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Hospice Family Caregiver Involvement in Care Plan Meetings: A Mixed Methods Randomized Controlled Trial

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Abstract

Background, Objective—Untrained family caregivers struggle with complicated medical management regimens for hospice patients. An intervention was tested to improve caregiver's perception of pain management and patient pain.

Design, Setting and Participants—The intervention was tested with a two group (usual care vs intervention) randomized controlled trial using parallel mixed methods analysis of 446 caregivers in three Midwestern hospice programs representing rural and urban settings.

Intervention—Web-conferencing or telephones were used to connect caregivers with the hospice care team during care plan meetings.

Measurements—Caregiver perceptions of pain management were the primary outcome. Secondary outcomes included caregiver quality of life, patient pain, and anxiety. Video recordings, field notes, caregiver and staff interviews provided qualitative data.

Results—The overall perception of pain management was not changed by the participation in hospice team meetings. Perceptions of fatalism improved for intervention participants and the intervention participants perceived their patients' pain was better controlled than those in the control group. The intervention was found to be feasible to deliver in rural areas. Caregiver anxiety

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and patient pain were correlated ($r=.18$; $p=.003$) and sub-analysis indicated that caregivers of cancer patients may benefit more from the intervention than other hospice caregivers. Qualitative analyses provided understanding of caregiver perceptions of pain, cost, and facilitators and barriers to routine involvement of family in care plan meetings.

Limitations, Conclusions—The Hospice philosophy is supportive of caregiver involvement in care planning, and technology makes this feasible; the intervention needs modification to become translational as well as additional measurement to assess effectiveness. Caregiver education and emotional support should occur outside the meeting and a strong leader should facilitate the meeting to control efficiency. Finally, the intervention may benefit caregivers of cancer patients more than others.

Keywords

Randomized controlled trial; interdisciplinary teams; caregiver; hospice; pain; cancer

Introduction

An estimated 1.5 to 1.6 million Americans were enrolled in hospice programs for care at the end of their life in 2014.(1) These patients were cared for by family members who were unpaid caregivers, and who provided an average of over 20 hours of care per week to their family member.(2) Family caregivers administer medications (including opioid pain relievers); maintain equipment; and feed, bathe, and assist their family member with other activities of daily living.(2) Hospice patients in the United States have a prognosis of less than six months, and 40% are cared for in a private residence and require around the clock care.(1) It is extensively documented that caregiving takes a toll on family members who worry about performing tasks safely, especially when their care recipient is in pain.(2, 3) Family caregivers are often the most knowledgeable about the patient's condition and ultimately responsible for implementing all plans of care.

Hospice interdisciplinary teams meet every two weeks to develop a care plan for each patient.(4) The meetings, required by Hospice Medicare Conditions of Participation are most often held in the local office of the hospice agency. The meetings will involve discussions of up to 100 patients and may last 3-4 hours.(4, 5) The purpose of these mandated meetings is to assure coordination of care and an interdisciplinary approach to symptom management. To effectively meet this goal the teams focus their discussion on patients with problems and briefly update the status of patients without difficulties.

Unlike an inpatient setting, patient or family participation in care planning is uncommon in community-based hospice because of the physical condition of the patient and caregiving demands that prevent them from traveling.(5) This challenges the hospice philosophy, which advocates for patient and family participation in care.(4) To facilitate family and patient access to hospice care plan meetings, we completed a randomized controlled trial using web-conferencing to facilitate patient and caregiver virtual attendance (Grant Number XXXXX). The intervention was called ACTIVE (Assessing Caregivers for Team Intervention via Video Encounters). We hypothesized that caregivers' interactions with the team would improve their comfort with and perceptions of pain management.

This four-year trial is one of very few randomized controlled trials in the hospice or palliative care setting focused on family caregivers.(6-11) We asked the following research questions: 1) What is the effect of ACTIVE on caregivers' perceptions of pain management, caregiver quality of life, caregiver anxiety, and patient pain? 2) Which caregivers benefit most from ACTIVE? 3) Is ACTIVE cost effective? 4) What are the facilitators and barriers to the future use of the ACTIVE intervention as reported by the informal caregivers and hospice staff?

Methods

Trial Design

A two-group (usual care vs intervention) randomized controlled trial design was paired with a parallel mixed methods analysis. A mixed methods approach was planned, providing both generalizable evidence and a deeper understanding of the findings.(12, 13) Details of the trial design, randomization, and intervention protocols are published elsewhere.(14) Briefly, upon admission into hospice, the nurse asked for permission for the research staff to contact the caregiver. Consenting patients were randomized into two equal groups using numbered, opaque, sealed envelopes in sequence. All caregivers for a particular patient received the same group assignment. Human subject's approval was obtained by the University of Missouri Health Sciences Institutional Review Board. Written consent was obtained from caregivers, patients who were physically and cognitively able, and hospice staff members participating in the care conferences.

Participants and Setting

Family caregivers were recruited from three hospices in the Midwest. Participants were required to be designated as a primary caregiver for an enrolled hospice patient, over the age of 18, involved in decisions related to pain management, having access to a high-speed Internet connection or phone line, and without a hearing or cognitive impairment that would impair communication. Patients were required to be over 18 years and enrolled in a participating hospice. Patients with Palliative Performance Scale (PPS) scores below 30 at admission and their caregivers were excluded, as they were unlikely to survive to attend a meeting.(15, 16) Staff members were required to be employees of a participating hospice. Patients, when able, consented to the study and were encouraged to participate in the team meeting. If multiple caregivers were involved in the care decisions, all were offered the opportunity to participate.

Intervention

Details of the intervention and its protocols are detailed elsewhere.(14) In summary, following consent and group assignment, individuals in the intervention group were trained on the use of web-conferencing and provided with a webcam. Participants without a computer joined the meeting with a telephone. The research staff established the connection and provided introductions, and the hospice team leader facilitated the discussion. Family members assigned to the intervention group were contacted by the research staff when it was their turn to be discussed. A speaker phone was used so all conversation was shared and when web conferencing was used both the family and group image were projected onto a

central screen. An assigned hospice staff member (usually a nurse) would give a brief report on the patient's condition and identify any concerns for discussion. Family members were encouraged to provide feedback and ask questions before a final plan of care was agreed upon. Participants assigned to the usual care group were not a part of the discussion and did not provide input. Hospice staff could not be blinded to group assignment as it was obvious which caregivers attended the meetings. In both groups, research staff contacted participants every two weeks to collect measurement data. Control arm subjects provided measurement data but otherwise received usual hospice care; they did not participate in any team meetings.

Outcomes

Based on our pilot work, the Caregiver Pain Medicine Questionnaire (CPMQ) was the primary outcome.⁽¹⁷⁾ Scores on CPMQ items vary from 1 to 5, with lower scores indicating more problematic perceptions of pain management. The Caregiver Quality of Life Index-Revised (CQLI-R)⁽¹⁸⁾ was collected as a secondary outcome. The CQLI-R consists of four domains (emotional, social, financial, and physical), each scored 0-10, with higher scores indicating higher quality of life. Patients or their caregiver proxies were asked to provide a numeric pain rating (0-10, higher scores indicating greater pain). After the first year of the trial, the Generalized Anxiety Disorder (GAD-7)⁽¹⁹⁾ was added to measure caregiver anxiety. Total scores for the GAD-7 range from 0 to 21, with higher scores representing more anxiety.

Interviews were conducted with caregivers 30 days following the death of their patient and with a convenience sample of staff on an annual basis. A semi-structured interview guide was developed and tested in our pilot work and is available elsewhere.⁽²⁰⁾ Structured interview questions for both groups asked subjects to rate their satisfaction with their personal knowledge and skills related to pain control, their understanding and comfort with pain medications by the end of their hospice experience, their overall satisfaction with the hospice team's management of their care recipient's pain, and their perception of their care recipient's pain control. Video recordings were made of a random sample (169) of hospice team meetings to allow observational analysis. Observations were documented with field notes. Time cost for the intervention was estimated by recording the time for each case discussion, and validated with observation of the video recordings. For discussions including caregivers via web-conferencing, time recording began when the discussion was initiated following a successful web-conferencing connection. Interdisciplinary team discussions of control group participants (who did not attend the meeting) began once the first hospice staff person started the discussion on the patient. Discussion times were averaged within groups (intervention and usual care) and compared.

Given the short average length of service (LOS) in hospice (median LOS = 18.5 days)⁽¹⁾ and challenges with lost data due to death in our pilot study,⁽¹⁷⁾ we collected outcome measures every two weeks for the first 4 weeks, every month through six months, and every 45 days thereafter. Research staff contacted participants by phone or provided a link to a Qualtrics (Provo, UT) Internet-based survey.

Statistical Analysis

We powered the study at 80% to detect a difference in mean CPMQ score of 2.5 points on the 1-5 scale. Based on results from our pilot work,(17) we determined a sample size of 440 (220 in each group) was needed. Near the end of our trial we analyzed the psychometric properties of the CPMQ. Despite its previously documented validity, the use of the instrument in a larger sample identified validity issues.(17, 21, 22) Validity improved with the elimination of four questions that were left out of all subsequent analyses.

All data were entered into a Microsoft Access database. Groups were compared at baseline according to demographic variables, setting, diagnosis, and other factors thought to be potential confounders. Two analyses were performed for each study outcome. The first analysis examined change from baseline to the last available measurement prior to death or the end of the study. The “pre/post” change was calculated for each subject and the Wilcoxon Rank Sum Test (WRST) was used to compare usual care and intervention groups with respect to changes. All randomized caregivers with at least one post-baseline measure were included in the analyses. The secondary analysis used a linear mixed model to test for group differences over time on the CPMQ, CQLI-R, and GAD-7 total scores. To account for the repeated measures nature of the data and the varying duration of participation, both subject specific intercept and slopes were treated as random effects. To minimize the leverage of a relatively small number of subjects with extremely long follow-up times, we limited the number of days followed to 122, which was the 75th percentile of the days in the study for the combined sample. In addition to the CPMQ total score, we also used the WRST to compare groups with respect to change on five CPMQ subscales (fatalism, stoicism, concern about tolerance, concern about side effects, and concern about addiction). To test the effect of dose (number of team meetings a caregiver attended) on association with overall CPMQ change, we used Spearman's rank correlation coefficient. We similarly examined the secondary outcome variables.

Finally, a sub-group analysis was done to identify who might benefit most from the intervention in terms of the secondary outcomes. While not powered to make definitive conclusions, we compared patient pain, caregiver anxiety, depression, and caregiver perception of pain control by patient diagnosis (cancer vs. other) using the WRST. Patient diagnosis and group (intervention vs usual care) were tested using generalized linear models. We identified a correlation between anxiety and patient pain in the two diagnosis groups.

Qualitative analysis

Qualitative data collection was conducted in parallel and with equal status as the quantitative measures. Data included observations, video-recordings, and interviews with caregivers and staff. Several sub-study analyses that were related to this study but had unique research questions and are reported elsewhere.(20, 23-34) Our protocol required coders to achieve inter-coder agreement of 80% or greater before independently coding data. Trustworthiness in analysis was assured through prolonged engagement, an extensive audit trail, multiple coders, and regular debriefing between all researchers.(35)

Merging data

While the quantitative data provides numerical precision, the qualitative data represents a descriptive precision. The use of the matrix to combine the two sets of analysis by research question allows us compare interpretations and legitimate and explain our findings.(36) We used a parallel mixed analysis wherein both statistical and qualitative analyses were done separately and merged in the final analysis. The statistical analysis was done at the end of the study after all data had been collected. Various qualitative analyses with individual research questions were done throughout the project. In a final analysis the statistical and various qualitative results were merged or mixed using a matrix for each research question. (36) Each matrix allowed for comparison and integration of all study results pertaining to the trial question. Within the matrix themes were developed, summarized, and reviewed by all researchers. Finally, all research question results were combined into Table 3.

Role of Funding Source

The National Institutes of Health had no role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; the preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

Results

We enrolled and collected data on 446 caregivers for 416 hospice patients between November 2010 and April 2014. The CONSORT diagram (Figure 1) details participant recruitment, randomization, and drop-out. There were no significant differences between those who agreed to study contact and those who did not regarding admission PPS score ($p=.33$), time to death ($p=.59$) and presence of cancer diagnosis ($p=.71$). Demographics and baseline measures for the randomized groups are reported in Table 1. Comparison of the groups found no significant differences except for income. Likewise, attrition and numbers of assessments were not significantly different between groups. The average number of assessments in the intervention group was 3.85, compared with 3.98 in the control group ($p=.64$).

Perceptions of Pain Management, Caregiver Quality of Life, Caregiver Anxiety, and Patient Pain

There were no significant differences found in any of the measured primary or secondary outcomes for the trial. Table 2 presents the CPMQ, GAD-7, and CQLI-R scores by group. There were 357 caregivers (80%) with two or more scores. Change in total CPMQ score between the first and last available measure did not differ between groups ($p=.18$). We found no evidence of association between the number of meetings attended (dose) and change in overall CPMQ score. The linear mixed model of repeated measures through 122 days post-enrollment found no significant between group differences in total CPMQ score or the rate of change between groups (group x time interaction). There was also no statistically significant time effect. Likewise, no statistically significant effects were found with any secondary outcome.

Analysis of CPMQ sub-scales identified one statistically significant association—fatalism—which improved more in the intervention group than in usual care ($p=.026$). Fatalism is the belief that pain is inevitable and cannot be controlled. Relatedly, the interview question asking the caregiver's impression of pain control also differed between groups, as the intervention participants felt pain was better controlled ($p=.015$).

In the mixed analysis we found three themes that enhanced our understanding of caregiver perceptions of pain (See Table 3). Team communication skills, caregiver knowledge, and psychosocial concerns were identified as influencing caregiver experiences and perceptions of pain.

Which Caregivers Might Benefit Most from ACTIVE

Table 4 details findings from the sub-analysis. One third ($n=126$) of the patients had a cancer diagnosis. We found that cancer patients had higher mean pain scores than non-cancer patients; these differences approached statistical significance late in the hospice stay ($p=.077$). Likewise, anxiety in caregivers of cancer patients, while initially lower, increased toward the end of life, while non-cancer caregivers' anxiety decreased; this difference also approached statistical significance ($p=.061$). On exit interviews, caregivers of non-cancer patients reported better pain control than caregivers of cancer patients ($p=.015$). Including both group and diagnosis in generalized linear models essentially parallels the mean comparisons. The correlation between caregivers' anxiety and patient pain is .26 ($p=.044$) for cancer caregivers compared with .15 ($p=.03$) for non-cancer caregivers, indicating a stronger correlation for cancer caregivers. Taken together, these findings demonstrate that pain is more intense, perceived to be more poorly managed, and more strongly associated with caregiver anxiety for cancer patients than others, suggesting that cancer patients and their caregivers might be most appropriate for participation in the ACTIVE intervention, were it to be found to be effective in promoting pain control.

The mixed analysis found that caregivers with specific communication patterns interact more with the team and had the potential for greater benefit. Caregivers with a tradition of fewer family hierarchical roles and a tendency toward more open conversation about death and dying were observed to be more adaptive, flexible, and process decisions and changes more easily with the hospice team.

Intervention Cost

The original cost effectiveness analysis was not possible because there were no statistically significant outcomes (benefits) to weigh against the intervention costs. Thus the analysis involved time cost only. When intervention caregivers participated in the meetings, discussions of their care recipient lasted an average of 6 minutes and ranged from 1-20 minutes. In contrast, discussions of control group patients under usual care conditions (no participation by caregivers) lasted only 3 minutes and ranged between 1-11 minutes. Observational analysis of the meetings found three major reasons for the increased time: 1) a lack knowledge by caregivers, especially related to pain issues, resulted in numerous questions, 2) a need for emotional support for caregivers resulted in lengthy supportive discussions (as long as 20 minutes), and 3) the lack of a strong facilitator.(34)

Facilitators and Barriers to Translation of ACTIVE into Hospice Practice

Facilitators and barriers to the translation of ACTIVE into hospice were identified (Table 3). Good team communication skills, technical quality of the web-conferencing, and participant satisfaction were found to facilitate successful intervention. Facilitating communication skills included attention to caregiver literacy, awareness of both team and caregiver non-verbal communication, expression of empathy, active listening, and encouragement of questions from caregivers. Good technical quality with the web-conferencing facilitated non-verbal communication and a virtual presence that both caregivers and staff found important. Finally, translation can be facilitated if both caregivers and staff are receptive to the intervention and recognized benefits.

Team communication skills, technical quality, cost, and team structure and roles were identified as barriers to intervention. Specifically, a lack of attention to non-verbal communication of the team or caregiver impaired the interaction as caregivers felt ignored or disrespected. Likewise, when the pace of the discussion was too fast for caregivers to understand, caregivers reported no value. Secondly, audio problems in web-conferencing sometimes impaired communication, creating frustration and lengthening the meeting. Thirdly, cost (staff time), is a barrier to translation. Given the length of the meetings (up to 3-4 hours), an intervention that prolongs them is problematic. Finally, team structure and roles, specifically leadership style and absence of a family's usual nurse, can be a barrier. If caregivers do not see familiar faces, they are less likely to actively participate and reported frustration. Likewise, if the leader does not have a process to include everyone, frustration and inefficiency are evident.

Discussion

Pain management is one of the major challenges facing hospice caregivers.(7, 37, 38) Untrained caregivers are required to make complex pain assessments and administer powerful opioids with complicated administration schedules.(39-42) The Institute of Medicine reports that 78% of family caregivers of cancer patients are administering 5-9 medications per day, including opioids for pain.(3) Managing a dying patient's pain regimen is known to be filled with tremendous stress, as caregivers often believe they may have had hastened or caused their care recipient's death.(39, 40)

Our pilot work found that including the “faces and voices” of informal caregivers and patients in team meetings, even for a short duration, resulted in collaborative interdependent goals between staff and patients/families, creating new activities and roles for patients/families within the team, requiring flexibility among individual members' role definitions. (17) Patient/family involvement resulted in collective ownership of all goals by team members, and the care outcomes could be evaluated through a reflection on the team process, again including feedback from patients/families.(43) Our hypothesis that caregivers' perceptions of pain could be changed was a result of these findings from our pilot work. The most frequent problem discussed by the team with the family involved pain, and the families most frequently noted benefit was an improved understanding of pain management.(43-45) Thus, the CPMQ was chosen as the primary outcome measure.

The analysis of the primary measure and the review of the qualitative analysis suggest explanations for the lack of statistical significance in our primary measure. Despite the success of the instrument in our pilot work(17) and the documented psychometrics in the development of the CPMQ (22), our work with a larger sample indicates validity concerns. (17, 21, 22) We chose to investigate the validity of the instrument because of challenges reported by our research staff in collecting the responses from participants in this larger sample. Even when improving the validity with the elimination of four items, we conclude the instrument weaknesses may have impacted the detection of changes in caregiver perception.

The qualitative analysis demonstrates that attendance at the care conferences does not always result in active participation. Likewise, active participation is not always constructive if the participation reflects a need for social support rather than a participation in a shared decision making process.(35) Additional training of staff and caregivers around shared decision making and participation may have improved the impact of the intervention.

Despite the lack of significance the trial has much to offer. This rare multi-site, multi-year trial provided the opportunity for in-depth longitudinal exposure in hospice with a robust sample to test a unique intervention. This trial was built with findings of a pilot study (Grant Number XXXX), which refined recruitment protocols, identified measures and allowed sample size projections. We experienced limited recruitment or randomization challenges, unusual in this setting.(46) This trial found the intervention feasible, with generally acceptable technical quality and noted benefits.(27, 32)

The mixed methods analysis, rare in a randomized controlled design,(47) allowed hypothesis testing with statistical methods while qualitative methods provided interpretation of findings, identified weaknesses in instrumentation, and suggested revisions in the intervention necessary for translation. This rather unique approach to clinical trials, in an area where instrumentation is known to have limitations, is advantageous in evaluating an intervention. (7, 17)

The unique relationship of caregiver anxiety and patient pain is an interesting finding and can impact hospice care. Because medication is often controlled and administered by caregivers, their perceptions, knowledge, and emotions are critical in implementing hospice pain management plans. If the caregiver is uncomfortable with the pain regimen and does not appropriately assess pain and follow the plan of care, the patient could suffer, yet traditionally, little to no attention has been given to caregivers' perceptions, and they have had little opportunity for discussion and input on those plans.(48) This study demonstrates that involving caregivers in meetings where decisions and plans are made is feasible and has reported benefits. The finding that ACTIVE may be most helpful for caregivers of hospice cancer patients is also important. Given the large number of hospice patient discussions in a meeting, focusing on those who may benefit the most would help manage the time and therefore cost of the intervention.

The study has limitations which impact its generalization and may explain the lack of statistical results. Given the nature of the intervention the teams could not be blinded to

group assignment as it was obvious who was and was not participating in the meetings. While observation of the video recordings for control and intervention participants did not indicate that behavior of the team changed over time we do not have a measure for this. Additionally, the challenges of validity with the CPMQ instrument may explain the lack of significant clinical findings. Likewise, it is noteworthy that this relatively rural homogeneous population limits the application to findings in more diverse hospice programs.

Conclusion

This study is significant despite the lack of statistically significant findings. To date, there have been only ten randomized controlled trials in US hospices that focused on patient or caregiver outcomes.(11) Interdisciplinary team involvement in care planning and shared decision-making with patients and family members is gaining momentum within health care, and this intervention demonstrates feasibility in the community-based hospice setting.(49) Family caregivers, responsible for implementing plans of care in outpatient settings, are not a recognized part of the health care system and too few interventions have been tested to improve their participation and recognition as partners in the care of terminally or critically ill patients.(6)

Our qualitative findings show there is a need to support care plan meeting participation with education and emotional support outside of the meeting Examination of the questions asked by caregivers in this forum indicates a need for additional education, especially on pain management during routine hospice visits. Similarly, observation of needed emotional support during the interaction with the team suggests a need for additional psycho-social support from team members. Finally, our observations suggest that a more structured decision making process led by a focused team leader may improve the time management of the meeting and thus the effectiveness of the intervention.(34) When the designated team leader did not manage time or participation proactively the meeting went long, team members became frustrated, and the decision making process was not effective.(34) While ACTIVE aligns with the hospice philosophy of family-centered care and is a feasible way to involve family, it requires further refinement and testing to lower costs and more clearly quantify the benefits. Specifically we believe the intervention needs to be enhanced with additional education and support of caregivers outside the team meeting and a structured focus decision making process with a strong facilitator within the team meeting.

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Figure 1.
Consort Diagram

Table 1

Baseline and clinical characteristics of caregivers enrolled in the study, by group [Number and (row percentage) unless otherwise indicated].

Measure (number missing)	Intervention	Usual care	p-value *
Site			
Hospice 1	100 (50.5)	98 (49.5)	.96
Hospice 2	94 (50.0)	94 (50.0)	
Hospice 3	29 (48.3)	31 (51.7)	
Demographic characteristics			
Age in years [mean (standard deviation)]	60.1 (12.5)	59.2 (13.3)	.51
Education			
Less than high school	11 (30.6)	25 (69.4)	.091
High school or equivalent	53 (50.5)	52 (49.5)	
Trade school or some college	66 (49.6)	67 (50.4)	
College graduate or professional degree	90 (53.9)	77 (46.1)	
Employment			
Employed full-time	64 (47.8)	70 (52.2)	.49
Employed part-time	29 (58.0)	21 (42.0)	
Not employed	39 (44.8)	48 (55.2)	
Other	83 (50.3)	82 (49.7)	
Income (annual)			
Less than \$20,000	36 (40.0)	54 (60.0)	.027
\$20,000 – \$40,000	66 (51.6)	62 (48.4)	
\$40,001 – \$70,000	62 (62.6)	37 (37.4)	
Over \$70,000	40 (44.9)	49 (55.1)	
Unknown	14 (48.3)	15 (51.7)	
Lives with patient			
No	131 (49.2)	135 (50.8)	.70
Yes	92 (51.1)	88 (48.9)	
Marital status			
Divorced	27 (49.1)	28 (50.9)	.88
Married	157 (50.2)	156 (49.8)	
Widowed	15 (55.6)	12 (44.4)	
Other or unknown	23 (46.0)	27 (54.0)	
Race			
African-American	10 (43.5)	13 (56.5)	.46
White	204 (49.9)	205 (50.1)	
Other or unknown	9 (64.3)	5 (35.7)	
Relationship to patient			

Measure (number missing)	Intervention	Usual care	p-value *
Adult child	116 (48.1)	125 (51.9)	.68
Non-relative	23 (47.9)	25 (52.1)	
Spouse	59 (54.6)	49 (45.4)	
Other relative	25 (53.2)	22 (46.8)	
Sex			
Female	168 (48.0)	182 (52.0)	.11
Male	55 (57.3)	41 (42.7)	
Outcome measures [mean (standard deviation)]			
Caregiver rating of patient pain, 0-10 scale			
Baseline (8)	4.21 (2.82)	4.05 (2.96)	.57
Last (91) **	3.99 (2.85)	4.27 (2.86)	.36
Caregiver Pain Medicine Questionnaire(21) ‡			
Baseline	49.0 (7.43)	49.6 (7.30)	.41
Last (89)	50.5 (7.33)	50.3 (7.12)	.81
Caregiver Quality of Life Index-Revised(18)			
Emotional – baseline	7.61 (1.93)	7.06 (2.26)	.23
Emotional – last (89)	7.19 (2.03)	6.95 (2.08)	.28
Financial – baseline	6.70 (2.75)	7.06 (2.54)	.54
Financial – last (89)	6.70 (2.42)	6.48 (2.74)	.37
Physical – baseline	7.77 (1.62)	7.21 (2.42)	.25
Physical – last (91)	6.91 (2.15)	6.68 (2.17)	.31
Social – baseline	7.80 (2.20)	6.82 (2.60)	.06
Social – last (89)	6.75 (2.58)	6.75 (2.55)	.99
General Anxiety Disorder(19) ‡			
Baseline (138)	5.86 (5.16)	6.65 (5.33)	.18
Last (205)	5.56 (5.42)	6.37 (5.81)	.27

* Chi-square for categorical variables, t-test for continuous measures.

** Last follow-up measure recorded other than baseline.

‡ Modified by dropping items 7, 10, 13 and 16.(22)

† Data collection with this instrument began in September 2010. Only caregivers with baseline and all follow-up assessments using this instrument are included.

Table 2

Summary of comparison of intervention and usual care groups.

		N	Intervention	Usual Care	p-value
a. Change between first and last measure [mean (95% CI)]					
CPMQ	Total score	357	0.16 (0.08 – 0.23)	0.08 (0.02 – 0.15)	.18
	Addiction subscale		0.12 (0.01 – 0.24)	0.07 (–0.03 – 0.17)	.59
	Fatalism subscale		0.19 (0.09 – 0.29)	0.02 (–0.08 – 0.12)	.026*
	Side effects subscale		0.19 (0.10 – 0.28)	0.17 (0.09 – 0.25)	.73
	Stoicism subscale		0.06 (–0.03 – 0.14)	–0.03 (–0.12 – 0.06)	.30
	Tolerance subscale		0.22 (0.10 – 0.34)	0.15 (0.03 – 0.27)	.17
GAD-7 (anxiety)		243	0.16 (–0.62 – 0.94)	0.23 (–0.52 – 0.98)	.89
CQLI-R	Total score	357	–0.64 (–1.6 – 0.32)	–1.2 (–2.0 – –0.39)	.18
	Emotional		–0.06 (–0.37 – 0.25)	–0.36 (–0.67 – –0.06)	.15
	Financial		–0.04 (–0.38 – 0.31)	0.01 (–0.32 – 0.34)	.85
	Physical		–0.10 (–0.38 – 0.18)	–0.35 (–0.63 – –0.08)	.66
	Social		–0.44 (–0.84 – –0.05)	–0.48 (–0.77 – –0.18)	.40
b. Repeated measures					
CPMQ	Total score	357			
	Time (days)		0.0006	0.151	
	Group		–0.046	0.469	
	Group × time		0.0004	0.498	
GAD-7	Time (days)	243	–0.006	0.167	
	Group		–0.856	0.175	
	Group × time		0.006	0.369	
CQLI-R	Total score	357			
	Time (days)		–0.009	0.093	
	Group		0.682	0.369	
	Group × time		–0.006	0.449	

Table 3

Mixed Methods Analysis by Research Question

Research Question	Findings	Answers/Implications for Research Questions
What is the effect of ACTIVE on caregivers' perceptions of pain management, caregiver quality of life, caregiver anxiety, and patient pain?	<p>1. <u>Improved perception of fatalism and pain management</u>. Despite CPMQ validity issues, (22) fatalism improved for intervention participants and they perceived their patient's pain as more controlled than the usual care group. A significant correlation was found between anxiety and pain. Cancer patients may be better candidates for ACTIVE than patients with other diagnoses.</p> <p>2. <u>Team communication skills can impact caregiver comfort and understanding</u>. Caregiver perceptions of pain management were more positive with attention to literacy, lower number of medical words, increased use of passive sentences and the when pace of the conversation was slow enough for caregiver comfort and understanding. (20, 23-29, 31, 32)</p> <p>3. <u>Caregiver knowledge is improved</u>. Caregivers have numerous questions and report challenges with administration of medication, concerns about side effects of medications, and insecurity with pain assessment. (20)</p> <p>4. <u>Psychosocial support</u> Caregivers demonstrated need for emotional support in team meetings but often psychosocial issues were unaddressed. (20, 28, 30, 33, 34)</p>	<p>1. A stronger effect of ACTIVE may be related to anxiety for caregivers of cancer patients. The CPMQ should not be used as an outcome measure.</p> <p>2. Team communication skills training can improve the effectiveness of ACTIVE.</p> <p>3. ACTIVE needs to be strengthened with pain management education outside the team meeting.</p> <p>4. ACTIVE needs to be strengthened with increased emotional support related to pain management for caregivers outside the meeting.</p>
Which caregivers benefit most from ACTIVE?	<p>1. <u>Caregivers of cancer patients</u> rated their patient's pain with a higher mean pain score than non-cancer patients. Anxiety in caregivers of cancer patients, while initially lower, increased toward the end of life while non-cancer caregivers' anxiety decreased; this difference approached statistical significance, despite being under-powered.</p> <p>2. <u>Caregivers with specific communication patterns</u> interact more comfortably with the team. Caregivers with more flexible and open communication styles communicate better with the health care team. (23)</p>	<p>1. Caregivers of cancer patients may benefit most from the intervention.</p> <p>2. Caregiver communication patterns should be assessed to more actively involve caregivers in the interaction.</p>
Is ACTIVE cost effective?	<p>1. <u>Staff time was significantly increased</u> when team meeting time increased, resulting in increased cost for ACTIVE. (29)</p> <p>2. <u>Reasons time was increased</u> included need to educate caregiver, caregiver expression unmet emotional needs, lack of a clear team decision making process, and lack of a strong team facilitator. (34) (20, 28, 29)</p>	<p>1. ACTIVE is currently expensive and costs must be reduced to make translational.</p> <p>2. ACTIVE needs to include education and emotional support for the caregiver and process improvement and leadership for the team to reduce costs.</p>
What are the facilitators and barriers to the future use of the ACTIVE intervention as reported by the informal caregivers and hospice staff?	<p><u>Facilitators</u></p> <p>1. <u>Team Communication Skills</u>: Skills facilitating involvement included literacy, awareness of non-verbal communication, active listening, expression of empathy, and response to caregiver questions. (20, 23, 25-29, 31, 32)</p> <p>2. <u>Technical quality of web-conferencing</u> and facilitated the involvement of caregivers with the team. Video quality was acceptable. (27, 32)</p> <p>3. <u>Participant satisfaction</u>. Caregivers felt comfortable with team, a part of the decision making process, got questions answered, felt involved, respected and believed their knowledge and confidence increased. Staff reported they were doing a better job when the caregiver was present. (32, 34)</p> <p><u>Barriers</u></p> <p>1. <u>Lack of team Communication skills</u> influence the interaction negatively in the absence of a demonstration of empathy, use of medical words, and non-verbal communication. Caregiver understanding and comfort declines as the pace of the discussion increases. (20, 23-28, 31, 32)</p> <p>2. <u>Technical quality of web-conferencing audio</u> impedes interaction and delays the meeting, specifically audio problems. (27, 32)</p> <p>3. <u>Deficits in caregiver knowledge and need for caregiver emotional support</u> are barriers to decision making and lengthen the meeting time. (29, 33, 34)</p> <p>4. <u>Team structure and roles</u> confuse caregivers when their visiting hospice staff is not present. Team leadership and a structured process increased caregiver participation. (28, 29, 34)</p>	<p>1. Team skills training to attend to the expression of empathy, non-verbal communication cues, use of medical words, and pace for the discussion so as to make the interaction inclusive of caregivers</p> <p>2. Video-conferencing platform allows caregivers to engage in meaningful conversations when using good communication techniques however, a back up system when audio issues arise needs to be readily available.</p> <p>3. Support for ACTIVE by staff and caregivers is important for success.</p> <p>4. Education and emotional support need to occur outside the team meeting.</p> <p>4. Staff roles need to be clear to caregivers, proxies for absent staff need to be knowledgeable, a designated facilitator with a structured decision process may increase caregiver involvement and time efficiency.</p>

Table 4

Caregiver anxiety and patient pain, by primary diagnosis

Variable	N	Cancer diagnosis (n=126)	Other diagnosis (n=312)	P-value *
Patient pain (mean, 0-10 scale)				
First measure	438	4.24	4.08	.59
Last measure	355	4.58	4.00	.077
Difference between first and last measures	349	0.11	0.09	.84
Anxiety (mean, GAD-7)				
First measure	345	5.85	6.17	.58
Last measure	263	6.68	5.46	.18
Difference between first and last measures	263	+0.69	-0.45	.061
Exit interview question: "Was your loved one's pain controlled" (mean) [†]	182	8.26	8.81	.015 *
Correlation between final anxiety score and final pain rating	59;203 [‡]	0.26	0.15	<.05 (for both)

* Wilcoxon Rank Sum Test, except for correlation.

[†] Scale of 0-10, with 10 being highest feeling of pain controlled.

[‡] N for cancer diagnosis and other diagnosis, respectively.