Title: ACCESS (Access for Cancer Caregivers for Education and Support for Shared Decision Making)

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Protocol

Abstract

We have designed a Cluster Cross-over pragmatic randomized controlled trial CCXOPRCTto test an intervention for a population seldom studied—hospice family caregivers—targeting an identified need (decision-making), and measuring a core set of caregiver outcomes (anxiety, pain knowledge, and patient pain). This will be the first shared decision making intervention in the hospice setting. This project proposes an intervention for hospice family caregivers called ACCESS (Access for Cancer Caregivers to Education and Support for Shared decision-making). Our preliminary work (R01NR011472) found that it is feasible to use web-based conferencing to facilitate family caregiver attendance at the hospice care plan meetings. Qualitative feedback indicates this attendance is beneficial to family members. However, we conclude that simply enabling attendance at these meetings is not sufficient to change clinical outcomes. For caregivers' anxiety to be changed they need to be prepared for these encounters and actively engaged with the hospice staff in shared decision-making. There is a critical need to arm hospice family caregivers with necessary information and a strengthened emotional state so they may become decision-makers. We propose using the Facebook platform to improve emotional support and caregiver knowledge to better prepare caregivers for participation and decision-making.

A CCXOPRCT design initially randomly assigns hospice sites to two of three groups: 1) Group 1 participants will serve as the control and receive usual hospice care enhanced by hospice staff training in shared decision making, 2) Group 2 participants will receive enhanced usual care as well as participate in a private Facebook support group to increase their knowledge and provide social/emotional support, 3) Group 3 participants will receive enhanced usual care, participate in the Facebook support group, and participate in hospice team meetings with a shared decision making process. After 12 months the group goes through a 90 day (or less if all have completed the trial earlier) washout period so all participants can complete the study. The group then is assigned to a second arm of the study for another 12 months. Again following a washout period so all participants complete the trial and then re-assignment to their first study arm again. Each cluster will go through two arms of the intervention, although participants will only complete one arm. A schedule has been developed. We will use qualitative and quantitative methods in parallel and equal status to measure the efficacy of the intervention.

Our overall hypothesis is that ACCESS will improve hospice cancer family caregiver knowledge and emotional state (via Facebook), thereby facilitating a shared decision making process, which will result in improved caregiver anxiety and knowledge and improved pain control for patients.

Objectives

We have three specific aims: 1) Evaluate the effect of ACCESS on hospice family caregiver anxiety, pain knowledge, and patient pain; 2) Evaluate the effect of social media as a decision aids and decision support for pain management by family caregivers; 3) Evaluate the satisfaction of staff and family caregivers with a shared decision making process for pain management and patient care.

Background

The Institute of Medicine reports 40% of patients at the end of life have severe, unrelieved pain. Those dying of cancer carry a disproportionate burden of the likelihood of dying in pain. Unrelieved pain has been attributed to inadequate communication between providers, caregivers, and patients. Pain management and family caregiver (FCG) support are core components for quality end of life care, and with 78% of FCGs of cancer patients administering an average of 5-9 medications per day, including narcotic medication for pain, the burden on families is tremendous. Caregiving takes a toll when the family member worries about performing tasks safely, especially when their loved one is in pain. Although FCGs show concerns about reporting pain to health care teams and administering pain medications to their dying loved ones, many health care providers fail to address these concerns. Research has found that pain management is especially troublesome for FCGs of cancer patients, causing them anxiety and distress related to the administration of narcotics. As one participant in our preliminary trial stated, “I’m not a doctor, and I do not know if I helped her go faster or slower or what, hell I do not know.” This project addresses the anxiety of FCGs of hospice cancer patients by involving them in shared decisions related to managing pain at the end of life.

Although frequency and type of adverse effects vary, our studies find that one-third of FCGs of hospice patients are moderately to severely anxious, and more than one-half are depressed. Given the number of patients at the end of life who experience pain, the challenges experienced by FCGs who manage their pain, and the resultant FCG anxiety, the IOM suggest that FCGs should be integrated into the health care team and be provided training and support. However, hospice FCGs and patients are routinely absent from the care plan meetings where key decisions are made. When FCG input is lacking, care plans suffer from incorrect assumptions about the patient and family perspectives. We have pilot-tested implementing the IOM recommendation for family involvement in the hospice interdisciplinary care plan meeting. This meeting is required by Medicare conditions of participation and occurs every 14 days for each patient. While these meetings can offer opportunity for family integration with the hospice team and have potential to facilitate shared decision-making, it is not common practice to include FCGs in hospice care planning meetings.

Shared decision-making (SDM) is a process wherein a healthcare choice is jointly made by a healthcare provider (in this case, hospice) and a patient and/or patient’s proxy (FCG). While hospice principles support SDM, evidence for SDM in the hospice setting does not exist. To test the feasibility of FCG participation in hospice care plan meetings, we have recently completed an extensive preliminary trial, using web conferencing to facilitate FCG attendance of hospice team care plan meetings (R01NR011472). We demonstrated the feasibility of including FCGs in meetings through web-conferencing. We found FCGs lacked the knowledge to fully understand providers and often used meeting time to seek information and emotional support. We also found that FCG anxiety and patient pain are correlated and FCGs of hospice cancer patients reported higher anxiety and higher patient pain than FCGs of non-cancer patients, leading us to focus on cancer patients and their FCGs.

Study Procedures

We propose an intervention to target education and emotional support to FCGs based on a structured process for SDM. ACCESS (Access for Cancer Caregivers to Education and Support for Shared decision- making) has three components; 1) Facebook groups to provide education and emotional

support to FCGs, 2) web-conferencing to involve FCGs in care plan meetings and, 3) a structured SDM process to guide team discussion. These components will facilitate SDM between the hospice staff and FCGs, lower FCG anxiety, and increase FCG knowledge regarding patient pain, resulting in less pain for cancer patients. A pragmatic cluster randomized controlled trial (PC-RCT) will randomly assign hospice sites to one of three groups: FCG participants at Group 1 sites receive only enhanced usual care (EUC), FCG participants at Group 2 sites receive EUC and participate in Facebook (FB) groups for informational and emotional support, FCG participants at Group 3 sites receive EUC, participate in Facebook groups and the interdisciplinary team meeting for SDM (FB/SDM). Usual hospice care will be enhanced through education on SDM for all staff.

This study will last five years. Participants will be in the study for up to 120 days, depending on the death or discharge of their patient. Team meetings are held every other week, Facebook groups will be visited at least two times per week. Data collection will be done on the following schedule: baseline (day one), day 14, day 30, day 60, day 90, and on or before day 120. Data collection may end earlier at 14-21 days after the death or termination of the patient from hospice services or if a study volunteer chooses to end their participation. A qualitative interview will be done on or around the same day that the last quantitative measures are gathered.

We propose a pragmatic cluster randomized three-group design with a mixed methods analysis where qualitative and quantitative data are collected at the same time and given equal status in evaluating the effectiveness of the intervention. We propose a pragmatic trial rather than an explanatory trial because by testing ACCESS in a real-world context we will be able to determine if it will reduce FCG anxiety, improve FCG knowledge of pain, and reduce patient pain. This trial is considered pragmatic because 1) it has broad inclusion criteria, 2) hospice staff are not told how to apply the intervention, 3) the intervention is applied by the entire hospice team, 4) the Enhanced Usual Care (EUC) training on SDM will be given to all hospice clinical staff and all participants without restriction, 5) the primary outcome (anxiety) is a clinically meaningful one and does not require extensive training to evaluate, 6) compliance with either the intervention or EUC will not be monitored (although it will be documented), 7) there are no special strategies to motivate the hospice staff adherence to SDM, and 8) the analysis will include all participants in an intention-to-treat fashion. EUC as a comparator is appropriate when the goals of a trial are pragmatic rather than explanatory. A mixed-methods approach will involve conducting statistical analyses of measures supplemented by qualitative analysis of video-recorded team discussions, Facebook data, and interviews.

Inclusion/Exclusion Criteria

Exclusion/Inclusion Criteria: FCGs are the focus of the study. They must be at least 18 years of age, involved in daily decisions related to the patient's care, and be a designated family/friend caregiver for a cancer patient enrolled in a participating hospice. Subjects must be willing to use or set up an email account. Participants in Group 2 must further be willing to use a Facebook account. Participants in Group 3 must be willing to use a Facebook account and video conferencing (VSee). FCGs without an Internet-enabled device will be supplied with a smartphone and data plan (restricted to Facebook posting, answering study correspondence and surveys, and care planning meeting time) for the duration of their participation.

Caregivers are the focus of the study, and as many hospice patients are too ill to participate they will not be enrolled. The inclusion criteria include a terminal cancer diagnosis for the care recipient, enrolled in the participating hospice, and a FCG at least 18 years of age (to reflect the typical hospice patient population) willing to use the required technology. Patients of FCGs must have a likely life expectancy of more than two weeks as determined the hospice nurse.

Hospice staff (e.g., nurses, social workers, physicians), also study subjects, must be employees of participating hospices and be at least 18 years of age to be included in the study.

Randomization
We will use a cluster randomization design because:

1. Our aims contain individual level and organizational level outcomes. Study aim 3 can then be assessed at the organizational level as well as the individual level.
2. Given the large geographic distance covered by the six participating hospice sites, it is far more cost effective to focus our intervention costs at specific hospice sites rather than across all sites. This will allow us to assess the total impact of an agency wide intervention. In keeping with the pragmatic goal of our trial this is more reflective of how implementation would actually be done at a hospice site, as individuals would not be given random interventions in real life.
3. We will avoid the contamination between the intervention groups and the control group- an unavoidable consequence of having both groups in one hospice site. We believe contamination may have lowered our ability in the pilot study to detect the change in the primary outcome.
4. These sites provide us with a diverse sample. We will have rural and urban hospice programs, a greater number of under represented minorities, and a more diverse hospice staff.

We have chosen a cross over design to increase precision as each arm of the study may serve as its own control group, thus reducing the number of participants necessary to have adequate power. This has been the recommended design for small numbers of clusters that are not meeting recruitment goals.

Recruitment

The hospice agency will include a flyer about the study in their admissions packets. They will also include an an opt-out form, allowing individuals to note that they do not want the research staff to contact them with information about the research. Hospice staff will refer all other caregivers to the research staff. Research staff will call or email and establish a time to explain the study and offer FCGs the opportunity to participate. Participants will verbally consent to participate and baseline measures will be obtained via telephone. It is anticipated that the data will be entered directly into REDCap as the survey is performed, thus preserving anonymity. Participants may choose to have follow-up measures over the phone or electronically, except for Group one where telephone contact will be continued as a way to maintain engagement and reduce losses to follow-up. The waiver of documentation of consent will be emailed to each participant. As needed, participants will be assisted with setting up and using email addresses, Facebook accounts, smartphones, and VSee.

Intervention

Table 1 summarizes the intervention design. Details are included below.

Table D.2.1 Summary of Theoretical Components, Intervention, Components, and Design				
Intervention component	Theoretical component (outcome)	Group 1 EUC	Group 2 FB	Group 3 FB/SDM
Usual hospice care (philosophy, visits, team meets every 14 days)	Organizational structure (non-profit vs for profit, rural vs urban)	x	x	x

Enhanced usual hospice Staff training in SDM process	Team Process(staff knowledge SDM)	x	x	x
Pain education via Facebook support group shared resources and peer discussion	Team Process: Communication Climate (pain questionnaire)		x	x
Emotional support via Facebook peer support group	Team Process: Communication Climate (general anxiety)		x	x
Structured SDM process in team meeting	Team Process(9 step SDM process in meeting)			x
Participation in team SDM	Team Structure(FCG participation with team)			x

Group 1: Enhanced Usual Care Group: Participants in this group will receive usual hospice care that does not include participation in a Facebook support group or the ability to participate in team SDM via web-conferencing. The enhanced care is a result of the staff training in SDM.

Group 2: Secret Facebook Group: Research specialists will train FCGs assigned to Group 2 and Group 3 (Facebook or Facebook + SDM groups) to use Facebook. They will demonstrate how to adjust privacy settings and use Facebook. FCGs will also be given a printed guide to Facebook (including Rules of Conduct) as a reference. Research specialists will assist FCGs with their first post, which will introduce them to the group. Secret Facebook groups are not searchable on the Internet, and only members authorized by the administrator can view what is shared. Research Specialists will serve as administrators. We will create a secret Facebook group for all participants randomized to either Group 2 or 3 in each hospice. Participants will be asked to log onto Facebook at least twice weekly and read the content. They are encouraged, but not required, to respond. Dr. Washington (co-investigator) will monitor all Facebook groups to provide continual assessment of emotional distress and compliance with rules of conduct. Hospice staff will not be a part of the Facebook groups to ensure intervention fidelity across intervention arms.

As in our pilot study, research specialists will monitor discussion daily via Facebook notifications, with support from Drs.Washington. Weekly, research specialists will post a link to vetted pain information and other resources to their Facebook group, and provide a discussion question. Previous postings will be available to new members for a set period of time. In our pilot work, resources and discussions increased pain knowledge of FCGs and generated peer emotional support as FCGs shared their common caregiving challenges and emotions. Guidelines for participation detail rules of conduct, including that participants will not give medical advice, and will not be critical of one another. Guidelines were honored in the pilot without concern. The research specialists will communicate FCG concerns to hospice staff in an agreed upon manner (text, email, etc.).

Although Facebook is an excellent platform for delivering educational content, it is important to address the ethical issues of monitoring the accuracy of information and protecting group members from unintentional disclosure. We have dealt with these issues in Section E of the proposal, which describes our policy and procedures for managing anticipated privacy concerns. Before posting links, clinical accuracy of material will be verified by Co-Investigator Dr. Tatum (a national leader and

board-certified physician in hospice and palliative medicine), Dr Audrey Wallace (radiation oncologist), and Dr. Popejoy (APRN, PhD). When FCGs have clinical questions or concerns, research specialists will forward them to hospice nurses or medical directors for response via traditional methods.

Group 3: Facebook+ SDM: Individuals assigned to this group will receive the Facebook intervention and will additionally attend the bi-weekly hospice team meeting (via web-conferencing) to participate in SDM. They will be trained on use of the web-conferencing software, the purpose of the team meeting, and how best to prepare for participation. Training will include how to create a list of problems, questions, and requests in advance, using the 9-step SDM process, and how to identify items appropriate for the meeting versus items appropriate for staff home visits. As in our preliminary trial, we will use web conferencing tool VSee to connect intervention-group FCGs with biweekly care plan meetings. On the day before the meeting, the hospice will provide our research specialist a list with the order for patient care plan discussions. This will allow research staff to estimate the time when study participants will be discussed and provide FCGs with a time estimate so they can be ready for the conference. Research staff will notify them via email or text message during the meeting about any delays. A projector allows the visualization of the FCGs and hospice team members on a large screen in the team meeting room, facilitating both verbal and non-verbal communication as the group discusses the care plan. The technology allows multiple users to participate, and additional providers or FCGs can join the meeting. This approach, which mirrors our preliminary trial, has worked well and proven satisfactory to staff and FCGs. Although FCGs and staff report benefits from video images, telephone conferences will be used in cases of technical difficulty with the video-conferencing.

Study Statistics

Measures/ Data AnalysisD.3.1 Measures F CG outcome measures will be collected at baseline, 14, 30, 60, 90, and 120 days. The collection schedule reflects that meetings are required to be held every 14 days and our desire to have a measure close to the patient's death without unduly burdening FCGs. Our experience showed that 75% of FCGs were no longer in the study after 90 days due to the death of their patient. Research Specialists will conduct phone interviews with all FCGs 14-21 days after their patient's death. Using a convenience sample of hospice staff an annual electronic survey will be distributed annually. Research specialists will perform all data collection using RedCap and/or the phone.

Hypothesis 1 (H1) FCG participating in both intervention groups will report lower levels of anxiety, increased levels of pain knowledge, increased perceptions of involvement in care, increased communication, decreased depression, increased quality of life, and lower patient pain compared to enhanced usual care.

Hypothesis 2: FCGs participating in SDM process in team meeting will report lower levels of anxiety, increased levels of pain knowledge, and lower patient pain compared to either the Facebook group or usual care group.

H3 The effect of the ACCESS intervention compared with the usual care will be greater for those with worse anxiety scores at baseline.

QUANTITATIVE AND QUALITATIVE MEASURES

LIST OF FAMILY CAREGIVER MEASURES (see REDCap survey attachments for specific questions/measures used):

Demographics- basic demographic information about the family caregiver, patient diagnoses, medication administration
GAD-7 Generalized Anxiety Disorder- primary outcome measuring anxiety
Family Pain Questionnaire- secondary outcome measuring family pain knowledge
Perceived Involvement in Care Scale- secondary outcome measuring involvement in patient's care and management of the illness in cooperation with the hospice staff
CCCQ Care Giver Communication Questionnaire- secondary outcome measuring hospice and caregiver communication and hospice support
PHQ 9 Public Health Questionnaire- secondary outcome measuring depression
SF12 General Health- secondary outcome measuring family caregiver health
CQLI-revised Caregiver Quality of Life- secondary outcome measuring family caregiver quality of life
Edmonton Symptom Assessment- secondary outcome measuring patient symptoms, including pain
Zarit Burden Inventory- secondary outcome measuring personal and role strain of family caregiver
Facebook Survey Items- (Group 2 and 3 only) measures family caregiver response to Facebook educational topics

LIST OF STAFF MEASURES (see REDCap staff survey attachment for specific items/questions)
Staff Demographics- basic information including job title, site, number of years in hospice, number of years at the specific hospice site
Leeds Concordance of Care II- revised- measures hospice staff satisfaction with involvement of patients and family caregivers in treatment planning and shared decision-making

RESEARCH QUESTION MEASURES

RQ1 In what ways do roles of team members change when FCGs are in team meeting?
Measures:
Video recordings of team meetings
Annual Staff survey

RQ2 In what ways does Facebook affect FCG information and emotional state for SDM for intervention groups?
Measures:
Facebook group postings
Family Pain Questionnaire
Facebook Survey Items

RQ3 What are the barriers and facilitators for SDM in the team meeting?
Measures:
Video recordings of team meetings
Care Giver Communication Questionnaire

RQ4: What are the perceptions and satisfaction of FCGs and staff with both intervention groups.
Measures:
Leeds Attitude Concordance II
Perceived Involvement in Care Scale
FCG Interviews

Statistical Analysis

Statistical Assumptions: We will routinely test assumptions of linearity, independence and homoscedasticity by calculating and plotting residuals and Cook's distance for all models. Where data are missing, we will substitute the mode for categorical data and the median for continuous data, given that <0.5% of data were missing for any measure in our preliminary trial. If the proportion of missing data is higher, we will use multiple imputation. We use the final measure provided by caregiver before patient death in the analysis. Because individuals are randomly allocated and the sample size is relatively large, we expect that both known and unknown confounders will be distributed evenly among the three groups. Because randomization will be stratified by hospice, equivalent proportions from each hospice will be allocated to each group. However, we will test for an interaction effect between study group and hospice to assess whether the effect of the intervention differs between hospices. This will be tested by introducing a Study Group X Hospice interaction term into each of the regression models discussed below. We acknowledge that this study is not powered to detect small interaction effects. Additional confounders will only be introduced as covariates if we find evidence of imbalance between groups at baseline.

We will test whether randomization created balanced groups by comparing baseline measures and demographic characteristics, using chi-square or t-test analysis for categorical or continuous variables, respectively. Variables that differ significantly between groups will be included in regression models as potential confounders. To compare outcomes for Hypotheses 1-4 (H1-H4), we will use the last available measure post-baseline and prior to death or the end of the study. The last available measurement typically represents the FCG's measure at the last point prior to the patient's death. This is a last observation analysis. Carpenter and Kenward argue that, in such analyses, time to this event should be taken into account. We will therefore include time from study enrollment to the last observation as a covariate. We will report estimates with 95% confidence intervals. To draw inferences from our study to the likely benefit to an equivalent population where the intervention under trial is a model of service delivery, all analyses of outcomes will be by intention-to-treat. The intention-to-treat analysis, consistent with the objectives of a pragmatic trial, will minimize the influence of "informative missingness" of the data and preserve groups' comparability.

<u>Statistical Analysis H1- H3</u>

H1: FCGs participating in both intervention groups (Facebook and ACCESS) will report lower levels of anxiety (GAD-7), increased levels of pain knowledge (FPQ), and lower patient pain (BPI) compared to the EUC group at last follow-up.

H2: FCGs participating in the SDM process in team meeting will report lower levels of anxiety (GAD-7), increased levels of pain knowledge (FPQ), and lower patient pain (BPI) compared to either the Facebook-only group or the EUC group.

Drs. Kruse and Kapp will work with our statistical consultant Dr. Albright to examine differences between longitudinal profiles of the three study groups for each of the outcomes (GAD-7, FPQ, and patient pain). We will use mixed (hierarchical) models with repeated outcome measures nested within participants (see model below, where ij represents the ith observation of the jth participant). This will allow us to draw inferences about how outcome measures change through time (slope) between the three study groups. These models are able to accommodate differing numbers of measurements at varying time intervals for participants. As above, we will include covariates when indicated.

Last post-baseline measure = β_0 + β_1[study group] + β_2[baseline measure] + β_3[time since enrollment]

H3: The effect of the intervention compared with EUC will be greater for those with lower (worse) anxiety scores at baseline.A multiple linear regression model will be used as fo r H1 above, but with an additional interaction term (study group X baseline GAD-7) to examine the modifying effect of baseline GAD-7 score. If the β_4 coefficient is statistically significant, we will conclude that the effects of the ACCESS intervention are conditional on baseline perceptions:

Qualitative Analysis Dr. Washington will lead the analysis of qualitative data throughout the project. We will begin our initial coding from our preliminary work.

Qualitative Data
Video-recording: We will record 100% of all care plan meeting days with the web- conferencing intervention participants and 100% of meetings where all group participants are discussed for comparison using qualitative analysis until June 10, 2020 Facebook posts: We will also maintain 100% of the Facebook conversations for analysis and track all “likes” noted on posts. FCG Interviews: We will interview 100% of all FCGs in each group (total of 642 interviews) 14-21 days following their patient’s death. The interviews will be semi-structured based on guides developed in our preliminary work (see Appendix) and will include a post GAD-7 measure to evaluate post-care stress. Staff surveys: convenience sample annually by REDCap and distributed through the hospice sites email using the LEED questionaire.

Risks

Human subjects will incur minimal risk by participating in the study. Potential risks could include frustration or anxiety with learning new skills or malfunctioning or technically deficient equipment. Some individuals might be nervous having a ‘camera’ in the home despite their ability to control when it is on and off. As in most studies, despite efforts to protect confidentiality, potential exists for a privacy breach that could cause distress or embarrassment. All paper forms ????? and computerized data will be stored in secure environments to minimize this possibility. Finally, there is a potential for frustration about having additional activities to manageWe will continue to minimize these risks by being considerate as we contact family caregivers by phone and/or email to schedule activities. We also assure patients, both verbally and in writing, that they may withdraw from the study at any time.. Finally, the hospice admissions nurse will not release names of any patients or FCGs to the research team without first allowing them to ‘opt out’ of the study. Once referrals are obtained, the Research Specialist will then call the family to assure convenience and interest in the study.

We have chosen the videoconferencing solution called VSee (Vsee Inc, Sunnyvale, CA), which is free to download and use for both personal and commercial use (similar to Skype). While both Skype and VSee are free videoconferencing systems, VSee is considered more secure. VSee uses open industry standard—FIPS 140-2 compliant 256-bit AES encryption—on all control and media traffic. Unlike Skype, VSee uses RSA public/private key to exchange the AES session key such that the VSee servers do not have access to the AES session key. This means only the people participating in a conversation can decrypt data passed through VSee conversations (whereas Skype has the ability to monitor individual conversations). For this reason, VSee is often referred to as a “telemedicine” videoconferencing tool and has been endorsed by numerous health care systems and organizations as a videoconferencing tool throughout the country (including Stanford Hospitals and Clinics, Trinity Health, Intermountain Healthcare etc.) (http:vsee.com). In a study by the Office of High Performance Computing and Communications at the NIH National Library of Medicine, investigators concluded that “VSee provided secure encrypted video that looked superior to other low-band width products.”

The Facebook platform requires special considerations of risk and privacy. The consent form ????? will make these issues known, and the protocol will require research staff to review participants' privacy settings (we recommend the strictest settings). They will be told that if they agree to participate in this study, their name will be added to a "closed secret" Facebook page, giving them access to other hospice FCGs enrolled in the study. Although the research team controls membership in this group, which is not available to the general public, participants will be advised to protect their personal information and privacy with their individual privacy settings. Members of the Facebook group may contact one another through the Facebook website. However, the research team will not share participants' personal contact information. To participate in the study, participants must join Facebook and have an account. They will be advised to read the Facebook privacy policy and set their Facebook privacy settings with the tightest controls. Our research staff will walk them through the privacy settings to assist in understanding their meaning. However, participants will decide on their Facebook privacy settings. They will be told that the settings of other group members might impact the privacy of what they share. They will also be informed of the Facebook policy that Facebook owns all materials placed on the Facebook website, and they will be advised to read the policy carefully if posting photos.

Likewise, we will tell FCGs that, as members of the secret Facebook group, they will be able to discuss experiences, share caregiving advice, and access questions and concerns regarding similar issues with others enrolled in the study. Each week, the research staff will provide a new information posting and discussion prompt. We will tell participants that nothing is required of them and that they may log into the site and read and respond (or not respond) to the discussion as they choose. Our research team will supply discussion information and review all comments and responses to determine the needs of members and the helpfulness of the Facebook page for FCGs.

Participants will be given a Rules of Conduct document outlining the ethical conduct expected of participants of this Facebook group (see Appendix). These rules include items like not giving medical advice to other FCGs and not being critical of other FCGs. If a participant does not follow these rules, the research staff can speak privately with them and, if necessary, after consultation with the Principal Investigator and research team, revoke their access to the page. The need for this never occurred in our pilot studies.

This Facebook group does not replace hospice services. Neither the research staff nor any member of the Facebook group will provide mental health services such as counseling. If the research staff becomes concerned about a caregiver's mental well-being, they will contact the hospice social worker to assure the safety of the caregiver and others.

Adequacy of Protection against Risks

Recruitment and Informed Consent: Initial recruitment of subjects will take place through the hospice agency. Hospice staff, in compliance with privacy and confidentiality regulations, will screen eligible participants. The staff will briefly explain the study to families, provide an informational flyer, and document if a family chooses to 'opt-out' of the study. After a referral is supplied, the Research Specialist will call to explain the research process in detail. A waiver of consent will be reviewed with every patient and family member who is interested in participating, and will be emailed to them if they choose to participate. The Research Specialist will also explain the waiver of consent form to hospice staff. The form contains detailed information about the purpose of the study and contact information for the University of Missouri Health Sciences Institutional Review Board (MUHSIRB). The waiver of consent form emphasizes that the caregiver can discontinue study participation at any time, and that refusal or termination of participation will not affect the patient or caregivers relationship to the hospice agency or the quality of care delivered.

Protection against Risk

Caregiver confidentiality and comfort with the technology are protected, for they must agree to use the video component of the web-conferencing. Our web conferencing software is encrypted, and access is password-protected. Caregivers are “called” by the Research Specialist to gain entry into the conference. We used this technology in our preliminary trial with no privacy issues.

Training staff to understand their role in preventing a breach will address protection of data confidentiality. All paper forms and recordings will be kept in locked cabinets in locked offices within a locked suite. All computerized data will be stored on password-protected and encrypted computers and networks. Only study personnel with a specific need to use data will be granted permission to access it. Finally, all patient/family information provided by the caregiver or the hospice will be identified with an arbitrary identification code rather than a name. For meetings that are video recorded, FCGs’ and patients’ full names will be edited from the video. All research data that leave the hospice office will be maintained in a locked file cabinet and secure computer in the PI’s office. It is anticipated that referral information will be scanned and emailed directly through the hospice site to Research Specialists within the hospice email system, eliminating potential breach of confidentiality via mail or by “crossing” encrypted email systems.

Benefits

The proposed project has the potential to improve hospice services by allowing patients and their family caregivers better access to, and participation in, their hospice care. The Internet, telephone and social media platforms are tools that allow patients and families to participate in their team care plan discussions, and express their concerns, goals, and values as the care plan evolves. The social media platforms allow FCGs to obtain additional information and social support to improve the hospice experience.

Importance of the Knowledge to be Gained

This project will evaluate the value to FCGs not only of participating formally in team care plan meetings to help shape their end-of-life plan, but also of receiving enhanced information and social support through social media. The underlying concept is that technology can aid patients and FCGs in joining discussions about their needs and help assure that their care plan fulfills those needs. With knowledge from this study, we will develop a plan to translate the intervention into hospice practice, and we will advocate that policy governing hospice care include such patient/family participation as usual care. Because hospices serve more than 1.5 million individuals annually improving the quality of life of FCGs would have a significant impact.

Payment and Remuneration

Hospice Staff: All hospice staff at each participating site will receive $30 check for the REDCap completion of the LEED survey. At the end of the survey they will be asked to supply their name, address, and social security number for payment. .

Hospice Caregivers will each receive $50 for their effort in participating in the study.

Costs

There is no cost to participants who participate in this study other than the use of their Internet enabled device, cell phone and Internet plan. If a participant does not have an Internet enabled

device or a cell phone/Internet plan which allows them to enroll or participate the grant will provide a smartphone at no charge to the participant.

Single Site IRB: WUSTL Reliance on MU

MU will remain the single site for IRB when Dr. Parker Oliver transfers to Washington University (WUSTL). Effective October 1, 2020 Dr. Robin Kruse will become the PI overseeing the project through the MUIRB. Dr. Parker Oliver will file a Request to Rely with WUSTL IRB and the agreement will fall under the institutions master reliance agreement.

References

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