Title: Feasibility of Delivering an Avatar Life-review Intervention to Support Patients with Active Cancer

MCC Protocol #: MCC-18-14462

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Study Site: Dalton Clinic

Clinical Trial Phase: Feasibility Study

Study Disease: Not Applicable

Main Eligibility Criteria:
- All participants must be 18 years of age or older
- Patient must have active cancer
- Patient must be ambulatory

Primary Objectives:
Feasibility and acceptability of VoicingHan, an Avatar-Life Review Intervention, will be evaluated
1. Patient acceptability and comfort of study procedure, equipment, and questionnaires
2. Ability to recruit patients from the supportive care clinic
3. Patient’s perceived benefits of the intervention

Secondary Objectives:
1. Evaluate the time required for planning and set-up of the Avatar therapy, VoicingHan
2. Determine the average time per session and number of sessions as assessed by post intervention semi-structured interviews
3. Follow-up rates once patients are enrolled.
4. Unintended consequences
Exploratory Aims:
Post-session versus changes from baseline on quality of life as measured by the EORTC QLQ-C15-PAL quality of life score, ESAS symptom burden, and Functional Assessment of Chronic Illness Therapy-Spiritual Well-being Subscale (FACIT-Sp)

Endpoints:
Study Design: one-group observational design to establish feasibility and acceptability
Study Agent/ Intervention Description: Avatar-Life Review Therapy—an arts and technology integrated platform that supports patients with active cancer
Number of Subjects: 12
Subject Participation Duration: Unknown; Semi-structured interviews will be used to determine duration of the intervention

1. Background

1.1 Introduction

Patients with cancer face challenges that are multidimensional, extend beyond physical discomfort, and include psychological, spiritual, and existential distress. Unaddressed domains of the patient’s experience have a negative impact on their perceived quality of life.

Palliative care (PC) teams often use a combination of pharmacological and non-pharmacological interventions to mitigate the high symptom burden and distress experienced by patients. Our proposed study will use a dynamic, artistic medium, which facilitates patients’ interactive, storytelling performance using avatars. The avatars will be customized by patients to be digital representations of themselves during various life periods. Through storytelling, our avatar platform incorporates methods of drama therapy and psychodrama such as role playing, role-reversal, doubling, mirroring and soliloquy, creating a hybrid therapeutic model between virtual reality and theatre.

The avatar platform will facilitate life review, an intervention originally developed for elderly patients, and also incorporated into conceptual psychosocial models for patients with cancer. Positive outcomes reported after life review have included decreased despair, less spiritual distress and improved quality of life. We expect our patients with advanced cancer to experience similar benefits in multiple domains related to physical, psychosocial and spiritual aspects of their lives. We have named our intervention “Voicing Han,” since we believe the Korean mind/emotion model “Han” best reflects our goal of joining apparently contradictory states into “oneness” where an extreme state of grief can be combined with great hope when facing an impossible situation. Because this avatar based model has not been used previously in oncology patients, our study will be evaluating the feasibility of the intervention, including willingness of patients to participate, protocol refinement of process, and optimal frequency and duration of the intervention.

1.2 Non-pharmacological Interventions: Incorporating Art and Storytelling
There are limited data on the efficacy of specific non-pharmacological psychosocial interventions in patients with advanced cancer.\textsuperscript{1, 8} Ten different interventions implemented in Palliative Care Units (PCU) or Hospice settings from 18 studies were identified in a scoping review of non-pharmacological therapies for comfort.\textsuperscript{1} The comfort related outcomes included well-being, pain, suffering, anxiety, depression, stress and fatigue. Music therapy was the most common intervention while only one study incorporated art as an intervention. In that study, an Art Therapist provided a 1 hour intervention to 12 patients in a PCU, with significant improvements in pain, fatigue, depression, anxiety, and well-being, compared to baseline.\textsuperscript{9} A systematic review of Art Therapy in oncology yielded small, heterogeneous studies and a conclusion by the authors that research in this area was still in its ‘infancy’.\textsuperscript{10} Art Therapy also has some limitations in that a professional is required with accreditation and licensing to practice.

Life reviews have been used in PC to help individuals integrate memories into a meaningful whole, providing a balanced view of the past, present and future. Life review is also an evaluative process, enabling participants to examine how memories contribute to the meaning of their life.\textsuperscript{11} Life review has demonstrated improvements in cancer survivors treated with curative intent, and in patients at the end of life.\textsuperscript{12, 13} In a randomized controlled trial (RCT) of patients with advanced cancer, meaning centered therapy improved spiritual wellbeing and symptom burden but did not decrease anxiety and depression compared to those receiving massage therapy.\textsuperscript{14} More recently, a multicenter RCT using a combination of life-review therapy and memory specificity training, improved ego-integrity but not despair in oncology patients receiving palliative care.\textsuperscript{15} Two earlier trials of life review therapy from China and Japan found some (e.g. spirituality), but not all aspects of quality of life were improved.\textsuperscript{16, 17}

There are no intervention studies in PC using an Avatar based platform for facilitating storytelling and life review.

1.3 Interactive Avatar intervention

Although no studies have explored the intersection of technology-based therapy using Avatars, and palliative care, technology-based interventions may appeal to patients for reasons of familiarity and comfort yet retaining the option to remain anonymous.\textsuperscript{18}

Within psychiatry, some studies using an avatar have reported benefit in patients with psychosis and persistent auditory hallucinations. A recently published single-blind randomized controlled trial of 150 patients used a weekly therapist-facilitated avatar intervention over the course of 6-weeks.\textsuperscript{19} Unlike our proposal, the avatar was a digital representation of the presumed accuser rather than the patient. After 12 weeks, improvement was significantly greater than the control group with no evidence of adverse events. In another study of patients with substance use disorder, patients selected avatars to represent themselves during group counseling. Through counseling from separate, remote locations, this proof-of-concept study in 59 patients showed increased adherence to treatment sessions and lower rates of positive urine drug screens.\textsuperscript{18}

Although the technology is not new, the incorporation of avatars into patient care is relatively recent, and to our knowledge no studies have included oncology or palliative care patients. The intervention could benefit patients for a number of reasons.\textsuperscript{20} In other patient populations, engaging in movement-based creative expression helps foster positive health outcomes by reducing stress and depression. Creative expression may serve as a vehicle for patients with a life limiting illness in finding purpose and creating a sense of meaning.\textsuperscript{20} By integrating art and technology into a storytelling, life review platform, and engaging physical, psychological and
spiritual domains we anticipate our patients will be better supported in contemplating their own mortality.

Patients will select avatars from different age groups during their sessions, allowing them to retrieve specific, positive memories of different lifetime periods and facilitating a more candid autobiographical memory. The Avatar intervention reproduces the user’s gestures and lip-syncs with the user’s voice in a virtual environment, which can serve as a springboard for creative storytelling, revealing hidden consciousness, emotion, and memory. This technology could be applied in both inpatient and outpatient palliative settings, potentially mitigating existential suffering, and allow patients to pantomime and explore activities they can no longer physically complete. Our conceptual model is displayed below in Figure 1.

2. Objectives

2.1 Primary Study Aim
Feasibility and acceptability of VoicingHan, the Avatar-life review Intervention will be evaluated.

1. Patient Acceptability and comfort of the study procedure, equipment, questionnaires
2. Ability to recruit patients from the supportive care clinic
3. Patient Perceived benefit of the intervention as assessed by semi-structured interview questions facilitated by the investigator or research staff

2.2 Secondary aim

1. Evaluate the time required for planning and set-up of the Avatar therapy, VoicingHan
2. Determine the average time per session and number of sessions as assessed by post intervention semi-structured interviews
3. Follow-up rates once patients are enrolled
4. Unintended consequences

2.3 Exploratory Aims

Post-session versus changes from baseline on quality of life as measured by the EORTC QLQ-C15-PAL quality of life score, ESAS symptom burden, and Functional Assessment of Chronic Illness Therapy-Spiritual Well-being Subscale (FACIT-Sp) 21

3. Study Design, Data collection and Outcomes

3.1 Study Description
The objective of the study is to determine the feasibility and acceptability of an integrated art and technology, storytelling, life review platform for patients with active cancer. During the Avatar recording sessions, patients will be prompted with questions conducted by a facilitator (either Palliative care physician, psychologist or Artist) to help engage in reflection and mindfulness. TheAvatar provides a safe distance for users to freely explore their storytelling, which may otherwise be difficult to express.

VoicingHan, the software program that will be used in this study, provides an illusion that the Avatar is speaking, allowing users to observe their stories in real time, potentially
encouraging deeper reflection and memory retrieval. The technology uses motion capture (MoCap) to translate human movement into a digital platform. MoCap offers several advantages: lightweight, sensitive to minute movement, and user-friendly.

3.2 Study Design
This study will use a one-group observational design to establish feasibility and acceptability of Avatar therapy intervention in patients with advanced cancer. The VoicingHan interactive technology device will capture patient’s gestures, movements, and voice to input it on an avatar in a virtual environment. VoicingHan includes four male and four female avatars at four developmental stages: child, teenager, adult, and elder. The user will be able to choose any stage in life and customize simple elements such as skin color, hair, and outfits.

The real-time facial recognition feature will allow patients to freely act out representations of themselves, significant others, or family members in a personal and engaging way. This study will be a feasibility study to ensure suitability and acceptability in our patient population. We will use patient surveys, semi-structured interviews, recruitment rates, and assess technical barriers to evaluate acceptability and feasibility.

3.3 Study Duration
The study duration is expected to be one year. This includes 2 months to complete contract and regulatory requirements, 4 months to develop the technology into a software design, 6 months to conduct interventions and follow-up appointments, and 1 month for final analysis.

3.4 Data collection and Outcome Measures
Upon IRB and contract completion, we will recruit patients to participate in the Avatar Therapy intervention. This feasibility study proposes to enroll 12-patients receiving outpatient palliative care. This sample size is practical for a feasibility study within single centers as discussed by van Belle$^{22}$ and Julious$^{23}$, and should be adequate to evaluate outcome measures and generate preliminary data for future investigation.

Eligible participants will undergo an unknown number of sessions depending on acceptability of the intervention to subjects and the capacity of the team to provide the intervention.

Feasibility will be examined by calculating overall rates of eligibility and enrollment. Also, feasibility and acceptability will be explored through semi-structured interviews and patient’s satisfaction with the study using Likert scale. Following the Avatar session, a member of the research team will conduct a face-to-face interview that will consist of open-ended questions to elicit detailed responses. Questions will seek to understand participants’ attitude about the intervention, perceived effectiveness or lack of it, barriers to engagement, and challenges faced throughout the session.

The battery of questionnaires will assess exploratory aims of the intervention as questionnaires will represent improvements to patient’s quality of life. The completion rate of baseline responses vs subsequent responses to the surveys will be compared. The assessments investigating the effect of Avatar therapy on physical and psychological symptom burden will include the following: ESAS, Health-Related Quality of Life (HRQOL) as measured by the EORTC QLQ-C15-PAL quality of life score, and Functional Assessment of Chronic Illness Therapy (FACIT) Spiritual Well-Being Scale (SWB) subscale. The ESAS assesses nine symptoms: pain, fatigue, nausea, depression, anxiety, drowsiness, dyspnea, appetite, and well-being.$^{24}$ The ESAS is both valid and reliable for assessing the intensity of symptoms of patients with cancer.$^{25}$ The EORTC PAL15, will be used to focus mainly on physical symptoms and
global QoL. The EORTC PAL 15 is used in patients with advance cancer and has been proven as a valid and reliable scale in a palliative care setting. The FACIT-Sp subscale will focus mainly on assessing the psychosocial factor of patient’s spiritual well-being.

The outcome measures will include recruitment rate; number of subjects eligible; resources (e.g. cost), time scale; acceptability of the intervention; any barriers to data collection e.g. number of forms and questions patients are able to answer per session; response rates, adherence; the number of intervention sessions per patient and their perspective on recommending the study to others. Process issues including the potential for disruption of clinic flow, size of room constraints that may overwhelm patient or inhibit the patient narrative. The equipment acceptability and ease of use to patients (they will be attached to sensors) and sufficiently broad selection of avatars available for patients, based on age, ethnicity, etc. Patient demographic data will be recorded at the time of enrollment.

4. Patient Selection

4.1 Inclusion Criteria
This study will enroll adults diagnosed with metastatic or locally recurrent cancer. Individuals will be recruited from Massey Cancer Center (MCC), a national cancer institute. MCC treats hundreds of patients a year providing an ample sample to enroll study subjects.

- Participants must be 18 years of age or older
- Patient participants must have metastatic or locally recurrent cancer
- Participants must be able to understand English
- Participants must be ambulatory
- Ability and willingness to sign a written informed consent document

4.2 Exclusion Criteria
- Participants who cannot understand written or spoken English
- Any prisoner and/or other vulnerable persons as defined by NIH (45 CFR 46, Subpart B, C and D).

5. Study Entry and Withdrawal Procedures

5.1 Study Entry Procedures
Patients will be recruited from the Palliative Care Outpatient Clinic. Patients who present to VCU Massey Cancer Center: Dalton Oncology Clinic and meet eligibility criteria will be asked to participate in this feasibility study. Enrollment and initial screenings will be conducted by the PI and sub-investigator, both of whom have intimate knowledge of the palliative care patients at Dalton Clinic. No other clinicians will be involved in the recruitment and support of this study. If the PI or sub investigator identifies a patient might be eligible for study participation, they will briefly mention Avatar Therapy and emphasize that participation is entirely voluntary and would not impact their treatment if they do not wish to receive Avatar Therapy. No advertising or outside recruitment will be employed.

If patients express interest, they will meet with the investigator or research staff to review eligibility and provide an in-depth explanation of the study purpose, design, and required study procedures. The research staff will answer any questions participants have before obtaining written informed consent. If the subject agrees to participate, he/she will be asked to sign the
informed consent form. Once informed consent is obtained, a study ID will be assigned, and baseline data collection will commence.

5.2 Study Withdrawal Procedures
A patient may decide to withdraw from the study at any time. Participating is voluntary. However, a patient may be removed from the intervention for one of the following criteria: (1) unwillingness or inability of the patient to comply with the protocol requirements, (2) disease progression that prevents further administration of intervention, (3) general or specific changes in the patient’s conditions that renders the patient unacceptable for further treatment in the judgment of the investigator.

6. Intervention Plan

6.1 Intervention and Duration
After obtaining informed consent, VoicingHan will screen-capture patient’s storytelling performances as video files. Immediately before the first intervention, patients will complete an array of self-reported questionnaires to assess physical, spiritual, and psychological well-being and elicit relevant demographic and medical information. The assessments include the ESAS, FACIT-Sp subscale, and EORTC PAL 15. Subsequent administration of these questionnaires spaced 2-4 weeks apart will occur before each avatar session (pre-intervention). This will determine if intensity of the patient’s symptoms have changed over the course of the intervention. Following completion of the Avatar session, a member of the research team will conduct a semi-structured, open-ended interview to assess patients’ perception of intervention components and identify possible factors influencing intervention feasibility and any technical barriers.

Each session is expected to last 20-60 minutes depending on the engagement level of each participant. During the intervention, a trained facilitator will ask open-ended questions to help engage patients in reflection and storytelling. Patients will follow-up with their scheduled appointment in 2-4 weeks for an unknown number of intervention sessions. Based on previous interventions of non-pharmacological therapy to improve spiritual and psychological well-being in patients with cancer, we anticipate sessions will be conducted every 2-4 weeks over a 2-month period. A final administration of the questionnaires will be given approximately one month (± one week) after a patient’s last Avatar-Therapy session to evaluate if any sustained impact of the intervention occurred. A time frame of one month was chosen to prevent hampering of recall and to accommodate conflicts patients may encounter when scheduling follow up appointments (See Table 2).

7. Statistical Analysis
The investigators and biostatistician will perform all data analysis. This study is a feasibility study assessing the ability to deliver the intervention and obtain outcomes. As such, no statistical inference procedures will be used. Rather, means and standard deviations and frequencies and percentages will be calculated to inform future studies.

Exploratory aims of the study will be scored according to the questionnaires scoring manual. The EORTC QLQ C15 is composed of multi-item scales and single-item measures including functional scale, symptom scales, and global health status/QoL scale. Each of the multi-item scales includes different sets of items—no item occurs in more than one scale. EORTC QLQ
C15, FACIT-Sp, and the ESAS questionnaires will be analyzed via descriptive statistics at baseline, and subsequent follow up visits.

8. Dosing Delays/ Dose Modifications (Not Applicable)

9. Adverse Events

9.1 Potential Risks
It is expected that participation in this study will involve minimal risk to the participant. Every step will be taken to prevent risk of harm during an individual’s participation in this study. One potential risk of this study is the burden of questionnaires. It is possible that participation in this study could increase subjects’ feeling of burden or distress during a vulnerable period in their life. If at any point an individual reports distress or feeling overwhelmed, the research team will assess the patient and if necessary, provide a psychology to assist or schedule a follow-up at another time. All study procedures will be HIPAA compliant as outlined by VCU policy procedures.

9.2 Potential Benefits
This innovative intervention, which integrates art and technology, may potentially provide a platform to support patients and their families. There is no guarantee that patients will receive any benefits from being in this study. However possible benefits include lower levels of anxiety and depression and improvement of well-being. We hope the information learned from this study will provide more information about feasibility of intervention strategies to improve the quality of life for patients facing life-limiting illnesses.

9.3 Protection Against Potential Risks
To minimize respondent burden, we will inform all participants that participation in this study is voluntary and they may discontinue participation at any time. We will also inform potential participants that they have the option to refuse to answer any questions. The questionnaire was designed to be succinct and require minimal time for completion to further reduce burden. If the patient experiences anxiety or distress at any point during participation, they will be allowed to leave. Clinicians will be made aware and the appropriate referrals to support services within the institution may be made if deemed necessary.

10. Data and Safety Monitoring Plan (DSMP)

The study principal investigator, Egidio Del Fabbro, M.D., who has extensive clinical and research experience, will oversee all aspects of this study. The site principal investigator and/or sub investigators will perform periodic quality checks to ensure the accuracy of data collection and proper data management. The study team minimally consists of the principal investigator, sub-investigators, the clinical research associate, and the study biostatistician. The study team will meet at least monthly, and will meet at least quarterly with the study biostatistician, to review study status.

Regular meetings will allow for ongoing progress reports, including the number of participants currently involved in the study groups, attrition rates, and scheduled data collection from participants, as well as notification and review of any AEs. Safety monitoring for AEs will be conducted in real time by the PI and/or research staff. The following information about adverse events will be collected: 1) the onset and resolution of the AE, 2) an assessment of the severity
or intensity, 3) an assessment of the relationship of the event to the study, and 4) action taken (e.g., none or referral to physician). The PI will determine the severity of the event, will assign attribution to the event, and will monitor the event until its resolution. Any adverse events will be reported to the IRB in accordance with the IRB guidelines. To monitor possible adverse events, participants will be instructed to report any adverse effects of study participation as soon as possible to research staff; they will have contact information needed to report these problems to study personnel.
11. References


12. Tables and Figures
Figure 1: Schema of Intervention

Voicing Han Avatar Therapy → Distressed Patients with Advanced Cancer →

- Story-telling
- Self-expression coupled with physical motion
- Autobiographical Memory retrieval and reflection
- Exploration of Positive memories, and present and future hopes

Physical, Spiritual, Psychosocial domains
- Better Quality of life (EORTC QLQ C15)
- ↑ Spiritual Wellbeing (FACIT)
- ↓ Symptom burden (ESAS)
Table 1: Timeline of Avatar Session

<table>
<thead>
<tr>
<th>Timeline of Avatar Session</th>
<th>Screening Baseline</th>
<th>Pre-intervention (2-4 week follow up)</th>
<th>Post-Intervention (Immediately after session)</th>
<th>1-month follow-up (following last intervention session)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>x</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Inclusion/Exclusion criteria</td>
<td>x</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Demographic Data</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EORTC QLQ-C15-PAL</td>
<td>x</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>FACIT-Sp</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>ESAS</td>
<td>x</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Semi-structured interview</td>
<td>x</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
### Appendix A: Edmonton Symptom Assessment System

Please circle the number that best describes your average symptom over the past 24 hours:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Scores</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>0-10</td>
<td>Worst possible pain</td>
</tr>
<tr>
<td>Not tired</td>
<td>0-10</td>
<td>Worst possible tiredness</td>
</tr>
<tr>
<td>Not nauseated</td>
<td>0-10</td>
<td>Worst possible nausea</td>
</tr>
<tr>
<td>Not depressed</td>
<td>0-10</td>
<td>Worst possible depression</td>
</tr>
<tr>
<td>Not anxious</td>
<td>0-10</td>
<td>Worst possible anxiety</td>
</tr>
<tr>
<td>Not drowsy</td>
<td>0-10</td>
<td>Worst possible drowsiness</td>
</tr>
<tr>
<td>Best appetite</td>
<td>0-10</td>
<td>Worst possible appetite</td>
</tr>
<tr>
<td>Best feeling of wellbeing</td>
<td>0-10</td>
<td>Worst possible feeling of wellbeing</td>
</tr>
<tr>
<td>No shortness of breath</td>
<td>0-10</td>
<td>Worst possible shortness of breath</td>
</tr>
<tr>
<td>Best sleep/rest</td>
<td>0-10</td>
<td>Worst possible sleep/rest</td>
</tr>
</tbody>
</table>

Patient's Name ____________________________

Date _______________ Time _______________

Assessed by ______________________________

Complete by (check one):
- Patient
- Caregiver
- Caregiver assisted
Appendix B: EORTC QLQ C15- PAL

EORTC QLQ-C15-PAL (version 1)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: __________
Your birthdate (Day, Month, Year): __________
Today’s date (Day, Month, Year): __________

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at All</th>
<th>A Little</th>
<th>Quite a Bit</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have any trouble taking a short walk outside of the house?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Do you need to stay in bed or a chair during the day?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Do you need help with eating, dressing, washing yourself or using the toilet?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**During the past week:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at All</th>
<th>A Little</th>
<th>Quite a Bit</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Were you short of breath?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Have you had pain?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Have you had trouble sleeping?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Have you felt weak?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Have you lacked appetite?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. Have you felt nauseated?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**During the past week:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at All</th>
<th>A Little</th>
<th>Quite a Bit</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Have you been constipated?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11. Were you tired?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12. Did pain interfere with your daily activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13. Did you feel tense?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14. Did you feel depressed?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

For the following questions please circle the number between 1 and 7 that best applies to you

15. How would you rate your overall quality of life during the past week?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very poor</td>
<td>Excellent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix C: Functional Assessment of Chronic Illness Therapy- Spiritual Well-Being Scale (FACIT-Sp)

FACIT-Sp (Version 4)

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 past 7 days.

**PHYSICAL WELL-BEING**

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>G71 I have a lack of energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G72 I have nausea</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G73 Because of my physical condition, I have trouble meeting the needs of my family</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G74 I have pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G75 I am bothered by side effects of treatment</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G76 I feel ill</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G77 I am forced to spend time in bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**SOCIAL/FAMILY WELL-BEING**

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>G81 I feel close to my friends</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G82 I get emotional support from my family</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G83 I get support from my friends</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G84 My family has accepted my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G85 I am satisfied with family communication about my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G86 I feel close to my partner (or the person who is my main support)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

*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.*

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>G87 I am satisfied with my sex life</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
FACIT-Sp (Version 4)

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

**EMOTIONAL WELL-BEING**

<table>
<thead>
<tr>
<th>Q</th>
<th>Statement</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE1</td>
<td>I feel sad</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GE2</td>
<td>I am satisfied with how I am coping with my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GE3</td>
<td>I am losing hope in the fight against my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GE4</td>
<td>I feel nervous</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GE5</td>
<td>I worry about dying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GE6</td>
<td>I worry that my condition will get worse</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**FUNCTIONAL WELL-BEING**

<table>
<thead>
<tr>
<th>Q</th>
<th>Statement</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>GF1</td>
<td>I am able to work (include work at home)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GF2</td>
<td>My work (include work at home) is fulfilling</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GF3</td>
<td>I am able to enjoy life</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GF4</td>
<td>I have accepted my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GF5</td>
<td>I am sleeping well</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GF6</td>
<td>I am enjoying the things I usually do for fun</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>GF7</td>
<td>I am content with the quality of my life right now</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
**FACIT-Sp (Version 4)**

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

<table>
<thead>
<tr>
<th>ADDITIONAL CONCERNS</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel peaceful</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have a reason for living</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>My life has been productive</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have trouble feeling peace of mind</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel a sense of purpose in my life</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am able to reach down deep into myself for comfort</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel a sense of harmony within myself</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>My life lacks meaning and purpose</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I find comfort in my faith or spiritual beliefs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I find strength in my faith or spiritual beliefs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>My illness has strengthened my faith or spiritual beliefs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I know that whatever happens with my illness, things will be okay</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>