Cancer within a Pandemic: A Telemental Health Intervention Designed to Augment Psychological Resilience amidst Dual Health Threats

Wake Forest Baptist Comprehensive Cancer Center
WFBCCC #01520

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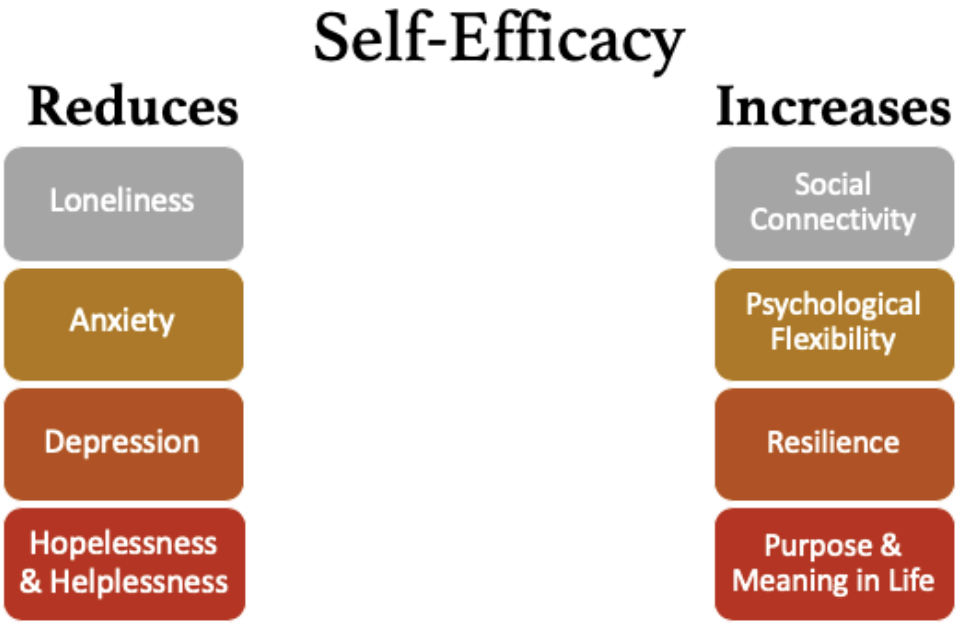
Self-Efficacy
Reduces
Loneliness
Anxiety
Depression
Hopelessness & Helplessness
Increases
Social Connectivity
Psychological Flexibility
Resilience
Purpose & Meaning in Life

1.0 Introduction and Background

Cancer poses challenges to physical, emotional, and social well-being. Concerns such as health anxiety, depression, reduced social connectivity, and acute stress, often in the form of trauma, thread across all diagnostic groups and can become threats to vitality. Researchers found that 25% of American cancer survivors reported poor physical health-related quality of life (HRQOL) and 10% of cancer survivors reported poor mental HRQOL; in comparison, the non-cancer adult population was 10% and 6%, respectively (Weaver et al., 2012). Impacts can be long lasting. Colorectal cancer survivors, for example, are at an increased risk for adjustment, anxiety, and substance-related disorders, delirium, dementia, body image concerns, and sexual dysfunction five years post-diagnosis (Lloyd et al., 2019). Cancer-related financial toxicity has been associated with higher levels of depressed mood, increased concerns about cancer recurrence, and an overall reduction in HRQOL (Kale & Carroll, 2016).

The SARS II COVID-19 pandemic has infected millions of individuals and killed hundreds of thousands. Navigating cancer survivorship in the midst of a pandemic further complicates coping processes and normal avenues of support. Cancer survivors commonly contend with reduced immune functioning, placing many at higher risk for viral contagion and/or comorbidities. Many are advised to seek an even greater degree of social isolation. Researchers have analyzed data from the outbreak in China and found that cancer survivors presenting with COVID-19 face a higher risk of being admitted to an intensive care unit, being placed on a ventilator, or death than non-cancer patients presenting with COVID-19 (Liang et al., 2020). The presence of routine medical appointments and existing financial distress may position them to make complex decisions regarding their safety and behaviors during such a stressful time.

While most global citizens have not endured a pandemic, data from recent epidemics can be informative as to psychological impacts. Researchers studying post-epidemic conditions have described the former SARS outbreak as a “mental health catastrophe,” with post-traumatic stress disorder (PTSD) as the most commonly noted psychiatric condition, followed by depressive disorders (Liang et al., 2020). Wu et al. (2005) found that people who perceived life threat during the SARS epidemic experienced anxiety, whereas depression was significantly associated with knowing someone who tested positive for SARS; the researchers also identified gender and education levels to be associated with avoidance symptoms. In 2009, researchers exploring long-term psychiatric comorbidities among SARS survivors urged preparedness among health care professionals to detect and respond to the psychological sequelae that co-exist with infectious disease outbreaks (Mak et al., 2008). Cancer survivors working to navigate disease survivorship and dynamic pandemic conditions then may be at even higher risk for emotional distress and trauma.

In our current world, internet usage has become ubiquitous. In 2019, virtually all young adults (YAs) used the internet (100% of 18-29 year olds and 97% of 30-49 year olds) and the majority of middle aged (88% of 50-64 year olds) and older adults (73% of those 65+) adopted this technology as well (Pew, 2019). Many people already use the internet as their primary source of health information, although only around 33% of adults have engaged in internet-based doctor-patient communication (Haluza et al., 2017). During the COVID-19 pandemic, more than half of U.S. adults (53%) have reported that the internet has been essential (Vogels et al., 2020). Furthermore, 64% of U.S. adults endorsed that the internet/phones will be useful but not a replacement for in-person contact, while 27% rated that it will be just as good as in-person contact (Anderson & Vogels, 2020).

This indicates that many Americans are open to utilizing virtual methods in lieu of in person contact at this time. Therefore, utilizing effective online methods for mental health treatment behooves researchers and clinicians alike, now more than ever. Online group counseling is considered to be accessible and cost-effective, and it also eliminates the risk of in-person contact between providers and other patients.

During the COVID-19 pandemic, it is reasonable to think that patients who have little to no experience with internet-based doctor-patient communication are rapidly being forced to adapt to these technologies. Cancer survivors in particular may find virtual telehealth interventions especially attractive due to the increased likelihood of exhibiting an immune-compromised status as well as the need to contend with frequent medical appointments that take them away from other responsibilities routinely. Particular sub-groups, including adolescent and young adults, rural or geographically distant, and economically distressed survivors, may find this modality especially inviting due to familiarity or enhanced access to care. YAs are considered to be digital natives because they have grown up in the digital age using the internet and computers, while digital immigrants are those who were not born into the digital world but rather adopted it at some point during their lifespan (Prensky, 2001). This distinction may be important in how users interact with, utilize, and adapt to technology use and online services. Recent research supports that digital immigrants (i.e., middle and older age adults) need additional coaching of how to use a technology than digital natives (Kasharwani, 2020). Additionally, digital natives were found to be more skeptical of the reliability of online health information and the reasonability of health information exchanged between providers and patients (Haluza et al., 2017). Thus, digital natives are a group that are able to adapt readily to the use of new technologies in novel contexts and they may better understand potential risks of utilizing an online platform.

This supports that focusing on a YA group for an initial study of the feasibility of an online group therapy for cancer patients is reasonable. Additionally, having a group with a higher baseline knowledge of technology as well as higher rates of skepticism of online platforms may lead to helpful feedback for future iterations of the group that will target additional patient populations. The SARS-II COVID-19 pandemic has served as a catalyst for requisite social distancing as well as increased familiarity with virtual meetings for those with the technological capacity.

Such a shared technological shift might make this type of group offering more feasible and attractive to prospective participants within the present circumstances. In response to the psychological vexations posed by simultaneous cancer and pandemic survivorship, we propose to create a virtual pandemic support group for cancer survivors that targets the constructs of health anxiety, depression, trauma, and social connectivity. The use of Acceptance and Commitment Therapy (ACT) (Arch & Mitchell, 2016) and Logotherapy (Mohabbat-Bahar et al., 2014) with cancer survivorship groups has demonstrated promising results, including the reduction of anxiety, depression, fatigue, fear of cancer recurrence, physical pain, and trauma-related symptoms, while also increasing meaning and purpose in life and a feeling of regaining some control over one's life. In line with the guiding principles of ACT and Logotherapy, this group will focus on coping strategies that enable positive psychosocial outcomes: Acceptance of cancer-related distress, reduction of cancer-related avoidance, identification of personal values, a commitment to making meaningful changes in one's behavior, and identifying meaning and purpose in life (Arch & Mitchell, 2016; Mohabbat-Bahar et al., 2014).

This will be a closed Young Adult (YA) group for the purposes of strategically covering essential skills needed for psychological flexibility, resilience, and meaning-making within these concurrent challenges to health. Pre-

and post-intervention assessments will assess change over time across a variety of variables, and researchers will analyze trends in self-selection and attrition to inform future interventions.

Psychosocial oncology providers within a comprehensive cancer center have the responsibility to assess and respond to the dynamic mental health needs of those navigating cancer care within their communities. A pandemic both augments the need for and complicates the provision of mental health care. Demand and need for psychological care intensifies while factors impeding in-person provision of care also multiply. To cater to the mental health needs of cancer survivors within evolving pandemic conditions, we plan to open groups that allow access to survivors coping with similar challenges. By offering carefully constructed virtual groups that target psychological symptoms and coping skills applicable to these dual health threats, we aim to empower and support the development of transferable coping skills within YA cancer survivors within our community. It is our hope that improved psychological flexibility will result in improved coping within their cancer care and pandemic responses.

2.0 Hypotheses:

Participants will demonstrate improvements in:

self-efficacy, psychological flexibility, resilience, social connectivity, sense of purpose and meaning

Participants will demonstrate reductions in:

loneliness, anxiety, depression, helpless/hopeless feelings

2.1 Primary Objective(s)

2.1.1 To improve self-efficacy for young adult cancer survivors navigating pandemic conditions

2.2 Secondary Objective(s)

2.2.1 To reduce depression and anxiety levels through meaning-making.

2.3 Exploratory Analyses:

2.3.1 To assess the feasibility of conducting a telehealth support group for cancer survivors within a pandemic.
2.3.2 To assess YA cancer survivors' interest in participation in a telehealth support group within a pandemic.
2.3.3 To enhance participants' strategies for engaging social connectivity and reduce feelings of loneliness amidst simultaneous forces promoting self-isolation (i.e., cancer diagnosis and pandemic).
2.3.4 To observe improvement in psychological resilience and flexibility skills in participants
2.3.5 To reduce feelings of helplessness.
2.3.6 To increase distress tolerance.

3 Patient Selection

Recruitment:

Investigators will attempt to recruit prospective participants through:

- Informing oncologists, APPs, and other clinicians who work with potentially eligible patients
- Advertising through hospital channels (clinic flyers, wating room TVs, intranet postings)
- Contacting YAs who have participated in former clinical or research offerings and shared their contact information (existing databases from Psychosocial Oncology and Public Health Sciences)
- Existing psychosocial oncology caseload

Experienced Investigators within the Psychosocial Oncology group will reach out to identified patients telephonically for introduction and pre-screens. The study will be explained and patients will be asked to answer the questions on the Pre-Screening form. Individuals who are interested in participating but do not meet eligibility criteria will be referred to an alternate, general support group and informed about future offerings for which they might be eligible.

3.1 Inclusion Criteria

3.1.1 Documented cancer diagnosis within the WFBMC medical record;

3.1.2 Outpatient Cancer Survivor (diagnosis, treatment, or post-treatment);

3.1.3 Aged 18-39;

3.1.4 Must speak English

3.1.5 Must have computer with audio and visual capabilities.

3.1.6 Must live within North Carolina

3.1.7 Must have experienced health-related anxiety and/or distress in last 3 months.

3.2 Exclusion Criteria

Exclusion criteria will be determined by pre-screening data and medical chart reviews

3.2.1 Active inpatient hospitalization;

3.2.2 Major cognitive impairment, marked concerns with working memory, concentration, or word finding difficulties that significantly impairs daily functioning documented in most recent clinic note or self-reported;

3.2.3 Recent suicide attempt(s), psychiatric hospitalization, or psychotic processing (last 3 years);

3.2.4 Bipolar disorder (I or II) diagnosis, as evidenced by an ICD-10 code within the past year or revealed during subject interview

3.2.5 Moderate to severe alcohol or drug abuse; as evidenced by an ICD-10 codes related to alcohol or illicit substance abuse in the medical record within the past year or revealed during subject interview.

3.2.6 Severe eating disorders; as evidenced by an ICD-10 code in the medical record such as anorexia nervosa or bulimia within the past year or revealed during patient interview

3.2.7 Repeated "acute" crises for example: repeated acute crises consisting of marked psychological distress that impairs function and warrants clinician intervention (e.g., occurring once a month or more frequently); this we be evaluated by the clinician screener

3.3 Inclusion of Women and Minorities

Men and women of all races and ethnicities who meet the above-described eligibility criteria are eligible to participate in this study.

Based on WFBCCC population estimates, we expect approximately 45% of participants to be women. Translating this to our sample size estimate of 15, we plan to enroll at least 7 women. Similarly, we expect approximately 3% of study participants to be Hispanic/Latino (N=~1). We plan to enroll at least 13% Black or African American (N=2). Due to the small sample size we do not anticipate recruiting American Indian/Alaska Native, or Asian subjects; however no eligible subjects will be denied participation. Should we not meet or exceed these estimates, the PI will engage the Office of Cancer Health Equity to discuss strategies to enhance recruitment in these target populations.

4 Registration Procedures

All patients entered on any WFBCCC trial, whether treatment, companion, or cancer control trial, **must** be linked to the study in EPIC within 24 hours of Informed Consent. Patients **must** be registered prior to the initiation of treatment.

You must perform the following steps in order to ensure prompt registration of your patient:

1. Complete the Eligibility Checklist (Appendix A)
2. Complete the Protocol Registration Form (Appendix B)
3. Alert the Cancer Center registrar by phone, *and then* send the signed Informed Consent Form, Eligibility Checklist and Protocol Registration Form to the registrar, either by fax or e-mail.

Contact Information:

Protocol Registrar PHONE [redacted]
Protocol Registrar FAX (336) 713-6772
Protocol Registrar E-MAIL (registra@wakehealth.edu)

*Protocol Registration is open from 8:30 AM - 4:00 PM, Monday-Friday.

4. Fax/e-mail ALL eligibility source documents with registration. Patients **will not** be registered without all required supporting documents.

Note: If labs were performed at an outside institution, provide a printout of the results. Ensure that the most recent lab values are sent.

To complete the registration process, the Registrar will:

- assign a patient study number
- other appropriate actions
- register the patient on the study

5.0 Study Outcomes and Study Measures

5.1 Primary Outcome

5.1.1 To measure self-efficacy for young adult cancer survivors navigating pandemic conditions.

5.2 Secondary Outcomes

5.1.2 To reduce depression and anxiety levels through meaning-making.

5.3 Exploratory Analyses

5.1.3 To assess the feasibility of conducting a telehealth support group for cancer survivors within a pandemic.
5.1.4 To assess YA cancer survivors' interest in participation in a telehealth support group within a pandemic.
5.1.5 To enhance participants' strategies for engaging social connectivity and reduce feelings of isolation amidst simultaneous forces promoting self-isolation (i.e., cancer diagnosis and pandemic).
5.1.6 To reduce feelings of helplessness.
5.1.7 To observe improvement in psychological resilience and flexibility skills in participants.
5.1.8 To increase distress tolerance.

Table 1: Study Measures

Type/Purpose of Measure	Variable	Measures
Primary Outcomes	Self-Efficacy	Cancer Behaviour Inventory-brief version (CBI-B)
Secondary Outcomes	Depression and Anxiety Level	CAS, MINI MAC, and Purpose in Life Test
Exploratory Analyses	Feasibility Interest Social Connectivity Psychological resilience and flexibility skills Helplessness and Hopelessness Distress tolerance	Number of subjects participating at the final visit Number of Sessions Attended UCLA Loneliness Scale Acceptance and Action questionnaire (AAQ) MINI MAC Impact of Event Scale (IES)

6.0 Intervention Plan

The study aims to initially recruit a single cohort of 15 patients. This is a virtual group interventional design in which investigators distribute the electronic assessment battery, perform the intervention, assess mid-way through, and reassess post-intervention. The virtual group will be conducted within a secure platform such as Microsoft WebEx. Assessments (pre-, post-, mid-way) will be distributed through REDCap, a secure virtual platform, as will session handouts and forms. If participants do not have headphones, these will be provided by the study team. The biostatistician will assist with the assessment of change over time within the instrumentation. The session content for this group is built on clinical experience and empirically informed practices, drawing upon elements of Acceptance and Commitment Therapy and Meaning Making approaches. Investigators/facilitators believe that in these unique times, it is optimal to pull elements from various (manualized) approaches that contribute important elements to the group experience. In short, we are making intentional decisions within session design in which we draw heavily from empirically supported practices yet combine them in a manner that seems appropriate for the circumstances based on clinical judgment.

The intervention will be conducted by graduate-prepared mental health providers who are licensed or working under the supervision of a licensed provider. Providers will co-facilitate at all times, with two providers available to respond to group dynamics and follow up with individual members as needed.

The clinicians leading the group will adhere to professional, legal, and ethical guidelines of confidentiality established by professional organizations and state law. Legal and ethical exceptions to confidentiality include: A clear or present danger that the patient intends to harm her/himself or another, knowledge of the abuse or neglect of a minor child or incapacitated adult, or responses to a court subpoena or as otherwise required by law. All members of the group will be required to sign confidentiality forms, in which they agree not to disclose

to anyone outside the group any information that may help to identify another group member. This includes, but is not limited to names, physical descriptions, biological information, and specifics to the content of interactions with other group members.

6.1 Methods

Steps: (Conducted by the Psychosocial Oncology group)

1. Advertise and Identify Prospective Candidates
2. Screen all referred candidates on rolling basis
3. Send out pre-group assessments electronically for completion
4. Begin eight weeks of group work
5. Send out post-group assessments electronically for completion

Session Content

Adapted from Eilenberg, Frostholm, & Kronstrand 2014 with elements on meaning making from Breitbart & Poppito, 2005, rev. 2011:

Session 1: Introduction to ACT and Meaning Making

Summary: The purpose of the 1st session is to introduce the framework and form of the group, as well as expectations for the 8 sessions. Our main focus is on willingness to engage in treatment, a basic understanding of ACT, mindfulness, and the importance and sources of meaning making—creative, experiential, historical, and attitudinal. We will start to practice experiencing each from this first session. The purpose is to introduce the framework of the group, logistics, and to create a safe and accepting atmosphere. Furthermore, we will briefly introduce participants to an understanding of what health anxiety in the context of cancer is.

Session 2: Previous strategies for Anxiety Control

Summary: The purpose of this session is to examine the individual's control strategies and experiences in coping with health anxiety. We will introduce the concept of pain vs. suffering and how cancer can enhance life meaning, maintain life meaning, or create loss of meaning. The purpose is to help the individual to examine whether the previously used strategies have been effective in the short- and long-term in relation to living a values-based, meaningful life.

Session 3:Introduction to Values Based Living

Summary: The purpose of session 3 is to extend the insights and experiences from the last session in relation to the control agenda's limited effect on anxiety. Through experiential exercises, the effect of the control agenda is further tested and examined. Further, values-based living is introduced as an alternative to an avoidance and control-driven life. Values are introduced in the context of willingness and a discussion will introduce "Life as Legacy" both in the past, the here-and-now, and the future.

Session 4: Acceptance as an Alternative to Control

Summary: The purpose of session 4 is to introduce acceptance as an alternative to attempting to control anxiety. The control-agenda is additionally challenged by looking at the lack of success in applying these strategies to internal states. Remind participants that mindfulness is a practice in willingness and that willingness may increase the ability to act on life. Acting on life includes being courageous, creative, and responsible.

Session 5: Defusion-A Method for Distancing Yourself from your Thoughts

Summary: The purpose of session 5 is to introduce the concept of defusion through various exercises. Participants experience the difference between being immersed in thoughts and experiencing distance from worrisome thoughts. Participants will be introduced to the techniques with a focus on creating distance from thoughts (e.g., Leaves on a Stream), as this can help the participant to act on thoughts and feelings in line with their values and purpose in life—rather than use control and avoidance behaviors. Experiential sources of love, beauty, and humor enhance one's ability to "Connect with Life."

Session 6: Identifying and Clarifying Values

Summary: The purpose of session 6 is to help participants further identify and clarify their own values and meaning in life in order to provide direction in their lives when treatment ends. Value-based action is introduced as an opportunity to expand the participants' repertoire with activities other than avoidance behavior, control or excessive preoccupation with bodily sensations. Participants will engage in creating a legacy project to foster creative, experiential, historical, and attitudinal meaning making. .

Session 7: Practice Observing Yourself

Summary: The purpose of session 7 is to provide an understanding and personal experience of the observing self—the perspective from which you can create distance from your thoughts and work with mindfulness techniques. The concept of the observing self can be crucial in terms of creating willingness to experience difficult feelings and observe thoughts, etc. without having to react automatically.

Session 8: Living Your Values

Summary: The purpose of session 8 is to help the individual further clarify their values and purpose in life by defining specific value-based steps which can be taken moving forward. Participants will share their Legacy Projects. The group is prepared for the end of the program by working on how to manage obstacles while continuing to move forward in life. The group will process termination.

Social media:

Many virtual group members like to meet on their own exterior to group meetings. While we will not sponsor such activities, group members are free to create forums for such interaction. During our groundrules session, we will discuss potential pros and cons of engaging in such social interaction.

6.1 Study-Related Activities

	Pre-Study[a]	Introduction to ACT and Meaning Making Week 1	Previous strategies for Anxiety Control Week 2	Introduction to Values Based Living Week 3	Acceptance as an Alternative to Control Week 4	Mid-Point Assessment	Defusion-A Method for Distancing Yourself from your Thoughts Week 5	Identifying and Clarifying Values Week 6	Practice Observing Yourself Week 7	Living Your Values Week 8	Post-study
Informed consent	X										
Demographics	X										
Medical history											
Pre-screening questionnaire:	X										
Group Evaluation Questionnaire:						X					X
Instrumentation Coronavirus Anxiety Scale (CAS)	X					X					X
Acceptance and Action Questionnaire (AAQ)	X					X					X
The Cancer Behaviour Inventory-brief version (CBI-B)	X					X					X
The Mini-Mental Adjustment to Cancer (MINI-MAC) 29-item questionnaire	X					X					X
UCLA Loneliness Scale Version 3	X					X					X
The Impact of Event Scale - Revised (IES-R)	X					X					X
The Purpose in Life Test	X					X					X
Group Sessions		X	X	X	X		X	X	X	X	

[a] The instruments are sent out the first week of ten weeks (week one=pre-intervention instruments sent; eight week intervention; post-instruments are pushed at week ten).

6.2 Intervention Administration

Instrumentation

Coronavirus Anxiety Scale (CAS)

"CAS is a reliable instrument (αs > .90), with solid factorial (single-factor; invariant across sociodemographics) and construct (correlated with anxiety, depression, suicidal ideation, and drug/alcohol coping) validity. The diagnostic properties of the CAS (90% sensitivity and 85% specificity) are comparable to related screening instruments, such as the Generalized Anxiety Disorder-7" (Lee, 2020).

Acceptance and Action Questionnaire (AAQ)

Acceptance and Action questionnaire (AAQ) assesses psychological inflexibility. It has been found to have high internal consistency and reliability across different types of psychopathology illnesses and different target groups.

Cancer Acceptance and Action Questionnaire

This 18-item questionnaire is used to assess psychological flexibility in cancer patients. It presents experiences such as avoidance and painful memories.

The Cancer Behaviour Inventory-brief version (CBI-B)

12-item validated questionnaire used widely as a measure of self-efficacy for coping with cancer, derived from the longer 33-item version. CBI-B has been reported to have good internal reliability (a = 0.84) and construct validity. The CBI-B measures coping self-efficacy.

The Mini-Mental Adjustment to Cancer (MINI-MAC) 29-item questionnaire

The Mini-MAC is a 29-item questionnaire measures patients' present experiences using a 4-point Likert scale ranging from ''Definitely does not apply to me'' (1) to ''Definitely apply to me'' (4). Five subscales include: Helpless–Hopeless, Anxious Preoccupation, Cognitive Avoidance, Fighting Spirit and Fatalism.

UCLA Loneliness Scale Version 3

A 20-item scale designed to measure one's subjective feelings of loneliness as well as feelings of social isolation. Participants rate each item on a scale from 1 (Never) to 4 (Often). The measure has high internal consistency (coefficient alpha = .96) and a test-retest correlation over a two-month period of .73.

The Impact of Event Scale - Revised (IES-R)

A short, easily administered self-report questionnaire that has eight intrusion and eight avoidance items, derived from the original IES. Six additional items assess for hyperarousal.

The Purpose in Life Test

This self-report questionnaire has 20 items that measure a person's sense of purpose and meaning in life and is based on Viktor Frankl's Logotherapy (Davies et al., 2014). Good reliability has been found, with split-half reliability coefficients of .90.

Pre-screening questionnaire

This investigator-created instrument is designed to assess group suitability, with attention to inclusion and exclusion criteria. It also will include technology training for group technology requirements.

Group Evaluation Questionnaire

This investigator-created instrument is designed to assess satisfaction and solicit feedback. It also will have questions pertaining to engagement with other group members exterior to group meetings.

7.0 Adverse Event Reporting

7.1 Reporting of Unanticipated Problems, Adverse Events or Deviations

Due to the nature and scope of this study, we do not anticipate any adverse events. However, any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate. The PI will be responsible for the monitoring and reporting of any adverse events. The co-investigators will be consulted as appropriate. All problems having to do with subject safety will be reported by the PI to the IRB. Specifically, the following will be reported, in writing: 1) all serious adverse events associated with the study procedures, and/or 2) any incidents or problems involving the conduct of the study or participation, including problems with the recruitment and/or consent processes. The PI will provide a discussion of any problems noticed during each year in the course of the study to the IRB on an annual basis

7.2 WFUHS IRB AE Reporting Requirements

Any unanticipated problems involving risks to subjects or others and adverse events shall be promptly reported to the IRB, according to institutional policy. Reporting to the IRB is required regardless of the funding source, study sponsor, or whether the event involves an investigational or marketed drug, biologic or device. Reportable events are not limited to physical injury, but include psychological, economic and social harm. Reportable events may arise as a result of drugs, biological agents, devices, procedures or other interventions, or as a result of questionnaires, surveys, observations or other interactions with research subjects.

All members of the research team are responsible for the appropriate reporting to the IRB and other applicable parties of unanticipated problems involving risk to subjects or others. The Principal Investigator, however, is ultimately responsible for ensuring the prompt reporting of unanticipated problems involving risk to subjects or others to the IRB. The Principal Investigator is also responsible for ensuring that all reported unanticipated risks to subjects and others which they receive are reviewed to determine whether the report represents a change in the risks and/or benefits to study participants, and whether any changes in the informed consent, protocol or other study-related documents are required.

Any unanticipated problems involving risks to subjects or others occurring at a site where the study has been approved by the WFUHS IRB (internal events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.

Any unanticipated problems involving risks to subjects or others occurring at another site conducting the same study that has been approved by the WFUHS IRB (external events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.

Any event, incident, experience, or outcome that alters the risk versus potential benefit of the research and as a result warrants a substantive change in the research protocol or informed consent process/document in order to insure the safety, rights or welfare of research subjects.

7.3 Data Safety and Monitoring

Since the study is a treatment for mental health concerns such as depression and anxiety, it is likely several participants may endorse clinical levels of each. Current/recent suicidality is an exclusion criteria for this study, therefore those who endorse that upfront will not be enrolled in the study and will be given alternative options (e.g., referred for other CPSP services). If a participant does express suicidal or homicidal ideation at any point throughout the 8 sessions, a therapist will engage them in a personal discussion outside of the group to further assess safety additionally, the study will require that patients allow us to have their preferred phone number and physical address on hand (we have in med chart but have them consent to us using for this purpose) so that appropriate follow-up after video sessions can occur if there is concern for personal harm or the need for a private conversation. Additionally the study team will request emergency contact information of a friend or family member who will be contacted in the event that the study team cannot reach the participant. If a patient endorses active suicidality during the group, we will refer them to appropriate follow up depending on the level (e.g., referred to CPSP individually, call 911/ED for imminent danger).

7.3.1 DSMC SAE Reporting Requirements

The Data Safety Monitoring Committee (DSMC) is responsible for reviewing SAEs for CCCWFU Institutional studies as outlined in Appendix D. All Adverse Events that occur during protocol intervention (defined below) and are coded as either 1) unexpected grade 4, 2) unplanned inpatient hospitalization > 24 hours (regardless of grade), or grade 5 (death) must be reported to the DSMC using the using the SAE console in WISER.

All CCCWFU Clinical Research Management (CRM) staff members assisting a Principal Investigator in

investigating, documenting and reporting an SAE qualifying for DSMC reporting are responsible for informing a clinical member of the DSMC as well as the entire committee via the email notification procedure of the occurrence of an SAE.

8.0 Data Management

Informed consent document	EPIC
Protocol registration form	WISER/OnCore
Coronavirus Anxiety Scale (CAS)	REDCap
Acceptance and Action Questionnaire (AAQ) [free, if a member of ACBS:	REDCap
The Cancer Behaviour Inventory-brief version (CBI-B)	REDCap
The Mini-Mental Adjustment to Cancer (MINI-MAC) 29-item questionnaire	REDCap
UCLA Loneliness Scale Version 3	REDCap
The Impact of Event Scale - Revised (IES-R)	REDCap
Purpose in Life Test	REDCap
Pre-screening questionnaire	REDCap
Group Evaluation Questionnaire	REDCap
Off study/Off Treatment/Survival	WISER/OnCore

This project will utilize REDCap Clinical Data Interoperability Services. This is a special feature for importing data into REDCap from WakeOne. It provides an adjudication process whereby REDCap users can approve all incoming data from WakeOne before it is officially saved in their REDCap project. REDCap Clinical Data Interoperability Services can only be enabled by a REDCap administrator who serves as an honest broker to PHI. REDCap's Clinical Data Interoperability Services can only be accessed by users with valid WakeOne credentials. Using the Clinical Data Interoperability Service requires using the Medical Record Number (MRN) as a key to automatically gather demographics and laboratory data and reduces data entry errors.

9.0 Statistical Considerations

9.1 Analysis of Primary Objective

The primary outcome, the improvement of self-efficacy for young adult cancer survivors navigating pandemic conditions, will be assessed by comparing the change in the Cancer Behaviour Inventory-brief version (CBI-B) from baseline to Visit 8. With an n of 15, power of 80% and a 2-sided alpha of 0.05, the confidence interval around our baseline, Visit 4,Visit 8, and change scores would have a width of

approximately 1.02 standard deviations. To test the change over the 8 weeks, a paired t-test (using the baseline and Visit 8 scores within the same patient) will be used; the expected difference in the CBI-B between the 2 scores would be no change (null hypothesis is mean is equal to 0). We would also calculate the difference between baseline and Visit 4 and test to see if that mean is significantly different from 0; this will help us understand that if a change occurs, does it occur earlier in the intervention or does the change happen closer to the end of the intervention.

9.2 Analysis of Secondary Objectives

To reduce depression and anxiety levels through meaning-making, three instruments will provide information on baseline, Visit 8, and change over time. The CAS, MINI MAC, and Purpose in Life Test will all be utilized to estimate depression and anxiety levels. With an n of 15, the width of the confidence interval around the baseline, Visit 4, Visit 8, and change between baseline and Visit 4 as well as Visit 8 scores would be approximately 1.02 standard deviations; a paired t-test will be used to assess the change in the scores. As this is a pilot study, no adjustment in the p-value will be done for multiple comparisons.

9.3 Exploratory Analyses

9.3.1 To assess the feasibility of conducting a telehealth support group for cancer survivors within a pandemic, we will measure how many subjects are still participating at the final visit (Visit 8); the proportion of subjects who are active at this visit can be calculated as n/enrollment (with the expectation of approximately 15 enrolled). When the sample size is 15, a two-sided 95% confidence interval for a single proportion will extend 25.3% from the observed proportion for an expected proportion of 50%; if the proportion is low or high, such as 10% or 90%, a two-sided 95% confidence interval will extend 15.2% from the observed proportion. These data could be used in sample size calculations to design future studies.

9.3.2 To assess YA cancer survivors' interest in participation in a telehealth support group within a pandemic, the data would be used to estimate the percentage of sessions attended for each participant and calculate the mean participation rate and standard deviation; these data could also be expressed as mean number of visits and standard deviation. These data could be used to help design future studies.

9.3.3 To enhance participants' strategies for engaging social connectivity and reduce feelings of isolation amidst simultaneous forces promoting self-isolation (i.e., cancer diagnosis and pandemic), the UCLA Loneliness Scale will be used. As this is a continuous measure, with an n of 15, the width of the confidence interval around the baseline,Visit 4, Visit 8, and change between baseline and Visit 4 as well as Visit 8 scores would be approximately 1.02 standard deviations; a paired t-test will be used to assess the change in the scores. As this is a pilot study, no adjustment in the p-value will be done for multiple comparisons.

9.3.4 To observe improvement in psychological resilience and flexibility skills in participants, the Acceptance and Action questionnaire (AAQ) will be used to estimate flexibility. As in 9.1, with an n of 15, the width of the confidence interval around the baseline, Visit 4,Visit 8, and change between baseline and Visit 4 and baseline and visit 8 scores would be approximately 1.02 standard deviations; a paired t-test will be used to assess the change in AAQ. As this is a pilot study, no adjustment in the p-value will be done for multiple comparisons.

9.3.5 To reduce feelings of helplessness and hopelessness, the MINI MAC will be used. With an n of 15, the width of the confidence interval around the baseline,Visit 4,Visit 8, and change between baseline and Visit 4 as well as Visit 8 scores would be approximately 1.02 standard deviations; a paired t-test will be used to assess the change in the scores. As this is a pilot study, no adjustment in the p-value will be done for multiple comparisons.

9.3.6 To increase distress tolerance, the Impact of Event Scale (IES) will be used to assess this measure. With an n of 15, the width of the confidence interval around the baseline,Visit 4,Visit 8, and change between baseline and Visit 4 as well as Visit scores would be approximately 1.02 standard deviations; a paired t-test will be used to assess the change in the scores. As this is a pilot study, no adjustment in the p-value will be done for multiple comparisons.

9.4 Power and Sample Size

With the planned sample size is 15, a two-sided 95% confidence interval for a single proportion will extend 25.3% from the observed proportion for an expected proportion of 50%; if the proportion is low or high, such as 10% or 90%, a two-sided 95% confidence interval will extend 15.2% from the observed proportion. If the outcome is continuous, with an n of 15, power of 80% and a 2-sided alpha of 0.05, the confidence interval around the estimate would have a width of approximately 1.02 standard deviations.

9.5 Estimated Accrual Rate

The study should accrue all subjects within a short period of time, approximately 4 weeks, based on a goal of 3 to 4 patients each week.

9.6 Estimated Study Length

The study should take 8 weeks to complete the visits, with a week of training before the study begins and another week to send out forms after the study ends, for a total of approximately 10 weeks.

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The following Appendices are required for all WFBCCC cancer treatment protocols.

Add additional appendices as needed.

***ALL** data collection forms must be included as protocol appendices at the time the protocol is submitted to the WFBCCC Protocol Review Committee (PRC) for review.*

Appendix A – Eligibility Checklist

IRB Protocol No.	**WFBCCC Protocol No. 01520**
Study Title: Cancer within a Pandemic: A Telehealth Intervention Designed to Augment Psychological Resilience amidst Dual Health Threats	
Principal Investigator: Katharine E. Duckworth, PhD.	

Inclusion Criteria (as outlined in study protocol)	**Criteria is met**	**Criteria is NOT met**	**Source Used to Confirm * (Please document dates and lab results)**
Documented cancer diagnosis within the WFBMC medical record	☐	☐	
Meets all pre-screen eligibility criteria	☐	☐	
Outpatient Cancer Survivor (diagnosis, treatment, or post-treatment)	☐	☐	
Aged 18-39	☐	☐	
Must speak English	☐	☐	
Must have computer with audio and visual capabilities	☐	☐	
Must live within North Carolina	☐	☐	
Must have experienced health-related anxiety and/or distress in last 3 months	☐	☐	
Exclusion Criteria (as outlined in study protocol)	**Criteria NOT present**	**Criteria is present**	**Source Used to Confirm * (Please document dates and lab results)**
Active inpatient hospitalization;	☐	☐	
Major cognitive impairment, marked concerns with working memory, concentration, or word finding difficulties that significantly impairs daily functioning documented in most recent clinic note or self-reported;	☐	☐	
Recent suicide attempt(s), psychiatric hospitalization, or psychotic processing (last 3 years);	☐	☐	

Bipolar disorder (I or II) diagnosis, as evidenced by an ICD-10 code within the past year or revealed during subject interview	☐	☐	
Moderate to severe alcohol or drug abuse; as evidenced by an ICD-10 codes related to alcohol or illicit substance abuse in the medical record within the past year or revealed during subject interview.	☐	☐	
Severe eating disorders; as evidenced by an ICD-10 code in the medical record such as anorexia nervosa or bulimia within the past year or revealed during patient interview	☐	☐	
Repeated "acute" crises for example: repeated acute crises consisting of marked psychological distress that impairs function and warrants clinician intervention (e.g., occurring once a month or more frequently); this we be evaluated by the clinician screener	☐	☐	

This subject is ☐ eligible / ☐ ineligible for participation in this study.

OnCore Assigned PID: ___ ___ ___ ___ ___ ___ ___ ___

Signature of research professional confirming eligibility: _____

Date: ___ ___ / ___ ___ / ___ ___

Signature of Treating Physician: _____

Date: ___ ___ / ___ ___ / ___ ___

Signature of Principal Investigator**: _____

Date: ___ ___ / ___ ___ / ___ ___

* Examples of source documents include clinic note, pathology report, laboratory results, etc. When listing the source, specifically state which document in the medical record was used to assess eligibility. Also include the date on the document. Example: "Pathology report, 01/01/14" or "Clinic note, 01/01/14"

**Principal Investigator signature can be obtained following registration if needed

Appendix B – Protocol Registration Form

DEMOGRAPHICS

Patient: Last Name: _____ First Name: _____

MRN: ___ ___ ___ ___ ___ ___ ___ ___ DOB (mm/dd/yy): ___ ___ / ___ ___ / ___ ___

ZIPCODE ___ ___ ___ ___ ___

:

SEX: ☐ Male ☐ Female Ethnicity (choose one): ☐ Hispanic

☐Non-Hispanic

Race (choose all that apply): ☐ WHITE ☐BLACK ☐ ASIAN ☐ PACIFIC ISLANDER ☐ NATIVE AMERICAN

Height: ___ ___.___ inches Weight: ___ ___ ___.___lbs.(actual)

Surface Area: ___ ___.___m^2

Primary Diagnosis: _____

Date of Diagnosis: ___ ___ /___ ___/___ ___

Performance Status: ___ ☐ ECOG

PROTOCOL INFORMATION

Date of Registration: ___ ___ / ___ ___ / ___ ___

MD Name (last) : _____

Date protocol treatment started: ___ ___ / ___ ___ / ___ ___

Informed written consent: ☐ YES ☐ NO

(consent must be signed prior to registration)

Date Consent Signed: ___ ___ / ___ ___ / ___ ___

PID # (to be assigned by OnCore): ___ ___ ___ ___ ___ ___ ___ ___

Protocol Registrar can be contacted by calling 336-713-6767 between 8:30 AM and 4:00 PM, Monday – Friday.
Compete the eligibility checklist in WISER and then give the completed Eligibility Checklist and Protocol Registration Form must be hand delivered, faxed or e-mailed to the registrar at 336-713-6772 or registra@wakehealth.edu, respectively.

Appendix C - Race & Ethnicity Verification Form

Thank you so much for helping us to verify your race and ethnicity to ensure the quality of our information. As a brief reminder, the information you provide today will be kept confidential.

1. Are you:
   - ☐ Hispanic or Latino/a
   - ☐ Not Hispanic or Latino/a

2. What is your race? One or more categories may be selected.
   - ☐ White or Caucasian
   - ☐ Black or African American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ Other, Please Specify: _____

Internal use only:

Name: _____ MRN#: _____

Was the self-reported race and ethnicity of the participant verified at the time of consent?
☐ **Yes** ☐ **No**

Was a discrepancy found? **Yes** ☐ **No** ☐
If yes, please provide what is currently indicated in the EMR:
Ethnicity: _____ Race: _____

Additional comments: _____
_____
_____

Appendix D Safety and Toxicity Review Committee Serious Adverse Events SOP

Data and Safety Monitoring Committee (DSMC) Serious Adverse Event (SAE) Notification SOP	**Date: 02/11/2021**

Mandatory DSMC SAE Reporting Requirements in WISER

This document describes reporting requirements of adverse events from **WFBCCC Investigator Initiated interventional trials to the Data and Safety Monitoring Committee (DSMC).** A trial is considered a **WFBCCC Investigator Initiated interventional trial** if the following criteria are met:

1) The Principal Investigator (PI) of the trial is a member of a department at the Wake Forest University Baptist Medical Center.
2) WFBCCC is considered as the primary contributor to the design, implementation and/or monitoring of the trial.
3) The trial is designated as "Interventional" using the Clinical Research Categories definitions provided by the NCI in the Data Table 4 documentation. (https://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4)

There are two distinct types of WFBCCC Investigator Initiated interventional trials based on where patient enrollment occurs. These include:

1) Local WFBCCC Investigator Initiated interventional trials defined as trials where **all patients are enrolled from one of the WFBCCC sites.** These include the main outpatient Cancer Center clinics (located in Winston-Salem) as well as WFBCCC affiliate sites located in Bermuda Run (Davie Medical Center), Clemmons, Lexington, High Point, or Wilkesboro.
2) Multi-Center WFBCCC Investigator Initiated interventional trials defined as trials where patients are enrolled from other sites in addition to WFBCCC sites.
   There are three types of trials that are included in this category:
   a. Trials sponsored by the NCI Community Oncology Research Program (NCORP) that are conducted at multiple sites where the PI is a member of a department at the Wake Forest University Baptist Medical Center.
   b. Trials sponsored by Industry that are conducted at multiple sites and the PI is a member of a department at the Wake Forest University Baptist Medical Center.
   c. Trials sponsored by WFBCCC that are conducted at multiple sites and the PI is a member of a department at the Wake Forest University Baptist Medical Center.

All Adverse Events (AEs) and Serious Adverse Events (SAEs) that occur on any patients enrolled on WFBCCC Investigator Initiated Interventional trials must be entered into the WISER system. The only exception to this requirement is for patients enrolled on NCORP trials at non- WFBCCC sites. AEs and SAEs for NCORP patients enrolled at WFBCCC sites must be entered into the WISER system. Once these

AEs and SAEs are entered in WISER, certain actions must be taken regarding the reporting of specific Adverse Events to the DSMC.

All Adverse Events that occur during protocol intervention (defined below) and are coded as either 1) **unexpected grade 4,** 2) **unplanned inpatient hospitalization > 24 hours (regardless of grade)**, or **grade 5 (death)** must be reported to the DSMC using the using the SAE console in WISER.

A research nurse or clinical research coordinator when made aware that an adverse event meets one of the above criteria has occurred on a WFBCCC Investigator Initiated interventional trial, is responsible for informing a clinical member of the DSMC by phone (or in-person) about the adverse event. The nurse/coordinator should contact the treating physician prior to calling the DSMC clinical member to obtain all details of the SAE, as well as all associated toxicities to be recorded along with the SAE. In addition, this nurse or coordinator is responsible for entering the adverse event information into the SAE console in WISER. Once the adverse event has been entered into the SAE console an email informing the entire DSMC will be generated.

THESE REPORTING REQUIREMENTS APPLY TO any staff member on the study team for a WFBCCC Institutional Interventional trial. Ultimately, the protocol PI has the primary responsibility for AE identification, documentation, grading and assignment of attribution to the investigational agent/intervention. However, when an AE event as described above is observed, it is the responsibility of the person who observed the event to be sure that it is reported to the DSMC.

What is considered during protocol intervention?

During protocol intervention is considered to be the time period while a patient is on study treatment or during the time period within 30 days of last study treatment (even if patient begins a new (non-study) treatment during the 30 days). This window of 30 days should be the standard window to be used in all protocols unless a specific scientific rationale is presented to suggest that a shorter window can be used to identify events. If it is a trial sponsored by Industry and the sponsor requires a longer window for monitoring of SAEs, then the longer window of time specified by the sponsor should be followed.

What is considered as an Unexpected Grade 4 event?

Any grade 4 event that was not specifically listed as an expected adverse event in the protocol should be considered as unexpected. A grade 4 adverse event can be considered to be unexpected if it is an event that would not be expected based on the treatment being received or if it is unexpected based on the health of the patient. In either case, if there is any uncertainty about whether a grade 4 adverse event is expected or unexpected it should be reported to DSMC.

DSMC notification responsibilities of the person (e.g., nurse) handling the reporting/documenting of the SAE in WISER:

1. Make a phone call (or speak in person) to the appropriate clinical member of the DSMC according to the schedule as listed below (page if necessary).

2. Enter a new SAE into the SAE module that is located in the Subject>> CRA Console inWISER WITHIN 24 HOURS of first knowledge of the event. Information can be entered and saved, but the DSMC members will not be notified until a date is entered into the DSMC Notification Date Field. This will ensure that all persons that need to be made aware of the event (i.e., PI, study team members and DSMC members) will be notified; remember to file a copy of the confirmation.
3. Document that the appropriate person(s) on the DSMC has been contacted. Indicate the name of the DSMC clinician that was contacted and the date and time contacted in the Event Narrative field in the SAE console of the particular subject.
4. Document whether or not the protocol should be suspended based on the discussion with the DSMC clinician. This is the major function of the email notification. Enter whether the protocol should be suspended in the Event Narrative Field.
5. Follow up/update the clinical member(s) of DSMC regarding any new developments or information obtained during the course of the SAE investigation and reporting process.

Elements needed to complete the SAE form in the Subject Console in WISER (see Screen Shot 3):

1. Event Date
2. Reported Date
3. Reported by
4. If Grade 5, enter Death Date
5. If Grade 5, enter Death occurred: within 30 days
6. Event Narrative: Brief description (include brief clinical history relevant to this event, including therapies believed related to event). Begin narrative with the DSMC clinician who was notified and Date/Time notified. In addition, state attribution by DSMC clinician as either "Unrelated", "Unlikely", "Possibly", "Probably", or "Definitely". Always include the following here:
    i. DSMC clinician name, date/time contacted and comments
    ii. Date of last dose before the event
    iii. Is suspension of the protocol needed? Y/N
7. Treating Physician comments
8. PI comments, if available
9. Protocol Attribution after discussion with DSMC clinician
10. Outcome (Fatal/Died, Intervention for AE Continues, Migrated AE, Not Recovered/Not Resolved, Recovered/Resolved with Sequelae, Recovered/Resolved without Sequelae, Recovering and Resolving)
11. Consent form Change Required? Y/N
12. SAE Classification ***This is required in order for the email notification to be sent***
13. Adverse Event Details – Enter all details for each AE associated with the SAE.
    a. Course start date
    b. Category
    c. AE Detail
    d. Comments
    e. Grade/Severity
    f. Unexpected Y/N

g. DLT Y/N
h. Attributions
i. Action
j. Therapy
k. Click ADD to attach the AE Detail to the SAE.

14. Enter Date Notified DSMC -- ***This is required for the email notification to be sent***
15. Click Submit. The auto-generated notification email will disseminate within 5 minutes. If you do not receive an email within 5 minutes, check that you have entered the "Date Notified DSMC" and the "SAE Classification". If these have been entered and the email still has not been received, take a screen shot of the SAE in WISER and immediately email it out to all of the DSMC members listed in this SOP. In the subject line, indicate that this is a manual transmission of the SAE in lieu of the auto-generated email. It is required that a notification goes to the DSMC members immediately so that their assessment can be obtained within the 24 hour period requirement. Contact the Cancer Center Programmer/Analyst to alert that there is an issue with the auto-generated email.

The Clinical Members of DSMC to Notify by Phone or Page:

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Lesser	Hughes	Goodman	Reed	Porosnicu	Seegars	Lesser
Hughes	Goodman	Reed	Porosnicu	Seegars	Lesser	Hughes
Goodman	Reed	Porosnicu	Seegars	Lesser	Hughes	Goodman
Reed	Porosnicu	Seegars	Lesser	Hughes	Goodman	Reed
Porosnicu	Seegars	Lesser	Hughes	Goodman	Reed	Porosnicu
Seegars	Lesser	Hughes	Goodman	Reed	Porosnicu	Seegars

Definition of Unavailable:

As a general guideline if the first clinician that is contacted does not respond to the phone call or page within 30 minutes, then initiate contact with the next DSMC clinician listed in the table above on the particular day the SAE is being reported. Allow up to 30 minutes for the new DSMC clinician to respond to a phone call or page before contacting the next member in the table. These times (30 minutes) are a general guideline. Best judgment as a clinical research professional should be used giving considerations of the time of day, severity of the SAE, and other circumstances as to when it is appropriate to contact backup clinicians. If the event occurs near the end of day, then leave messages (voice or email) as appropriate and proceed with submitting the DSMC notification form. It is important to take reasonable steps and to document that some type of contact has been initiated to one or more of the clinical members of DSMC.

DSMC CLINICAN RESPONSIBILITY:

It is the responsibility of the DSMC clinician to review all reported events, evaluate the events as they are reported; and communicate a response to the Investigator, event reporter and the members of DSMC. The review will include but not be limited to the information reported; there may be times when additional information is needed in order for an assessment to be made and further communication directly with the investigator may be warranted. DSMC reserves the right to disagree with the Investigator's assessment. If DSMC does not agree with the Investigator, DSMC reserves the right to suspend the trial pending further investigation. If there is any immediate danger or harm that could be present for a future patient based on the information provided in the DSMC report then an immediate suspension of enrollment should be considered.

AMENDMENTS TO PREVIOUS REPORTS

If all pertinent information is unavailable with the initial submission, once the additional information is available **do not submit a new report**. Rather, go to the original email that was sent to the DSMC and using that email "reply to all". Entitle this new email "**Amendment** for (list date of event and patient ID)" this will avoid duplications of the same event. List the additional information being reported. This information needs to be entered into WISER as well. To do this, go to the Subject console and click SAEs on the left column. Click on the appropriate SAE number that needs updating. Then click Update. This will allow additional information to be added.

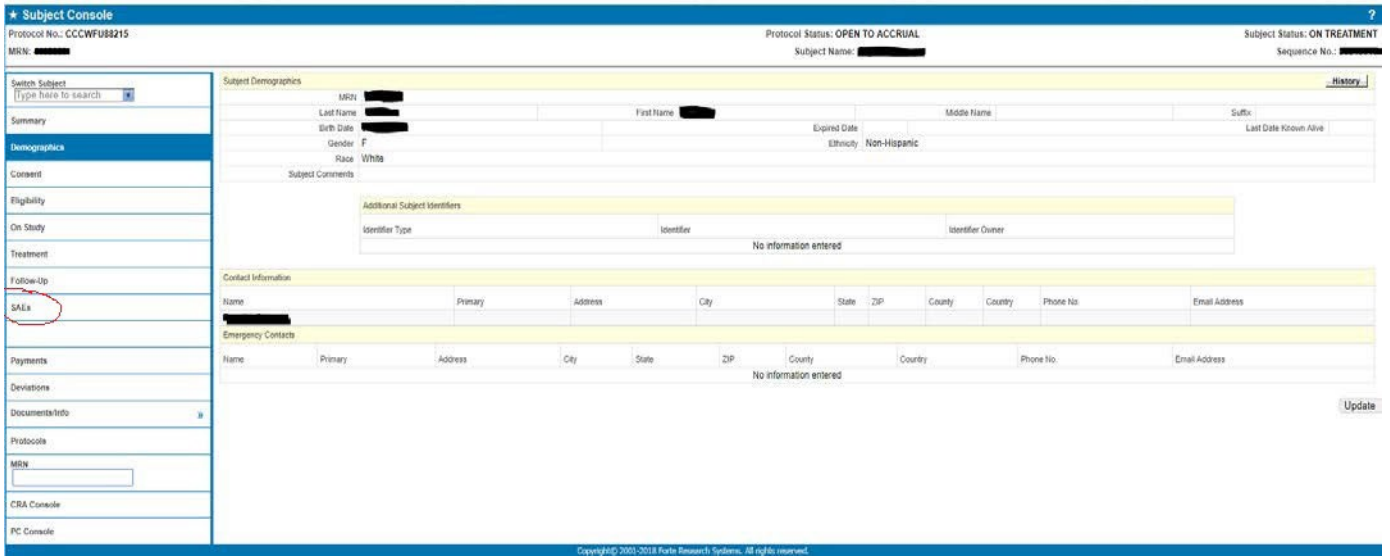
Acronyms

AE – Adverse Event
DSMC-Data and Safety Monitoring Committee
SAE-Serious Adverse Event
WFBCCC – Wake Forest Baptist Comprehensive Cancer Center
NCI-National Cancer Institute
WISER –Wake Integrated Solution for Enterprise Research

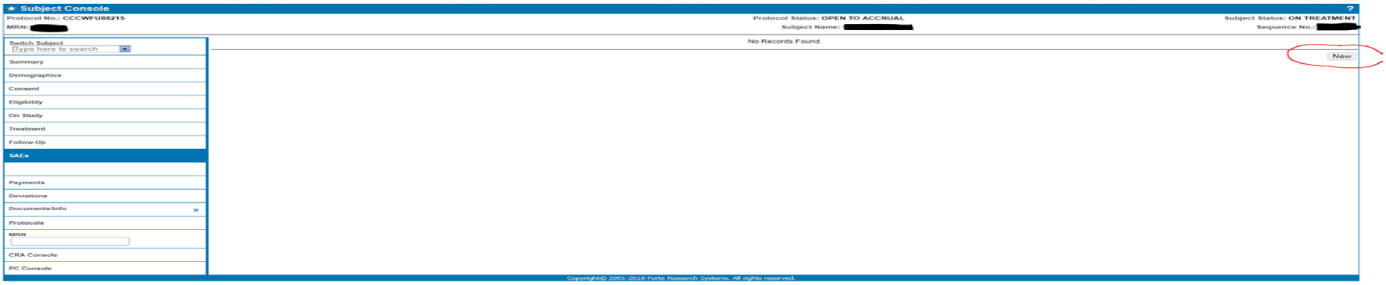
Screen Shots:

The following screen shots come from the SAE Console within the Subject Console in WISER.

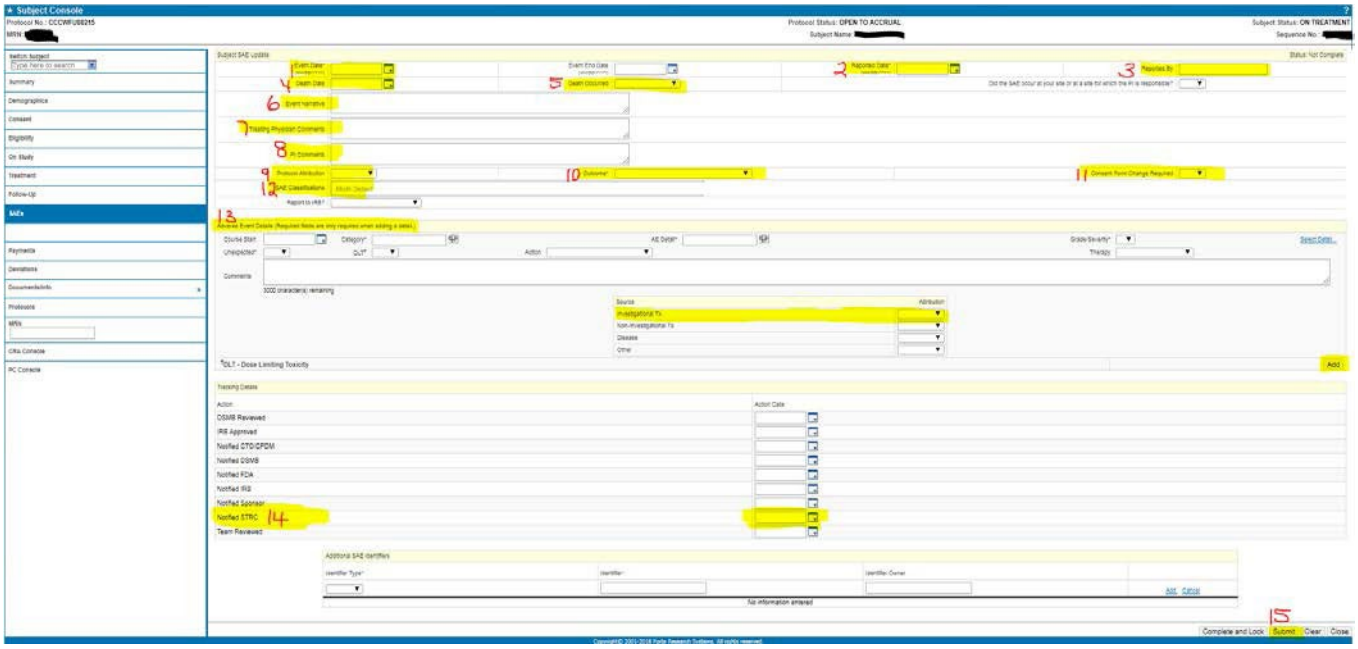
Screen Shot 1:



Screen Shot 2:



Screen Shot 3:



Screen Shot 4: