

Do Preparation and Life Completion Discussions Improve Functioning and Quality of Life in Seriously Ill Patients? Pilot Randomized Control Trial

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Abstract

Background: Significant palliative care intervention has focused on physical pain and symptom control; yet less empirical evidence supports efforts to address the psychosocial and spiritual dimensions of experience.

Objective: To evaluate the impact of an intervention (Outlook) that promotes discussions of end-of-life preparation and completion on health outcomes in dying persons, including pain and symptoms, physical function, emotional function (anxiety and depression), spiritual well-being, and quality of life at the end of life.

Design: A three-arm pilot randomized control trial. Subjects were recruited from inpatient and outpatient hospital, palliative care, and hospice settings. Intervention subjects met with a facilitator three times and discussed issues related to life review, forgiveness, and heritage and legacy. Attention control subjects met with a facilitator three times and listened to a nonguided relaxation CD. True control subjects received no intervention.

Measurements: Preoutcomes and postoutcomes included the Memorial Symptom Assessment Scale, QUAL-E, Rosow-Breslau ADL Scale, Profile of Mood States anxiety sub-scale, the CESD short version, and the Daily Spiritual Experience Scale.

Results: Eighty-two hospice eligible patients enrolled in the study; 38 were women, 35 were African American. Participants' primary diagnoses included cancer (48), heart disease (5) lung disease (10), and other (19) Ages ranged from 28–96. Participants in the active discussion intervention showed improvements in functional status, anxiety, depression, and preparation for end of life.

Conclusions: The Outlook intervention was acceptable to patients from a variety of educational and ethnic backgrounds and offers a brief, manualized, intervention for emotional and spiritual concerns.

Introduction

PALLIATIVE CARE SEEKS to reduce suffering and enhance quality of life for seriously ill patients.^{1,2} Increasing research has focused on physical pain and symptom control, yet less empirical evidence supports efforts to address the psychosocial and spiritual dimensions of experience. In fact, recommendations from the 2005 National Institutes of Health State of the Science in End of Life Care Conference called for increased efforts to understand the existential needs of patients and conduct and evaluate interventions to address these concerns.³

In our previous research on what constitutes quality at the end of life,^{4,5} we learned that patient emotional and spiritual

well-being were identified as part of two larger domains: end-of-life preparation and completion. Together, these domains incorporate both the need for looking back to assess the life lived as well as looking forward to prepare themselves and their family for the remaining weeks or months of life.⁴ For some patients, that assessment occurs within a traditional religious context, for others it is part of a larger process of meaning-making facilitated by locating their illness experience in the context of the values and preferences of a whole life. Completion and preparation included issues of reviewing life, resolving conflicts, achieving forgiveness, spending time with family and friends, contributing to others and saying good-bye.^{4,6}

Therefore, we developed a new intervention to foster expression of end-of-life preparation and completion and con-

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ducted a pilot randomized control trial to evaluate the impact of this intervention on physical functioning, emotional function (anxiety and depression) and quality of life at the end of life. In this paper, we present the results of the pilot trial. The intervention (called Outlook) content and structure is based on robust evidence from the social gerontology life review and the health psychology self-disclosure literatures.

Life review: Making sense of a life lived

For social gerontologists, late adulthood includes the developmental task of life review, which contains components of reminiscence, reconciliation, forgiveness, and resolution of past conflicts.⁷ It offers a chance to “edit” one’s life story, perhaps in the telling or review, “making it right” by integrating events in the broader arc of a full life-course.^{8–10}

In recent years, several studies have evaluated the effects of life review interventions on psychosocial outcomes. Haight’s trial of life review among homebound elderly showed improved psychological well-being and life satisfaction up to 8 weeks after the intervention.¹¹ Bohlheijmer et al.¹² and Erlin et al.¹³ each found improved levels of depression, and Erlin et al, using life review among persons with AIDS also demonstrated improved purpose, self-esteem, and quality of life. Finally Bohlmeijer et al.’s meta-analyses of 20 studies in depressed older adults showed improvements in depressive symptomatology. The effect sizes of 0.84 (95% confidence interval [CI] = 0.31–1.37) were statistically and clinically comparable to pharmacotherapy and psychological treatments. The majority of life review interventions have been conducted among persons with chronic mental or physical health conditions, with fewer conducted in patients facing the end of life.

Self-disclosure facilitates healing

An entire literature demonstrates a variety of positive outcomes associated with expressing personally stressful or emotionally laden experiences.^{14–20}

Conceptually, self-disclosure of stressful experiences is associated with the opportunity to develop a coherent personal narrative that allows a person to describe an event and explore its meaning and significance in their life’s context. By putting stress into words,²¹ individuals are able to identify, acknowledge, classify, and assimilate these emotional experiences into a larger spiritual and psychosocial framework.²²

A meta-analysis of 146 randomized control trials of disclosure that suggested this technique is effective with an average effect size of 0.075.²³ Studies with higher doses of disclosure (at least 3 sessions), increased session spacing (weekly), greater length (longer than 15 minutes), and with follow-up in less than 1 month, conducted among populations with current physical or psychological problems, and oral and in-person versus written have demonstrated larger effects sizes.

Conceptual model

Based on the literature outlined above, we developed the following conceptual model as the foundation for our intervention, which we call Outlook. Patients living with advanced serious illness face challenges associated with physical, psychosocial, spiritual, and emotional concerns. Attention to each is required to reduce suffering and increase quality of life.²⁴ Specific developmental tasks include: sense of completion in relationships, exploring issues of regret and forgiveness, sense of gratitude and appreciation, life review and transmission of knowledge and wisdom. These tasks have been identified as components of domains of end-of-life preparation and completion. Attention to these tasks is proposed to influence health outcomes including quality of life, depressive symptoms, and anxiety (Fig. 1).

Methods

Design

We developed a manualized treatment intervention consisting of three intervention session protocols, as well as a

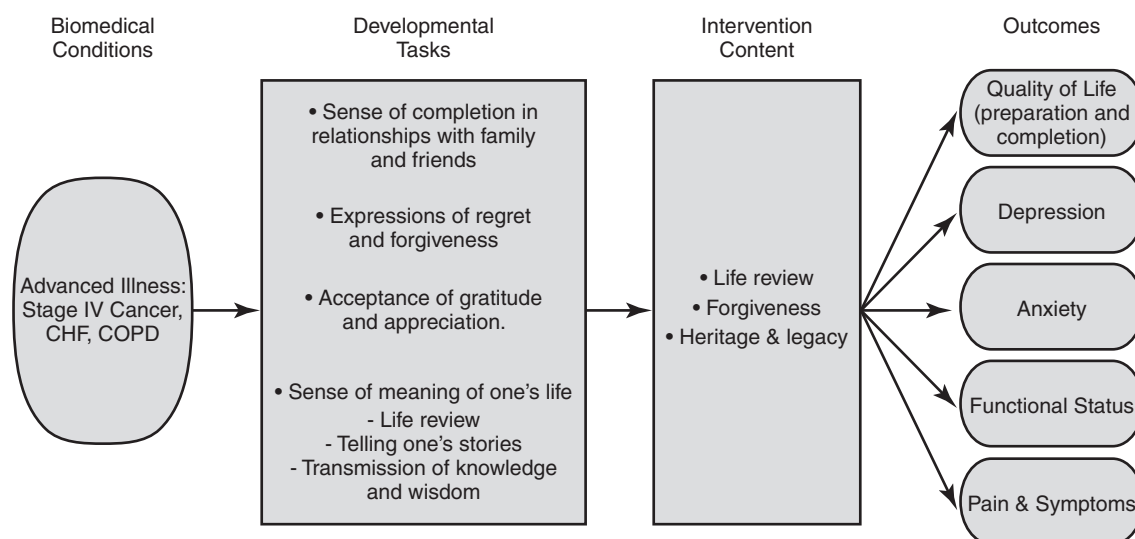


FIG. 1. Conceptual model.

nonguided relaxation CD, to use as an attention control. We then tested these in a three-armed trial of the intervention, attention control and true control on health outcomes. The pilot study goals were to assess feasibility and initial efficacy.

Subjects

Patients were recruited from: two local hospices, a palliative care service, home based care program, and the Extended Care and Rehabilitation Center at the Durham VA Medical Center and inpatient units at Duke University Medical Center. Patients were eligible if their physicians estimated them to have a prognosis of less than 6 months to live. To reduce selection bias, referral conversations focused on clinical criteria, versus physician judgment of willingness to participate. Patients unable to speak or severely cognitively impaired were excluded from the study. All other clinically eligible patients were approached for participation. In addition, because sessions occurred in patients' homes, we limited inclusion to subjects living within a 35-mile radius of Durham, North Carolina.

Procedure

After obtaining informed consent, participants completed a baseline survey, and then were randomly assigned to one of three groups. Subjects assigned to the first group ("treatment") were interviewed three times, spaced a week apart, for a period of 45 minutes to 1 hour each and asked to discuss issues related to life completion and preparation. Session 1, focused on life review, accomplishments, proudest moments, and cherished times. One week later, Session 2 focused on issues of forgiveness, things they would have done differently, things left unsaid or undone. In the final week, Session 3 focused on lessons learned, heritage, and legacy. To ensure replicability, the interventionist followed the questions outlined in the training manual. Probes were limited to asking if participants had more to add to each specific topic (Table 1).

Subjects in the second group ("relaxation meditation") also met with a facilitator, on three occasions, spaced a week apart, for a period of 45 minutes each and listened to a nonguided relaxation tape. The second group, led by a facilitator and with session time equivalence, was essential to demonstrating that the effects of "treatment" were not simply a result of greater attention but, in fact, due to the in-

tervention content of end-of-life preparation and life completion tasks. The third group of participants ("no intervention"—true control) was not contacted between pre-assessment and postassessment. One week and 2 weeks after the three sessions (or their timing equivalent, for controls), participants in all groups completed posttest measures. One research assistant conducted the intervention and relaxation meditation sessions. The other research assistant conducted preassessments and postassessments and was blinded to subjects' intervention group assignment (Fig. 2).

Measures

Baseline measures assessed pain and symptoms (Memorial Symptom Assessment Scale),²⁵ functional status (Rosow-Breslau ADL scale),²⁶ anxiety (Profile of Mood States subscale),²⁷ depression (Center for Epidemiologic Study of Depression CESD),²⁸ quality of life at the end of life (including preparation and completion domains) (the QUAL-E),⁶ and daily spiritual experience (The Daily Spiritual Experience Scale).²⁹ We also administered a brief measure of family social support.³⁰ To reduce burden, postmeasures did not include daily spiritual experience or family social support measures. All other measures were repeated after subjects completed the intervention period. Quantitative analyses were conducted using SAS 9.2 (SAS Institute, Cary, NC).

Results

Over an 18-month period we contacted 209 eligible patients. One hundred twenty-seven refused to participate (74%–58%, general refusal; 19%–15%, caregiver declined; 15%–12%, too much time; 19%–15%, too sick). Eighty-two patients enrolled in the study and 42 completed all data points. Of the 82 enrolled patients, 38 were women, 35 were African American. Forty-eight patients entered the study with a primary diagnosis of cancer, 5 with heart disease, 10 with lung disease, and 19 with other illnesses such as end-stage renal disease or neurodegenerative disease. Forty-eight were from Duke Hospital, 18 from local hospices, and 15 from the VA. In addition, 40% of the sample was married, 30% divorced, 12% widowed, and 13% never married. There was a breadth of educational background where 15% had less than a high school education, 47% graduated high school; 17% had some college, 9% were college graduates, and 11% had a graduate or professional degree. Ages ranged

TABLE 1. INTERVENTION QUESTIONS

| <i>Session 1—Life story</i> | <i>Session 2—Forgiveness</i> | <i>Session 3—Heritage and legacy</i> |
|-----------------------------|------------------------------|--------------------------------------|
| Tell me about your life | If you were to do things | What are your most |
| What are cherished times? | again, what might you do | valuable lessons learned? |
| Of what are you most | differently? | What would you like to |
| proud? | Are there things or times | share with future |
| If someone were to make a | you regret? | generations? |
| movie of your life, what | Is there anyone to whom | If you could choose one |
| would be important to | you would like to offer | thing to pass on as your |
| include? | forgiveness? | legacy what would that be? |
| | Is there anyone from | What things would you like |
| | whom you would like to | to accomplish? |
| | ask forgiveness? | |
| | Are you at peace? | |

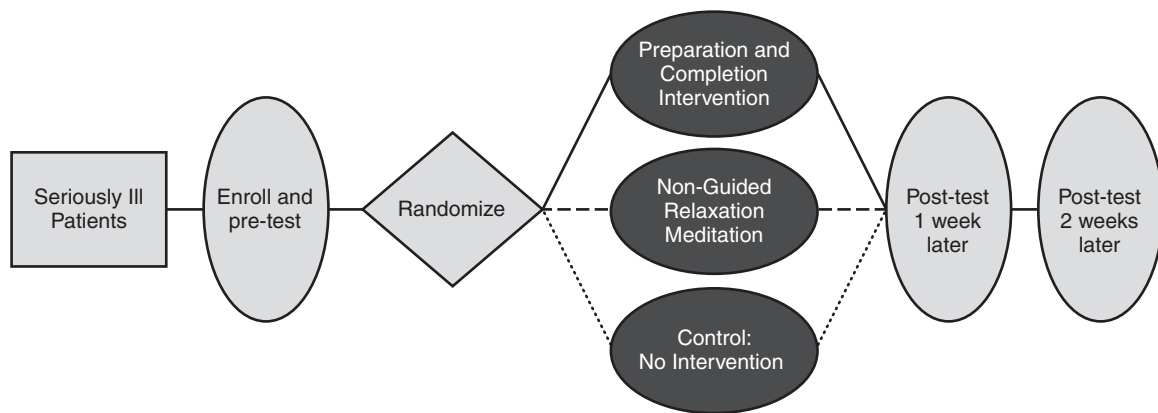


FIG. 2. Pilot study design.

from 28–96. Patients from varying backgrounds completed the intervention with similar facility and responded with ease to the semistructured formatted that set general parameters but self-guidance within. (Detailed qualitative results are reported elsewhere.)

At baseline, each arm contained 26 participants (Table 2), and, with attrition, the life completion intervention arm included 9 participants, relaxation meditation 11 participants, and control 16 participants. Because all participants were at the very end of life, attrition was due to severe functional decline (e.g. losing consciousness), or death. Differences in attrition by group were not thought to be associated with the intervention content or participation.

Intervention participants showed improvements in functional status, anxiety, depression, and preparation for end of life (a QUAL-E domain). For those in the intervention arm, functional status improved from a total score of 26.1 to 22.7, compared to attention control (26.3 to 24.8) and true control (28.4 to 28.3). Anxiety decreased among intervention patients from 6.4 to 3.7 as compared with anxiety increases in those in attention control (4.4 to 5.0) and true control (4.4 to 5.6).

Similarly, intervention participants' depression scores decreased (11.8 to 9.1) whereas attention control subjects' depressive symptoms were the same (10.1 to 10.0) and true control participant scores worsened (10.7 to 11.9). We did not see differences in completion scores, among the three arms. End-of-life preparation improved among intervention subjects from 3.4 to 3.7 and decreased for attention control (4.0 to 3.8) and true control (4.2 to 3.4).

To better understand the treatment effects in the pilot study, we examined predictors of attrition. Several patient-level characteristics were associated with differential rates of dropout. Patients who were widowed, older age, had lower daily spiritual experience scores, had lung disease, and were referred from hospice or home health care all were more likely to not complete the study (either due to illness or death). Including these predictors of dropout in the estimation of the main study outcomes relaxes the missing data assumption to missing at random (MAR). In MAR, missing data can depend on any observed data (i.e., other variables or the outcomes at earlier time points), but not the actual missing value. We, therefore, constructed a multivariate nor-

TABLE 2. OBSERVED OUTCOMES BY STUDY ARM, OVER TIME (MEAN AND SD)

| Arm by time | n | Functional Status ADLs | Anxiety POMS | Depression CESD | Preparation for the end of life QUAL-Ep |
|--------------|----|---------------------------|-----------------|--------------------|--|
| Intervention | | | | | |
| Pretest | 26 | 26.1 (5.3) | 6.4 (4.7) | 11.8 (4.6) | 3.4 (.7) |
| Posttest 1 | 12 | 25.1 (6.4) | 4.1 (3.5) | 8.3 (3.3) | 3.8 (.5) |
| Posttest 2 | 9 | 22.7 (4.0) | 3.7 (2.4) | 9.1 (2.7) | 3.7 (.4) |
| Relaxation | | | | | |
| Pretest | 26 | 26.3 (6.3) | 4.4 (4.3) | 10.1 (4.8) | 4.0 (.9) |
| Posttest 1 | 10 | 26.2 (6.2) | 3.9 (4.2) | 11.7 (5.5) | 3.6 (.8) |
| Posttest 2 | 11 | 24.8 (5.8) | 5.0 (5.4) | 10.0 (4.0) | 3.8 (1.0) |
| Control | | | | | |
| Pretest | 26 | 28.4 (7.3) | 4.4 (4.3) | 10.7 (5.1) | 4.2 (.7) |
| Posttest 1 | 18 | 28.6 (7.3) | 5.8 (5.3) | 12.3 (6.0) | 3.9 (.9) |
| Posttest 2 | 16 | 28.3 (8.8) | 5.6 (4.8) | 11.9 (6.1) | 3.4 (1.0) |

ADLs, Rosow-Breslau Activities of Daily Living; POMS, Profile of Mood States, anxiety subscale; CESD, Centers for Epidemiological Study of Depression scale; QUAL-Ep, preparation for the end of life subscale.

SD, standard deviation.

mal model, which included all of the predictors of dropout and calculated maximum likelihood estimates of the main study outcomes, stratified by treatment arm. The expectation-maximization algorithm (EM) in PROC MI (SAS, v9) was used for estimation (Table 3).

Results suggest very little improvement in any outcomes is seen in the "relaxation" and "true control" arms of the study. The intervention arm, however, shows improvement in all of the study outcomes. In other words, these analyses suggested several measurable factors were driving differential attrition. When we account for those factors that predict dropout, the intervention arm's positive trends remain.

Discussion

The Outlook intervention is brief, fully manualized, exportable, and acceptable to patients with a range of illnesses. Furthermore, patients participated with similar facility regardless of broad variation in social background and socioeconomic status. The intervention was conducted successfully by a nonphysician clinician demonstrating the usefulness of multi-disciplinary team. The results of this paper suggest discussions of preparation and life completion influence patient symptoms and quality of life among persons with advanced life-limiting illness.

Sample size was not large enough to demonstrate statistical significance; however, participants in the active discussion intervention showed improvements in functional status, anxiety, depression, and preparation for end of life (a QUAL-E domain). The life review literature cites improvements in depressive symptomatology as a consistent outcome.^{12,13} Similar trends from this study extend that work to the arena of end-of-life. In contrast, anxiety is not frequently assessed in life review randomized control trials. However, because many patients with advanced serious illness struggle with anxiety, finding interventions, like Outlook, that may improve that symptom will add to palliative clinicians' armamentarium. We also saw positive trends in functional status. For patients approaching the end of life, maintaining or improving independence and one's ability to

care for oneself is highly valued by patients and families⁴ and palliative care clinicians and researchers emphasize maximizing functional status as a key outcome for seriously ill and dying patients. Similarly, patients and families, identify preparation as a central domain of quality at end of life.^{4,5} The preparation subscale, which measures issues of regret, burden, and things done differently, showed positive movement in the intervention group.

We did not see changes in the QUAL-E subscale measuring relationships with health care provider or in the completion subscale. The completion subscale includes items measuring both internal completion (e.g., coming to peace) and external completion (e.g., saying important things to family). The stability in this measure may be due to the individual items which assessed sense of having a chance to say good-bye, feeling at peace, having someone with whom they could share their deepest thoughts and feeling that they were able to share important things with others. These items encompassed external expressions of completion and may not have tapped strongly the internal sense. The small sample size may have affected our ability to see differences. In a fuller test of the intervention, we will include an assessment of internally gauged faith and purpose. It may be that the post-tests did not have enough time from intervention to test change. Furthermore, it is possible that expectations changed due to the intervention resulting in response shifts that confounded the ability of the subscale to detect real change.

Previous tests of life review demonstrate improvements in anxiety, depression and quality of life. Our newly designed intervention included similar content, but also extended the literature in at least two important ways. Similar to the structure of other life review interventions, the first session focused on the past with discussion of biographical context, accomplishments, and cherished times. In the second session, we extended the life review content to probe in depth about issues of regret and forgiveness. Recent literature has begun to explore the centrality of this topic to overall quality of life.

Several studies have looked at the direct link between forgiveness and physical health.^{31,32-35} Although little is known

TABLE 3. MAXIMUM LIKELIHOOD ESTIMATES OF MEAN OUTCOMES BY STUDY ARM, OVER TIME

| <i>Arm by time</i> | <i>n</i> | <i>Functional status ADLs</i> | <i>Anxiety POMS</i> | <i>Depression CESD</i> | <i>Preparation for the end of life QUAL-Ep</i> |
|--------------------|----------|---------------------------------------|-------------------------|----------------------------|--|
| Intervention | | | | | |
| Pretest | 26 | 25.9 | 6.5 | 11.8 | 3.4 |
| Posttest 1 | 26 | 24.2 | 2.4 | 7.0 | 4.3 |
| Posttest 2 | 26 | 21.8 | 4.2 | 8.7 | 4.0 |
| Relaxation | | | | | |
| Pretest | 26 | 26.3 | 4.4 | 10.4 | 4.0 |
| Posttest 1 | 26 | 25.8 | 3.3 | 10.1 | 3.8 |
| Posttest 2 | 26 | 25.5 | 5.3 | 10.1 | 3.9 |
| Control | | | | | |
| Pretest | 26 | 28.3 | 4.6 | 10.7 | 4.2 |
| Posttest 1 | 26 | 28.5 | 5.5 | 11.8 | 3.9 |
| Posttest 2 | 26 | 28.3 | 4.9 | 10.5 | 3.6 |

ADLs, Rosow-Breslau Activities of Daily Living; POMS, Profile of Mood States, anxiety subscale; CESD, Centers for Epidemiological Study of Depression scale; QUAL-Ep, preparation for the end of life subscale.

empirically about the relationship between forgiveness and health, theorists suggest that forgiveness reduces hostility, and therefore should be related to: (1) a decrease in chronic blaming, anger, and hostility; (2) self-efficacy to take health-related actions; (3) social support; and (4) transcendent consciousness.^{36,37} Although in its infancy, this literature has demonstrated forgiveness to be negatively correlated with poor health habits. Most importantly and relevant to the findings presented here, increases in forgiveness have been correlated with less negative affect, such as anxiety and depression.^{32–34} The preparation subscale, which measures regret, did show improvements for those in the intervention arm.

In a second departure from many life review interventions, the intervention session provided participants with an opportunity to discuss their heritage and legacy and therefore ending with a future orientation. Involvement in discussions of lessons learned and wisdom to be shared with the next generation (Table 1) coincides with findings from previous studies documenting the importance of contributing to others as a central feature of quality at the end of life. Providing an opportunity to look forward and set goals for the future supports the human development model and assumes that personal growth may occur through out all stages of life. Indeed, participants in this study were within weeks and sometimes days of death.

In recent years, Chochinov et al.³⁸ have developed and tested a meaning-making intervention “dignity therapy” for those with terminal illness (particularly patients with advanced cancer). Participants complete eight sessions and produce a “generativity document” that is transcribed and made into hard copy. In their qualitative work to develop the intervention, the authors identify core components of dignity preserving perspectives and dignity preserving practices. The former includes: continuity of self, role preservation, generativity/legacy, maintenance of pride, hopefulness, autonomy/control, acceptance, and resistance. Related practices attend to living in the moment, maintaining normalcy, and seeking spiritual support. These topics are addressed explicitly in six clinician-guided sessions.

Interestingly, in the process of exploring life review, forgiveness and heritage and legacy, participants in our study came to address similar topics but through a briefer, more self-guided approach. This lends credence to viewing life review as a necessary developmental task that emerges at end of life, or may be forced to emerge with the challenges of life-limiting illness. Our intervention differs by being briefer and not producing a document. Findings suggest that the power of bearing witness, may prove equally powerful. In the handouts, participants were encouraged to develop legacy items, be they photo albums, letters, or other meaningful and tangible forms of legacy.

There were several limitations associated with the study. As noted, approximately 50% of participants were not able to complete the study due to functional decline or death. Dropout was particularly notable among hospice referrals, where the local lengths of stay mirror the short national median lengths of stay at approximately 15 days.⁵⁰ High attrition also is likely related to clinician prognostication, which when identifying patients with less than 6 months to live, often yields samples of patients with weeks to live.⁵¹ Future intervention may extend the inclusion criteria to patients

with advanced life limiting illness, as indicated by clinical criteria.

National consensus panels and a variety of clinicians and researchers have called for interventions to help seriously ill patients address issues of spirituality, meaning, and life review. The data from this pilot study suggest that Outlook is a brief, transportable, manualized intervention acceptable to patients from a variety of socioeconomic backgrounds and may be a useful means of addressing emotional and existential issues for patients at the end of life.

Acknowledgment

We wish to thank Belleruth Naparstek and Bruce Gigax for their work in developing the relaxation meditation language and music.

Author Disclosure Statement

No competing financial interests exist.

This material is the result of work supported with resources and the use of facilities of the Durham VA Medical Center. The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

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