Interventionist training and intervention fidelity monitoring and maintenance for CONNECT, a nurse-led primary palliative care in oncology trial

Gregg A. Robbins-Welty, Lisa Mueser, Chandler Mitchell, Nicole Pope, Robert Arnold, SeoYoung Park, Doug White, Kenneth J. Smith, Charles Reynolds, Margaret Rosenzweig, Marie Bakitas, Yael Schenker

* University of Pittsburgh, School of Medicine, United States
b University of Pittsburgh, Division of General Internal Medicine, United States
c University of Pittsburgh, Dietrich School of Arts and Sciences, United States
d University of Pittsburgh, Department of Psychiatry, Division Geriatric Psychiatry (Emeritus), United States
e University of Alabama at Birmingham, School of Nursing/Department of Medicine, United States
f University of Pittsburgh, Department of Critical Care Medicine, United States
g University of Pittsburgh, School of Nursing, United States

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ABSTRACT

Context: Intervention fidelity is a critical component of behavioral research that has received inadequate attention in palliative care studies. With increasing focus on the need for palliative care models that can be widely disseminated and delivered by non-specialists, rigorous yet pragmatic strategies for training interventionists and maintaining intervention fidelity are needed.

Objectives: (1) Describe components of a plan for interventionist training and monitoring and maintaining intervention fidelity as part of a primary palliative care trial (CONNECT) and (2) present data about perceived training effectiveness and delivery of key intervention content.

Methods: Post-training evaluations, visit checklists, and visit audio-recordings.

Results: Data were collected from June, 2016 through April, 2017. We include procedures for (1) identification, training and certification of oncology nurses as CONNECT interventionists; (2) monitoring intervention delivery; and (3) maintaining intervention quality. All nurses (N = 14) felt prepared to deliver key competencies after a 3-day in-person training. As assessed via visit checklists, interventionists delivered an average of 94% (SD 13%) of key content for first intervention visits and 85% (SD 14%) for subsequent visits. As assessed via audio-recordings, interventionists delivered an average of 85% (SD 8%) of key content for initial visits and 85% (SD 12%) for subsequent visits.

Conclusion: We present a 3-part strategy for training interventionists and monitoring and maintaining intervention delivery in a primary palliative care trial. Training was effective in having nurses feel prepared to deliver primary palliative care skills. As assessed via nursing checklists and visit audio-recordings, intervention fidelity was high.

1. Introduction

Given significant shortages of palliative care specialists, strategies to improve provision of ‘primary’ palliative care by non-specialists are needed [1,2]. CONNECT (Care management by Oncology Nurses to address supportive care needs) is an oncology nurse-led care management intervention designed to strengthen provision of ‘primary’ palliative care within oncology practices (3). CONNECT visits take place at the same time as a patient’s regularly scheduled oncology clinic appointment, occur monthly for at least 3 months, and may be conducted via telephone if a patient is unable to attend in person. A pilot trial demonstrated excellent feasibility, acceptability, and perceived effectiveness [3], and a multi-site cluster randomized efficacy trial is underway (ClinicalTrials.gov NCT02712229) [4].

Intervention fidelity is an important element of clinical trial design and conduct [5–8] that has received variable attention in previous...
Staffing reassignments allowed nurses to have protected time for training. A structured curriculum focused on (1) symptom assessment and management, (2) emotional support for the patient and caregiver, (3) advance care planning, and (4) care coordination. Simulated patients were used for role-playing, allowing nurses to practice and receive feedback on key communication skills.

Following each training, nurses completed a formal self-evaluation (see appendix), rating the extent to which they felt prepared to perform key competencies. In the event that a nurse did not report feeling ‘well’ or ‘very well’ prepared after the standardized training session, supplemental targeted training was provided in that area.

To ensure that each nurse was well-prepared to deliver the intervention, we conducted an individual, in-person certification visit several weeks after the training. During these visits, the nurse conducted an observed visit with a simulated-patient, which was rated for content and quality using standardized criteria (see appendix). Upon demonstrating each intervention visit component with a total quality rating of two (out of a possible three) or higher, the nurse was certified as a CONNECT interventionist and eligible to deliver the intervention.

2.1.2. Monitoring intervention delivery

After every CONNECT encounter, the CONNECT interventionist completed a protocol summary and session-specific checklist. The protocol summary checklist includes the encounter date, visit number, mode (in-person vs telephone), and a field to comment on the reason for any protocol deviation. Session-specific checklists include the visit components and a field note form for the interventionist to document any unusual circumstances surrounding each intervention session (see appendix). These checklists were completed on the same day as the encounter to ensure accurate and real-time monitoring of study procedures.

CONNECT interventionists also audio-recorded patient visits occurring both in-person or by phone, except in cases where audio-recording was deemed to be too sensitive or disruptive. In these cases, visit field notes and/or direct observation were substituted. Interventionists used study tablets for audio-recordings, which were directly uploaded to secure study files for review by research staff. To ensure that any issues with intervention fidelity were addressed in a timely fashion, the first two visits by each CONNECT interventionist were reviewed by the Nurse PM. Subsequently, for each CONNECT interventionist, a randomly-selected subset of audio-recordings (20% of anticipated visits for the entire trial) were reviewed and rated for content and quality. Visit Evaluation Forms and Standardized Visit Quality Rating criteria were used to review and rate audio-recorded visits (see appendix). Our threshold for intervention content, based on audio-recorded encounters, was the presence (yes/no) of ≥80% of key components of the intervention.

Visit audio-recordings were audited by research staff and student assistants. In order to maximize reliability, all raters were trained by experienced staff using a three-step process: (1) listening to audio-recordings and rating together; (2) listening to audio-recordings together and rating separately; and (3) listening to audio-recordings and rating separately. Training was considered complete when raters achieved agreement (within 10%) for the visit content score.

2.1.3. Maintenance of intervention quality

The Nurse PM conducted a weekly telephone supervision session with each CONNECT interventionist. During these sessions, session-specific checklists and visit audio-recording evaluations were reviewed together. The Nurse PM shared visit evaluation scores with each CONNECT interventionist, identifying well-performed skills and opportunities for improvement. All scores falling below content thresholds were reviewed jointly to identify solutions. The Nurse PM also sent a weekly e-mail to all CONNECT interventionists with helpful tips and reminders about key competencies and conducted a monthly site visit to meet with each nurse in-person and review study procedures. Finally,
a booster training session was held with CONNECT interventionists every six months to maintain intervention skills.

If problems with protocol adherence or intervention delivery were identified (e.g., failure to conduct CONNECT visits or delivery of < 80% of key intervention components in audio-recorded visits), the Nurse PM and PI worked with the Nurse Advisory Board to implement a remediation plan. Remediation plans included meeting individually with the CONNECT interventionist to identify barriers and discuss strategies to improve adherence, observing the nurse’s work flow processes to provide recommended strategies for improved protocol adherence, meeting with clinic staff and leadership to discuss opportunities for improvement, and providing targeted training in specific skills, followed by re-evaluation. The CONNECT Nurse PM also evaluated all subsequent visits until 2 consecutive visits were performed above the adherence threshold. If no acceptable solution was found after the remediation plans had been implemented, a different oncology nurse would be identified and trained to serve as the interventionist.

3. Results

3.1. Identification, training, and certification of CONNECT interventionists

To date (August, 2017), four three-day CONNECT training sessions have been held and 14 nurses have completed training. All nurses reported feeling well, or very well, prepared in key primary palliative care skill after training; no supplemental targeted training was required. Nurses reported that CONNECT training had the greatest impact on their preparedness to administer the Edmonton Symptom Assessment Scale (ESAS), explain their role as a CONNECT nurse, set a visit agenda, complete a shared care plan, and help a patient to complete an advance directive. Table 1 summarizes results from post-training evaluations.

In addition, nurses rated the CONNECT training as ‘very important’ to the development of their own clinical skills (mean 4.9/5, SD 0.3) and unanimously rated their commitment to changing specific clinical behaviors as very high (mean 5/5, SD 0). Specific goals that nurses identified included overcoming fear of discussing end of life issues, displaying empathy, engaging with patients, addressing emotional needs, and working with advance directives. Nurses found the CONNECT training length to be ‘just right’ and strongly agreed that they would recommend this training for others (mean 4.9/5, SD 0.3). One nurse commented that training provided a ‘critical part of oncology nursing that has sadly been missing.’ Others noted that ‘repetitive role playing was a huge help’ and that the training provided ‘a skill set I believe will stick with me for quite a long time.’

In-person certification visits with each nurse were conducted an average of 2 weeks after the 3-day training. In these visits, all nurses demonstrated delivery of intervention components with adequate quality and were certified to begin delivering the intervention. The average content rating for certification visit was 91% (range 84%–100%), while the average quality rating was 78% (range 67%–94%).

3.2. Monitoring intervention delivery

Thirteen nurses had completed CONNECT intervention visits at the time of this analysis. Each of the nurses completed an average of 10 visits (range 2–31). CONNECT nurses completed 100% of protocol summary and session-specific checklists for the first 131 CONNECT visits (63 first visits and 68 subsequent visits). Most nurses completed the checklists using study tablets for direct database entry immediately following the CONNECT encounter. Some nurses chose to bring paper versions of these forms as a reminder of key content and completed them in real time.

| Question                                                                 | Average Score Before Training (SD) (1 = not well prepared; 5 = very well prepared) | Average Score After Training (SD) (1 = not well prepared; 5 = very well prepared) | Average Score Change from Before to After Training |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------|
| Establish rapport with a patient                                       | 3.2 (1.0)                                                                         | 4.9 (0.4)                                                                      | + 1.6                                            |
| Explain role as CONNECT RN                                             | 1.9 (0.9)                                                                         | 4.9 (0.4)                                                                      | + 2.9                                            |
| Set Visit Agenda                                                       | 1.9 (1.1)                                                                         | 4.8 (0.6)                                                                      | + 2.9                                            |
| Assess patient views about his or her illness                          | 3.1 (1.1)                                                                         | 4.7 (0.5)                                                                      | + 1.6                                            |
| Assess how a patient is coping                                         | 3.1 (1.0)                                                                         | 4.6 (0.5)                                                                      | + 1.6                                            |
| Provide emotional support                                              | 3.4 (0.6)                                                                         | 4.9 (0.3)                                                                      | + 1.5                                            |
| Administer the Edmonton Symptom Assessment Scale (ESAS)                | 1.8 (0.8)                                                                         | 4.9 (0.3)                                                                      | + 3.1                                            |
| Administer the NCNN distress thermometer                               | 2.2 (1.2)                                                                         | 4.9 (0.3)                                                                      | + 2.7                                            |
| Identify and assess symptom needs                                     | 3.6 (0.8)                                                                         | 4.9 (0.4)                                                                      | + 1.2                                            |
| Help patients to focus on symptom goals                                | 3.1 (0.8)                                                                         | 4.9 (0.4)                                                                      | + 1.7                                            |
| Consider barriers to symptom management                                | 3.1 (0.8)                                                                         | 4.8 (0.4)                                                                      | + 1.7                                            |
| Use the “ask-tell-ask” approach to address a patient’s symptoms        | 2.4 (0.9)                                                                         | 4.7 (0.5)                                                                      | + 2.3                                            |
| Complete a shared care plan with a patient                            | 1.8 (0.7)                                                                         | 4.6 (0.6)                                                                      | + 2.9                                            |
| Use evidence-based symptom pathways to address common symptoms         | 2.8 (1.0)                                                                         | 4.6 (0.6)                                                                      | + 1.9                                            |
| Help a patient to identify a surrogate decision maker                  | 2.0 (0.9)                                                                         | 4.5 (0.6)                                                                      | + 2.5                                            |
| Elicit a patient’s readiness to think about the future                 | 1.9 (0.7)                                                                         | 4.5 (0.6)                                                                      | + 2.6                                            |
| Elicit how a patient would like their surrogate decision maker to approach decisions | 1.7 (0.8)                                                                         | 4.4 (0.6)                                                                      | + 2.6                                            |
| Elicit a patient's hopes for the end of life                           | 1.9 (0.7)                                                                         | 4.4 (0.7)                                                                      | + 2.5                                            |
| Elicit a patient's fears for the end of life                           | 2.1 (1.0)                                                                         | 4.4 (0.6)                                                                      | + 2.3                                            |
| Help a patient to talk with their family about the future              | 2.2 (0.9)                                                                         | 4.5 (0.6)                                                                      | + 2.3                                            |
| Help a patient to ask their oncologist questions                       | 3.5 (0.9)                                                                         | 4.9 (0.3)                                                                      | + 1.4                                            |
| Help a patient to complete advance directive                           | 1.8 (0.8)                                                                         | 4.8 (0.4)                                                                      | + 3.0                                            |
| Discuss a patient’s symptoms with the oncologist                      | 3.9 (0.7)                                                                         | 4.9 (0.3)                                                                      | + 1.0                                            |
| Discuss a patient’s preferences and goals with the oncologist          | 3.5 (0.8)                                                                         | 4.9 (0.4)                                                                      | + 1.4                                            |
Ninety-nine percent of visits were conducted in-person. Fifty-six visits (43%) included the patient only and 75 visits (57%) included the patient and a caregiver. Nurses reported an average length of 46 min (SD 25) for first visits and 42 min (SD 18) for subsequent visits.

Nurses reported delivering most visit components for first visits (mean 94%, SD 13) and subsequent visits (mean 85%, SD 14). For 62% of first visits and 33% of subsequent visits, CONNECT nurses reported delivering all visit components. Table 2 summarizes results from inter-rater reliability monitoring and fidelity data.

Interventionists audio-recorded 97% (N = 127) of the first 131 patient visits. Four raters (including 2 medical students, a pre-medical student, and a social work student) were successfully trained to review and rate visit audio-recordings by the PI and Nurse PM. Adequate inter-rater reliability was achieved after reviewing an average of 13 audio-recordings.

Table 3 summarizes the results of visit evaluation forms completed for the 45 audio-recorded visits (N = 19 first visits and N = 26 subsequent visits) evaluated to-date, excluding the first two visits conducted by each CONNECT nurse. Each of the 12 eligible nurses had an average of 3 audio-recorded visits evaluated (range 1–9). For first visits, nurses performed an average of 85% (SD 8) of intervention components, with an average total quality rating of 71% (SD 11). For subsequent visits, nurses performed an average of 85% (SD 12) of the intervention components, with an average total quality rating of 75% (SD 7). CONNECT nurses consistently administered the ESAS and distress scales (100% of visits) and explained their role as the CONNECT nurse (95% of first visits). The least performed intervention component was the teach-back (asking patients to repeat back the plan to verify understanding), which CONNECT nurses performed during 32% of first visits and 42% of subsequent visits.

### 3.3. Maintenance of intervention quality

To date, four first CONNECT visits and nine subsequent visits have been below key content thresholds, warranting a discussion with the Nurse PM. Two interventionists have demonstrated more persistent quality deficits or drift in interventionist skills, necessitating supplemental individualized training and review of intervention components. After individualized remediation, both nurses subsequently delivered consecutive visits with adequate (> 80%) content scores.

### 4. Discussion

As part of a cluster-randomized trial to evaluate the efficacy of a nurse-led primary palliative care intervention, we developed and implemented a rigorous plan for intervention fidelity monitoring and maintenance. In describing the key components of this plan and sharing our assessment tools, we provide a framework for other investigators seeking to monitor delivery of palliative care interventions. Several key findings emerged from our fidelity data.

First, training was effective in having nurses feel prepared to deliver key communication and supportive care skills. This preparation was evident in post-training evaluations and was demonstrated in certification visits, in which all nurses demonstrated intervention delivery with adequate quality. While our certification rate was 100%, nurses reported that certification visits were helpful in providing an additional opportunity to practice and receive feedback in their own oncology clinics before conducting their first CONNECT visit with a patient. Training two nurses per site also proved to be an effective approach. To date, two nurses have moved on to positions elsewhere, but these sites were able to remain active in the study with a single CONNECT interventionist seeing patients until a second nurse could be identified and trained at a later date.

Second, using both self-report checklists and audio recordings is a useful and novel strategy for monitoring and maintaining intervention fidelity. Checklists are simple and effective tools for improving delivery of medical care [14]. Traditionally used in surgical settings, checklists have more recently been developed for palliative care communication interventions [15–17]. However, self-reported checklists may not accurately capture intervention content. In our study, audio-recording intervention visits proved feasible and provided ‘gold standard’ data about intervention delivery [18,19]. Discrepancies between audio-
recorded and self-reported content informed opportunities for individual and group feedback. For example, nurses reported conducting a “teach-back” far more frequently on self-report checklists than this element was identified on review of audio-recordings, illuminating a common misconception among nurses about what constitutes a ‘teach-back’ (i.e., asking the patient to repeat the plan, rather than simply asking if the patient has any questions). This misconception was the subject of follow-up training and feedback. For administering the ESAS, this was frequently reported by nurses but not captured on review of audio-recorded visits if it was done before the audio-recording was started and not uploaded into the database. This discrepancy provided an opportunity to remind nurses about the importance of uploading the ESAS and referencing this scale during the visit itself.

Finally, nurses who demonstrated deficits in intervention delivery were able to improve after remediation training. We used specific visits that had been audio-recorded to collectively brainstorm ways to incorporate key skills that were missing and reframed remediation training as a positive, non-punitive opportunity for additional feedback. CONNECT interventionists responded positively to the support and additional training and both nurses who underwent remediation have remained active in the study.

Our approach has limitations. First, the 3-day training, while comparable to other palliative care interventions [20], is intensive and may not be feasible at all clinic sites. Future work is needed to determine whether similar fidelity can be achieved with a shortened in-person training. Furthermore, the study includes 14 nurses from multiple clinics within a single cancer center network. Findings may not generalize to other nurses at other cancer center sites. Similarly, the 45 audited visits were not evenly distributed among the interventionists due to the randomization method and time at which data was collected. This may represent a bias in our data. Our intervention fidelity monitoring and maintenance plan involves frequent telephone contact and monthly site visits from our Nurse PM. Future work is needed to determine whether similar results could be achieved with less intensive oversight. Finally, this study is being conducted at oncology practices in Western PA within a single cancer center network. Experiences may differ at other sites.

In conclusion, a 3-part strategy for training interventionists and monitoring and maintaining intervention fidelity is an effective way of ensuring quality ‘primary’ palliative care intervention delivery and will facilitate accurate conclusions about intervention efficacy.

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Conflicts of interest

None.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.conctc.2018.03.006.