Meaning-Centered Group Psychotherapy: An effective intervention for improving psychological well-being in patients with advanced cancer

Breitbart, et al

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A RANDOMIZED CONTROLLED TRIAL OF GROUP PSYCHOTHERAPY INTERVENTIONS FOR CANCER PATIENTS

MSKCC NON-THERAPEUTIC/DIAGNOSTIC PROTOCOL

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Please Note: A Consenting Professional must have completed the mandatory Human Subjects Education and Certification Program.

Collaborating Institution (s):
(If applicable)

Fordham University- Department of Psychology	Barry Rosenfeld, Ph.D.

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Table of Contents

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Table of Contents

1.0 PROTOCOL SUMMARY AND/OR SCHEMA

Spirituality and its role in end-of-life care has emerged as a central issue in palliative care. There have been several recent studies of terminally ill cancer and AIDS patients by our research group demonstrating the central role of spiritual well being, and sense of "meaning" in particular, in buffering against depression, hopelessness, and desire for hastened death. We have previously developed, manualized, and pilot-tested (with support of an R21 pilot grant from the NIH National Center for Complementary and Alternative Medicine, MSK Protocol # 02-050, closed on 3/14/06) an ***8-week*** Meaning-Centered Group Psychotherapy (MCGP). This intervention, based on the principles of Viktor Frankl's Logotherapy, is designed to help patients with advanced cancer sustain or enhance a sense of meaning, peace and purpose as they approach the end-of-life. Preliminary findings suggest that the Meaning-Centered Group intervention significantly reduces psychological distress and desire for hastened death, and significantly increases spiritual well-being and a sense of meaning and purpose in life in a sample of patients with advanced cancer with a life expectancy of less than 6 months.

This project's overall aim is to conduct a randomized controlled trial of the efficacy of this new and unique group psychotherapy intervention for advanced cancer patients. Specifically, we will examine the efficacy of Meaning-Centered Group Psychotherapy, compared to a standardized Supportive Group Psychotherapy, in enhancing spiritual well being and quality of life, and reducing psychological distress (anxiety and depression) and end-of-life despair (conceptualized as hopelessness, desire for hastened death, and suicidal ideation). In addition, we will examine clinical and demographic variables that may mediate or moderate treatment response to Meaning-Centered group psychotherapy in this population of 256 advanced cancer patients with stage IV solid tumor cancers; or Stage III solid tumor cancers (excluding breast and prostate cancer) who are receiving ambulatory care at Memorial Sloan-Kettering Cancer Center,will be randomized to receive either Meaning-Centered Group Psychotherapy or a standardized Supportive Group Psychotherapy. Subjects will be assessed with a battery of self-report measures at 3 points: baseline/pre-intervention, post-intervention (following the 8 week intervention), and at about 2-months post-intervention (follow-up). This study will provide essential efficacy data on a novel and innovative psychotherapy intervention for patients with advanced cancer, incorporating spiritual (meaning-centered) elements, which holds great promise in the treatment of suffering at the end-of-life.

Study Timeline

Memorial Sloan-Kettering Cancer Center IRB Protocol

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Study Timeline

Screening Assessment	Pre-Intervention (WEEK 0)	Post-Intervention (WEEK 8)	Follow-Up (WEEK 16)
• MMSE	• BDI	• BDI	• BDI
• KPRS	• BHS	• BHS	• BHS
• Clinical Interview	• IE-12	• IE-12	• IE-12
• Socio-demographic Data	• FACIT	• FACIT	• FACIT
• Pre-randomization Questionnaire	• HADS	• HADS	• HADS
• Health Status Interview	• SAHD	• SAHD	• SAHD
	• LOT-R	• LOT-R	• LOT-R
	• McGill QOL	• McGill QOL	• McGill QOL
	• MSAS	• MSAS	• MSAS
	• HAI	• HAI	• HAI
	• PTGS	• PTGS	• PTSG
	• BFS	• BFS	• BFS
	•FSSQ	•Group Cohesion Scale	•Clinical Interview/ Health Status Update
		• Post-intervention Questionnaire	•KPRS
		•Clinical/ Health Status Interview Update	
		•KPRS	

2.0 OBJECTIVES AND SCIENTIFIC AIMS

1. To conduct a randomized controlled trial comparing the efficacy of Meaning-Centered Group Psychotherapy (MCGP) versus a standardized Supportive Group Psychotherapy (SGP) in reducing psychological distress (depression and anxiety), end-of-life despair (hopelessness, desire for hastened death, and suicidal ideation), and improving spiritual well-being and overall quality of life in a sample patients with advanced cancer.

2. To assess the relative impact of Meaning-Centered Group Psychotherapy on different aspects of spiritual well-being (e.g., a sense of meaning and purpose versus spirituality linked to religious faith).

3. To examine clinical and demographic variables that may correspond to differential responses to Meaning-Centered Group Psychotherapy (e.g., potential mediating and moderating influences such as illness severity, religion and religiosity, level of education, race/ethnicity, level of pre-intervention social support, presence of pain and physical symptom burden).

3.0 BACKGROUND AND RATIONALE

Memorial Sloan-Kettering Cancer Center IRB Protocol

IRB#: 07-094(10)

Screening Assessment

• MMSE

• KPRS

• Clinical Interview

  • Socio- demographic Data

  • Pre-randomization Questionnaire

  • Health Status Interview

Amended: 12/27/11

- 2 - Pre-Intervention (WEEK 0)

• BDI

• BHS

• IE-12

• FACIT

• HADS

• SAHD

• LOT-R

• McGill QOL

• MSAS

• HAI

• PTGS

• BFS

•FSSQ

Post-Intervention (WEEK 8)

Follow-Up (WEEK 16)

• BDI

• BDI

• BHS

• BHS

• IE-12

• IE-12

• FACIT

• FACIT

• HADS

• HADS

• SAHD

• SAHD

• LOT-R

• LOT-R

• McGill QOL

• McGill QOL

• MSAS

• MSAS

• HAI

• HAI

• PTGS

• PTSG

• BFS

• BFS

•Group Cohesion Scale

•Clinical Interview/

• Post-intervention Questionnaire

Health Status Update

•Clinical/ Health Status

•KPRS

Interview Update

•KPRS

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1. To conduct a randomized controlled trial comparing the efficacy of Meaning-

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differential responses to Meaning-Centered Group Psychotherapy (e.g., potential mediating and moderating influences such as illness severity, religion and religiosity, level of education, race/ethnicity, level of pre-intervention social support, presence of pain and physical symptom burden).

3.0 BACKGROUND AND RATIONALE

Interventions for Spiritual Suffering at the End-of -Life:

With the exception of some theoretical and preliminary clinical work in the areas of self-transcendence and logotherapy, very little work on psychotherapy interventions for spiritual suffering or distress at the end of life has been conducted. Palliative care practitioners have begun to deal with the issue of spirituality in the dying and interventions for spiritual suffering (Puchalski and Romer 1999, Rousseau 2000). Rousseau (2000) outlined an approach for the treatment of spiritual suffering composed of: 1) controlling physical symptoms; 2) providing a supportive presence; 3) encouraging life review to assist in recognizing purpose value and meaning; 4) exploring guilt, remorse, forgiveness, reconciliation; 5) facilitating religious expression; 6) reframing goals; 7) encourage meditative practices, focus on healing rather than cure. Rousseau's approach includes facilitating religious expression that may be useful to many patients, but is not applicable to all patients and not necessary an intervention that clinicians feel comfortable providing. Psychotherapeutic techniques particularly adaptive to psychotherapy with the dying, such a life narrative and life review (as described by Viederman, 1983), are utilized and found to be clinically beneficial. Recently, Chochinov and colleagues (2002) have described an individual format psychotherapy for terminally ill patients they call "Dignity Conserving Psychotherapy", whose central component is the creation of a "generativity document". This intervention is closely related in concept to other narrative psychotherapies utilized in various patient populations. What the work of Rousseau, Viederman, Chochinov and others suggests is that new, novel psychotherapeutic interventions aimed at improving spiritual well being, sense of meaning and diminishing hopelessness, demoralization, and despair are critically necessary to develop at this time in the development of end-of-life care. Such interventions can be individual or group psychotherapy interventions. Group psychotherapy interventions may in fact be more effective and powerful than individual psychotherapies for cancer patients. Below is a description of group psychotherapy interventions for cancer patients, including spiritually based interventions, and a description of a novel "Meaning-Centered Group Psychotherapy" intervention (Breitbart 2002; Breitbart et al 2004) which we are proposing to study in this study.

Traditional Group Psychotherapy Interventions for Cancer Patients:

There is clear evidence that group psychotherapy interventions (particularly group interventions that combine *supportive* and *psychoeducational* elements) for cancer patients are time-efficient, cost-effective, and highly effective in improving quality of life, reducing psychological distress, anxiety and depression, improving coping skills, and reducing symptoms such as pain and nausea and vomiting (Fawzy & Fawzy 1998; Spiegel et al 2000). While group psychotherapy interventions for cancer patients have been applied mostly to newly diagnosed or relatively early-stage cancer patients, several studies have demonstrated significant quality of life, mood, coping and symptom control benefits for patients with advanced, metastatic cancer, and even dying patients (Yalom and Greaves, 1977; Spiegel, Bloom & Yalom 1981; Spiegel et al 1989; Spiegel et al

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Logotherapeutic Group Psychotherapy in Cancer:

A relatively small, but growing, literature is developing around group psychotherapy interventions for cancer patients that is based on non-traditional, alternative, spiritually based interventions that are grounded in theoretical perspectives that range from yoga, meditation and Buddhist philosophy (e.g. Lerner et al 1987) to those that are based on concepts and theories of self-transcendence (Hiatt 1986; Coward 1998; Chin-A-Loy and Fernsler 1998), and those based on Viktor Frankl's Logotherapy (Lazer 1984; Quirk 1979; Zuehlke and Watkins 1975). The majority of this psychotherapy intervention work has utilized the related concepts of "Self-Transcendence" and "Meaning" as developed by such theoreticians as Frankl (Frankl 1955/1986, 1959/1992, 1969/1988, 1975/1970) and Pamela Reed (Reed 1983, 1989, 1991a, 1991b). Self-transcendence has been shown, primarily in the nursing literature, to be associated with indicators of well-being and mental health in older adults, breast and prostate cancer patients, and AIDS patients (Reed 1991b, Coward 1991, 1993, 1995, 1996, 1998; Chin-A-Loy and Fernsler 1998).

The application of Logotherapy to medically ill populations is extremely limited, with no group psychotherapy interventions conducted with cancer patients utilizing logotherapy or a meaning-centered approach. Lazer (1984) conducted logotherapeutic support groups for patients with cardiac disease. No systematic assessment of the impact of these groups was conducted. Quirk (1979) outlined an 8-week "Logogroup" consisting of didactics, experiential exercises, and homework. This intervention was not applied to a medically ill population and not evaluated systematically. Zuehlke and Watkins (1975) adapted individual logotherapy to patients with terminal cancer, meeting for 6 individual 45-minute sessions over 2 weeks. The logotherapy provided: 1) enhancing rapport with therapist; 2) eliciting sources (e.g. activities, relationships) that provided meaning in the patient's life; 3) focusing on the impact of illness; 4) dealing with the fear of dying using the technique of "dereflection"; and finally 5) enhancing a sense of closure with significant others in one's life as death approached. Patients who participated (N=6) experienced a stronger feeling of purposefulness and meaningfulness than controls (N=6), as measured by the Purpose in Life Test.

Meaning-Centered Group Psychotherapy for Advanced Cancer Patients:

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Meaning-Centered Group Psychotherapy for Advanced Cancer Patients:

The importance of spiritual well-being and the role of "meaning" in particular in moderating depression, hopelessness and desire for death in terminally ill cancer and AIDS patients demonstrated by our research group, led us to look beyond the role of antidepressant treatment for depression in this population, and to focus new efforts on developing non-pharmacologic (psychotherapy) interventions that can address such issues as hopelessness, loss of meaning and spiritual well being in patients with advanced cancer at the end of life. This effort led to an exploration and analysis of the work of Viktor Frankl and his concepts of logotherapy or meaning-based psychotherapy (Frankl 1955, 1959, 1969, 1975). While Frankl's logotherapy was not designed for the treatment of cancer patients or those with life threatening illness, his concepts of meaning and spirituality clearly, in our view, had applications in psychotherapeutic work with advanced cancer patients, many of whom seek guidance and help in dealing with issues of sustaining meaning, hope and understanding cancer and impending death in the context of their lives.

Frankl's main contributions to human psychology have been to raise awareness of the spiritual component of human experience, and the central importance of meaning (or the will to meaning) as a driving force or instinct in human psychology. Frankl's basic concepts include: 1) Meaning of life- life has meaning and never ceases to have meaning even up to the last moment of life, meaning may change in this context but it never ceases to exist; 2) Will to meaning - the desire to find meaning in human existence is a primary instinct and basic motivation for human behavior; 3) Freedom of will - we have the freedom to find meaning in existence and to choose the attitude towards suffering; 4) The 3 main sources of meaning in life are derived from creativity (work, deeds, dedication to causes), experience (art, nature, humor, love, relationships, roles) and attitude- the attitude one takes towards suffering and existential problems; 5) Meaning exists in a historical context- thus legacy (past, present and future) is a critical element in sustaining or enhancing meaning.

The novel intervention we developed and call "Meaning-Centered Group Psychotherapy" is based on the concepts described above and the principles of Frankl's Logotherapy, and is designed to help patients with advanced cancer sustain or enhance a sense of meaning, peace and purpose in their lives even as they approach the end of life (Greenstein and Breitbart, 2000; Breitbart 2002; Breitbart et al, 2004). We have conducted an R21 funded pilot study utilizing this meaning-centered approach in a cohort of advanced cancer patients (MSKCC IRB # 02-050, closed on 3/14/06, see Preliminary Findings below) in order to establish the feasibility, practicality, applicability, acceptance, and efficacy of such an intervention. Through this process, we have developed, implemented, and refined a treatment manual (see Appendix A) for an eight-week (1 ½ hour weekly sessions) group intervention that utilizes a mixture of didactics, discussion and experiential exercises that focus around particular themes related to meaning and advanced cancer. The session themes include: Session 1 – Concepts and Sources of Meaning; Session 2 – Cancer and Meaning; Session 3 – Historical Sources of Meaning: Legacy (past); Session 4 – Historical Sources of Meaning: Legacy (present and future); Session 5 – Attitudinal

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Amended: 12/27/11

Sources of Meaning: Encountering Life's Limitations: Session 6 – Creative Sources of Meaning: Creativity and Responsibility ; Session 7 – Experiential Sources of Meaning: Nature, Art, and Humor; Session 8 – Termination: Goodbyes, and Hopes for the Future. Patients are assigned readings and homework that are specific to each session's theme and which are utilized in each session. While the focus of each session is on issues of meaning and purpose in life in the face of advanced cancer and a limited prognosis, elements of support and expression of emotion are inevitable in the context of each group session (but limited by the focus on experiential exercises, didactics and discussions related to themes focusing on meaning).

Pilot Study of Meaning-Centered Group Psychotherapy for Advanced Cancer Patients:
As a result of the compelling data on the benefits of enhanced spiritual well-being, in particular a sense of meaning, it became clear that a psychotherapeutic intervention targeted for patients with advanced cancer and aimed at enhancing spiritual well-being and a sense of meaning was needed by those who care for cancer patients at the end of life. We developed Meaning-Centered Group Psychotherapy based on the principle's of Viktor Frankl"s Logotherapy, and designed this intervention to help patients with advanced cancer sustain or enhance a sense of meaning even as they approach the end of life (Breitbart, et al. 2004). With funding from an R21 grant (R21 Grant # AT/CA 01031, MSKCC IRB Protocol # 02-050, closed on 3/14/06), we conducted a pilot, randomized, controlled study of Meaning-Centered Group Psychotherapy (MCGP) vs. Supportive Group Psychotherapy (SGP) for patients with advanced cancer.

Method:
Patients with advanced cancer (stage III or IV solid tumors) were recruited from the ambulatory care facilities of Memorial Sloan-Kettering Cancer Center between December of 2002 and December of 2004. Patients who participated were randomized to one of two 8-week group psychotherapy interventions (MCGP or SGP). Groups were established once a cohort of 8 patients had been recruited. Patients were administered a battery of self-report questionnaires at four time points: at the time of recruitment (baseline), immediately prior to the first group session (pre-treatment), following the final group session (post-treatment), and two months after completing the group (follow-up). The measures administered included the FACIT Spiritual Well-Being Scale (SWBS), the Schedule of Attitudes toward Hastened Death (SAHD), the Beck Hopelessness Scale (BHS), the Beck Depression Inventory (BDI), the Hospital Anxiety and Depression Scale (HADS), and the Life Orientation Test (LOT). The study was approved by the Institutional Review Board of MSKCC (protocol #02-050).

Results:
138 patients with advanced cancer were recruited for this pilot study (8 participants per group). While difficult to estimate because of the varied modes of recruitment, we estimate that the acceptance rate to the study was approximately 80%. Of these 138 prospective participants, 55 were unable to begin treatment, primarily because of deteriorating illness or scheduling constraints (e.g., conflicts with other treatment

Memorial Sloan-Kettering Cancer Center IRB Protocol

IRB#: 07-094(10)

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obligations). Thus, a total of 83 individuals were randomized and began one of the 2 interventions (52 were randomized to MCGP and 31 to SGP). Of the 83 individuals who began treatment, 51 completed the 8 week intervention and 5 were currently in a group at the time of this analysis); 27 of the 83 dropped out of treatment. Thus, our pre-treatment attrition rate was 40%, and an additional 19% dropped out during treatment. Of note, much of the attrition occurred prior to beginning the groups (i.e., patients who had consented to the study but never began the group), in part because our limited resources precluded optimal recruitment, resulting in delays between accrual and initial group participation. Thirty-six of the 51 patients who completed treatment also provided follow-up data two months after the last group. All participants had stage III or IV cancers (solid tumors), although 75% had stage IV cancer. The sample was 46% male (n=62) and 54% female (n=76), with an average age of 59 (range: 21 to 84). The majority were Caucasian (81%), with 10% Black, and 9% Hispanic. Cancers represented included advanced prostate, breast, lung, colon, pancreas, ovarian, and melanoma, with some patients having multiple cancers (e.g. prostate and colon cancer).

A preliminary analysis of the efficacy of this intervention (Table 5) revealed substantially stronger effects for spiritual well-being and several measures of end-of-life despair (desire for hastened death, anxiety, and hopelessness, when measured with a modified version of the BHS; Abbey et al., in press), while depression was somewhat less responsive. A comparison of the pre- and post-intervention data demonstrated significant improvement in spiritual well-being (SWBS scores) and desire for hastened death (SAHD scores) and improvement on the measure of hopelessness approached significance ($p < .10$).

Table 5
Change in Psychological Functioning following Meaning-Centered Group Psychotherapy

	Pre-Treatment Mean	Post-Treatment Mean	Effect size	p	Follow-up Mean	Effect size	p
SWBS Total	2.10	2.49	.64	.002	2.72	.83	.001
SWBS Meaning	2.28	2.78	.72	.001	3.12	.92	.001
SWBS Faith	1.71	1.88	.33	.09	1.91	.46	.04
SAHD	3.98	3.23	.38	.03	3.03	.73	.008
Hopelessness	7.62	5.88	.24	.21	6.11	.16	.46
Hopelessness-SF	2.38	1.91	.07	.72	1.81	.41	.06
Depression (HADS)	1.99	1.88	.08	.23	1.76	.27	.22
Anxiety (HADS)	2.27	2.17	.27	.17	1.94	.60	.04

Note: SWBS: Facit Spiritual Well-being Scale; Hopelessness-SF: Abbreviated 7-item version of the Beck hopelessness scale;
Effect size statistics refer to change from pre-treatment mean

Importantly, an analysis of the data from the 2-month follow-up assessment demonstrated that the benefits of this intervention continued to grow after treatment had concluded.

Table 6
Change in Psychological Functioning following Supportive Group Psychotherapy

	Pre-Treatment Mean	Post-Treatment Mean	Effect size	p	Follow-up Mean	Effect size	p
SWBS Total	2.14	2.13	-.05	.11	2.17	.18	.61
SWBS Meaning	2.29	2.41	.06	.48	2.42	.14	.68
SWBS Faith	1.86	1.57	-.28	.03	1.67	-.23	.51
SAHD	3.83	4.00	-.00	.99	3.70	.08	.82
Hopelessness	8.07	8.08	-.02	.94	9.11	-.17	.63
Hopelessness-SF	2.82	2.31	.29	.30	3.11	-.24	.48
Depression (HADS)	2.04	1.95	.07	.78	2.02	.08	.82
Anxiety (HADS)	2.35	2.31	.37	.20	2.20	.25	.47

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Table 5 Change in Psychological Functioning following Meaning-Centered Group Psychotherapy

Pre-Treatment Post-Treatment Follow-up Mean Mean Effect size p Mean Effect size p

SWBS Total 2.10 2.49 .64 .002 2.72 .83 .001 SWBS Meaning 2.28 2.78 .72 .001 3.12 .92 .001 SWBS Faith 1.71 1.88 .33 .09 1.91 .46 .04 SAHD 3.98 3.23 .38 .03 3.03 .73 .008 Hopelessness 7.62 5.88 .24 .21 6.11 .16 .46 Hopelessness-SF 2.38 1.91 .07 .72 1.81 .41 .06 Depression (HADS) 1.99 1.88 .08 .23 1.76 .27 .22 Anxiety (HADS) 2.27 2.17 .27 .17 1.94 .60 .04 _____ Note: SWBS: Facit Spiritual Well-being Scale; Hopelessness-SF: Abbreviated 7-item version of the Beck hopelessness scale; Effect size statistics refer to change from pre-treatment mean

Importantly, an analysis of the data from the 2-month follow-up assessment demonstrated that the benefits of this intervention continued to grow after treatment had concluded.

Table 6 Change in Psychological Functioning following Supportive Group Psychotherapy

Pre-Treatment Post-Treatment Follow-up Mean Mean Effect size p Mean Effect size p

SWBS Total 2.14 2.13 -.05 .11 2.17 .18 .61 SWBS Meaning 2.29 2.41 .06 .48 2.42 .14 .68 SWBS Faith 1.86 1.57 -.28 .03 1.67 -.23 .51 SAHD 3.83 4.00 -.00 .99 3.70 .08 .82 Amended: Hopelessness 12/27/11

Hopelessness-SF 8.07 2.82 8.08 -.02 .94 2.31 .29 .30 9.11 -.17 .63 3.11 -.24 .48 Depression (HADS) 2.04 Anxiety (HADS) 2.35 _____

1.95 2.31 - 7 -

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Note: SWBS: Facit Spiritual Well-being Scale; Hopelessness-SF: Abbreviated 7-item version of the Beck hopelessness scale; Effect size statistics refer to change from pre-treatment mean