

Psychooncology. Author manuscript; available in PMC 2015 February 18.

Published in final edited form as:

Psychooncology. 2014 February; 23(2): 216–221. doi:10.1002/pon.3390.

Spiritual quality of life in advanced cancer patients receiving radiation therapy

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Abstract

Objective—The aim of this randomized controlled trial for patients with advanced cancer receiving radiation therapy was to determine the effect of a multidisciplinary intervention on spiritual quality of life (QOL) at the end of the intervention (week 4) and at two follow-up time points (weeks 26 and 52).

Methods—One hundred thirty-one persons were randomized to either the intervention or control (forms only) groups. The intervention included six 90-min in-person sessions based on the physical, emotion, social, and spiritual domains of QOL. Three sessions included the spiritual component. Caregivers were present for four sessions, one which included a spiritual component. Ten follow-up phone calls were made to the patients in the intervention group during the 6-month follow-up period. Patients completed the Functional Assessment of Cancer Therapy: General Scale, the Linear Analog Self-Assessment which includes an assessment of spiritual QOL, and the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp) at enrollment, and weeks 4, 27, and 52.

Results—Following the intervention, the intervention group demonstrated improved spiritual QOL on the FACIT-Sp, whereas the spiritual QOL of the control group decreased, resulting in significant mean changes between groups (total score: 1.7 vs. -2.9; p < 0.01; meaning/peace subscale: 1.0 vs. -3.5; p < 0.01; faith subscale: 3.1 vs. -1.7; p = 0.04).

Conclusions—The results indicate that a multidisciplinary intervention which includes a spiritual component can maintain the spiritual QOL of patients with advanced cancer during radiation therapy.

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Introduction

Spirituality is one of the most salient domains of quality of life (QOL) for those with life-limiting medical illnesses including advanced cancers. The poor prognosis associated with advanced cancers and the symptom burden resulting from cancer treatments often bring patients' spiritual concerns to the forefront [1–5]. Although some patients may seek and receive spiritual care from chaplains, pastors, or other providers [6], opportunities to address and impact the spiritual QOL of patients with advanced cancer may be unrecognized and underutilized [7,8]. There is some research that examines the benefit of a structured intervention on spiritual QOL for patients with advanced stage cancer [1,9], but more is needed (Figure 1).

This study was designed following the successful outcome of a randomized, controlled, multidisciplinary QOL trial that included a spiritual component for patients with advanced cancer receiving radiation therapy (Study 1) [9]. In this previous study (Study 1), the overall QOL of the intervention group was maintained during radiation, whereas the QOL of the control group (who received questionnaires only) decreased. Additionally, the spiritual QOL was higher in those who received the intervention when compared with the spiritual QOL of the controls, directly following the intervention [9].

Based on feedback from Study 1 participants, this subsequent study (Study 2) reduced the number of intervention sessions from eight to six. Additionally, caregivers were included in four of the six intervention sessions, and ten follow-up phone calls over 6 months were added.

The primary endpoint of Study 2 was to determine whether the augmented structured multidisciplinary intervention maintained patient QOL, as measured by the Functional Assessment of Cancer Therapy: General Scale (FACT-G), at the end of intervention (week 4) and at the follow-up time points (weeks 27 and 52). The aim of this secondary analysis was to determine the effect of this augmented intervention on spiritual QOL, following the intervention and at the follow-up time points.

Methods

Design

This institutional review board-approved study was a randomized controlled trial designed to maintain or improve the QOL of patients with advanced cancer receiving radiation therapy. Patients were stratified by type of primary malignant disease (brain vs. head/neck vs. lung vs. ovarian vs. gastro--intestinal vs. other), Eastern Cooperative Oncology Group (ECOG) performance status (0 vs. 1 vs. 2), age (<50 vs. 50), and planned treatment (radiation therapy vs. chemotherapy vs. both).

Participants

Enrollment began following the approval of the Mayo Clinic Institutional Review Board. The primary participants were patients who had been diagnosed with advanced stage cancer within the past year and were receiving radiation therapy. Inclusion criteria required patients

to have a projected life expectancy of greater than 6 months but less than 5 years (i.e., estimated 5 year survival of 0–50%). We selected this group because they have significant physical and psychosocial needs associated with the advanced stage of their cancer and their limited life expectancy, and because others have documented that the psychosocial needs of patients with cancer are often unmet [10,11].

Excluded were patients with ECOG performance status of greater than 2, which indicates severe medical decompensation. Also excluded were those determined by a psychologist or psychiatrist to be actively suicidal or too cognitively impaired to participate in the study, based on the Beck Depression Inventory-II and the mini-mental state examination scores, respectively. Secondary participants were patients' designated caregivers, one per patient. After enrollment, patient—caregiver pairs were randomly assigned to receive the structured multidisciplinary intervention or standard medical care. To be eligible for inclusion in the analysis, patients in the intervention group must have supplied baseline data and attended at least four of the six sessions.

Intervention

The multidisciplinary intervention included six 90-min scheduled in-person sessions for the patient-participants. The topics of each session were based on the physical, emotion, social, and spiritual domains of QOL. Sessions started with 15 min of physical therapy and ended with a 15 min relaxation exercise. Each session was led by a psychologist or a psychiatrist and co-facilitated by an advanced practice nurse, a licensed social worker, or a board-certified chaplain. Non-professional caregivers, generally family members or close friends, participated with the patient-participants in four of the six sessions. A complete description of the intervention has been reported elsewhere [12].

The spiritual component of the intervention was led by board-certified chaplains and was included in three of the six sessions. Key spiritual themes relevant in facing life-threatening illness framed these sessions, i.e., life review, meaning and purpose, and grief and acceptance (presented in sessions 2, 3, and 5, respectively) [5,9,12]. Structured prompts were developed by the multidisciplinary team based on a thorough review of the literature and their clinical experiences to facilitate participants' reflection on these themes and to encourage discussion with the other participants and the chaplain [13–16] (Table 1).

The caregivers were present for the session on meaning and purpose, but they were not included in the sessions that dealt with life review or grief and acceptance. Based upon participant feedback on the previous study, it had been hypothesized that the presence of the caregivers may inhibit candid communication by the patient-participants regarding these more sensitive issues.

Ten follow-up phone calls were made to the patients during the 6-month follow-up period. Eight of the phone calls were made by a psychologist, and two were made by a physical therapist. The content of the phone calls was related to the content in the intervention sessions. Structured questions were asked related to the patient's use of the material provided in the intervention, and suggestions for compliance were given. The expectation

was that both caregiver involvement and the follow-up phone calls would reinforce the material presented in the invention and increase its efficacy for the patient-participants.

Measures

Patients completed QOL assessments, including the FACT-G, the Linear Analog Self-Assessment (LASA), and the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp) at enrollment, at 4 weeks (or end of face-to-face intervention) and 27 and 52 weeks after enrollment.

The FACT-G (version 4) is a well-validated 28-item general patient-rated QOL life measure for cancer patients with any tumor type. It has been used widely in clinical trials and has demonstrated sensitivity according to performance status and extent of disease. The FACT-G has four subscales: functional well-being (WB), physical WB, social/family WB, and emotional WB [17,18].

The LASA consists of 12 items and is a general measure of QOL that was constructed at Mayo Clinic for use in cancer patients [19]. Other studies have validated LASA items as measures of global and dimensional QOL constructs in numerous settings [20]. The current study focused on the spiritual QOL item which asked, 'How is your spiritual well-being over the past week?' using a scale from 0 (as bad as it can be) to 10 (as good as it can be).

The 12-item FACIT-Sp was used to measure overall spiritual QOL. It has been found to be a reliable and valid for measurement of spiritual QOL for people with cancer and other chronic illnesses. We also used the two author-identified subscales which differentiate between meaning and peace (items 1–8) and faith (items 9–12) [21–23].

Statistical analysis

Each assessment was scored according to its specific scoring algorithm and scores were converted to a 0- to 100-point scale for comparability, with 100 being QOL as good as it can be. Changes from baseline values were calculated. Comparison of scores between arms was conducted using chi-square or Wilcoxon tests as appropriate. Relationships between QOL scores were characterized using Pearson correlation coefficients. The study was designed to evaluate the multidisciplinary intervention as a whole, and therefore, no analysis of the specific components of the intervention was attempted.

Results

One hundred thirty-one eligible patients were randomized (65 to the intervention group and 64 to the control group). Of these, 117 (54 intervention and 63 control) were evaluable for the primary endpoint. Reasons for the patients being non-evaluable for the primary endpoint were not attending at least four of the six intervention sessions (one died and seven were absent due to illness) and not completing both baseline assessments and week 4 assessments (three intervention participants and one control participant). Fourteen patients left the study and were non-evaluable (11 from the intervention arm and three from the standard care arm). None of them completed week 4 evaluations, so we had no endpoint data available.

There was no difference in the demographic variables or admission spiritual QOL between those evaluable and those non-evaluable for analysis.

The distribution of patient baseline characteristics was balanced between arms (Table 2). The mean age of patients was 59.3 years. The majority of patients were male (66%), married (87%), and employed (59%). Almost all were Caucasian (97%). Over half reported their religious affiliation as Protestant (57%) and over one third as Catholic (35%). Patients with a variety of tumor types participated (37% gastrointestinal, 22% brain, 16% head/neck, 13% lung, and 12% other). Almost all had had surgery (95%), and 86% were receiving chemotherapy, in addition to radiation.

Overall QOL, assessed by FACT-G, at week 4 was significantly higher in the intervention group compared with the control group (mean of 74.2 vs. 68.7; p = 0.02) [10]. The change from the baseline scores showed that the intervention group maintained their overall QOL, whereas the control group experienced a reduction in their overall QOL (mean change of -1.4 vs. -6.2; p = 0.01). There were no differences between groups at week 27 or 52.

At week 4, the intervention participants demonstrated improved spiritual QOL on the FACIT-Sp (total score and both subscales), whereas the spiritual QOL of the control participants decreased, resulting in significant mean changes between groups (mean change in total score: 1.7 vs. -2.9; p < 0.01; mean change in meaning/ peace subscale: 1.0 vs. -3.5; p < 0.01; mean change in faith subscale: 3.1 vs. -1.7; p = 0.04). Spiritual QOL as measured with the spiritual well-being item (SWB) on the LASA showed no statistically significant differences between groups at week 4. No differences in spiritual QOL were detected between groups at week 27 or 52 on either the FACIT-Sp or SWB LASA (Table 3).

To characterize associations between spiritual QOL as measured by the FACIT-Sp and the SWB LASA, correlation statistics were calculated. The correlations of the FACIT-Sp total score and the SWB LASA score were moderate in value at each time point (baseline, r = 0.64; week 4, r = 0.49; week 27, r = 0.67; week 52, r = 0.58). Correlations between the subscales of the FACIT-Sp and the SWB LASA were also consistently moderate over time (FACIT-Sp faith subscale and the SWB LASA: baseline, r = 0.56; week 4, r = 0.44; week 27, r = 0.63; week 52, r = 0.47).; FACIT-Sp Meaning/Peace subscale and the SWB LASA: baseline, r = 0.53; week 4, r = 0.41; week 27, r = 0.53; week 52, r = 0.49).

Discussion

This randomized controlled trial demonstrated that a multidisciplinary intervention with a spiritual component maintained overall QOL and spiritual QOL in advanced cancer patients receiving radiation. This finding supports the growing literature that structured interventions can impact the spiritual QOL of patients with advanced cancer and provides further suggestions for a structured process of spiritual care designed to benefit patients with advanced cancer dealing with the additional challenges of radiation therapy. Because spiritual distress has been associated with declines in physical and mental health in various populations, an intervention that has a positive impact on spiritual QOL is very advantageous [24–26] and warrants further exploration.

From a clinical and patient care perspective, the board-certified chaplains involved in this study were impressed with the depth and richness of the discussions that occurred during the intervention sessions. The themes and the prompts used in the spiritual intervention could easily be incorporated into spiritual conversation with individual cancer patients and their caregivers by chaplains. The resulting discussions may lead to important life review and integration that inevitably leads to patient and caregiver well-being [13].

In the development of subsequent QOL interventions for patients with advanced cancer, it will be important to identify strategies to promote and enhance long term-spiritual QOL. Given their poor prognosis, spiritual issues may continue to be important to them, and they may benefit from conversation with a chaplain following an in-person intervention [27]. Perhaps, follow-up phone calls from a chaplain to reinforce the spiritual aspects of the intervention and provide spiritual dialogue about spiritual concerns or questions would be beneficial. Another strategy would be to incorporate the patients' local spiritual providers and resources into follow-up care to foster long-term spiritual QOL.

The limitations of our study include the fact that most of our study population contains very minimal religious diversity. Most are Protestant or Catholic, and most attend religious services. Additionally, almost all participants were Caucasian. Thus, the generalizability of our findings is limited. Future studies should attempt to enroll a more religiously and ethnically diverse group of participants.

Another limitation of this project is the restrictedness of the spiritual data collected. In addition to very brief demographic information, spirituality was assessed only through two instruments both focused on SWB. Despite moderate correlations between them, only one of these, the FACIT-Sp, demonstrated a difference between groups. Questionnaires assessing other aspects of spirituality may have shed light on the reason for this finding. Additionally, future research could involve a qualitative analysis of transcripts of the spirituality sessions and qualitative interviews assessing key components of the spiritual intervention to obtain more personalized information regarding changes in spirituality. The results would make an important contribution to the understanding of spiritual QOL and spiritual struggle in patients with advanced cancer. The results would make an important contribution to the understanding of spiritual QOL and spiritual struggle in patients with advanced cancer. Current spiritual constructs are considered 'fuzzy' [28–30], and a qualitative investigation into the material discussed may lead to more precise definitions, and consequently, add to the efficacy of interventions and measurement.

Conclusion

The results of this study support previous findings indicating that a multidisciplinary intervention which includes a chaplain-led spiritual component has a significant impact on overall QOL and spiritual QOL in patients with advanced cancer during the challenging experience of active radiation therapy. These results offer important information for researchers and clinicians seeking to develop best practice clinical interventions for patients with advanced cancer. They also suggest the importance of investigating further the meaning of spiritual QOL for these patients and the trajectory of their spiritual QOL over time.

Acknowledgments

This study was supported by the Linse Bock Foundation and the Saint Mary's Hospital Sponsorship Board Inc., Rochester, MN.

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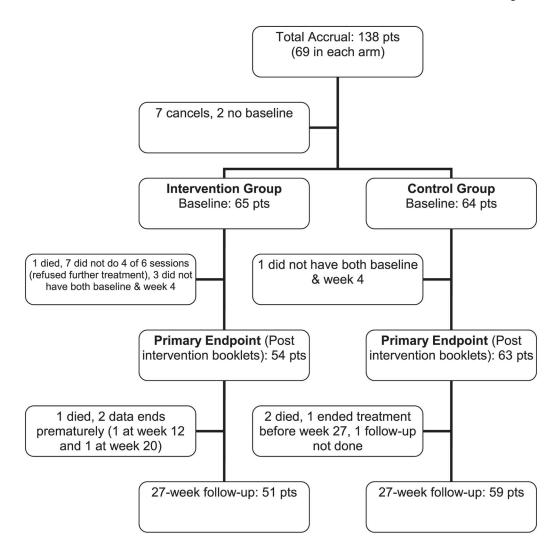


Figure 1. Patient enrollment and follow-up

Table 1

Sample prompts from spiritual intervention

Life review (session 2)

- Tell me about yourself.
- Do you have any spiritual beliefs or practices that have been part of your life?
- Tell me about being diagnosed with cancer.
- · What are your current goals?

Meaning and purpose (session 3 - caregiver present)

- Today, what would you say gives your life meaning?
- How do you feel about what you have accomplished thus far in your life?
- Have there been any mentors or guides who have helped you along the way?
- · Who or what do you find helpful during times of change or difficulty?

Grief, loss, acceptance, and integration (session 5)

- What has been the most difficult part of this cancer experience thus far?
- · How have you been able to cope with it?
- What helps you feel peace, maintain inner harmony?
- Has your cancer experience helped to clarify your faith or spiritual beliefs?

Table 2

Baseline patient characteristics

Characteristics	Intervention group $(n = 65)$	Control group $(n = 66)$	<i>p</i> -value
Age, years: mean (SD)	58.7 (10.6)	59.9 (10.9)	0.61 ^a
Sex			0.54^{b}
Female	24 (37%)	21 (32%)	
Male	41 (63%)	45 (68%)	
Race			0.26^{b}
Caucasian	63 (97%)	64 (97%)	
Currently employed			0.67^{b}
Yes	37 (57%)	40 (61%)	
Marital status			0.07^{b}
Divorced	0	6 (9%)	
Married	59 (91%)	56 (85%)	
Single	1 (2%)	2 (3%)	
Widowed	5 (7%)	2 (3%)	
Religious affiliation			0.23^{b}
Catholic	18 (28%)	28 (42%)	
Protestant	39 (60%)	35 (53%)	
None	5 (8%)	2 (3%)	
Other	3 (4%)	1 (2%)	
Attend religious services	50 (76.8%)	58 (87.9%)	0.10^{b}
Tumor type			0.47^{b}
Brain	11 (17%)	18 (27%)	
Gastrointestinal	25 (39%)	24 (36%)	
Head and neck	10 (15%)	11 (17%)	
Lung	10 (15%)	7 (11%)	
Other	9 (14%)	6 (9%)	

SD, standard deviation.

 $^{^{}a} \! \text{Wilcoxon signed-rank test.}$

 $[^]b\mathrm{Chi} ext{-square test.}$

Table 3

Mean (standard deviation) spirituality scores from Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp) and the Linear Analog Assessment spiritual well-being item (LASA spiritual WB)

Week	Scale	Intervention	Control	<i>p</i> -value ^a
0	FACIT-Sp meaning/peace subscale	80.4 (15.6)	82.8 (16.2)	0.27
	FACIT-Sp faith subscale	70.2 (28.4)	80.2 (22.0)	0.052
	FACIT-Sp total score	77.0 (17.0)	81.9 (15.4)	0.07
	LASA spiritual WB	77.2 (21.8)	83.2 (12.8)	0.27
4	FACIT-Sp meaning/peace subscale	81.4 (16.01)	79.3 (17.75)	0.61
	FACIT-Sp meaning/peace subscale change from baseline	1.0 (11.58)	-3.5 (10.89)	< 0.01
	FACIT-Sp faith subscale	73.3 (22.26)	78.5 (20.10)	0.18
	FACIT-Sp faith subscale change from baseline	3.1 (16.23)	-1.7 (13.10)	0.04
	FACIT-Sp total score	78.7 (15.31)	79.0 (16.45)	0.72
	FACIT-Sp total score change from baseline	1.7 (10.42)	-2.9 (8.93)	< 0.01
	LASA spiritual WB	74.3 (19.48)	78.4 (18.07)	0.23
	LASA spiritual WB change from baseline	-3.0 (16.33)	-4.8 (13.78)	0.58
27	FACIT-Sp meaning/peace subscale	78.1 (15.24)	80.8 (16.46)	0.24
	FACIT-Sp meaning/peace subscale change from baseline	-2.4 (14.87)	-2.8 (13.49)	0.59
	FACIT-Sp faith subscale	70.5 (25.68)	76.4 (23.60)	0.27
	FACIT-Sp faith subscale change from baseline	0.4 (21.86)	-3.1 (17.86)	0.52
	FACIT-Sp total score	75.5 (16.12)	79.3 (16.27)	0.20
	FACIT-Sp total score change from baseline	-1.5 (15.05)	-2.9 (12.36)	0.45
	LASA spiritual WB	78.5 (16.11)	80.4 (18.18)	0.37
	LASA spiritual WB change from baseline	0.4 (18.10)	-2.6 (18.10)	0.58
52	FACIT-Sp meaning/peace subscale	80.0 (15.92)	78.7 (14.85)	0.71
	FACIT-Sp meaning/peace subscale change from baseline	-1.0 (14.57)	-4.7 (15.66)	0.12
	FACIT-Sp faith subscale	73.0 (23.40)	78.4 (22.58)	0.20
	FACIT-Sp faith subscale change from baseline	5.2 (19.76)	-1.7 (15.32)	0.11
	FACIT-Sp total score	77.7 (15.9)	78.6 (13.8)	0.87
	FACIT-Sp total change from baseline	1.1 (14.30)	-3.7 (12.74)	0.07
	LASA spiritual WB	75.6 (18.03)	83.4 (14.13)	0.05
	LASA spiritual WB change from baseline	-1.8 (19.85)	1.1 (15.28)	0.40

^aWilcoxon signed-rank test.