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Interim Analysis of Attrition Rates in Palliative Care Study on Dignity Therapy

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Abstract

A routine threat to palliative care research is participants not completing studies. The purpose of this analysis was to quantify attrition rates mid-way through a palliative care study on Dignity Therapy and describe the reasons cited for attrition. Enrolled in the study were a total of 365 outpatients with cancer who were receiving outpatient specialty palliative care (mean age 66.7±7.3 years, 56% female, 72% White, 22% Black, 6% other race/ethnicity). These participants completed an initial screening for cognitive status, performance status, physical distress, and spiritual distress. There were 76 eligible participants who did not complete the study (58% female, mean age 67.9±7.3 years, 76% White, 17% Black, and 7% other race). Of those not completing the study, the average scores were 74.5±11.7 on the Palliative Performance Scale and 28.3±1.5 on the Mini-Mental Status Examination, whereas 22% had high spiritual distress scores and 45% had high physical distress scores. The most common reason for attrition was death/decline of health (47%), followed by patient withdrawal from the study (21%), and patient lost to follow-up (21%). The overall attrition rate was 24% and within the a priori projected attrition rate of 20%−30%. Considering the current historical context, this interim analysis is important because it will serve as baseline data on attrition prior to the outbreak of the COVID-19 pandemic. Future research will compare these results with attrition throughout the rest of the study, allowing analysis of the effect of the COVID-19 pandemic on the study attrition.

Keywords

Attrition; Spirituality; Cancer; Palliative Care; Dignity Therapy

Introduction

Attrition from a study may impact the generalizability of study findings,[1] especially in palliative care studies, which often suffer from high rates of attrition.[2,3] In past studies and prior to the COVID-19 pandemic, the decline of patient health was a primary cause for withdrawal prior to completion. This reason for attrition is not easily modifiable, but other reasons for loss of participants may offer insights for improving study processes. Ongoing monitoring of reasons for attrition over the study period, therefore, is vital for palliative care studies. The purpose of this study was to examine attrition mid-way through a multi-site randomized clinical trial of Dignity Therapy provided in outpatient oncology palliative care.

Current research on palliative care studies indicates that high attrition rates are common. Participant withdrawal from a study prior to its completion can have many negative effects on the study.[4] Previous palliative care studies have shown that high attrition rates can compromise the validity of findings. Retaining participants for palliative care studies has been cited as being especially challenging when participants are patients with cancer.[1] Although predictors of attrition are still an area of ongoing research, investigators have identified links between certain characteristics, such as increases in physical symptoms or pain, with a higher likelihood of the participant withdrawing from a study.[5]

Although previous investigators described primary reasons for attrition, this is an area of study that still needs further research. The global COVID-19 pandemic has the potential to increase attrition in palliative care studies. This analysis of the mid-way attrition in the Dignity Therapy study[6] will serve as a baseline of attrition rates prior to the COVID-19 pandemic. The aim of this analysis was to determine the rate of attrition, reasons for it, and characteristics of the participants who completed and did not complete the study.

Methods

The Dignity Therapy trial is a stepped-wedge design randomized trial testing the efficacy of the Dignity Therapy intervention.[7–9] Dignity Therapy allows participants to speak one-on-one in a recorded conversation with a nurse or chaplain about the things they feel are important to be documented and remembered.[6] The conversation is transcribed and the participant's words are transformed into a Legacy Document and given to the participant for sharing with others. Data from the initial screening of eligible patients were used in this descriptive study of the trial's attrition rates. The study was approved by the Institutional Review Boards at all participating institutions. Data were collected at six sites across the United States: Northwestern Feinberg School of Medicine, Rush University, MD Anderson Cancer Center, Emory University, University of California San Francisco, and University of Florida.

Sample

Eligible patients were adults age 55 or older with a cancer diagnosis and receiving outpatient palliative care. Additional requirements for eligibility included the ability to speak and read English, and the physical and mental capacity to complete the study.[6] Participants completed a written informed consent prior to the screening procedures. The sample included 365 adults with a mean age of 66.7 ± 7.3 years. Participants identified as: female (56%), White (72%), Black (22%), and other race/ethnicity (6%).

Measures

During the initial screening, participants completed four questionnaires: the Palliative Performance Scale (PPS),[10] Mini-Mental State Examination (MMSE),[11] Religious and Spiritual Struggles Scale (RSS),[12] and Patient Dignity Inventory (PDI).[13] The PPS was used to assess participant's functional status and likelihood of survival for the 4–6 week trial period. A score of greater than 50 out of 100 was necessary for participants to be eligible for the trial. The average length of survival for an individual scoring a 50 was

projected to be 53 days,[10,14–18] which would be enough to complete the trial. The MMSE was used to assess cognitive ability, and a score greater than 24 out of 30 was required for participants to be eligible for the study. Religious/spiritual struggles occur when some aspect of religious/spiritual belief, practice or experience becomes a focus of negative thoughts or emotions, concern or conflict. We used a 14-item version of the RSS that assesses struggles with the Divine or demonic, as well as interpersonal and intrapersonal religious/spiritual struggles.[12] The RSS items were score on a 0–4 scale. The PDI evaluates the level of dignity-related distress in the participants with items that assess a broad spectrum of end-of-life issues including physical, psychological, existential, and spiritual sources of distress.[13] The participants rate each item on a 1–5 scale, and a score of at least 3 indicates that this item is a problem for the patient.

Analysis

Descriptive statistics of characteristics were obtained for those who did and did not complete the study. Independent t tests and Fisher's exact test were used to compare the groups of completers and non-completers for differences in age, gender, race/ethnicity, and dichotomized PPS, MMSE, RSS and PDI scores. Additionally, the reason for attrition was examined by patient characteristics. Statistical significance was set *a priori* at $p < .05$.

Results

At the time of the analysis, of the 404 referred patients, 365 were eligible and consented to participate. 241 (66%) completed the study, 48 (13%) were active at the time of this analysis, and 76 (21%) did not complete the study. The descriptive statistics for age, gender, race, ethnicity, and screening measures are shown in Table 1 for completers and non-completers (excluding those still active). The completer and non-completer groups differed significantly only on performance status; a larger proportion of participants with a PPS score less than 70 did not complete the study. Table 2 shows distribution of cancer diagnoses for participants completing and not completing the study.

Reasons recorded for attrition appear in Figure 1. The most common reason for attrition was decline of health or death, followed by participant withdrawal and participant lost to follow-up.

To gain additional insight into the patterns of attrition, the reasons are displayed by characteristics of the participants, including age, gender, race, and PPS score in Figures 2 through 5. In this small sample of those not completing the study, there were no statistically significant differences in reason for attrition by age, gender, race or PPS score.

Discussion and Conclusion

The current attrition rate of 24% falls within the range of 20–30% that the investigators expected prior to initiating the trial.[6] This finding indicates that, pre COVID-19 pandemic, attrition rates for the Dignity Therapy study align with what can be expected for a palliative care study. As might be expected for this population of patients, nearly half of the attrition was due to decline of health or death of a participant. Only PPS scores differentiated those

who completed the study and those who did not. Attrition was significantly more frequent among those with a PPS score of less than 70.

Our finding that the decline of a participant's health or their death was the most common reason for attrition in the DT trial is similar to other palliative care studies on cancer patients.[1,2] Another longitudinal study of palliative care with cancer patients also suggested a link between lower performance scores and attrition.[5] However, investigators measured functional status with the Karnofsky performance status (KPS) as opposed to the PPS in our Dignity Therapy trial.[5] Other investigators used the Eastern Cooperative Oncology Group (ECOG) performance status as a measure and also noted that patients who ultimately withdrew from the study often had lower performance scores.[2] Further research is necessary to identify which performance measure is most predictive of study attrition.

We compared the personal characteristics of those who did not complete the study with those who did and found that only the PPS score differed significantly between the two groups in this sample. Since the Dignity Therapy intervention in this study occurs over a 4–6 week period, a strategy to reduce attrition could be to minimize delays in study procedures for a participant with a PPS score of 60 in our study since our inclusion criteria is a PPS score greater than 50. Other clinical or personal characteristics, not measured in this study, could be predictors of participants not completing a palliative care study.

In addition, as the Dignity Therapy study is ongoing, future research should compare these preliminary attrition rates with the rates at the conclusion of the study. This comparison will be especially important considering the current historical context of the global pandemic of COVID-19, which has the potential to greatly affect research. Our current analysis will be used as a baseline to compare the rates of attrition following the pandemic with these from before the pandemic. A comparative analysis between pre and post COVID-19 attrition will provide important information regarding the effect of the pandemic on palliative care research attrition.

Limitations of our study include the general nature of reasons given for participants not completing the trial. For situations where a patient withdrew prior to completion (n=16), detail was not provided as to why the participant made the decision. In addition, for patients who were lost to follow-up (n=16), it is unclear why they chose to suspend participation in the trial. Further detail on the decisions made by participants could be helpful in understanding the implications of the attrition rate. However, this limitation has also been identified in other studies on attrition in palliative studies.[1,5] In this analysis, we did not address comorbid illness. The source of disability and reduced PPS score could relate to a comorbid illness such as COPD or CHF with different prognostic trajectory to the cancer diagnosis.

In conclusion, analyzing the reasons for attrition provides important insights into the possible problems with retention in a palliative care study. Decline of health was a primary reason given for not completing the study. This finding along with the significantly higher portion of low PPS scores among the non-completers shows a need to pay attention to physical and functional health status issues when planning and implementing studies

of the palliative care patient population. For example, adaptations may be needed in study protocols for participants who experience a decline in health after study enrolment. Participants lost to follow-up was also a common reason for attrition. Protocols for the Dignity Therapy trial ensure that multiple modes of contact are obtained for each participant, but additional methods of maintaining contact with participants may be needed to address this cause for attrition. Further study on why follow-up was lost will be integral to developing future study protocols.

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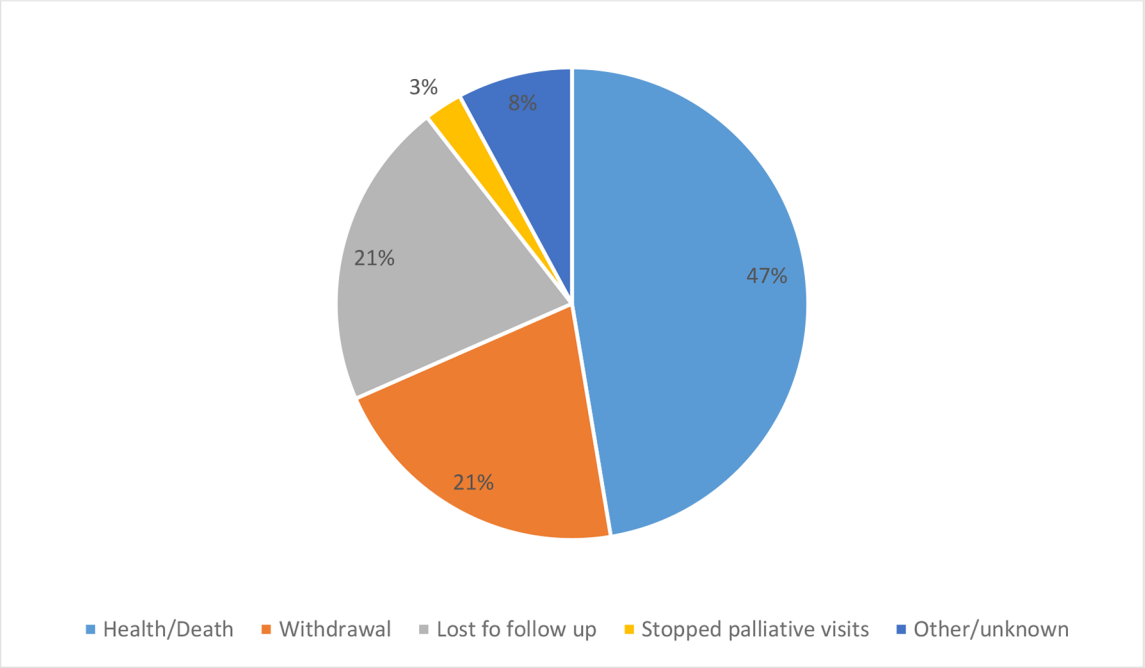

Figure 1.
Frequency distribution: Reasons for attrition

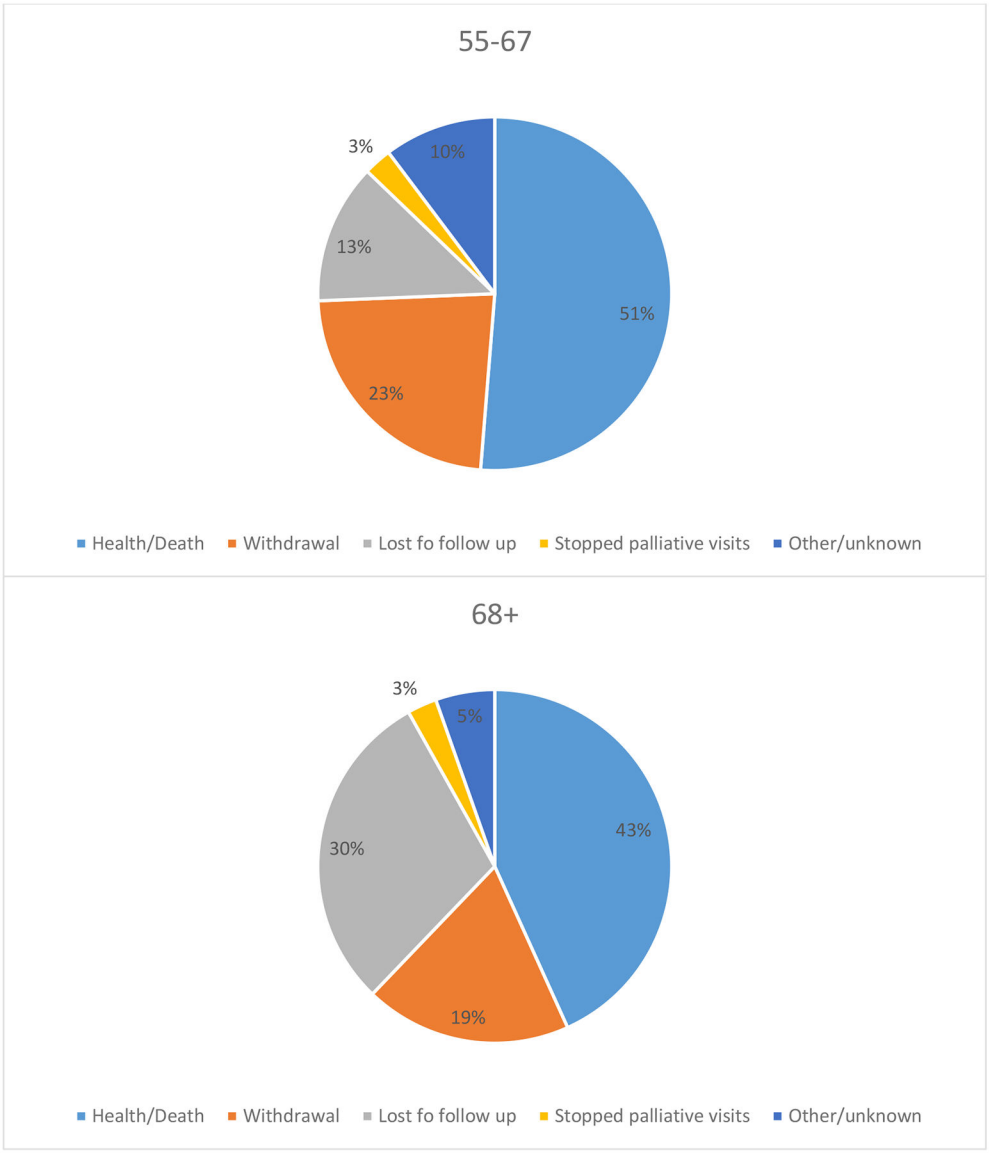

Figure 2:
Attrition by Age

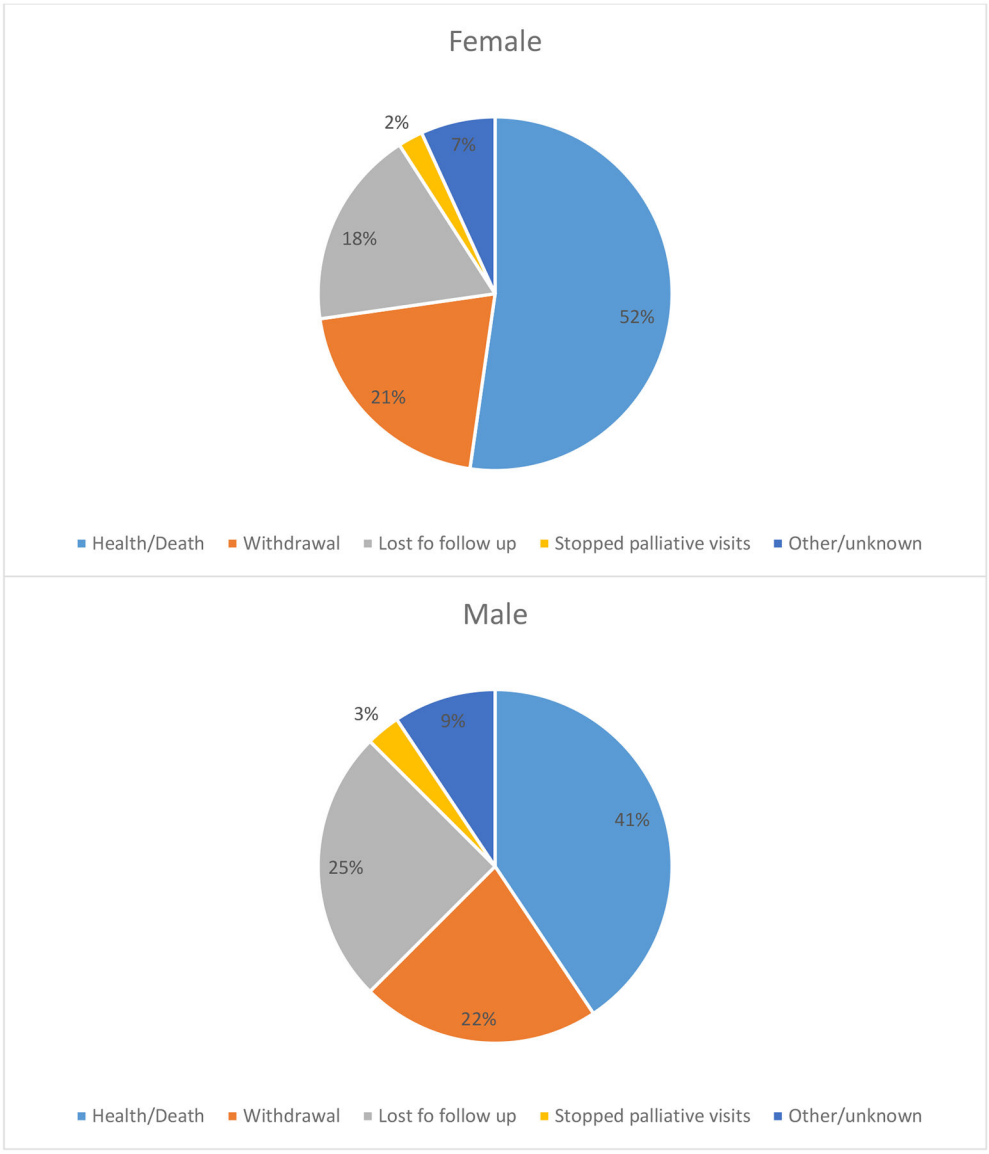

Figure 3:
Reason for Attrition by Gender

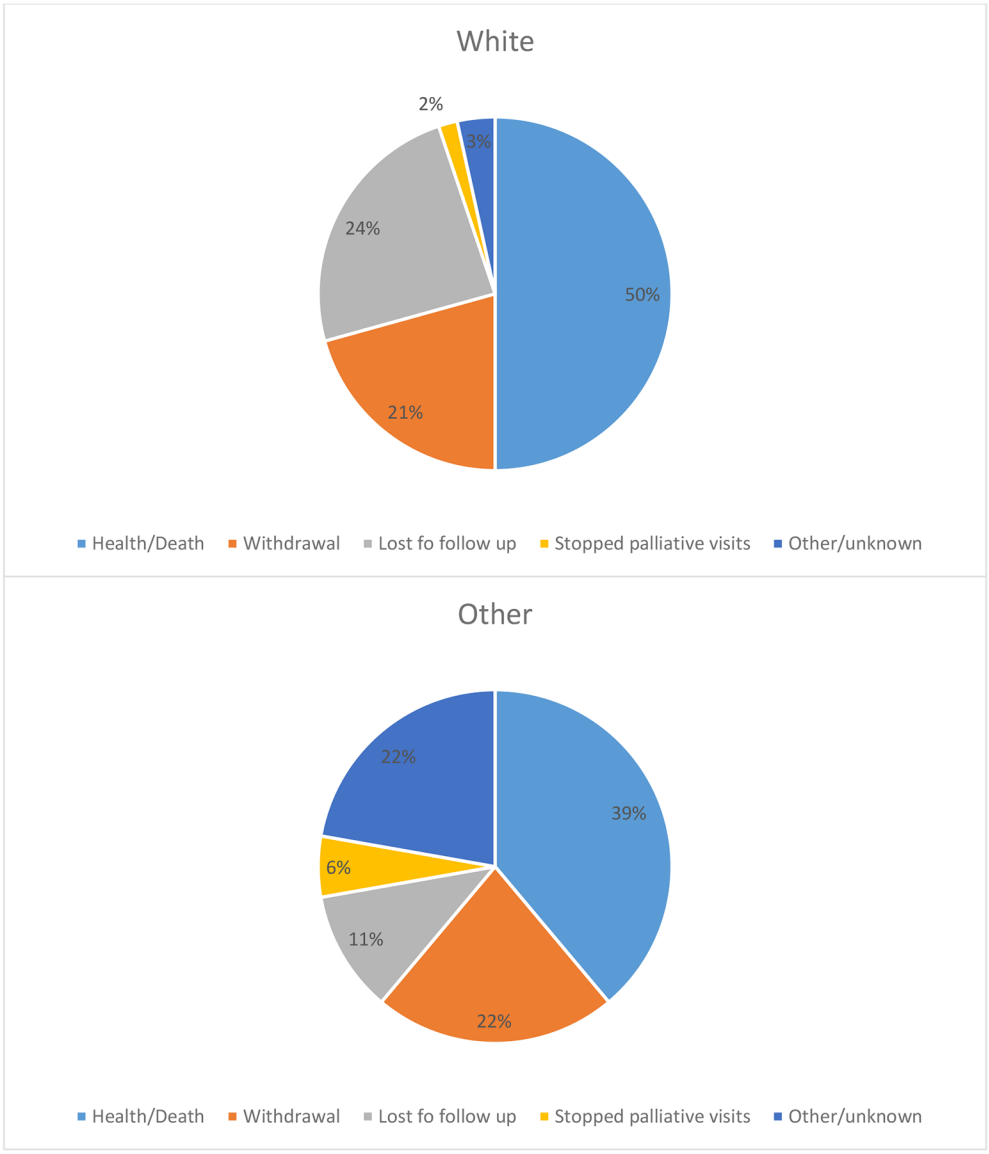

Figure 4:
Attrition by Race

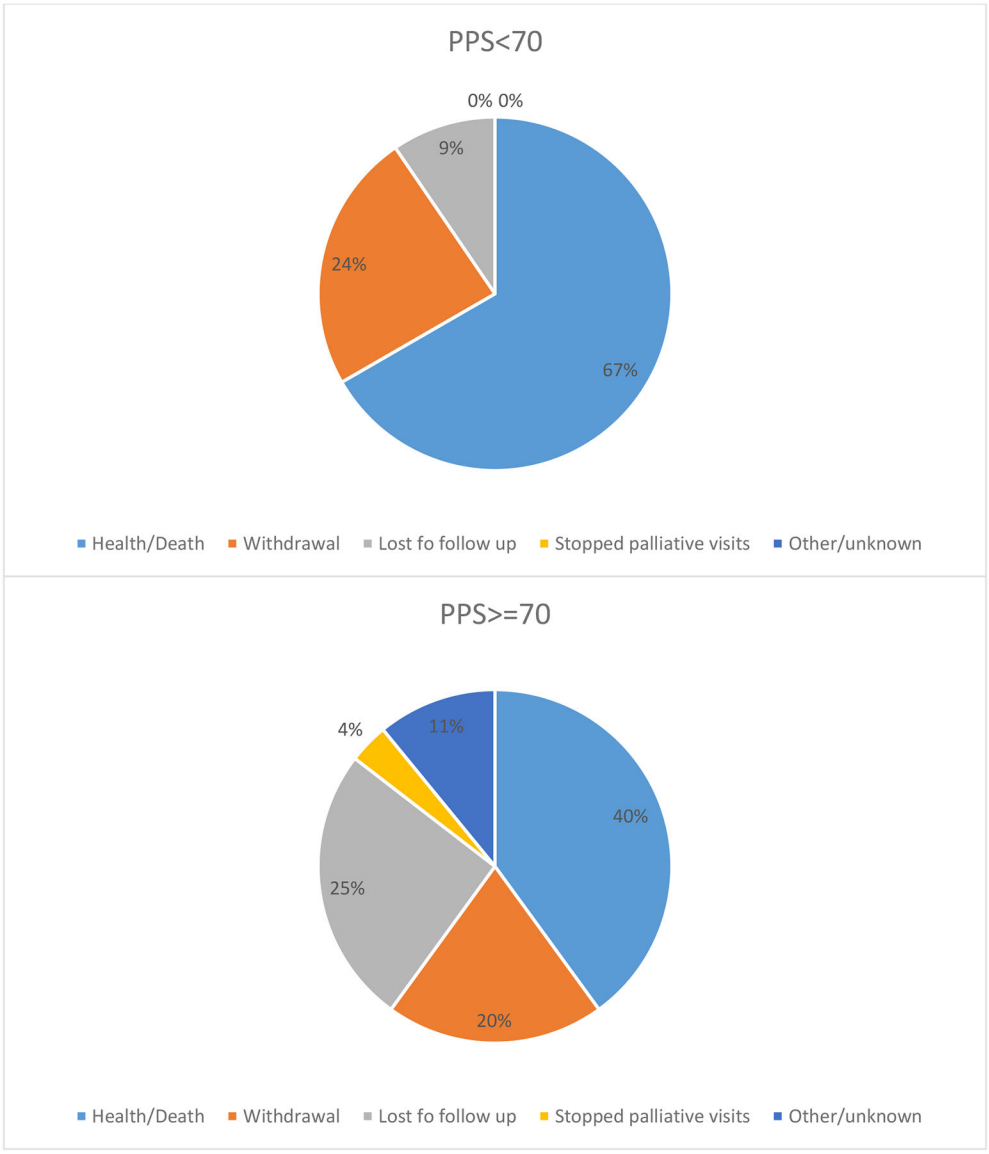

Figure 5:
Reason for Attrition by Score on Palliative Performance Scale

Table 1.

Demographic characteristics for patients completing and not completing the study (N=317)

Variable	Missing	Category	Completer	Non-Completer	p
Age	0	Mean (SD)	66.6 (7.2)	67.9 (7.3)	.18
Gender	2	Female	53%	58%	.51
		Male	47%	42%	
Race	0	Other	31%	24%	.25
		White	69%	76%	
Ethnicity	12	Hispanic	4%	6%	.53
		Non-Hispanic	96%	94%	
Performance status (PPS)	0	<70	13%	28%	.01
		≥70	87%	72%	
Mental status (MMSE)	0	Mean (SD)	28.4 (1.5)	28.3 (1.5)	.91
Physical distress (PDI)	0	High	38%	45%	.35
		Low	62%	55%	
Spiritual distress (RSS)	3	High	21%	22%	1
		Low	79%	78%	

Key: PPS = Palliative Performance Scale, MMSE = Mini Mental Status Exam, PDI = Patient Dignity Inventory, RSS = Religious and Spiritual Struggles Scale

N excludes 48 participants active at the time of the analysis (total N=365)

Table 2.

Types of cancer for patients completing and not completing the study (N=365)

Type of Cancer	Completer	Non-completer
Brain	1%	1%
Breast	13%	11%
Colorectal	7%	3%
Gastro Intestinal	4%	14%
Genital Urinary	15%	13%
Head & Neck	7%	4%
Leukemia	2%	7%
Lung	20%	17%
Lymphoma	3%	3%
Melanoma	2%	0%
Myeloma	7%	5%
Pancreas	5%	11%
Prostate	7%	9%
Sarcoma	1%	0%
Other cancer	5%	3%