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Conducting the ACTIVE Randomized Trial in Hospice Care: Keys to Success

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Abstract

Background—Untreated pain is common for patients at the end of life. Informal caregivers, often family or friends of patients, are responsible for working with hospice staff to provide pain management. Interdisciplinary team meetings conducted in hospices every two weeks provide an opportunity for hospice staff to communicate about pain management with informal caregivers of hospice patients.

Purpose—We present challenges, solutions, and keys strategies for carrying out a randomized trial in the hospice setting.

Methods—We are conducting the ACTIVE study (Assessing Caregivers for Team Intervention through Video Encounters) to determine whether regular videoconferencing between hospice patients' informal caregivers and the hospice care team alters caregivers' perceptions of pain management and patients' pain. Participants must be primary caregivers for a hospice patient, at least 18 years of age, capable of providing informed consent, and have access to a computer with a high-speed Internet connection or a telephone. We randomized caregivers to participate in biweekly team meetings through video or phone conferencing (intervention) or to receive usual care from the hospice. All patients receive standard hospice care regardless of the group assignment of their informal caregiver.

Results—As of July 1, 2012, there has been 1038 new admissions to the participating hospices. Of 391 cases in which no contact was made, 233 patients had died or had life expectancy less than 14 days. Home visits were made to 271 interested and eligible caregivers; 249 caregivers of 233 patients were randomly assigned to the usual care or intervention arm. Enrollment is on pace to meet recruitment goals.

Lessons Learned—Thorough pilot-testing of instruments and procedures helped us overcome barriers to conducting research in this vulnerable population. Keys to success included obtaining support from hospice medical directors, including hospice staff in study preparation, minimizing the burden on hospice staff, housing research staff in each participating hospice, using newsletters to enhance communication, developing and maintaining a detailed procedural manual, producing

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regular data quality reports, developing a secure site to facilitate coding videos for qualitative studies, and holding regular teleconferences with key staff.

Limitations—Late enrollment of many patients in hospice left little to no time for their caregivers to take part in the intervention. Assisting caregivers of patients with very short life expectancy may require different methods.

Conclusions—The challenges of conducting randomized trials with hospice patients and caregivers can be addressed with appropriate study design, well-tested research methods, and proactive monitoring of any issues or problems.

Keywords

hospice; randomized trial; pain management; videoconference; caregivers; interdisciplinary teams

Background

Hospice is a special concept of care that provides support and comfort to patients and their families when a patient's life expectancy is six months or less. While there are some inpatient hospice facilities, most hospice care in the United States is provided in patients' homes, family members' homes, or nursing homes (78.1% in 2010 [1]). This model puts informal caregivers—often family members—in the role of managing patients' pain medications. Hospice staff members comprise a multidisciplinary team that provides care and support to both the patient and the patient's caregiver(s). Hospice staff members regularly visit patients in their homes throughout the course of their hospice enrollment. Additionally, payment under Medicare requires hospice staff to meet every two weeks to discuss the care plan for every patient and family. Attendance at this interdisciplinary team meeting is required for the medical director, nurses, social workers, and other counselors. The emphasis is on controlling pain and discomfort, but a variety of other services are provided as well, including care coordination, counseling, and emotional support. A patient who has been receiving hospice care for six months may continue to do so if their life expectancy remains less than six months. If it is determined that a patient's prognosis is likely greater than six months, they may be designated as ineligible for hospice services, and their hospice care is “decertified.”

Hospice care is a difficult and stressful time for patients and their families. Referrals are often late—within a few weeks of death—providing a short time frame to conduct research studies involving hospice patients and/or caregivers. Patients are often cognitively impaired due to their conditions or medications, making informed consent difficult. All of these factors can make research, particularly randomized trials, difficult in this population. While some have even questioned the ethics of conducting research involving hospice patients, the current view is overwhelmingly favorable towards conducting research in this population [2]. Research is important for improving knowledge, the quality of life for patients and their families, and the quality of care in the hospice setting. Given the vulnerability of both patients and family members, researchers must take care to place as little burden as possible on participants [3].

Research studies can provide insight into pain management, one of the challenges in hospice care. Severe, untreated pain is common among patients at the end of life, even for patients in a hospice setting, where pain control is a primary concern [4,5]. Informal caregivers often fear that they will administer too much medication, perceive that pain is inevitable, or worry that patients will become addicted to pain medication [6–9]. The interdisciplinary team meetings that hospices conduct every two weeks to develop and discuss care plans for all patients provide an opportunity to communicate with informal caregivers regarding pain

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management. We are conducting a randomized trial (Assessing Caregivers for Team Intervention through Video Encounters, ACTIVE) to determine whether regular communication of patients' informal caregivers (typically family members or friends) with the hospice care team through videoconferencing during interdisciplinary team meetings alters caregivers' perceptions of pain management and caregiver's perceptions of patients' pain. Our overall goal is to alter caregivers' perceptions, thereby improving pain management and reducing patients' pain.

Secondary objectives include evaluating the cost effectiveness of the intervention and translating the intervention into standard care. Developing a protocol manual to translate the intervention into standard care is planned for the final year of the study. In addition, the research team plans several qualitative analyses of communication in the hospice setting, caregiver anxiety and depression, and technical quality of the intervention. Determining uptake of the intervention will be a goal for future study. A recent review by Wohleber and colleagues [2] provides a framework for conducting research with hospice populations. Using this framework, we will highlight challenges and strategies we employed to address them as we planned and implemented the intervention, providing specific examples from our study.

Methods

Preparation

The ACTIVE study was built upon a long-term research agenda that included conducting several pilot studies, including an federally-funded pilot of the intervention (R21 CA120179), to determine the feasibility of recruitment, the intervention, and several instruments [7,10–16]. These activities took place over several years and provided assurance that the research plan and recruitment targets were feasible.

Upon securing grant funding (1R01NR011472-01), research staff proceeded with typical preparatory tasks, e.g., finalizing instruments, writing the procedural manual, obtaining Institutional Review Board (IRB) approval. Given the potential vulnerability of the population under study, we sought to make the consent process as straightforward as possible with a HIPAA waiver of authorization. Obtaining the waiver required some negotiation with the IRB regarding how to contact potential participants and the data elements we were allowed to collect. These preparatory activities occurred over the course of approximately 5 months. Formal recruitment began on November 2, 2010 at site 1 and on December 1, 2010 at site 2. In addition to suggested scripts and data collection forms, the procedure manual includes potential complications with suggested responses (for example, what to do if a caregiver is unusually depressed). The study manual is updated regularly to reflect any changes in study procedures.

Participants

Identifying the appropriate target population is an important aspect of study design. During the pilot study we found that most hospice patients were unable to participate due to their deteriorating health and cognition, and that informal caregivers were often in charge of pain management. We therefore focused the ACTIVE intervention on informal caregivers of hospice patients. To be eligible for inclusion, caregivers must be at least 18 years of age, able to provide informed consent, be a primary caregiver for the hospice patient, have access to either a telephone or functioning computer with a high-speed Internet connection, and be able to participate in the bi-weekly team meetings. We exclude informal caregivers of hospice patients who have a life expectancy less than 14 days because they are not likely to have the opportunity to participate in any team meetings if assigned to the intervention arm.

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Hospice staff members assess life expectancy with the Palliative Performance Scale [17]. Because scores of 10–20 are associated with 72% mortality within 7 days [18], caregivers of patients with scores under 30 are not approached by research staff. Patients live in their own homes or in nursing homes. Caregivers do not have to reside with the patient. The intervention takes place with caregivers wherever they reside.

We initially planned to enroll one caregiver per patient, but pilot work revealed that almost 10% of patients had more than one informal caregiver. Thus, multiple caregivers per patient are eligible for enrollment provided each is importantly involved in caring for the patient. Patients who are able to give informed consent may enroll, but no study activity is required of patients. The patient's consent is not required for the caregiver to participate. Caregivers may participate only once even when they are informal caregivers for multiple patients.

Because communicating with informal caregivers through video- or teleconference involves hospice staff, professional members of the hospice team are also study participants. While consent of staff members is not required for caregivers and patients to participate in team meetings, we developed a multi-level consent process that allows individuals to specify how they will participate in the study. Hospice staff members separately consider consenting to 1) have their participation in team meetings video-recorded, 2) have their image appear on the teleconference web interface that the caregiver sees, and 3) participate in annual study interviews. Should staff choose not to have their image appear on the web interface they are advised to choose a position in the room which is out of sight of the camera. Consent of hospice staff members is not related to enrollment of caregivers and patients.

Recruiting hospice staff

As with staff in long-term care facilities [19], it is well documented that hospice staff tend to be protective of their patients regarding research, often acting as a barrier to recruitment [3,20]. We experienced this behavior in the pilot study and adapted our methods to overcome it [10]. First, we involved hospice staff at each site in the recruitment planning process. When hospice admissions personnel conducted home visits early in the study, research staff accompanied them to teach them simple and expeditious ways to present the study. Secondly, the medical directors at each site signed a letter of support that is included in the admission packet for all hospice patients. Additionally, a research staff person is located within the hospice agency offices, has a desk near key staff, and constantly focuses on building relationships, assisting in any way possible, and determining the status of each hospice admission. Finally, research staff members are trained as hospice volunteers. Certification regulations for hospices require that volunteers provide at least 5% of total patient care hours [1] and that volunteers be considered as employees. Training our research staff as hospice volunteers integrates them into the agency, requires them to honor confidentiality, and provides the same access as any volunteer [21]. Thus, research staff members located within the hospice offices are viewed as team members, not outsiders.

Consent of hospice staff members was obtained before we proceeded with caregiver enrollment; hospice staff also attended a short intervention training session prior to any caregiver enrollment. Training involved an introduction to the intervention goals, brief discussions on encouraging caregiver participation during videoconferencing, and emphasizing that all actions are visible to the caregiver during videoconferences. Because hospice staff members interact with intervention group caregivers every other week they could not be blinded to the random assignment of this group. However, hospice staff is unaware of which caregivers declined to participate so that the usual care group is indistinguishable from the general hospice population. Hospice staff has been very accommodating of the study. To recognize their efforts, hospice staff members are entered into an annual lottery drawing; one name is chosen at each hospice to receive an all-expense

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paid trip to a national conference, for example, the National Hospice and Palliative Care Organization Clinical Team Conference and Pediatric Intensive.

Recruiting caregivers and patients

One full-time research staff member is responsible for recruiting informal caregivers at each hospice, minimizing any time required of hospice staff. In addition to a brief introduction by the admissions nurse and the letter from the hospice medical director in support of the study, new patients and their caregivers receive a “Decline Permission to Contact” form. The patient or the caregiver(s) can decline to be contacted by signing and returning this form. We retain a small amount of information from patients or caregivers who decline to be contacted to allow us to determine the percent of hospice admissions that participate in the study: hospice admission date, whether the patient has cancer, Palliative Performance Scale [18] score at admission, and, eventually, date of death.

Caregivers who do not decline to be contacted are contacted by telephone within 72 hours. The study representative describes the study; a home visit is scheduled whenever the caregiver is eligible and interested. The voluntary nature of the study is emphasized. In general, three unsuccessful telephone contacts are considered a tacit decline. The study representative assures patients and informal caregivers that all hospice patients are entitled to usual care whether they participate or not, and that non-participation will not affect their treatment in any way.

Enrollment

Prior to study onset, the central Data Manager (RK) computer-generated a sequence of random numbers for each hospice site and primary diagnosis (cancer, dementia, other) to ensure equal distribution of assignments to study arms across diagnosis groups within sites. Sequences were generated in randomly chosen blocks of 6, 8 and 10 to prevent any study personnel from being able to forecast group assignment. The Data Manager does not participate in the enrollment process. An individual not connected to the study sealed the randomization letters in several hundred opaque envelopes. Envelopes were labeled with the primary diagnosis and the sequence in which they were to be used (numbered from 1 to n). Study representatives (one at each site) carry a supply of randomization envelopes with them to home visits to interested and eligible caregivers.

When a caregiver consents, the study representative proceeds with randomization during the home visit. After ascertaining the patient's primary diagnosis, the study representative opens the next envelope in the sequence for that diagnosis. All of the patient's caregivers are randomized to the same group; for patients with multiple caregivers, it would not be feasible to randomize caregivers to different groups given the nature of the intervention. Caregivers are assured that their participation is very valuable regardless of their group assignment.

Participants may choose to withdraw from the study at any time. Patients whose hospice care is decertified no longer receive any care from the hospice and are no longer discussed at interdisciplinary team meetings. Because hospice staff no longer assists with pain management and caregivers assigned to the intervention arm no longer can participate in the team meetings, caregivers of all such patients are removed from the study regardless of study arm.

The intervention

The ACTIVE intervention uses two technology options to connect informal caregivers with the bi-weekly hospice team meetings during which every patient is discussed. ACTIVE caregivers participate in team meetings until the patient dies, is decertified from hospice, or

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the caregiver withdraws from the study. Average time for informal caregiver participation in team meetings is 6 minutes, compared to an average 3 minutes for discussions of usual care in which the caregiver does not participate. Equipment in the informal caregiver's home includes either a telephone or a computer connected to high-speed Internet service that has a project-supplied web camera and headphones. A research staff representative installs the equipment and provides training and printed instructions to the informal caregiver.

The hospice office also has a computer with a web camera and high-speed Internet service that is connected to a projector that displays an enlarged image of the caregiver for the hospice team (Figure 1). A conferencing telephone is used to provide an audio connection for caregivers without Internet access. One day before each team's meeting, the team coordinator generates a list of patients to be discussed and the order of the discussion. A member of the research staff confirms that study participants are continuing to receive hospice services and telephones caregivers in the intervention group to remind them of the meeting and to estimate the time at which they should log onto the videoconferencing website. Before the meeting, the study representative connects and tests all equipment to insure proper functioning. Participation of caregivers is facilitated with the web-based video-conferencing platform Virtually Interactive Families (www.vifamilies.com). This platform has a “waiting room” feature that allows caregivers to log onto the site without hearing discussion of another patient. When the discussion of a patient is finished, the patient's caregiver is disconnected and the research staff member transfers the next caregiver from the waiting room into the live conference.

Measures

A complete list of data collection instruments is included in Table 1. Following randomization, a set of baseline data collection instruments is administered in person to each participating caregiver. All caregivers are called for follow-up data collection at two and four weeks post-randomization, every month until month six, then every 45 days thereafter until the patient dies, is decertified from hospice, or the caregiver withdraws from the study. The interval between contacts lengthens with time in the study to help prevent study burnout. At least two weeks after a patient dies we contact each caregiver for an interview.

Our primary outcome is the caregiver's overall perception regarding pain management using the Caregiver Pain Medicine Questionnaire (CPMQ) [6]. The CPMQ measures caregiver agreement with statements regarding pain management; for example, “I am concerned about hospice patients becoming addicted to pain medications.” Higher scores (1=strongly agree, 5=strongly disagree) indicate more problematic perceptions regarding pain management. Individual item responses are averaged to derive an overall score and five subscale scores that range from 1 to 5. Because our focus is caregiver attitudes toward pain and pain medications, we retained the 16 items (of 22) that relate to fatalism, stoicism, addiction, tolerance and side effects. We dropped six items related to difficulty administering pain medications.

We regularly collect several secondary measures from caregivers. The Caregiver Quality of Life Index-Revised [22] measures self-reported quality of life in four domains–emotional, social, financial and physical–plus an overall score that is a sum of four items. Caregivers also are asked to provide their perceptions of the patients' overall pain during the previous 24 hours on a 0–10 scale commonly used by hospices (Numeric Pain Scale). The Lubben Social Network Scale [23] is a six-item instrument that assesses the caregiver's social support and social networks. This instrument has two subscales, i.e., family and friends. Caregiver anxiety is measured with the 7-item Generalized Anxiety Disorder instrument (GAD-7) [24]. The 9-item depression scale from the Patient Health Questionnaire (PHQ-9) is used to assess depression among caregivers [25].

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We collect demographic information from hospice staff members who agree to participate. At enrollment and every six months thereafter, staff members are asked to complete a Modified Index of Interdisciplinary Collaboration (MIIC) [14]. The MIIC is an instrument that measures the extent of collaboration between staff members, providing a sense of the culture within the hospice. Annually we interview a convenience sample of hospice staff members about the benefits and challenges of participating in the study. During each team meeting, research staff members collect basic information about the team meeting (Team Observation Scale) [26] and on the technical quality of each conversation with caregivers in the intervention arm (Technical Quality Form) [27].

We video-record a convenience sample of team meetings to permit pre-specified qualitative analyses. A research assistant records the session using Camtasia Studio® software (TechSmith Corporation, Okemos, MI). The video files are edited to allow separate storage of each caregiver's conversation by the unique identification number and the date of the team meeting.

Quality and safety monitoring

A research steering committee conducts weekly teleconferences to discuss challenges and solutions and to monitor recruitment. Face-to-face meetings are conducted at least annually. A monthly newsletter, tailored to each site, helps keep hospice staff informed and engaged. Newsletters have been well-received at both sites.

Several measures have been taken to prevent a breach of confidentiality of personal information about patients and caregivers, including encryption and password-protection of study laptops, storage of data back-ups on a secure network directory that requires both a password and access rights, using arbitrary study identifiers on paper forms, and storage of consent agreements in a locked cabinet within an office that is locked when unoccupied. The Principal Investigator and Data Manager are responsible for monitoring safety centrally; to date, no adverse events have occurred among enrolled caregivers. Because virtually all hospice patients who consent to participate in the study are expected to die, patient deaths are not considered adverse events that must be reported to the IRB.

Data management

Computer-assigned identification numbers are used on data collection forms and electronic records. All contacts and project data are recorded in identical project databases at each site. Each local database is stored on a password-protected, encrypted laptop computer that is dedicated to the study. For backup purposes, a copy of each local database is submitted to the Data Manager at study headquarters through a secure connection for backup. The centrally stored copies are used to monitor recruitment as well as to generate *ad hoc* reports as needed by the research team. Reports of potentially erroneous or missing data are generated regularly by the central Data Manager so that data can be obtained or corrected while information is still available.

Statistical analysis

The caregiver is the unit of analysis. A small number of caregiver pairs (16) provide care for the same patient. Measures from caregiver pairs might be more correlated than measures between unpaired caregivers. However, their scores could also differ substantially. We will use hierarchical (mixed) model to assess whether having multiple caregivers is associated with the primary outcome, nesting caregivers within patients. Results from the hierarchical model will be compared to those from a model that assumes independence to determine how parameter estimates are affected. Because the last data collected from caregivers of decertified patients could be several months prior to the patient's death, they will not be

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included in the main analysis. We will conduct a sensitivity analysis to determine whether including or excluding data from caregivers of decertified patients affects any association between group assignment and outcome.

The overall scores from each caregiver's latest post-baseline CPMQ comprise the primary outcome measure. Based on pilot data, we conducted an *a priori* power analysis to insure an adequate target sample to answer the research question without using unnecessary time, energy, or resources. Assuming a significance level of 0.05, 544 participants will provide 90% power to detect a difference of 2.5 on the 5-point CPMQ scale.

Because time between the latest CPMQ score and randomization may vary up to six weeks, we will include time to the last observation as a covariate. The primary analysis will use multiple linear regression with the last post-baseline CPMQ score as the dependent variable. Independent variables include study group, baseline CPMQ score, and time since randomization. We also will test for interaction between study group and baseline CPMQ score to examine the modifying effect of baseline CPMQ score.

We will analyze cost from the perspective of both hospice and informal caregivers. Analysis will focus on cost per unit change on the CPMQ overall score, represented by the difference between baseline and last CPMQ score.

Qualitative analysis

For the first nine months, we digitally video-recorded a convenience sample of 175 case discussions during 47 interdisciplinary team meetings for use in qualitative substudies. All final interviews with caregivers and hospice staff are digitally audio-recorded as well. While each sub-study has its own research questions and coding frame, we have developed a coding website and overall procedures to facilitate analyses.

Results: Current Status of ACTIVE Trial

Recruitment and Enrollment

Recruitment and enrollment in the ACTIVE trial began late in 2010. Figure 2 summarizes the flow of study participants. As of July 31, 2012, 1038 newly-admitted hospice patients and their caregivers have been reported to study staff. Study personnel contacted 467 caregivers. In the majority of the 391 available cases where no contact was made (233, 59.6%) the patient had either died or was not expected to survive for two weeks; of these 233 cases, 211 patients (90.6%) died within two weeks of hospice admission. Home visits were made to 271 caregivers; only 38 did not consent to participate following the visit. Randomization was accomplished for 249 caregivers of 233 patients, with 126 caregivers of 116 patients assigned to the intervention arm and 123 caregivers of 117 patients assigned to usual care. Sixteen caregiver pairs were randomized to the same group (10 intervention, 6 usual care). A few of caregivers expressed disappointment at not being assigned to a specific group. The study representative reassured these caregivers that all participants provide valuable information. Enrollment is on target for completing recruitment in December 2013 as planned. No caregiver or hospice staff member has declined to be video-recorded, appear on camera, or be interviewed.

Follow-up

All caregivers have completed baseline data collection. Follow-up data collection has been completed at least once (two weeks) for 92 caregivers (73%) in the intervention arm and 103 (84%) caregivers in the usual care arm. For most caregivers with no follow-up data (43 of 54, 80%), the patient died within two weeks of enrollment. The distribution was unequal,

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with 15 in the usual care arm and 28 in the intervention arm. Of 116 patients whose caregivers are in the intervention arm, 94 (81%) have been discussed in at least one team meeting. A few caregivers who have participated much longer than anticipated reported follow-up "burnout." For participants who have been followed for more than six months, we extended the interval for follow-up data collection instruments from monthly to 45 days.

Data management and analysis

Local research staff members have uploaded copies of their database to the central database weekly. Data are imported into SAS® 9.2 for Windows (SAS Institute, Cary, NC) to produce weekly enrollment reports and monthly reports of internal data inconsistencies. Field personnel have asked the data manager to add several variables and reports to the database to improve its functionality, again highlighting the benefits of flexibility.

Several interim analyses have been performed to produce interim reports required by the funding agency, identify caregivers who live a considerable distance from patients, analyze follow-up time, and examine the technical quality of video-based intervention conversations. In addition, database queries have provided lists of patients who are eligible for several qualitative studies.

Qualitative analysis

The qualitative coding website has been used to explore communication between caregivers and the hospice team for two analyses conducted thus far. One analysis examined empathy in communication encounters between caregivers and staff and another study applied a five-step approach to improving communication with families called VALUE (value family statements, acknowledge family emotions, listen to the family, understand the patient as a person, and elicit family questions) [28]. For both studies the coding website was used to connect and facilitate coders who were geographically separated.

Discussion

Improving hospice care depends in part on high quality research. The challenges of conducting research in a hospice setting can be addressed through appropriate and thoughtful study design that allows adequate preparation time [2]. We have implemented the ACTIVE study successfully in two hospices, enrolling caregivers for a little over one year. Only 15 caregivers have dropped out.

Lesson Learned: Key strategies

Preparation allowed us to hire research staff and begin recruitment within two months of receiving funding to conduct the ACTIVE study. Most changes to initial procedures took place during pilot testing, thus minimizing changes to the main study once it was initiated. Thorough preparation also provided us with the flexibility to deal with reductions by the funding agency in both the amount and the period of the award. The support of hospice medical directors helped us to gain support from hospice staff, patients and caregivers. Training and involving hospice staff members in the preparation process forestalled inclinations to "protect" patients and caregivers from our study. Further, housing research within each hospice fostered a sense of teamwork. We also used newsletters to inform hospice staff of the study's progress and build relationships.

Study procedures were designed to avoid additional burden to hospice staff. Careful selection of inclusion and exclusion criteria helped us to avoid enrolling large numbers of participants who could not complete the study. Development and maintenance of a procedural manual helps to ensure that all members of the research team adhere to the

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approved protocol. Data management, editing, and correction are concurrent with data collection. Flexibility in data management has improved the usefulness of the database for field personnel. A secure, Internet-based coding site has proven invaluable for conducting qualitative analyses. Finally, regular teleconferences of key research staff members have enhanced communication and allowed us to identify and address potential problems quickly.

Limitations

The primary reason for non-participation of caregivers has been late enrollment of patients in hospice, leaving little to no time to take part in the intervention. Different study designs and interventions may be appropriate for studying pain management among short-term patients. Because many patients were too ill or cognitively impaired to enroll, we obtained pain ratings from the caregivers, which may not be an accurate reflection of the pain experienced by patients [29].

Conclusion

Randomized studies can be conducted with hospice patients and caregivers if research methods are well-tested and not overly burdensome. Thorough pilot testing allowed us to estimate the target sample size, define the appropriate population, and test recruitment methods, technology and instruments. Results of our study have the potential to improve pain management for hospice patients, a significant problem in this population. A final key task for the ACTIVE investigators will be the translation of the intervention into practice, if it proves to be beneficial in this randomized trial, by developing an implementation manual and testing the intervention in a hospice without dedicated research staff in a future study.

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References

1. NHPCO Facts and Figures: Hospice Care in America. National Hospice and Palliative Care Organization; Alexandria, VA: 2012. Available at: http://www.nhpco.org/files/public/Statistics_Research/2011_Facts_Figures.pdf [(accessed 7 August 2012)]
2. Wohleber AM, McKitrick DS, Davis SE. Designing research with hospice and palliative care populations. American Journal of Hospice and Palliative Medicine. 2011 Epub ahead of print: DOI 10.1177/1049909111427139.
3. Addington-Hall J. Research sensitivities to palliative care patients. European Journal of Cancer Care. 2002; 11:220–224. [PubMed: 12296842]
4. Hermann C, Looney S. The effectiveness of symptom management in hospice patients during the last seven days of life. Journal of Hospice & Palliative Nursing. 2001; 3:88–96.
5. Field, MJ.; Cassel, CK. Approaching death improving care at the end of life. National Academy Press; Washington, DC: 1997.
6. Letizia M, Creech S, Norton E, et al. Barriers to caregiver administration of pain medication in hospice care. Journal of Pain & Symptom Management. 2004; 27:114–124. [PubMed: 15157035]
7. Parker Oliver D, Demiris G, Wittenberg-Lyles E, et al. Caregiver participation in hospice interdisciplinary team meetings via videophone technology: A pilot study to improve pain

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management. American Journal of Hospice & Palliative Medicine. 2010; 27:465–473. [PubMed: 20299692]

8. Parker Oliver D, Wittenberg-Lyles E, Demiris G, et al. Barriers to pain management: caregiver perceptions and pain talk by hospice interdisciplinary teams. J Pain Symptom Manage. 2008; 36:374–382. [PubMed: 18495415]
9. Meeker MA, Finnell D, Othman AK. Family caregivers and cancer pain management: a review. Journal of Family Nursing. 2011; 17:29–60. [PubMed: 21343621]
10. Parker Oliver D, Demiris G, Wittenberg-Lyles E, et al. Recruitment challenges and strategies in a home-based telehealth study. Telemedicine Journal & E-Health. 2010; 16:839–843. [PubMed: 20815752]
11. Parker Oliver D, Demiris G, Wittenberg-Lyles E, et al. The use of videophones for patient and family participation in hospice interdisciplinary team meetings: a promising approach. European Journal of Cancer Care. 2010; 19:729–735. [PubMed: 19832889]
12. Wittenberg-Lyles E, Parker OD, Demiris G, et al. Interdisciplinary collaboration in hospice team meetings. Journal of Interprofessional Care. 2010; 24:264–273. [PubMed: 19995271]
13. Demiris G, Oliver DP, Wittenberg-Lyles E, et al. Video-mediated communication in hospice interdisciplinary team meetings: examining technical quality and content. AMIA Annu Symp Proc. 2009:135–139. [PubMed: 20351836]
14. Parker Oliver D, Wittenberg-Lyles EM, Day M. Measuring interdisciplinary perceptions of collaboration on hospice teams. American Journal of Hospice & Palliative Medicine. 2007; 24:49–53. [PubMed: 17347505]
15. Wittenberg-Lyles E, Oliver DP, Demiris G, et al. Inviting the absent members: examining how caregivers' participation affects hospice team communication. Palliat Med. 2010; 24:192–195. [PubMed: 20007820]
16. Parker Oliver D, Washington KT, Wittenberg-Lyles E, et al. 'They're part of the team': participant evaluation of the ACTIVE intervention. Palliat Med. 2009; 23:549–555. [PubMed: 19443524]
17. Anderson F, Downing GM, Hill J, et al. Palliative performance scale (PPS): a new tool. J Palliat Care. 1996; 12:5–11. [PubMed: 8857241]
18. Harrold J, Rickerson E, Carroll JT, et al. Is the palliative performance scale a useful predictor of mortality in a heterogeneous hospice population? Journal of Palliative Medicine. 2005; 8:503–509. [PubMed: 15992191]
19. Greenspan SL, Nace D, Perera S, et al. Lessons learned from an osteoporosis clinical trial in frail long-term care residents. Clinical Trials. 2011 Epub ahead of print: DOI 10.1177/1740774511430516.
20. McMillan SC, Weitzner MA. Methodologic issues in collecting data from debilitated patients with cancer near the end of life. Oncol Nurs Forum. 2003; 30:123–129. [PubMed: 12515990]
21. Centers for Medicare & Medicaid Services (CMS). Medicare and Medicaid programs: hospice conditions of participation. Final rule. Federal Register. 2008; 73:32087–32220. [PubMed: 18677823]
22. Courtney K, Demiris G, Oliver DP, et al. Conversion of the Caregiver Quality of Life Index to an interview instrument. Eur J Cancer Care (Engl). 2005; 14:463–464. [PubMed: 16274469]
23. Lubben J, Blozik E, Gillmann G, et al. Performance of an abbreviated version of the Lubben Social Network Scale among three European community-dwelling older adult populations. Gerontologist. 2006; 46:503–513. [PubMed: 16921004]
24. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006; 166:1092–1097. [PubMed: 16717171]
25. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001; 16:606–613. [PubMed: 11556941]
26. Cole KD, Waite MS, Nichols LO. Organizational structure, team process, and future directions of interprofessional health care teams. Gerontol Geriatr Educ. 2003; 24:35–49. [PubMed: 15871929]
27. Demiris G, Speedie S, Finkelstein S, et al. Communication patterns and technical quality of virtual visits in home care. J Telemed Telecare. 2003; 9:210–215. [PubMed: 12952691]
28. Curtis JR, White DB. Practical guidance for evidence-based ICU family conferences. Chest. 2008; 134:835–843. [PubMed: 18842916]

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29. Lobchuk MM, McClement SE, Daeninck PJ, et al. Asking the right question of informal caregivers about patient symptom experiences: multiple proxy perspectives and reducing interrater gap. J Pain Symptom Manage. 2007; 33:130–145. [PubMed: 17280919]

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Figure 1.
Image of projected screen in hospice team meeting with view of caregiver and team members. The caregiver has a similar view on the home computer.

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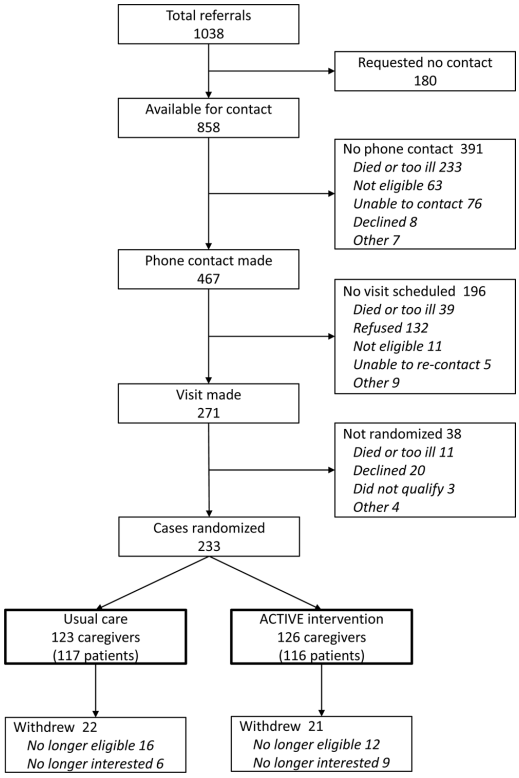

Figure 2.
Recruitment, enrollment, and randomization of participants for the ACTIVE study. Participants are consenting caregivers of patients admitted to participating hospices through July 1, 2012.

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Table 1

Data collection instruments and schedule for administration in the ACTIVE trial.

Instrument	Collection schedule
Hospice staff members	
Hospice staff demographics	At enrollment
Modified Index of Interdisciplinary Collaboration	At enrollment and every six months thereafter
Hospice staff interview	Annually, upon leaving hospice employment and upon study termination
Informal caregivers	
Decline Permission to Contact	Upon hospice admission
Referral tracking and demographics form	Upon hospice admission (*if Decline Permission to Contact is not signed*)
Caregiver tracking and demographics form	At enrollment
Caregiver Pain Medication Questionnaire (CPMQ)	At enrollment, 2 weeks, 4 weeks, monthly until month 6, then every 45 days thereafter
Caregiver Quality of Life Index-Revised (CQLI-R)	
Lubben Social Network Scale (LSNS-6)	
Numeric pain rating scale	
Caregiver Health Questionnaire (CHQ)	
General Anxiety Assessment (GAD)	
Caregiver Interview	At least 2 weeks after patient's deaths
Interdisciplinary team meetings	
Team Observation Scale	During each team meeting, one form for each intervention group participant
Technical Quality Form	