issues related to personnel, time, and budget that might impact the feasibility of the larger trial; and developing a proposal to secure research funding.19-22,28

Eligibility and recruitment. Recruitment feasibility was evaluated by examining the overall pool of participants as well as willingness to participate in a future study.22-25 Mechanisms were implemented in four pilots to track screening, recruitment, reasons for refusal or withdrawal from the trial, number of persons disqualified, and loss to follow-up.19-21,29 This alerted researchers to the need for additional research sites and/or alternate recruitment/retention strategies in order to obtain an adequate sample within a reasonable time frame. Strategies to improve recruitment included the use of newspaper ads, postcard mailings, posters and flyers, phone screening followed by a baseline appointment, developing and testing alternative processes for distribution and return of questionnaires, short versus long versions of questionnaires, and alternate communication strategies to ensure accurate tracking of questionnaire distribution and response rates.19,23-25 Barriers recognized were the use of more demanding treatment regimens and/or diagnostic tests.22,28 Recruitment strategy preferences were relative to specific health service delivery settings. After debriefing with clinic staff, Marcus et al23 decided to recruit clients through initial contact by mail rather than personal contact with clinic staff in order to minimize disruption to clinic routines. In contrast, van Teijlingen et al23 noted benefits of personal midwife contact to recruit people to a survey study in home settings in addition to hospital setting approaches. Cost and efficiency were important considerations when recruiting different clinics in one large pilot.21

Data collection and management. Methods related to data collection included identifying data sources and procedures to obtain these data,28 examining the quality and accuracy of data sources,28 developing protocols to track and collect missing data and document error rates,19 developing a practical approach to distribute study forms to multiple sites for each measurement time period,28 using participant feedback for assessment of instrument burden,20 and evaluating instrument validity and/or instrument performance.19,25,27-29

Where multiple sites were involved, site-specific strategies for transferring data to the research office were established.20

Data analysis. Data analysis and computer technology issues were addressed in areas such as selecting appropriate hardware and software27 and testing the database structural format.20,28

Every stage of the research process demonstrated the overlapping theme of tracking logistical issues and concerns that arose in the pilot study in order to evaluate and revise the study protocol for use in the planned larger trial.

Review summary. Although this review was limited to settings other than hospitals and included different and more recent studies than Prescott and Soeken’s review,15 the literature search also revealed a lack of published studies meeting recognized pilot study aims. Therefore, pilot studies continue to be under-discussed, under-used, and under-reported. Many studies labeled as pilots, either by the author or database indexers, were completed research (of small sample size) that were not intended precursors to a larger trial and had no clear rationale for being labeled pilot studies. The term continues to be used inconsistently; the need persists for a clearer understanding of the criteria with which both researchers and library science abstractors label research a “pilot study”. Despite this, the results of this systematic review unveiled practical methodological data to enable development of a framework to guide the development of the authors’ leg ulcer treatment pilot study.

Discussion

Planning the bandaging trial (CBT). The recognized pilot study aims, processes, and methodologies used in previously reported community pilot studies provided guidance in planning an effective pilot trial, as well as procedures relative to specific research processes. These methodologies were used to develop the PReP Framework (see Figure 1) to serve as an organizing schema template in working with the authors’ clinical partners. The framework incorporates recognized pilot study aims and research process methods; thereby, clarifying the intent and process for planning and implementing an effective pilot study. However, given the lack of published pilot studies specific to a large-scale pragmatic community leg ulcer bandaging trial, it was necessary to utilize the PReP in conjunction with the authors’ knowledge and experience related to leg ulcer care research and the specific aims and needs for the large CBT.

Phase 1: Early Planning Phase of CBT pilot study. As outlined in the PReP, an early planning phase will be necessary to address three main issues in collaboration with the authors’ clinical partners: 1) establishing effective communication
across sites; 2) developing initial study protocol, determining necessary sample size and study duration, and addressing financial, ethical, and administrative matters. Decisions also would be necessary regarding database development and selection of software; and 3) conducting a needs assessment (setting and nurse learning needs). It will be essential to understand the learning needs of nurses in order to implement the study protocol and to develop resources for preparation and training required before the pilot study is conducted. Although the assessment of nurse learning needs specific to leg ulcer care was not addressed in these particular studies, it will be necessary to conduct a formal learning needs assessment of all research sites and participating nurses related to the assessment and management of leg ulcers. This will help determine whether the nurses have the requisite knowledge and skills to implement the study protocol, deliver the intervention, and help secure the “fit” of the protocol with site-specific policy and practice issues.

Phase 2: Pilot Trial — implementing the research protocol of the CBT pilot study. In keeping with recognized pilot study aims, the conduct of the pilot study will involve the trial of the protocol to be used in the CBT. Although the PReP provides direction regarding steps to be taken at each stage of the pilot study process, none of the studies included in this review involved front-line community nurses at all stages of the research protocol (recruitment, randomization, intervention, and data collection and management). In addition, little practical advice was found about integrating a research protocol with routine clinical care at multiple time points by numerous nurses in multiple home and outpatient health care community settings. Because this pragmatic trial will involve front-line nurses throughout steps 1 to 4 (Phase 2) of the PReP (see Figure 1), collaboration will be necessary among clinical partners to develop efficient ways of implementing the protocol at the front-line level. In addition, the inevitable differences in policies, procedures, and practices across numerous agencies and provincial home care authorities mean that standard template protocols will be complemented by sitespecific processes in the planned trial. For instance, site-
specific approaches conducive to conducting the necessary initial 2-hour leg ulcer assessment, screening, and recruitment will need to be aligned with usual care. Screening and recruitment tracking mechanisms for study data will be necessary, with regular liaison with the research office.

Randomization will present special challenges when care is delivered in the home. No practical advice was provided about this important aspect of a clinical trial. For the authors’ project, a system will be needed whereby nurses can contact the research office directly with participant information and, in turn, the research office can provide them with the research ID number and treatment allocation. Randomization stratification procedures also will need to be tested. Methods to alert front-line nurses to upcoming data collection requirements, integrate data collection and management into clinical care, and ensure blinding of treatment allocation to an independent reviewer confirming healing will need to be developed.

Given the need to develop and test databases, data tracking mechanisms, and data analysis for a large-scale study, concrete advice from completed pilots to achieve these aims would be useful. Remaining issues include creation of databases (research office and site use) for tracking screening, recruitment, data collection, concerns, form errors, and pending follow-up phone calls; user-friendly variable code books; databases to accommodate multiple data collection time points and various analysis procedures; detailed protocols for checking data entry errors; and methods to test the analysis processes for a larger trial.

Finally, the pilot study will need to address cost/resource planning issues as follows: 1) track time taken to complete all aspects of the research protocol to prepare for resource requirements in the larger study, and 2) track cost effectiveness of the treatment protocol and develop and test methods of tracking treatment costs and benefits (ie, related to supplies, resource personnel, need for home visits, and hospital costs).

Although many do not consider publishing their pilot experience, the useful information gleaned from the included studies in this review demonstrates how this practical experience contributes to the design of better studies and merits publication. Pilot study designs are needed to confidently apply to one’s own unique clinical settings. The experience gained in the pilot study will improve the quality of the larger CBT trial and greatly assist in its alignment with routine community nursing care, creating a positive rather than negative impact from the conduct of the research (aside from useful results).

**Limitations**

Limitations to the review and the development of the PReP included the paucity of information in the literature, which meant that the conclusions drawn and development of the PReP framework were based on limited research. Because the PReP was created through a synthesis of pilot study methods specific to community settings, unique challenges inherent in hospital-based pilots may not be addressed in this framework.

**Conclusion**

Developing a pilot study protocol was challenging due to the paucity of research literature on pilot study methodology, the inconsistent use of the term pilot study in published research, few multiple setting examples, and the lack of pragmatic community pilot study designs whereby the research protocol was interfaced with routine clinical care.

The 11 studies included in this review provided direction for procedures and methods relative to planning an effective pilot and research process procedures and were used to develop a framework for pilot study methodology (PReP).

Despite limitations, the synthesis of current knowledge for community pilot study methods provides a foundation and guiding framework to plan the preliminary and pilot work to prepare for conducting the CBT. The practical guidance outlined in the PReP’s Early Planning Phase includes all the main areas that would be necessary to plan for the pilot study (developing communication strategies, refining protocols, undertaking a needs assessment of nurses and settings). The learning needs assessment will be essential in order to effectively implement the CBT study protocol, including the Leg Ulcer Care Protocol. Therefore, the PReP will be used in conjunction with the aims of the CBT study protocol to plan the preliminary research and pilot work.

Finally, the PReP Framework forms a foundation for others to analyze or develop a pilot study methodology. By incorporating recognized pilot study aims and research process methods, the framework clarifies the intent and process of such studies and provides a guide to capturing information meaningful for planning future pilot or feasibility studies.

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