Self-affirmation intervention for people newly diagnosed with advanced cancer: A preliminary efficacy trial

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Study Title: Self-affirmation intervention for people newly diagnosed with advanced cancer: A preliminary efficacy trial

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Hypothesis *and/or* Specific Aims *or* Objectives

The **primary aim** of this study is to explore the effects of self-affirmation via writing on patients newly diagnosed with advanced cancer, calculate effect sizes of the outcome variables, and estimate the appropriate sample size for the main study.

The **secondary aim** is to test the validity of the functional assessment of chronic illness therapy- spiritual well-being 12 item scale (FACIT-Sp-12), in its current (**Appendix A**) and revised forms (**Appendix B**).

It is hypothesized that: self-affirmation at the time following a diagnosis of an advanced cancer by affirming values or beliefs that are salient to self will help patients enhance self-esteem, reinforce spiritual well-being, decrease levels of anxiety or depression, and improve quality of life (QoL).

Study Design and Procedures

A single group time series study design will be employed **(Figure 1)**.

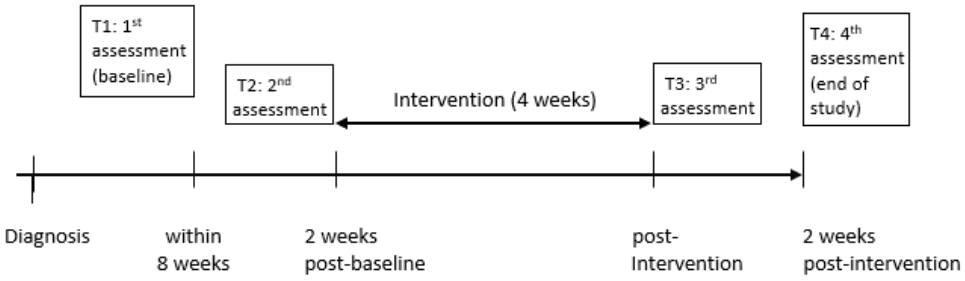

Figure 1: Timeline for the four data collection points

<u>The intervention</u> Participants will be asked to write as guided by the researcher starting from Time 2 (two weeks post-baseline) for 4 weeks.

Specific criteria on the writing task:

1) write with a focus on affirming one's fundamental values and beliefs,
2) write in connection with one's cancer diagnosis, and
3) write at least once for a minimum of 20 minutes per week for four weeks.

To ensure that participants understand the nature and essence of the intervention, each patient will receive a page of writing instructions and a brief educational/informational session with the principal investigator (PI), both of which occur at two weeks post-baseline (Time 2 or T2); the writing instructions clarify the key expectations for the participants with respect to the writing intervention (in line with the criteria above) followed by examples to address what self-affirmation writing is and is not for this intervention.

Both an online portal and notebooks for drafting and submitting the writings will be created for participants; patients may choose either approach to perform the writing task. At the end of the study period (or any other point), participants have the option to share their writings with the PI. However, given the high privacy nature of the content, sharing writings with the researchers is not required (which will be clarified with the participants) in order to encourage writing without reservation.

Study Population

The targeted participants are adult patients (age 18 or older) newly diagnosed with advanced cancer, and the total number of subjects to be enrolled will be a minimum of 50 This sample size is chosen based on an estimated effect size of 0.4-0.5 to test differences between paired observations in one sample, with α 0.05 and power 0.80 (Cohen, 1988).

The sample size estimate is tentative given the exploratory nature of this pilot study as the actual attrition rate as well as effect size may not be accurately predicted due to the high variability as found in the literature (Bai, 2021).

Recruitment Strategy

Patient recruitment for this pilot study will take place at two study sites: the Winthrop P. Rockefeller Cancer Institute at the University of Arkansas for Medical Sciences (UAMS) and the Arkansas Hospice.

The UAMS Winthrop P. Rockefeller Cancer Institute is Arkansas' only academic cancer treatment and research facility. The PI will work with a study coordinator or a research assistant who helps identify and, if possible, consent eligible patients into the study. Specifically, the PI will receive patient referrals directly from the study coordinator or the research assistant for enrollment, meet with the potential participants, verify their eligibility before inviting them to join the study. The PI may also work directly with collaborating clinicians and/or accessing the electronic medical records to facilitate the enrollment progress. A waiver of the HIPAA authorization requirement will be requested for study enrollment purposes that permits the PI accessing the electronic medical records to identify potential study participants and/or verify their eligibility.

The Arkansas Hospice is the state's largest, non-profit hospice organization dedicated to enhancing quality of life for those facing serious illness and loss. The collaborating clinicians at the Arkansas Hospice will help identify eligible research participants and then refer these potential patients to the PI. The PI will go to meet with the potential participants and verify their eligibility before obtaining informed consent and the subsequent data collections.

The PI will closely monitor the recruitment progress weekly and adjust/modify the recruitment method as necessary or seek/develop alternative recruitment strategies to ensure that the study recruitment proceeds timely.

Inclusion Criteria

- 1) within 8 weeks of being informed of diagnosis (primary or recurrent)
- 2) cancer stage III or IV of a primary solid tumor, or a high-grade hematological malignancy, and
- 3) age 18 years or older

Exclusion Criteria

- 1) medical condition precluding participation (e.g., too ill or fatigued, acute mental confusion as determined by the treating physician), or
- 2) enrolled in other psychosocial experiments

Measures

Self-esteem

The Rosenberg Self-Esteem Scale (RSES) is an extensively used scale measuring self-esteem with demonstrated validity and excellent reliability (Rosenberg, 1965; Rosenberg, 1979). Empirical studies have also demonstrated its sensitivity to change among the cancer population (Joseph et al., 2019; Mohd-Sidik et al., 2018). RSES is rated on a 4-point scale from strongly agree to strongly disagree. Scores range from 3 to 0, with higher score indicating higher level of self-esteem. For this study self-esteem will be assessed by summing scores of the 10-item RSES (**Appendix C**).

Spiritual Well-being

The 12-item Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being scale (FACIT-Sp-12) (version 4) (Peterman et al., 2002) is one of the most widely used spiritual well-being scales. The scale is made up of 12 items scored on a 5-point scale evaluating levels of spiritual well-being during the previous week as indicated by the sense of peace and harmony, meaningfulness in life as well as strength and comfort derived from faith (Fitchett et al., 1996) (**Appendix A**).

An overall score of spiritual well-being can be calculated by summating all the 12 items in the three factors of Peace, Meaning and Faith, ranging from 0 to 48, with higher scores indicating higher level of overall spiritual well-being. Prior studies supported high internal reliabilities of the scale (e.g., Bai & Dixon, 2014; Peterman et al., 2002), however with questionable construct validity on the Faith factor (Bai et al., 2016).

In the revised version of this scale, the term “spiritual” will be replaced with “fundamental values and beliefs”, thereby overcoming the possible misinterpretation associated with

the word “spiritual”. Pease refer to the enclosed measures for details of the revision (**Appendix B**).

Anxiety and Depression

The Hospital Anxiety and Depression Scale (HADS) is a self-assessment scale that has been developed and found to be a reliable and valid instrument for detecting states of depression and anxiety in the setting of a hospital medical outpatient clinic as well as measuring severity of the emotional disorder (Zigmond & Snaith, 1983). A two-factor dimensional structure of the HADS was generally supported in the literature (Bjelland et al., 2002). The recommended thresholds for screening depression are 15 for the HADS total, 7 for the HADS depression subscale (Vodermaier & Millman, 2011) (**Appendix D**).

Quality of Life

The Functional Assessment of Cancer Therapy-General (FACT-G) (version 4) (Cella et al., 1993) was selected as measure of QoL in this study. FACT-G contains 27 items that are scored on a 5-point Likert scale (0-4), evaluating QoL of the previous week with high scores denoting better results. An overall QoL score can be calculated by summating all the 27 items in the 4 sub-scales of physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), and functional well-being (7 items). Reliability, validity as well as equivalence by mode of administration (interview vs. self-administration) has been supported for this scale (Cella et al., 1993; Webster et al., 2003).

An evaluation of QoL using a total score is different from a global rating of QoL (Ferrans, 2007). For the purpose of this study, both the total and global QoL will be assessed. The score of the single item of GF-7 in the functional domain of the FACT-G will be used to evaluate the global assessment of QoL, which explicitly asks the patient to rate the extent of contentment to current QoL. In prior studies, GF-7 demonstrated a significant relationship with overall QoL pinpointing the four specific domains (Brady et al., 1999; Whitford et al., 2008) (**Appendix E**).

Checklist of Intervention Implementation

Due to the exploratory nature of the trial, patients’ feedback to the intervention as well as the variables to be controlled (as evidence of intervention fidelity) will be collected in the checklist of the implementation of the intervention. The checklist (**Appendix F**) contains questions about the extent to which they felt the writing had helped them affirm their important values and beliefs, as well as the start timing, duration, focus/topic as well as duration of the writing.

In addition to the demographic information (**Appendix G**), as well as other health information (including medical conditions and cancer treatments) to be collected from the medical records, patients will be asked to rate the perceived threat (Parle et a., 1996) at the baseline whether and to what extent (on a 4-point scale) they viewed the cancer

diagnosis as a threat. During each data collection meeting, participants will be asked to make global ratings of changes (GRC) (Jaeschke et al., 1989) in QoL and spiritual well-being on the five-point response categories (Cella et al., 2002) at the scale and factor levels.

Finally, it has been suggested that measuring the patients' assessment of the importance of different life quality domains over time is one way to gather possible changes in attitude and values, and aid interpretation of the outcome changes (Rustøen et al., 2000). The importance ratings for each subscale of the FACT-G and the FACIT-Sp-12 will be collected at each data-collection meeting.

Table 1 The schedule of administration of questionnaires

Questionnaires	Baseline (1st meeting)	2 weeks post-baseline (2nd meeting)	6 weeks post-baseline (3rd meeting)	8 weeks post-baseline (4th meeting)
Perceived threat	X			
RSES	X	X	X	X
FACIT-Sp-12*	X	X	X	X
HADS	X	X	X	X
FACT-G	X	X	X	X
Demographic Form	X			
Progress of the disease		X	X	X
Intervention implementation debriefing checklist**			X	X

FACIT-Sp-12, the 12-item Functional Assessment of Chronic illness Therapy-Spiritual Well-Being Scale; **FACT-G**, the Functional Assessment of Cancer Therapy-General; **HADS**, the Hospital Anxiety and Depression Scale; **RSES**, the Rosenberg Self-Esteem Scale.
*including the original scale and the revised items (Please refer to the enclosed measures for details)
**including the start time, duration, frequency and the focus/topic of the writing as well as the perceived helpfulness

Additionally, an exit survey (**Appendix H**) will be used to capture the number of eligible patients who decline or refuse participation, lost to follow-up at any point of study, as well as reasons of the lost to follow-up and/or withdrawal.

Note: data collections will occur at the above scheduled windows +/- 3 days.

Risks and Benefits

Although the aim of the writing assignment has been strictly focused on value/belief affirmation rather than emotion ventilation, it is possible that some subjects might still experience slight psychological distress during writing; every effort will be made to support subjects throughout their involvement in the study. In addition, subjects might find it burdensome to complete study outcome measures; the meetings with the researcher will be scheduled at the time and place convenient to the subjects and they will be given as much time as needed to complete measures comfortably. Subjects may also stop at any time and reschedule the data collection if they would like. It will be explained to subjects that they may withdraw from the study at any time without repercussions. Subjects identified with depression as evidenced by a total score of 15 or higher on the HADS, or a score of 7 or higher on the HADS depression subscale (Vodermaier & Millman, 2011) will be informed of their scores and encouraged to tell their physician how they are feeling. If they do not wish to inform their physician, they will be encouraged to use the psychosocial support resources available and/or accessible.

There are no direct benefits for patients participating in this study. However, knowledge gained from the study may provide important information for examining whether and how this intervention works. This information may be used by clinicians in their care of patients with advanced cancer and may help researchers to develop interventions to help other patients. Ultimately, we hope this study will contribute to our understanding whether and how patients may overcome the challenges imposed by a newly diagnosed advanced cancer by themselves.

Data Handling and Recordkeeping

The PI will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study.

We will do everything we can to protect participants' privacy. Research data (including writings, if turned in) will be collected in a private place and stored in password-protected database that is held on a UAMS secure server. All hard copies of questionnaires and forms will be filed in locked file cabinets at a locked office. By signing the consent form, participants authorize the researcher to use the de-identified data for current and future data analyses.

A study number (or code) rather than the subject's name will be used on study records and databases for each study participant enrolled. The key that links the study numbers to the subjects will be securely stored in a password-protected database that is held on a UAMS secure server. All the data collected from participants will be strictly maintained as private and confidential throughout the entire study period and after the completion of the data analyses. Participants' names and other facts that might point to the patients will not appear in any presentation or publications. When the results are published or discussed in conferences, no information will be included that reveals research subjects' identity.

At the conclusion of the study, the data will be retained and later destroyed in accordance with institutional policy. The anticipated future use of the data may include secondary analysis of the writings from the participants, qualitative as well as quantitative. The key linking identifiers to the study numbers (or codes) will be destroyed after all the data analyses are completed.

Data Analysis

***Specific Aim 1*.**

a. *Intervention fidelity and feedback from the participants*

Fidelity of treatment in outcome research requires assessment and confirmation of the implementation of the independent variable as well as careful definition and operationalization of the intervention (Moncher & Prinz, 1991). For the purpose of this study, evidence of treatment fidelity will be assessed in the following aspects: 1) whether writing occurred at least once and (if so,) lasted for a minimum of 20 minutes each week, 2) whether writing was connected with the cancer diagnosis, and finally 3) whether writing focused on affirming one's fundamental values and beliefs.

Due to the exploratory nature of the pilot study, both the variables to be explored (that is, allowed to vary and without definitions) and the intervention parameters to be controlled (as specified above) will be collected in a checklist of the implementation of the intervention (**Appendix F**). Specifically, the participants' feedback on the start time, duration, frequency, the topic of the writing, helpfulness of the study as well as the potential improvement in design), will be requested along with their response to questions concerning the evidence of treatment implementation (including whether writing occurred, whether the minimum amount of writing duration/frequency, and the prescribed focus of the writing as well as the relevance to cancer diagnosis were met).

b. *Explore the intervention effects, calculate effect sizes of the outcome variables, and estimate the appropriate sample size for the main study.*

Mean changes in patients' self-esteem, spiritual well-being (at the scale and factor levels), anxiety and depressive symptoms as well as QOL (global, total score and each subscale) will be evaluated using regression models for longitudinal data (i.e., repeated measures analysis of variance). The importance ratings for each subscale of the FACT-G and the FACIT-Sp-12 will be collected during each data collection meeting to aid interpretation of the intervention effect. Perceived threat at baseline and disease progression at each follow-up data collection meeting will be analyzed as moderators for exploratory analysis; psychosocial counseling or other supportive therapy/service/treatment received will be included as covariates. SAS® software will be used to perform all the proposed analyses. For hypothesis testing, an alpha (α) of 0.05 will be selected.

The standardized mean difference (Cohen's *d* statistic), or effect size will be computed by dividing the mean change by the standard deviation (SD) at the baseline (Kazis et al., 1989). In addition, raw score changes from baseline to follow-up will be assessed to interpret the clinical significance of the change by comparing with the established estimates of the minimal clinically important difference (MCID) (Jaeschke et al., 1989) for

the FACT-G. Raw scores at the baseline and follow-up will be compared with the norm reference or thresholds for clinical consideration, if available in the literature.

Although psychological adaptation seems to be fundamentally independent from diagnostic group (Cassileth et al., 1984), treatment modality may exert an effect on quality of life outcomes (Oates et al., 2014). The type of anticancer treatment patient received will be collected from the patient's chart; analysis of intervention effect and change over time will take treatment modality (as well as the diagnostic groups) into consideration (in subgroup or post-hoc exploratory analysis).

Specific Aim 2. **Test the validity of the 12-item functional assessment of chronic illness therapy- spiritual well-being scale (FACIT-Sp-12), in its current and revised forms.**

To verify the understanding of the updated Factor items in the revised FACIT-Sp-12 and compare with the original scale, patients will be asked about their interpretation of the items in the Faith factor for both the original and revised scales (Schuman, 1966).

Cronbach's coefficient alpha will be computed to examine internal consistency reliability for both the revised and the original FACIT-Sp-12. The homogeneity of the total scale and three factors of Meaning, Peace and Faith will be examined by the mean inter-item correlations, item-total correlations and item-rest correlations for both the original and revised FACIT-Sp-12. Construct validity will be explored by assessing the associations of the FACIT-Sp-12 (original and revised) with QoL (global and total FACT-G), self-esteem, and psychological distress (anxiety and depression).

The threshold for the clinically important difference for the FACIT-Sp-12 at the scale and factor levels has not yet been reported in the literature. In this study, the MCIDs for scores of the scales and subscales from both the original and the revised FACIT-Sp-12 will be estimated using the criterion of global ratings of changes (GRC) on the five-point response categories (Cella et al., 2002).

In addition, to examine whether the associations between the individual items and any sample characteristic may differ, which could suggest *item bias* or differential item functioning (Groenvold, Bjorner, Klee, & Kreiner, 1995), the validities of the FACIT-Sp-12 concerning the Faith factor will be further examined with the differential item functioning analysis in both the original and the revised FACIT-Sp-12.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the IRB as required.

Participants will receive $25 in compensation for their time and effort at the end of each data collection meeting (a total of $100 if the patient completes baseline and all the three follow-up data collections).

The informed consent of each subject, using IRB-approved consent materials, will be obtained before that subject begins any study procedures. All subjects for this study will be provided a consent form on paper describing this study in language understandable to the study population. Consent materials will provide sufficient information for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain what the subjects need to know about the study, including study requirements, study risks and benefits. The consent process will take place in a designated office for research at the study sites. The consent discussion will occur right before the planned study participation. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject and the person obtaining the consent. The participant will receive a copy of the signed consent form, and the informed consent process will be documented in the research record.

The consent process will be documented separately via a written note in the research or medical chart for each subject.

The study involves protected health information (PHI) as described in this protocol. Plans to protect identifiers are described in the Data Handling and Recordkeeping section. A partial HIPAA wavier for recruitment purposes is requested in order for PHI to be accessed/used for screening purposes.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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FACIT-Sp-12

Below is a list of statements that other people with your illness have said are important**. Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

		Not at all	A little bit	Some-what	Quite a bit	Very much
Sp1	I feel peaceful	0	1	2	3	4
Sp2	I have a reason for living	0	1	2	3	4
Sp3	My life has been productive	0	1	2	3	4
Sp4	I have trouble feeling peace of mind	0	1	2	3	4
Sp5	I feel a sense of purpose in my life	0	1	2	3	4
Sp6	I am able to reach down deep into myself for comfort	0	1	2	3	4
Sp7	I feel a sense of harmony within myself	0	1	2	3	4
Sp8	My life lacks meaning and purpose	0	1	2	3	4
Sp9	I find comfort in my faith or spiritual beliefs	0	1	2	3	4
Sp10	I find strength in my faith or spiritual beliefs	0	1	2	3	4
Sp11	My illness has strengthened my faith or spiritual beliefs	0	1	2	3	4
Sp12	I know that whatever happens with my illness, things will be okay	0	1	2	3	4

ID #
Visit Date:

FACIT-Sp-12 Rev.*

Below is a list of statements that other people with your illness have said are important**. Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

		Not at all	A little bit	Some-what	Quite a bit	Very much
Sp1	I feel peaceful	0	1	2	3	4
Sp2	I have a reason for living	0	1	2	3	4
Sp3	My life has been productive	0	1	2	3	4
Sp4	I have trouble feeling peace of mind	0	1	2	3	4
Sp5	I feel a sense of purpose in my life	0	1	2	3	4
Sp6	I am able to reach down deep into myself for comfort	0	1	2	3	4
Sp7	I feel a sense of harmony within myself	0	1	2	3	4
Sp8	My life lacks meaning and purpose	0	1	2	3	4
Sp9a	I find comfort in my fundamental values or beliefs	0	1	2	3	4
Sp10a	I find strength in my fundamental values or beliefs	0	1	2	3	4
Sp11a	My illness has strengthened my fundamental values or beliefs	0	1	2	3	4
Sp12	I know that whatever happens with my illness, things will be okay	0	1	2	3	4

*revised with permission

ID #
Visit Date:

RSES

Below is a list of statements dealing with your general feelings about yourself.

If you strongly agree, please circle **SA**. If you agree with the statement, please circle **A**.

If you disagree, please circle **D**. If you strongly disagree, please circle **SD**.

1	On the whole, I am satisfied with myself.	SA	A	D	SD
2	At times, I think I am no good at all.	SA	A	D	SD
3	I feel that I have a number of good qualities.	SA	A	D	SD
4	I am able to do things as well as most other people.	SA	A	D	SD
5	I feel I do not have much to be proud of.	SA	A	D	SD
6	I certainly feel useless at times.	SA	A	D	SD
7	I feel that I'm a person of worth, at least on an equal plane with others.	SA	A	D	SD
8	I wish I could have more respect for myself.	SA	A	D	SD
9	All in all, I am inclined to feel that I am a failure.	SA	A	D	SD
10	I take a positive attitude toward myself.	SA	A	D	SD

HADS

Below are statements describing feelings you may be having.

Think about what each statement says, then fill in the bubble that most closely indicates **how you have been feeling this past week**. Please fill in one bubble for each item.

1) I feel tense or 'wound up':

○	○	○	○
Most of the time	A lot of the time	From time to time, occasionally	Not at all

2) I still enjoy the things I used to enjoy:

○	○	○	○
Definitely as much	Not quite so much	Only a little	Hardly at all

3) I get a sort of frightened feeling as if something awful is about to happen:

○	○	○	○
Very definitely and quite badly	Yes, but not too badly	A little, but it doesn't worry me	Not at all

4) I can laugh and see the funny side of things:

○	○	○	○
As much as I always could	Not quite so much now	Definitely not so much now	Not at all

5) Worrying thoughts go through my mind:

○	○	○	○
A great deal of the time	A lot of the time	From time to time, but not too often	Only occasionally

6) I feel cheerful:

○	○	○	○
Not at all	Not often	Sometimes	Most of the time

7) I can sit at ease and feel relaxed:

○	○	○	○
Definitely	Usually	Not often	Not at all

8) I feel as if I am slowed down:

○	○	○	○
Nearly all the time	Very often	Sometimes	Not at all

9) I get a sort of frightened feeling like 'butterflies' in the stomach:

○	○	○	○
Not at all	Occasionally	Quite often	Very often

10) I have lost interest in my appearance:

○	○	○	○
Definitely	I don't take as much care as I should	I may not take quite as much care	I take just as much care as ever

11) I feel restless as if I have to be on the move:

○	○	○	○
Very much indeed	Quite a lot	Not very much	Not at all

12) I look forward with enjoyment to things:

○	○	○	○
As much as I ever did	Rather less than I used to	Definitely less than I used to	Hardly at all

13) I get sudden feelings of panic:

○	○	○	○
Very often indeed	Quite often	Not very often	Not at all

14) I can enjoy a good book or radio or TV program:

○	○	○	○
Often	Sometimes	Not often	Very seldom

FACT-G

Below is a list of statements that other people with your illness have said are important**. Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

FACT-G

Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

ID #
Visit Date:

Checklist for the intervention implementation

1. How frequently did you write?

_____times per week

2. How long on average did you write each time?

_____minutes each time

3. In a few words, please indicate what your writings focused on:

_____

4. Did you find the process putting thoughts to writing helpful?

☐ very helpful ☐ somewhat helpful ☐ not sure ☐ not very helpful

4a. If helpful, how did it help?

_____

4b. If not helpful, what makes you think so?

_____

5. Do you think the timing of the writing as arranged in this study appropriate?

_____

5a. Would it have helped more if you were able to write earlier?

_____

6. How much do you think writing is helpful for you to affirm or recall important values in your life?

☐ very helpful ☐ somewhat helpful ☐ not sure ☐ not very helpful

7. Do you have any recommendation for how to make this writing intervention stronger?

_____

Demographic Form

Below are some basic questions that are related to this study. We appreciate you answer them to the best of your knowledge. Please write down your responses or circle answers that fit.

1. What is your sex/gender? ☐ Male ☐ Female

2. What is your Age? _____

3. What is the date that you were informed of the diagnosis? _____

4. Are you Hispanic or Latino? ☐ No ☐ Yes

5. What is your race? _____ (White, African American, Asian, American Indian, Other)

6. What is your current marital/relationship status? (singe/never married, married, divorced, widowed)

7. What is your highest grade of school completed (up to 8th grade, high school, college, graduate school)

8. What is your religious affiliation? (None, Protestant, Catholic, Jewish, Muslim, Other)

   8a. Do you practice your religion? (no, occasionally, about weekly, daily)

   8b. Do you think being spiritual must have a religious affiliation to associate? ☐ No ☐ Yes

9. Do you prefer to talk about your cancer diagnosis with others, or *not* to talk? ____ (no/yes/not sure)

10. Have you received or are seeking psychosocial counseling or other supportive therapy/service/treatment?

    ☐ No ☐ Yes

11. Have you ever put thoughts in your diary during stressful time in life? ____ (no/yes)

12. Would you please indicate your preference for filling out questionnaires in this study?

    ☐ paper and pencil ☐ iPad tablet ☐ read aloud by the investigator ☐ other (please specify)

Exit Survey

We understand that you are unable to participate in this study at this time and we fully respect your decision. If possible, would you **please circle the reason(s) for declining participation** in the study? This will help the investigator further improve the study. Thank you in advance for your time.

1 Too busy to participate; lack of time
2 Too tired to participate
3 Not interested
4 Other reason*

*If you chose to decline participation for other reasons, please specify below the specific reason. Thank You.

_____

_____

_____

_____