Barriers to recruitment into a randomized controlled trial comparing two modes of emergency department-initiated palliative care

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Abstract

Background: Emergency department (ED) visits among older adults are common near the end of life. Palliative care has been shown to reduce ED visits and to increase quality of life among patients, but recruitment into these programs is often challenging.

Methods: Research coordinators monitored factors that prevented enrollment into a multi-site randomized controlled trial investigating two modes of community-based palliative care delivery for patients in the ED who are discharged home. Reasons for non-participation were documented and analyzed to identify themes within refusal data.

Results: Enrollment rate across all sites was 45%. Of the 504 eligible patients who refused to participate, 237 (47.0%) refused due to barriers related to illness severity. Patients commonly refused due to misconceptions/stigma related to palliative care (123 [24.4%]). One-hundred forty-three patients (28.4%) refused due to the mode of palliative care delivery. Less commonly, patients refused due to general research barriers (16.5%), family/caregiver barriers (11.7%), and physician-related barriers (.1%).

Discussion: Patients with advanced illnesses often refuse to participate in palliative care research due to the severity of their illness, misconceptions about palliative care, and the mode of care delivery. Robust training programs are crucial to overcome these misconceptions and to educate patients and providers about the role of palliative care. Future palliative care programs and study designs should recognize the burden this vulnerable population endures and consider alternative modes of care delivery in an effort to increase participation and enrollment.

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Trial Time Period: March 28, 2018 – January 31, 2020

Background

Multiple studies have shown that palliative care improves quality of life in patients with advanced illness. Patients receiving palliative care utilize fewer resources, have reduced Emergency Department (ED) visits and fewer hospital admissions, leading to reduced cost of medical care and higher satisfaction for patients and families. Nonetheless, engaging older adults with advanced illness in research is challenging for multiple reasons. The dearth of literature on this topic identifies significant barriers to enrolling patients in palliative care programs. Patients are often too sick or burdened by their illness to participate, and limited life-expectancy among this population complicates data collection. Additional recruitment barriers include patient, family, and provider refusal, difficulties in communication regarding end-of-life care, and lack of training in palliative care amongst providers.
Despite these barriers, the limited research that does exist highlights the overwhelmingly positive benefits of palliative care in patients with advanced illnesses.\textsuperscript{1,2,11} Furthermore, recent studies point to the ED as a potential setting in which to enroll patients in palliative care programs, as ED visits are extremely common among patients with advanced illness.\textsuperscript{12} Recruiting patients into palliative care research in the ED setting may pose unique challenges due to the fast-paced environment, lack of an ongoing relationship with the patient, and high symptom burden that brought patients there to begin with.\textsuperscript{13,14} Additional research is needed to understand how best to engage this vulnerable population in research and to optimize methods of palliative care delivery.

Emergency Medicine Palliative Care Access (EMPallA), is a five-year multi-site randomized controlled trial (RCT) designed to compare the effectiveness of two modes of community-based palliative care delivery for patients with advanced illness. Patients are recruited into the study from the ED or observation unit and randomized to either the nurse-led telephonic case management or the outpatient specialty palliative care arm.

**Aim**

The aim of this study is to understand the barriers to enrolling patients with advanced illness from the ED into a multi-site palliative care trial, as lessons learned can assist in achieving recruitment goals and inform future researchers who are interested in recruiting this vulnerable population.

**Methods**

The EMPallA peer-reviewed trial leveraged the Clinical Trials Transformation Initiative (CTTI) framework prior to active recruitment in order to maximize recruitment strategies and best practices.\textsuperscript{15} Eleven EDs across the country were responsible for recruiting patients into the EMPallA multi-site study.

Eligibility criteria for the study included patients 50 years of age or older who presented to the ED with a qualifying illness. Qualifying illnesses included advanced cancer or end-stage organ failure (defined as New York Heart Association Class III or IV heart failure), End-Stage Renal Disease with glomerular filtration rate <15 ml/min/m\textsuperscript{2}, or Global Initiative for Chronic Obstructive Lung Disease (Stage III, IV, or oxygen-dependent Chronic Obstructive Pulmonary Disease) among patients who are scheduled for ED discharge or observation status. Patients were also required to have health insurance, speak English or Spanish, and reside within the geographic area. Patients were excluded from the study if they had previously received hospice or palliative care, were admitted to inpatient services, had dementia, or lived in a skilled nursing facility (SNF) or similar assisted living facility (ALF). Additional study details can be found in the published protocol paper.\textsuperscript{16} The study was submitted to and approved by the NYU School of Medicine Institutional Review Board Ethics Committee.
The NYU Research Team was responsible for developing the trial design and protocol development, trial site selection, and recruitment communication planning.\textsuperscript{15} Research coordinators from each of the eleven respective EDs were responsible for collecting data regarding patient eligibility and enrollment into the EMPAllA study. All ineligible or patient refusal data was recorded by research coordinators and logged in REDCap, a secure, web-based application that served as the research database.\textsuperscript{17} The NYU Research Team closely monitored site performance and extracted and analyzed recruitment barriers from REDCap.

Prior to active patient recruitment, all research coordinators received extensive training. Trainings leveraged stakeholder feedback from physicians, as well as the EMPAllA Study Advisory Committee (SAC) patient stakeholder group, to ensure proper messaging as per the CTTI recruitment communication planning recommendation.\textsuperscript{15} Additionally, research coordinators had the opportunity to practice the script and pitch with SAC members via teleconference to obtain feedback and suggestions for improvement prior to approaching study participants. Once training was complete, research coordinators screened electronic health records to identify patients with a disease qualifying illness. If a patient met study criteria, research coordinators approached the patient using the script and attempted to enroll the patient at bedside. Every patient who enrolled and completed the baseline survey received a $40 gift card as study compensation.

During the daily electronic health record screening process, research coordinators documented reasons for non-eligibility and refusals. For patients who met one or more of the disease qualifiers but were determined ineligible, the reasons were documented. Patients could be ineligible for more than one reason (e.g. have dementia and live in a SNF). For patients who were eligible but declined participation in the study, they were asked to provide a reason for their refusal. Research coordinators recorded their responses using a pre-determined list of common refusal reasons in REDCap. Patients were permitted to provide more than one reason. Patient refusals were not mutually exclusive, and each reason for refusal was accounted for in the analysis. Weekly team meetings of research coordinators from all the eleven sites occurred as an opportunity to discuss each refusal reason and strategize potential solutions in an effort to maximize recruitment. In order to monitor eligibility and enrollment, data was organized into a Consolidated Standards for Reporting of Trials (CONSORT) diagram (Figure 1).\textsuperscript{18–20} All data represented in this study is from the reporting period (March 28, 2018 - January 31, 2020).

Results

The CONSORT diagram (Figure 1) depicts the process of patient recruitment from screening to consent. As of January 31, 2020, 12,756 patients with a qualifying illness have been identified, of which 1,062 were deemed eligible for the study (8%). The majority of patients (11,029) were not eligible for the study because they met one or more exclusion criteria. Additionally, there was a subset of patients (665) for whom the screening tool was not completed because research coordinators were not able to approach them prior to discharge. Of the 1,062 eligible patients, 483 were successfully enrolled and 579 were unable to be enrolled, yielding an overall enrollment rate of 45%. Enrollment rates varied widely across sites (ranging from 8% to 92%). Notably, of the 579 patients who were eligible but not enrolled in the
study, 75 patients were unable to provide reasons for refusal. This was frequently a result of either insufficient documentation by research coordinators, or patients not feeling well enough to engage in conversation with the research coordinators to provide thorough rationale. Thus, 504 patients provided reason(s) for their refusal to participate in EMPallIA.

Table 3 outlines the frequency of each refusal by category. Results are based on the number of patients that cited each reason, and patients were allowed to give more than one reason. Of the 504 eligible patients who refused to participate, 237 (47.0%) refused due to “barriers related to illness severity.” Of these patients, 98 (19.4%) stated that they were too burdened by other appointments or did not have enough time to participate. One-hundred eleven patients (22.0%) said that they were satisfied with their current care, often stating, “I’m happy with the care that I’m getting” or “I have everything I need.” A smaller proportion of patients (42 [8.3%]) did not feel well enough to participate. Patients also commonly refused due to “misconceptions/stigma related to palliative care” (123 [24.4%]). Of these 123 patients, more than half did not feel that their illness was serious enough to need palliative care (80 [15.9%]). The remainder of patients refused because they associated palliative care with hospice and/or death (60 [11.9%]), making statements such as: “I'm not dying” and “I'm not there yet.” One-hundred forty-three patients (28.4%) refused due to the mode of palliative care delivery. The overwhelming majority of these patients (133 [26.4%]) did not want to or could not commit to attending the outpatient clinic visits. In contrast, only 21 patients (4.2%) stated that they did not want to receive telephonic palliative care. In some instances, patients wanted the choice to be placed in one intervention arm over another but refused study participation since they could not be guaranteed placement into their preferred treatment arm.

Eighty-three patients (16.5%) refused to participate for reasons categorized as “general research barriers.” Patients typically exhibited a lack of interest in research participation (79 [15.7%]). However, some patients reported a fear of privacy breach or had negative feelings towards research (8 [1.6%]). A small proportion of patients did not participate due to family or caregiver barriers (59 [11.7%]), and in some cases, a family member or caregiver recommended the patient not participate (38 [7.5%]). Twenty-one (4.2%) reported that they did not want to make a decision without a family member or a caregiver present. Only four patients out of 504 (0.1%) refused because of physician-related barriers. Two patients preferred not to make a decision without consent from their physician, and there were two instances in which the physician declined on behalf of the patient.

**Discussion**

**Main Findings**

The aim of this study was to assess the reasons why patients in the ED refused to participate in a palliative care, randomized controlled trial. The most common patient refusal reasons were barriers related to 1) the severity of the patient’s illness, 2) misconceptions or stigma related to palliative care, and 3) the mode of palliative care delivery. Barriers including illness severity, misconceptions and family/caregiver and physician gatekeeping are previously cited in the literature, but the mode of
palliative care delivery is a finding that is unique to this study. We hypothesized that family/caregiver and physician gatekeeping would be a more prevalent refusal reason and barrier, but we found these to be far less common in our study. Thus, our findings provide insights into ways in which researchers can tailor recruitment strategies as well as design palliative care programs which meet the needs of this patient population.

Aligning with lessons learned from the Principal Investigator’s prior randomized controlled trial of Palliative Care in ED, our enrollment goal was 50% and overall enrollment rate was 45% across the eleven sites. Despite being slightly under our target goal, the data we have collected thus far provide valuable lessons learned for future research in this field. As it is well documented that research within palliative care populations is difficult, this enrollment rate is not particularly surprising. The FamCope Trial, which aimed to test the feasibility of nurse-led, family-coping-oriented palliative home care in patients with advanced cancer, encountered higher refusal rates in comparison to our study (66% vs. 55%) but cited some similar reasons for refusal such as a “lack of energy” or being “too sick.” In contrast to the FamCope Trial, our study found that patients often declined to participate because they felt that they were satisfied with their current care. Although this is not a frequently reported barrier in the literature, other studies also have reported that patients with advanced cancer often refuse to participate in palliative research due to satisfaction with their current care. Presumably, there are some patients with advanced illness whose needs are being met with their current care, and thus do not feel as though they would benefit from palliative care.

To date, research suggests that some providers still hold perceptions that palliative care is only appropriate at the end of life. Although other studies have cited this as a barrier, we did not find physician or family/caregiver gatekeeping to be a major recruitment barrier within our study. We believe the rationale of why physicians were not a barrier is because the last several years have brought about a shift of attitude toward palliative care within the healthcare community. Recent studies have found physicians have a greater understanding of the role of palliative care and are more confident in referring patients to palliative care services. Physicians were given the opportunity to opt-out their patients in the EMPallIA study prior to recruitment, but few took the study team up on the offer. Additionally, a recent study analyzing the perceptions of palliative care among healthcare providers before and after implementation of a palliative medicine division found increased attendance in educational activities and increased confidence in palliative care. Within the same study, providers who favored co-management with palliative care held core values that aligned with current concepts, such as advanced care planning. We expect that as the number of palliative care programs in hospitals across the country increases, understanding and acceptance of palliative care amongst providers will continue to grow and foster a new set of beliefs and norms. Our results also demonstrated that family and caregivers did not impede recruitment. We hypothesize they did not hinder the recruitment process, as research coordinators anecdotally expressed many patients were often alone in the ED when approached. More detailed data collection is needed to understand this concept more deeply.
In regard to the perceptions of our patient population, patients refused participation as they held preconceived notions that to enroll in palliative care implied that they were giving up or were ready to die. These notions were rarely alleviated despite research coordinators’ explanations that palliative care would not and should not replace current treatment. Other studies have reported similar barriers to recruitment, with patients often associating palliative care with hospice or death.\textsuperscript{7,14}

This study also further demonstrates that the mode of palliative care delivery often factored into a patient’s decision to participate in the study. Of the patients who did not participate due to mode of palliative care delivery, the majority indicated that they did not want to be randomized into the outpatient palliative care arm, due to inability or unwillingness to make it to in-person clinic visits. In contrast, relatively few patients said that they did not want to receive telephonic care. This finding is noteworthy for future researchers and healthcare system leadership as it demonstrates that patients may be more open to receiving palliative care if they do not have to attend in-person outpatient clinic visits. To our knowledge, these are new findings which have not been reported in other studies. Aligning with our results, these findings suggest that patients with advanced illness may be reluctant to add an additional in-person clinic appointment to their schedules, as they may be overburdened with multiple appointments. Telemedicine visits (e.g. phone call, video chat) may be a feasible alternative to in-person clinic visits, and other studies have demonstrated success of telephonic palliative care.\textsuperscript{27,28} Future studies should continue to explore the effectiveness of telehealth visits as an alternative mode of care delivery for this specific population.

**Implications for Future Studies**

The findings from this paper provide important lessons for future studies with palliative care populations, both in general and in the context of the ED. We suggest implementing a robust training infrastructure and documentation system for research coordinators. Creating a systematic and standardized approach can minimize bias and may increase fidelity of research coordinators. Training should include CTTI recruitment communication planning such as: developing a standard patient-centered script, shadowing senior research coordinators, supervised patient recruitment by senior research coordinators, proper documentation of each encounter, and ongoing supervision and oversight of all research coordinators by either the site project manager or principal investigator. Involving a palliative care physician in the training process is crucial, as they can provide important feedback regarding proper language and messaging techniques. For this population specifically, tailored messages should be developed so that both patients and their families understand that palliative care can provide an added layer of support and can be delivered in conjunction with life-prolonging treatment.

Prior to active recruitment, we recommend research coordinators role-play patient recruitment scenarios with patient stakeholder groups like the SAC in order to receive constructive feedback. The training infrastructure should be closely monitored. To minimize site variations in the context of our multi-site...
study, we conducted in-person site visits prior to launch, developed standard materials that could be personalized with site specific logos, and implemented weekly calls to discuss recruitment barriers and facilitators. Calls were also used to brainstorm strategies in overcoming recruitment barriers. All facilitators were disseminated to all sites enrolled in the study. As the NYU Research Team closely monitored and evaluated recruitment metrics as per the CTTI framework recommendation, high performing recruitment sites were paired with low performing sites to provide feedback and support.

More research is needed on how best to engage physicians to ensure they are allies, rather than barriers, in the recruitment process. We suggest providing physicians with the autonomy to exclude their patients, as we did within this study. Another suggestion could include engaging physician stakeholders during the development of the research project, as they likely hold unique perspectives on the best ways to recruit patients.

**Strengths/Limitations**

The major strength of this paper is the generalizability of the results across different geographic ED contexts (11 unique EDs across the country), thus demonstrating that it is feasible to recruit patients who have multiple disease etiologies into palliative care research studies. Understanding patient barriers within this sub-population is integral in order to plan and develop trials that leverage successful recruitment strategies. In addition to including patients from across the United States, our study included a broad patient population with multiple disease etiologies. While other palliative care studies are limited to patients with advanced cancer, our study recruited patients with advanced cancer, congestive heart failure, chronic kidney disease, and chronic obstructive pulmonary disease. By including these patients, we have captured a wider scope of patients with advanced illness and improved the generalizability of these findings. Furthermore, it is relatively uncommon for studies to record reasons for refusal. In the context of such a large study, these refusal reasons provide unique insight into the reasons why patients with advanced illnesses are hesitant to engage in palliative care research.

Our CONSORT diagram reveals that a significant portion of patients were deemed ineligible due to hospital admission. This posed a unique limitation to EMPallIA, as we were unable to collect refusal data from patients admitted into the hospital. Nonetheless, this exclusion criterion was essential for our study design in order to target a specific group of patients who may not otherwise have access to palliative care programs. Notably, palliative care services are available to admitted patients, but few resources exist for patients who are discharged home from the ED.29–31

Furthermore, our study identified that family and caregiver gatekeeping was not a common barrier to enrollment in our patient population, but we are unable to draw definitive conclusions due to limited data collection specific to this refusal reason. In research, it is challenging to capture information and the rationale of non-participants; thus, future studies should try to incorporate qualitative methods such as content analyses in order to thoroughly interpret findings.
Conclusion

By providing greater insight into why patients with advanced illness refuse to participate in palliative care research, we have been able to explore the ways in which we can successfully engage this patient population. In particular, misconceptions related to palliative care may prevent patients from enrolling in palliative care programs, so it is essential that patients have a clear understanding of the role of palliative care. This requires a strong training infrastructure for research coordinators. Furthermore, engagement with palliative care physicians and ongoing communication across recruitment sites are essential in order to overcome enrollment challenges. Future studies with palliative care populations must design programs that meet the needs of this population, which may include some form of telemedicine. Although it is often difficult to engage patients with advanced illness in palliative care research, our study demonstrates that it is both feasible and imperative that we continue efforts to engage with this patient population.

List Of Abbreviations

Assisted Living Facility (ALF); Consolidated Standards for Reporting of Trials (CONSORT); Clinical Trials Transformation Initiative (CTTI); Emergency Department (ED); Emergency Medicine Palliative Care Access (EMPallA); Randomized Controlled Trial (RCT); Research Electronic Data Capture (REDCap); Study Advisory Committee (SAC); Skilled Nursing Facility (SNF).

Declarations

- Ethics approval and consent to participate: Approved by the New York University Grossman School of Medicine Institutional Review Board.
- Consent to participate: written informed consent was obtained from study participants.
- Availability of data and materials: All data generated and/or analysed during the current study are available from the corresponding author on reasonable request.
- Competing interests: The authors declare that they have no competing interests.
- Funding: This work was supported through a Patient-Centered Outcomes Research Institute (PCORI) Award (PLC-1609-36306). PCORI has been involved in the design of the study and collection.
  
  DISCLAIRER: All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.
- Authors’ contributions: JB: drafting and critically revising the manuscript. MF: Data analysis, drafting the manuscript, and critically revising the manuscript. AC: drafting and critically revising and reviewing the manuscript. JC: drafting and critically revising the manuscript. CRG: conception of the design of the study, data analysis, drafting and critically revising the manuscript. The EMPallA Investigators’ development of the protocol and manuscript review. All authors approved of the final version of the manuscript.
- Acknowledgements: We would like to thank the members of the EMPallA Study Advisory Committee.
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**Table**

Owing to technical limitations, Table 1 can be accessed in the Supplementary Files

**Figures**
Figure 1

CONSORT Diagram.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- RecruitmentBarriersBMCPallCareTable1.pdf
- RecruitmentBarriersAppendixCONSORTBMCPall3420.pdf
- EMPallAResearchInvestigatorList2020.xlsx