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Nurse-delivered symptom assessment for individuals with advanced lung cancer

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Abstract

Objectives: The primary purpose of this manuscript is to report feasibility results of an intervention derived from Self-Regulation theory (SRT) to promote well-being for individuals with advanced lung cancer.

Sample and Setting: 45 adults with advanced stage lung cancer, receiving chemotherapy at an ambulatory setting.

Methods: Participants were randomized to one of two conditions: 1) the intervention group received a structured symptom assessment via telephone call, weekly x8 or, 2) usual care control group. Feasibility assessment focused on recruitment, retention, design, methods, and fidelity. Outcome measures of quality of life, symptoms, and distress were collected at four time points.

Main Research Variables: symptoms, quality of life, distress

Results: Participation rate was 79%, retention rate was 62%. Participant loss was most often due to progressive disease and occurred early in the study. High fidelity was noted for delivery of the intervention as planned and outcome data collection by telephone. The mean number of interventions delivered was 5.5 of a planned 8. A high level of acceptability was reported for those completing the intervention.

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Conclusions: While it was possible to deliver the SRT derived intervention with fidelity; feasibility findings do not warrant intervention replication in this population.

One of the most challenging clinical problems in oncology for patients, families and clinicians is the occurrence of multiple symptoms. Unrelieved symptoms result in decreased functional status, decreased quality of life, increased distress and increased mortality (C. S. Cleeland et al., 2013; Cooley, 2000; Cooley, Short, & Moriarty, 2003; Flannery, Phillips, & Lyons, 2009; Gift, 2007; Given, Given, Azzouz, Kozachik, & Stommel, 2001; Reilly et al., 2013; Sarna & Brecht, 1997). While the experience of multiple co-occurring symptoms is well established as a frequently occurring clinical issue, research establishing effective interventions for multiple symptoms has been minimal. Efforts have begun to identify interventions that are effective for more than one symptom, but research in the field is in its infancy, with limited studies in selected oncology populations examining specific clusters of symptoms (Berger, Yennu, & Million, 2013). Therefore, the continued finding of multiple co-occurring unrelieved symptoms warrants ongoing development and examination of effective nursing interventions.

One intriguing strategy that has been related to decreased symptom burden and improved patient outcomes is ongoing structured symptom assessment (Basch, Deal, et al., 2017; Cooley et al., 2015; Lobach et al., 2016). In these studies, standardized symptom assessment is followed with trigger alerts to clinicians and/or symptom management interventions. To capitalize on this finding we asked the question: What if we could standardize and enhance the symptom assessment process so that it functions as an effective intervention for multiple symptoms? Based on intriguing empirical findings that repeated symptom assessment is related to improved outcomes and on principles of Self-Regulation Theory (SRT), the intervention standardized the symptom assessment process by asking questions that would guide the individual to develop a more detailed understanding of the symptom and promote the individual's self-monitoring and focus on problem-solving symptom management strategies. The primary purpose of this manuscript is to report feasibility results of a pilot randomized clinical trial of a structured symptom assessment to promote functional well-being for individuals with advanced lung cancer.

Background

Assessment of symptoms to guide self-care and clinician recommendations has long been recognized as a primary component of oncology nursing practice. Traditionally, assessment is conceptualized as an information gathering strategy however, there is some limited evidence to suggest that repeated assessment may actually function to reduce symptom distress and improve functional health. Researchers have examined the impact of individual's completion of a symptom checklist which is shared with the clinican with the expectation that it would improve patient-provider communication and better direct symptom management recommendations. However, several authors reported intriguing unanticipated results; beneficial effects of the completed assessment for the participants were found even when assessment results were not shared with clinicians.

In a randomized controlled trial (RCT) Hoekstra examined the effects of a weekly administered symptom monitoring instrument that was intended to be shared with their care providers (Hoekstra, de Vos, van Duijn, Schade, & Bindels, 2006). In carrying out the study however, the assessment was actually shared with the care provider only 18% of the time. Nevertheless, improvements in both symptom occurrence and symptom severity were found for the intervention group. Although this study was underpowered for statistical significance and different findings were reported for different symptoms, findings remain intriguing and suggest that symptom occurrence and severity may be altered by repeated assessment even when results are not communicated with clinicians.

Velikova reported a RCT where individuals with cancer receiving chemotherapy completed repeated quality of life assessments (including nine symptom items)(Velikova et al., 2004). Statistically significant improved functional well-being was reported in those completing assessments when compared to those receiving usual care. This study used a three group design, with the attention control group completing weekly questionnaires that were not shared with clinicians. An unexpected finding was that the attention control group also had better outcomes than the usual care group lending support to the hypothesis that the mechanism is not related to patient/provider interaction.

Despite beginning evidence of the relationship, there has been little work directed at understanding the mechanisms responsible for the link between the assessment process and an individual's redirection in self-care and coping activities to improve well-being. The framework for studying this area has traditionally been focused on the patient as a passive participant. We propose to use a framework where the patient is an active participant who, when prompted to complete a structured symptom assessment, becomes involved in a very active information process. The premise of an active process is supported by findings from qualitative research interviews with individuals with lung cancer who describe a complex cognitive evaluation and interpretation of their symptom experiences which includes symptom anticipation, impact of symptoms on daily life, familiarity of symptom with past experience, and attribution of the symptom to manageable causal factorst67(Lowe & Molassiotis, 2011).

Theoretical Framework.

In the current study, we use SRT to build on preliminary findings that symptom assessment results in improved outcomes. SRT asserts that knowledge is stored in memory as mental representations, sometimes referred to as schemas (Johnson, 1999). These representations "are described as explanatory working models of reality" (Severtson, Baumann, & Brown, 2008). For example, someone feels sore and achy and thinks of their representation of pain; depending on the content in their individual pain representation they may think of distress, causative factors, or management strategies. If the information that is being processed from the representation has concrete objective features, "attention is focused on the concrete, objective aspect of the experience and coping is focused on problem-solving and direct actions" (Johnson et al., 1997, p.1042). Examples of "concrete objective" information are sensory-based aspects – what an experience feels like, the timing of the symptom experience, things that make the symptom better or worse. (Note: in SRT this sensory based

content activates the functional pathway rather than the emotional pathway -information that is emotion focused would activate the emotional pathway). SRT-based interventions promoting cognitive processing with preparatory information formatted as “concrete objective” sensory information tested in individuals receiving radiation therapy and chemotherapy have consistently demonstrated improved functional outcomes (Burnish, Snyder, & Jenkins, 1991; Johnson, Fieler, Jones, Wlasowicz, & Mitchell, 1997; Johnson, Lauver, & Nail, 1989; Reuille, 2002).

Although research based on SRT has primarily focused on the nurse’s provision of concrete objective information as content for teaching about the treatment experience, within this study, SRT was extended to examine how the nurse’s structured symptom assessment questioning can direct an individual to the somatic aspects (rather than the emotional) of the experience of symptoms. SRT suggests that a focus on these aspects activates a functional cognitive pathway that integrates problem solving into the representation and which subsequently activates self-management skills. Rather than a vague, undeveloped mental representation of an overwhelming global symptom experience, we posit that the intervention will promote a more detailed, precise, differentiated mental representation specific to each co-occurring symptom. Requesting an individual to conduct repeated assessments promotes self-monitoring. More specifically, if an individual determines that a discrepancy exists between the symptom they have and their desired goal (e.g., no pain), this will serve as a motivational factor to engage in activities to achieve their desired goals, with ongoing opportunities to focus attention on the symptom experienced, recognize details surrounding the experience and increase recognition of patterns that can lead to symptom self- management activities.

While the intervention is theoretically applicable to any individual with multiple symptoms, we tested the intervention in individuals with advanced lung cancer receiving systemic therapy. This population provides a rigorous test of the intervention because, compared to persons with other cancer diagnoses, individuals with lung cancer report the highest number of symptoms, worst symptom severity, and highest levels of symptom distress (Degner & Sloan, 1995; Iyer, Roughley, Rider, & Taylor-Stokes, 2014; McCorkle & Benoliel, 1983). Furthermore, lung cancer is the second most commonly occurring cancer in both men and women and is the leading cause of cancer mortality (Siegel, Miller, & Jemal, 2017). Although much research has been focused on improving symptoms in this population, many of the interventions are complex and multi-component, and have not been widely adapted in practice (Cooley et al., 2015; Given et al., 2004).

The initial step in testing a new intervention is to conduct an examination of its feasibility (Bowen et al., 2009). We conducted a pilot randomized clinical trial (RCT) to examine the feasibility of a structured symptom assessment derived from SRT for individuals with advanced lung cancer. Importantly, in this design choice a control arm was included. The primary study purpose was to: 1) establish feasibility data and 2) an exploratory aim, to provide preliminary evaluation of efficacy data.

Methods

A pilot study with a randomized control design was conducted. Participants were randomized to one of two conditions: 1) the intervention group received an eight-week phone-delivered structured symptom assessment, or, 2) the usual care control group. The feasibility assessment focused on recruitment, retention, design, methods, and ability to deliver the intervention as planned (Thabane et al., 2010). The human subject review board approved the study.

Recruitment occurred at an ambulatory academic cancer center from December 2012 to May 2014. Participants were adult, non-hospitalized individuals diagnosed with lung cancer. Inclusion criteria were: ≥ 18 years, advanced lung cancer diagnosis (Stage IIIB or greater non-small cell or extensive stage small cell), current oncology treatment (chemotherapy, radiation therapy, targeted treatment, or combined therapy), report pain since cancer diagnosis (yes), ability to speak English, and access to a telephone. (Report of pain was an inclusion criteria to target enrollment by individual's who were symptomatic at enrollment.) Individuals were screened with the General Practioner Assessment of Cognition (GPCOG) (Brodaty, Kemp, & Low, 2004); those with a score greater than 5 were ineligible to participate. (Note: no screened individuals had ineligible scores). Total sample size was 45. Sample size justification in pilot studies is based on the ability to provide useful information for determining feasability (Thabane et al., 2010). Therefore, the sample size of 45 for the pilot RCT was selected to permit adequate feasibility assessment. A 2:1 group assignment was used with n=30 experimental and n=15 usual care control group members to facilitate adequate observations in the experimental arm. Randomization was programmed and generated by computer program with group assignment predetermined by study ID number.

Procedures and Intervention

The principal investigator (PI) met with potential participants in clinic after a visit. The study was explained and, if the individual was interested, screening was conducted and written informed consent was obtained. Table 1 outlines the study procedures. All participants (usual care and intervention) received outcome telephone calls from one team of study personnel (blinded to treatment assignment), every three weeks times four. These phone calls included questions related to symptoms, distress, and QoL (see Measures for more information). In addition, participants in the intervention group received weekly telephone calls from a different study team of interventionists; this phone call included structured symptom assessment. The participant's medical record was reviewed and demographic and cancer data extracted. All telephone calls were recorded (both outcome and intervention as a source for fidelity evaluation and as the raw data). Manuals for instruments with directions for use by telephone were used as the training manual. A research team member telephoned the participant, the questions were read and participant responses were entered by the researcher directly into a computer via the Research Electronic Data Capture system (REDCap). REDCap is a secure, web-based application for building and managing online surveys and databases (Harris et al., 2009). The responses were converted into a d-base file by the program eliminating the need to record on paper and then enter data.

Individuals randomized to the intervention received weekly telephone calls for eight weeks. The intervention was a structured assessment of 16 common symptoms in lung cancer (Mendoza et al., 2011). For any symptom endorsed as present, the interventionists asked a series of six structured questions that were based on SRT and focused on the somatic aspects of the symptom experience, consistent with SRT's tenants. Refer to Figure 1 for questions asked. The symptom assessment was the intervention. Note these are very basic and familiar questions that are readily familiar and transferable to practicing oncology nurses. We did not ask about symptom distress as that would involve the emotional pathway and is not consistent with SRT.

The PI conducted the intervention initially and trained two additional interventionists. Two independent team members conducted fidelity assessment by both listening to the recorded call and reviewing data entered on REDCap. Thirty calls were reviewed and only two issues (skipped questions) were noted; both occurred early in the study and were addressed by the PI.

Measures

Demographic and Cancer variables were obtained from a medical record review. In addition, the **Karnofsky Performance Status Scale (KPS)** a measure of functional status was collected; a single item scored 0 to 100 based on self-care ability, symptoms and activity. The scale takes less than 5 minutes, has been administered by telephone and used in lung cancer. Construct validity has been reported as an indicator of overall physical functioning (Yates, Chalmer, & McKegney, 1980). **Feasibility Variables** included recruitment rate, reasons for study refusal, percentage of symptom assessment administered as planned, percentage completion of outcome calls, attrition rate and reasons by group assignment. Feasibility questions for the research staff to answer were integrated through all phases of the design. For example, after completing each telephone call research team members completed a series of feasibility questions that included: time required to make the call, if the participant was reached on the initial attempt, if all questions were answered, and the assessment of the procedures and electronic data base. A structured **Exit Interview** was completed at study exit to assess participant acceptability, 5 semistructured questions were asked about study participation as has been used in prior studies with similar individuals but the psychometric properties are not established (Wells, Hepworth, Murphy, Wujcik, & Johnson, 2003).

For preliminary assessment of efficacy the outcome variables of quality of life (QoL) and symptoms were collected. Quality of Life was measured with the **Functional Assessment of Cancer Therapy–Lung Cancer (FACT-L),** an instrument specific to lung cancer with 44 items in four domains of well-being (physical, social/family, emotional, and functional) (Cella et al., 2002). The scale takes five to ten minutes to complete and has been administered by telephone. Reliability is reported as acceptable. Concurrent validity with performance status, sensitivity to change over time and clinically meaningful differences have been established (Cella et al., 2002). A single item captured **symptom related distress** on a numeric rating scale of zero to ten, similar to the summary distress thermometer but administered orally. Single-item distress scales have previously been used with cancer

samples, take less than a minute to complete and have demonstrated construct validity (Wells, Murphy, Wujcik, & Johnson, 2003). A single item was used to capture **global quality of life (QoL)** scored zero to 100. Single-item QoL data correlate well with multi-item instrument scores, and are responsive to change over time (Bernhard, Sullivan, Hurny, Coates, & Rudenstam, 2001; Cunny & Perri, 1991). The **MD Anderson Symptom Inventory–Lung Cancer (MDASI-LC)** was used to assess symptoms including severity for 16 commonly occurring symptoms in lung cancer. Scoring is zero to ten. The scale takes five minutes to complete and has been administered by telephone(C. Cleeland, 2016) (https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/md-anderson-symptom-inventory.html). The test, retest and internal consistency (Cronbach's alpha .83 or higher) are adequate and criterion validity has been established with the SF- short form and sensitivity to disease progression (Mendoza et al., 2011).

Statistical Analysis

Data were examined by checking frequencies and cleaned as needed. SPSS version 22 (SPSS Inc., Chicago, IL) was used for all analyses. Scoring guidelines were used for the FACT-L (http://facit.digiflare.com/FACITOrg/Questionnaires)check(Facit.org, 2010) and MDASI User's Guide instructions for administration and scoring. Summary scale scores were computed. For aim 1 establishing feasibility, analysis with descriptive and nonparametric statistics was performed. For aim 2 examination of preliminary efficacy data non parametric statistics was used to compare between group differences because of the small sample size. Because this was a pilot study and findings were exploratory only, p-values were not adjusted for multiple testing.

Results

Recruitment and Retention

A CONSORT diagram (Figure 1) provides an overview. Recruitment was from the Wilmot Cancer Center thoracic oncology clinic, conducted by the PI at 65 half-day clinic sessions and completed within 15 months. At pre-clinic meetings schedules were reviewed for potential eligible subjects and a total of 145 were identified; of those 145; 95 were asked by their oncology provider if they would be willing to talk to the research team. Those who were not asked by the oncology team were often too ill or had their appointment cancelled; many were approached at a subsequent visit. Of the 95 who were asked by their oncologist, 76 (80%) agreed to talk to the researcher. Of those 76, when approached by the researcher, 19 did not want to talk about a study. Fifty seven individuals agreed to talk about the study and were asked to consent; 12 declined participation. Reasons for declining included: four did not want to talk on the telephone, two did not have enough telephone minutes, two did not have enough time, one was not feeling well, and three stated no reason. Forty-five individuals consented, for a 79% (45/57) participation rate.

We defined "completers" as subjects who completed more than one outcome assessment. Overall retention rate was 62% (28/45). Fifteen participants were randomized to the usual care control arm and four did not complete the study (73.3% retention): one was a screen

failure, one had disease progression, one died and one moved out of state. For the 30 participants in the experimental arm, 13 did not complete the study (57% retention). Eight subjects were randomized but withdrew prior to receiving any symptom assessment calls, five withdrew during the study. The reasons they withdrew included hospitalization, disease progression, not enough time, death in the family or reason not stated. The majority of subject loss occurred in the first three weeks of the study. There was decreased retention in the intervention arm compared to the usual care control arm, although the difference was not statistically significant (Chi Square = .34).

Description of Sample

Participants were 56% male, with a mean age of 62.62 years (s=8.71), KPS M=72.05 (s=17.20), 73% were living with others, and 51% had less than a high school education. Forty had non-small cell lung cancer (73% Stage IV) and five had extensive stage small cell lung cancer. All were receiving systemic chemotherapy or targeted therapy and ten were also receiving concurrent radiation therapy. All had co-morbid conditions and 16 (36%) had a palliative care consult. Over the nine week study, 14 participants had progressive disease, 13 participants had a change in treatment, six had partial response and two entered hospice care.

Feasibility Findings

Because of the differences noted in retention between the two study arms, we examined baseline differences in those who were retained in the study and those who withdrew. As displayed in Table 2, there was a consistent pattern that those who completed two or more outcomes had a higher performance status, were living with a partner, had greater than a high school education, had a higher cognitive screening score, had a lower number and severity of symptoms, and had lower distress scores. Tested with Chi-Square (nominal variables) or t-test (numeric variables), significant differences were found in the number and severity of symptoms and the level of distress ($p<.05$). Those participants who remained in the study longer had lower distress and less severe symptoms than at the study entry.

We completed 112/180(62%) planned outcome calls; 68 calls were completed on the first attempt (44 required additional attempts). 62 calls were completed in less than 15 minutes (50 required 15–30 minutes). For the 28 subjects who were retained, 20 completed all four outcome calls as planned. Blinding of outcome data collectors was not maintained as many participants disclosed that they were also receiving intervention telephone calls.

We completed 121/240(50%) planned symptom assessment calls; 70 required rescheduling or repeated attempts, and 98 calls were completed in less than 15 minutes. The number of symptoms discussed in each phone call ranged from 3–13, with the mean decreasing from 6.42 to 4.08 over the eight weeks. Of the 17 participants retained in the intervention arm, the number of intervention calls received was M=5.50 (s=2.48); 8 of 17 participants received all eight interventions.

Individuals completing the exit interview at week nine reported that participating in the study was easy or very easy. Three individuals (all in intervention arm) mentioned that calls were repetitive, one mentioning that their answers were difficult because it depended on the

time of day when questions were asked, as their symptoms varied. Seven individuals indicated that they appreciated an ability to learn things about themselves or being glad to participate in doing something to help other individuals with cancer. All but one participant reported no problems with the telephone calls; one individual mentioned difficulty talking because of their laryngectomy. All but one participant stated they would recommend participating in the study to other individuals. When asked in what ways participating in the study changed the way they thought about their symptoms, about half of the participants (13 of 24) commented that they did not think differently. However, many individuals commented that study participation had changed their thinking (i.e., participation had made them "deal with what I got," "am more aware," " accepted," "think I'm lucky not to be worse," "realize other people also deal with this," and "opened my eyes"). Acceptability data was not collected for individuals who withdrew early.

Treatment Effect

The outcome variables included the FACT-L total (and subscale scores), Global Quality of Life (possible range 0–100, higher scores indicate better quality of life) and distress (possible range 0–10, higher scores indicate increased distress). Outcomes were assessed with a change score and therefore, were examined for patients who completed more than one outcome measure. See Table 3 for baseline scores by group assignment. Because of the small sample size, we used nonparametric analysis and did not control for any covariates. We computed change scores from baseline to week nine for all outcome variables and examined group differences with Kruskal-Wallis Test (See Table 4).

No statistically significant differences were found between the usual care control and intervention arms on outcomes. Examining mean scores for groups, from baseline to week nine, total FACT-L scores increased (improved) for the intervention group and decreased for the usual care control group. Functional well-being improved for both groups, with a larger mean increase for the intervention arm. Global single item QoL scores decreased six points for the control group and increased three points for the intervention group. Distress scores increased for both groups.

Discussion

The primary rationale for conducting this pilot study was to address an important clinical problem (multiple symptoms), following up on limited but intriguing empirical findings that symptom assessment can have a beneficial effect on an individual's well-being. SRT provided a possible theoretical explanation for this effect and guided the development of a nurse delivered structured symptom assessment as the intervention. The primary aim of this study was to establish the feasibility of this intervention. Feasibility findings were mixed. Feasibility was established for the method of telephone collection of outcome measures, intervention delivery and fidelity of intervention delivery. Feasibility assessment also provided specific data on time requirements for study personnel and participants. Feasibility concerns included issues related to recruitment, retention and inability to deliver the planned dose of the intervention. Acceptability of the study was rated as high by participants who remained in the study for nine weeks.

Recruitment of this population was feasible, although time intensive. The recruitment of 45 subjects took over one and a half years, this rate of accrual would not be scalable to a larger clinical trial. The recruitment occurred on 65 clinic days (approximately 1 day a week) and would need to be expanded to additional clinics/ providers for timelier enrollment. Considering reasons for study refusal, six individuals' reasons for refusal was related to not wanting to talk on the telephone, or to use phone minutes for study-related calls. This is particularly relevant as the telephone is increasingly being used for delivery of both research measures and clinical care; there may be concerns for a subset of patients that do not make the telephone a preferred patient-centered approach.

Examining the challenges to retention, the participants who did not complete the study were the high risk patients who we most wanted to reach with our intervention (i.e., those who were sicker, had more symptoms and were more distressed). When working with individuals with advanced lung cancer over a nine week interval, some attrition was expected and the primary reason for participant withdrawal was worsening disease. The RCT design allowed us to identify that withdrawal was higher on the intervention arm than on the usual care arm (although not statistically significant). The planned dose of the intervention was not able to be delivered. On average, participants in the intervention arm received 5.5 of the planned eight weekly telephone calls. While receiving every three-week outcome calls appeared to be an acceptable burden, the planned weekly telephone calls over eight weeks were only able to be delivered to slightly more than a third of participants.

The exploratory aim was to obtain preliminary data on the efficacy of the intervention. Examination of the effect of the intervention was hampered by: 1) small sample size, 2) variable retention to study arms, and 3) decreased dose of the intervention. No statistical differences were found. Findings tended to be in the direction favoring the intervention arm for participants who remained in the study. These findings should be interpreted with extreme caution because of the small sample size. The study was not designed to establish efficacy and these finding do not provide support to recommend the intervention to practicing oncology nurses.

Although the overall feasibility findings do not support replication, much was learned during the conduct of this pilot study. The choice of an RCT design was a major strength as it allowed examination not only of the intervention but also provided a comparison group. The choice of a 2:1 randomization scheme made it more difficult to detect the pattern of differential loss in the two arms and in future pilots a 1:1 randomization model will be selected. There are many alternative explanations for the findings. The assessment may not have been done at the correct dosing interval, the two trained interventionists were not experienced oncology nurses, the selected population of individuals with advanced lung cancer receiving systemic treatment may have been too ill or had too great a symptom burden, and/or the underlying rationale may have been incorrect.

While it was possible to develop and deliver an SRT-based intervention, this study did not provide support for the extension of SRT to examine this clinical problem in this population. SRT based interventions were originally conducted with less ill and symptomatic individuals. The intervention involved a series of questions that prompted the individual to

conduct a focused self-assessment of any symptom they were experiencing. Participants were not provided any symptom management recommendations by study personnel (they received usual care from their clinicians). Participants in the intervention arm identified experiencing multiple symptoms, so had to access multiple representations – it is possible that this diluted the ability to change content in any specific symptom representations. Other authors have advocated using a SRT/ representational approach for education around a solitary symptom (Donovan et al., 2007; Reuille, 2002) or specific subset of symptoms and as a nurse delivered educational intervention.

Limitations.

This was a pilot feasibility study and was not designed to establish efficacy/effectiveness of the intervention. Feasibility results raise concern about the ability to retain and deliver this intervention to high risk patients. Although we attempted to have data collectors blinded this was not maintained as participants often disclosed that they were receiving additional symptom assessment calls.

Implications for Nursing

The clinical problem of multiple unrelieved symptoms continues for many individuals with advanced cancer. Assessment of symptoms has long been recognized as a primary component of oncology nursing practice. Although some differences exist in content, virtually all national guidelines for symptom management (e.g., pain, fatigue) including those developed by the National Comprehensive Cancer Network, the Oncology Nursing Society, and the American College of Cheat Physicians provide recommendations for repeated symptom assessment (Griffin, Koch, Nelson, & Cooley, 2007; Kwekkeboom & Ameringer, 2005; National Comprehensive Cancer Network, 2017; Network, 2017). Although there is an increased use of standardized symptom assessment tools, this practice remains highly variable across oncology settings (Cooley & Siefert, 2016). It is critical that oncology nurses continue to conduct systematic and repeated symptom assessments as the initial step in the process on minimizing symptom burden. The structured symptom assessment questions are familiar assessment questions to practicing oncology nurses (i.e. timing of symptom, aggravating factors) and remain appropriate for oncology nurses in assessment of symptoms.

Conclusion

In designing an intervention, to address the clinical problem of multiple symptoms, the literature review revealed intriguing and potentially promising findings on the benefit to patients of participating in research studies that focused on repeated symptom assessment. Since the initiation of this study, researchers have continued to examine the effects of routine collection of symptom assessments from patients (often referred to as Patient Reported Outcomes or PROs). Designs often integrate data capture into the Electronic Medical Record with real time availability to clinicians and occasionally integrating electronic delivery of symptom management interventions to patients (Basch, Pugh, et al., 2017; Berry et al., 2014; Cooley & Siefert, 2016). Recently Basch and colleagues (Basch, Deal, et al., 2017) reported a survival benefit for individuals with advanced cancer who were randomized to

electronic patient symptom reporting. Despite this growing body of work there remains a knowledge gap, the underlying mechanism that explains the efficacy of repeated symptom assessment is not established. The intervention delivered in this study was based on one theory (SRT) that provided a plausible argument on why repeated symptom assessment would be associated with improved outcomes. However, feasibility results did not provide support for continuing to utilize the intervention with this high risk very ill population. Continued research is needed to build the science and establish evidenced based interventions that are easily transferable to practicing oncology clinicians.

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Knowledge Translation:

- Feasibility findings do not support replication of this intervention as designed with this population.
- Study withdrawal was most common in individuals with increased symptoms, lower education, and poorer performance status warranting careful consideration of participant burden in intervention design for this high-risk, very ill population.
- Barriers and concerns about weekly telephone contact were the most commonly reported reasons for not consenting to the study, raising possible design considerations for telephone delivered interventions.

Have you had any pain? If no, skip to the second question. If yes, start with the first question.

- What number would you assign for the worst pain you have had? (0 is no pain, and 10 is pain as bad as you can imagine.
- How much of the time have you had the pain? (0 is not at all, and 10 is all the time.)
- What kinds of things make the pain better?
- What kinds of things make the pain worse?
- What words would you use to describe pain?
- In the past week, how much relief have treatments for pain provided? (0 is no relief, and 100 is complete relief.)

FIGURE 1.
Structured Self-Regulation Theory-Based Questions

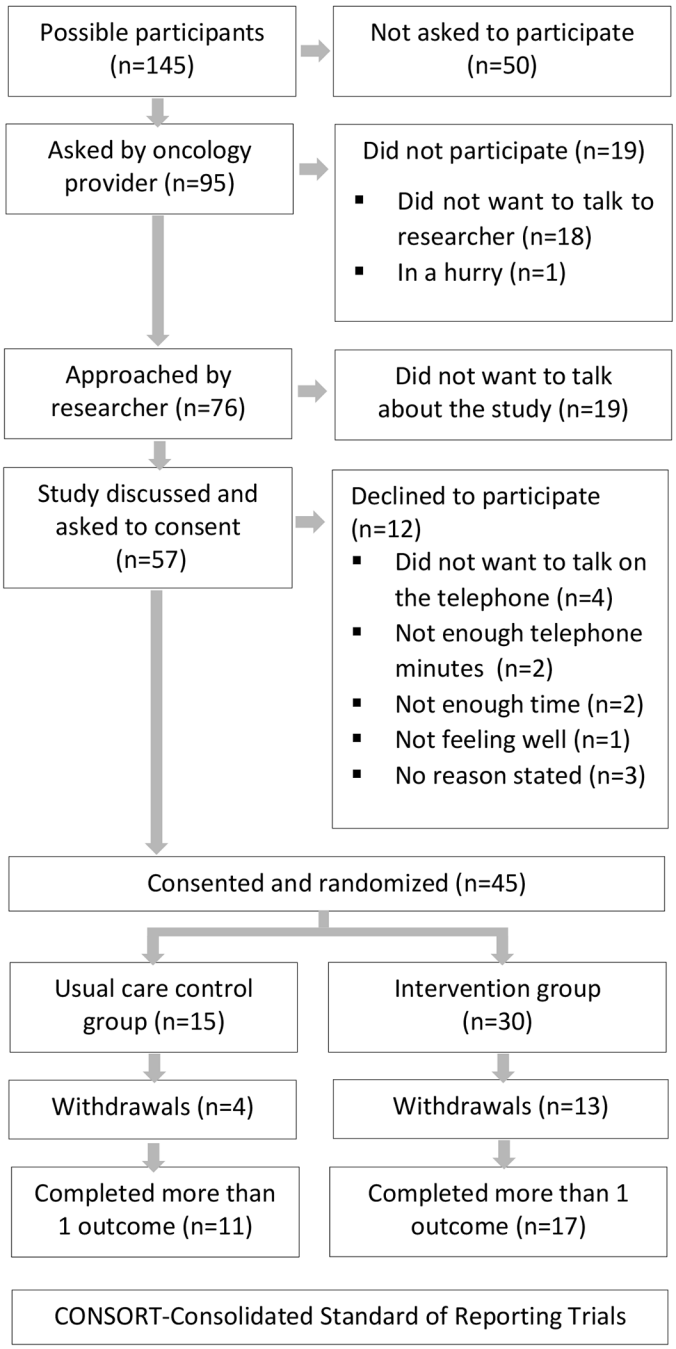

FIGURE 2.
CONSORT Flow Diagram for Sample

TABLE 1.

Study Procedures by Week

Procedure	Entry	W1	W2	W3	W4	W5	W6	W7	W8	W9
All Patients										
Recruitment	X									
Demographic & cancer history	X									X
Outcomes										
Symptom and QOL measures		X		X			X			X
Exit interview		X		X			X			X
Intervention arm only										
SSA		X	X	X	X	X	X	X	X	X
Study Personnel										
Feasibility measures	X	X	X	X	X	X	X	X	X	X

QOL-quality of life; SSA-structured symptom assessment; W-week

TABLE 2.

Sample Characteristics by Group for Patients Completing Versus Withdrawing From the Study

Characteristic	Withdrew (N = 17)		Completed Study (N = 28)		X^2
	$\bar{X}$	SD	$\bar{X}$	SD	
Age (years)	60.82	9.33	63.71	8.29	0.29
GPCOG	7.41	1.37	8.11	1.03	0.06
KPS	64.55	18.1	75	16.22	0.09
Characteristic		n		n	X^2
Greater than a high school education		8		15	0.67
Married or living with a partner		11		22	0.33
Male		9		16	0.78
Characteristic	Withdrew (N = 11)[a]		Completed Study (N = 28)		X^2
	$\bar{X}$	SD	$\bar{X}$	SD	
MDASI interference severity	4.27	2.15	2.63	2.07	0.03*
MDASI severity	4.82	1.55	3.42	1.39	0.01*
MDASI symptom count	10.82	3.49	9.54	2.96	0.25
Outcome measures					
Distress	4.64	2.38	3.04	2.06	0.04*
FACT-L	86.73	17.51	94.11	14.91	0.19
Quality of life	65.45	11.93	67.5	20.02	0.75

*P<0.05

[a]Some individual did not complete baseline outcome measures.

FACT-L-Functional Assessment of Cancer Therapy-Lung: GPCOG-General Practitioner Assessment of Cognition; KPS- Karnofsky Performance Status Scale; MDASI-MD Anderson Symptom Inventory

Note. MDASI severity scores range from 0–10, with higher scores indicating increased severity. For MDASI symptom count, there were 16 possible symptoms. Distress scores range from 0–10, with higher scores indicating increased distress. FACT-L scores range from 0–135, with higher scores indicating improved quality. Quality-of-life scores range from 0–100, with higher scores indicating improved quality.

TABLE 3.

Baseline Demographic and Outcome Variables by Group Assignment for Individuals Who Completed More Than One Outcome

	Control Group (N = 11)		Intervention Group (N = 17)		
Characteristic	$\bar{X}$	**SD**	$\bar{X}$	**SD**	X^2
Age (years)	60.73	8.87	65.65	7.52	0.13
GPCOG	8.27	0.79	8	1.17	0.5
KPS	76.36	16.29	74.12	16.61	0.73
Characteristic		n		n	X^2
Caucasian		10		16	0.75
Greater than a high school education		4		11	0.14
Married or living with a partner		8		14	0.75
Male		6		10	0.57
Characteristic	$\bar{X}$	**SD**	$\bar{X}$	**SD**	
MDASI symptom count	10.73	2.05	8.76	3.25	0.06
Outcome measures					
Distress	4	1.9	2.41	1.97	0.04
FACT-L	96.88	14.77	92.31	15.17	0.44
Functional well-being	18.27	5.83	16.18	4.53	0.3
Quality of life	69.09	20.23	66.74	20.45	0.47

$^{*}p<0.05$

FACT-L-Functional Assessment of Cancer Therapy-Lung; GPCOG-General Practitioner Assessment of Cognition; KPS- Karnofsky Performance Status Scale; MDASI-MD Anderson Symptom Inventory

Note. 5 people in the usual care control group and 6 in the intervention group had disease progression.

Note. MDASI included 16 possible symptoms. Distress scores range from 0–10, with higher scores indicating increased distress. FACT-L scores range from 0–135, with higher scores indicating improved quality. Functional well-being subscale scores range from 0–28, with higher scores indicating better quality. Quality-of-life scores range from 0–100, with higher scores indicating improved quality.

TABLE 4.

Outcome Variables for Individuals Who Completed More Than One Outcome

Outcome	Control Group (N = 11)		Intervention Group (N = 17)		X^2
	$\bar{X}$	SD	$\bar{X}$	SD	
Distress					0.85
Baseline	4	1.9	2.41	1.97	
Week 9	5.55	3.01	4.08	3.29	
FACT-L					0.73
Baseline	96.88	14.77	92.31	15.17	
Week 9	94.85	20.5	98.09	25.81	
Functional well-being					0.75
Baseline	18.27	28	16.18	4.53	
Week 9	19	6.8	19.34	7.56	
Global quality of life					0.58
Baseline	69.09	20.23	66.47	20.45	
Week 9	62.73	29.78	69.58	23.3	

FACT-L-Functional Assessment of Cancer Therapy-Lung

Note. The Kruskal-Wallis test was used to calculate X^2

Note. Distress scores range from 0–10, with higher scores indicating increased distress. FACT-L scores range from 0–135, with higher scores indicating improved quality. Functional well-being subscale scores range from 0–28, with higher scores indicating improved quality. Quality-of-life scores range from 0–100, with higher scores indicating improved quality.