Comprehensive Cancer Center of Wake Forest University (CCCWFU)

**CCCWFU 99516** 

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### 1.0 Background, Rationale and Context

In preparation for a full-scale randomized clinical trial (RCT) of an internet-delivered positive affect (PA) intervention for young adult cancer survivors, the EMPOWER study will collect pilot data on the feasibility and acceptability of a theoretically-driven, empirically-grounded, individual intervention to promote positive affect (PA). An innovative, intervention for HIV patients (Lessons in Linking Affect and Coping: LILAC) will be adapted for use with young adult cancer survivors. This intervention teaches eight cognitive and behavioral skills to enhance PA, which may broaden and enhance an individual's resources for adapting to stressful events. Feasibility and acceptability data will be collected with reports of daily positive and negative affect, general and domain-specific health-related quality of life, psychological well-being, and health behaviors. This will provide data to support further intervention studies, including an R01 proposal of a full-scale randomized clinical trial.

The number of people surviving cancer and even thriving with cancer grows annually. Historically, positive adjustment and growth in cancer has received little attention compared to impairment, disability and psychosocial morbidity. Today, this important area of research is demonstrating increased growth and interest <sup>3,4,5,6,7</sup> with significant potential applications for cancer control and population sciences. <sup>8</sup>

A number of different psychosocial interventions have proven effective with cancer patients. The majority of these interventions are group-based and focus on alleviating the psychosocial burden of cancer by reducing or managing psychological distress. 9-12 Few interventions explicitly target PA. However, such interventions show promise for not only reducing the negative psychosocial impact of cancer and its treatment but for enhancing its positive psychosocial impact as well. 13-16 A potential limiting factor of these PA interventions is that they are primarily group interventions targeted towards advanced cancer patients. Little is known about individualized PA interventions for cancer patients or survivors, but emerging and innovative research of a PA intervention for newly diagnosed HIV patients<sup>17-18</sup> may have applications for cancer patients. Guided by Fredrickson's broaden-and-build theory of positive emotions<sup>22</sup> and funded by the NIMH (R01MH084723), Moskowitz's RCT of a 5-session evidence-based intervention is designed to teach skills for increasing the frequency and intensity of daily PA and to examine the intervention's effects on subsequent psychological well-being. health behaviors, and physical health after diagnosis with HIV. Patients with HIV experience similar negative and positive psychosocial seguelae as patients with cancer. 19-22 This manualized web-based and home-delivered intervention (LILAC) focused explicitly on increasing positive affect, and has shown good feasibility, acceptability, and preliminary efficacy in people coping with significant healthrelated stress <sup>23,24</sup> including women with advanced breast cancer. Thus. Moskowitz' empirically-based PA intervention research may have beneficial

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parallels to inform this current project. In this application, we propose to build on this prior work to adapt the LILAC intervention to improve health-related quality of life (HRQOL) for young adult survivors of cancer.

### 2.0 Objectives

- 2.1 Primary Objectives
  - 2.1.1 To adapt an individualized positive affect intervention that was developed for newly diagnosed HIV patients to use with young adult cancer survivors.
  - 2.1.2 To pilot test the positive affect intervention with young adult cancer survivors to determine its feasibility and acceptability.
- 2.2 Secondary Objective
  - 2.2.1 To describe health related quality of life, psychological well-being, and health behaviors in young adult cancer survivors

### 3.0 Study Population

60 young adult cancer survivors will be recruited through the Comprehensive Cancer Center of Wake Forest University (N=40) and the Robert H. Lurie Comprehensive Cancer Center of Northwestern University (N=20).

All patients will meet the following inclusion criteria:

- Able to read and understand English
- Past history of a cancer diagnosis (excluding basal cell skin carcinoma)
- 15 to 39 years of age at diagnosis of first cancer and currently between the ages of 18-39
- Within 0-5 years post-active treatment for initial diagnosis or recurrence
- Wireless internet connection or a home computer that is connected to the internet

#### Exclusion criteria:

- Currently receiving palliative or hospice care
- Significant psychiatric history

We anticipate a large percentage of our target sample to have active mywakehealth accounts, and we plan to use the secure MyChart portal to send study information to potentially eligible patients to gauge their interest in the study and communicate as necessary with consented participants.

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#### 4.0 Methods

#### 4.1 Registration Procedures

All patients entered on any CCCWFU trial, whether treatment, companion, or cancer control trial, **must** be registered with the CCCWFU Protocol Registrar or entered into ORIS Screening Log 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 B)
- 2. Complete the Protocol Registration Form (Appendix A)
- 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.

\*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
- register the patient on the study

#### 4.2 Study Design

Patients will be recruited through RHLCCC and CCCWFU. Study staff will work with the Wake Forest Health Sciences Comprehensive Cancer Center's Cancer Informatics Group to identify potential CCCWFU patients from the electronic medical record and/or cancer registry. Potentially eligible patients will be recruited through a direct in-clinic approach as well as mailed letters followed by a phone call by a study team member. The recruitment call will be followed by an email

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outlining the details discussed during the phone call and instructions on next steps and a link to the screening questionnaire (*Recruitment Email Script*). IRB-approved study flyers will be placed in the community at large, the Comprehensive Cancer Center at Wake Forest Baptist Medical Center and other strategic locations associated with Wake Forest Baptist Medical Center. IRB-approved study flyers may also be disseminated through email blasts or postings on websites of local cancer support agencies such as Cancer Services.

Patients will then be screened for eligibility using an online screening questionnaire on Qualtrics. Those that are ineligible will be displayed a message stating that he/she was ineligible. Patients who are eligible based will be navigated to the consent form and initial study questionnaire on Qualtrics, an online data collection tool that enables researchers to create study-specific websites for capturing patient data securely online. The instrument library includes self-report batteries or profiles from Patient-Reported Outcomes Measurement Information System (PROMIS) and the NIH Toolbox which include many of the measures that will be used in the study. At completion of the baseline questionnaire, all patients will be given access to the PA intervention.

The PA intervention is a 5 session online intervention that teaches 8 skills for increasing the frequency of positive emotions: 1) noting daily positive events<sup>25-28</sup> 2) capitalizing on or savoring positive events;<sup>29-30</sup> 3) gratitude;<sup>31-33</sup> 4) mindfulness;<sup>34-37</sup> 5) positive reappraisal;<sup>38-45</sup> 6) focusing on personal strengths;<sup>42-43,49-52</sup> 7) setting and working toward attainable goals;<sup>53-54,55-58</sup> and 8) small acts of kindness.<sup>59-63</sup> The skills are presented over the course of 5 weeks. A week will consist of 1-2 days of didactic material and several days of brief, real-life skills practice and reporting, with each day's "home practice" taking approximately 20-30 minutes to complete. Patients cannot skip ahead, but they can return to old lessons or exercises if they choose. Most exercises are done in a "diary" format in which patients' past responses are displayed next to their new ones, so that every time the patient visits that exercise they see their growing list of past positive experiences. Patients will be permitted up to 8 weeks to complete this self-guided intervention to account for normal interruptions and unexpected delays in life.

Acceptability Interview. Research staff will conduct a 30-minute audio-recorded, post-intervention phone interview with all patients approximately one week after the intervention is complete to gather acceptability data. The semi-structured interview includes questions where participants rank the skill sessions in terms of favorite topics, the likelihood of referral to others (a friend or someone diagnosed with cancer) and the likelihood of practicing learned skills. There is also a section with open-ended questions, including questions about participant experiences with use of the website and home practice exercises

Patient Incentives. Each patient will be paid \$10 for each completed assessment for a maximum of \$30. Patients will be paid in full upon completion of the study via virtual gift card.

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Fidelity Monitoring. Whether patients understood and remember the intervention content will be assessed via multiple-choice "quiz" questions within each lesson. If patients are not able to answer a question, it will trigger a review of the relevant material (patients can also choose to review past material at any time). How frequently patients visit the website and how many times they complete the daily practice exercises for each skill will also be recorded. This information can be used in "dose-response" analyses to determine whether greater exposure to the exercises leads to stronger intervention effects. Patient progress will be monitored during the study and patients who appear to be having trouble or are disengaging from the intervention will be contacted. Our experience indicates that even very brief human contact can increase patients' commitment to the intervention. Patients will receive an email or phone call from a study staff member if they fail to visit the website more than 3 days in a week. Patients who cannot be reached or who do not resume visiting the website but also don't ask to leave the study will be re-contacted once per week for 3 weeks. After that they will be counted as noncompleters, though we will still try to contact them to obtain post-intervention measures. Patients who do not reach the final lesson at the end of 8 weeks will also be considered non-completers and will be asked to take the post-intervention measures at that time.

#### 5.0 Study Outcomes and Study Measures

Patients will complete self-report questionnaires at baseline (pre-test), approximately 8 weeks after baseline (post-test), then at 12 weeks (follow-up) for a total of 3 assessments, each lasting approximately 25-30 minutes. All measures will be completed from home via patients' personal computers. In addition to the measures listed below, key demographics will be assessed (race/ethnicity, education, household income, insurance status), cancer type, time since diagnosis, type of treatment, and time since treatment (See Appendix 3 for a complete list of measures).

#### 5.1 Primary Outcomes

The primary outcomes for this study are measures of feasibility – accrual, refusal, retention, adherence and acceptability.

#### 5.2 Secondary Outcomes

**5.2.1** Health-Related Quality of Life (HRQOL). The PROMIS global health items will be used to assess overall HRQOL, 68 and the PROMIS-2969-70 to assess domain-specific aspects of HRQOL. The PROMIS Global scale consists of 10 items that assess general health, including overall physical and mental health. The PROMIS-29 consists of 29 items that assess physical functioning, anxiety, depression, fatigue, sleep disturbance, social

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functioning, pain interference, and pain intensity. These PROMIS measures will be supplemented with additional items from the PROMIS physical function short form<sup>71</sup> and the PROMIS anger short form.<sup>72</sup> The 4 PROMIS items for depression in this measure do not assess suicidality.

- **5.2.2** Psychological well-being. Psychological well-being will be assessed with NIH Toolbox short forms for positive affect, life satisfaction, and meaning and purpose. In addition, the NIH PROMIS General Self-Efficacy short form will be administered as it is a closely related construct to psychological well-being and positively associated with better patient-reported outcomes.
- **5.2.3** *Health Behaviors.* Healthy behaviors often associated with enhanced coping and better adjustment will be assessed. Physical health behaviors will include: diet, exercise, alcohol consumption, and cigarette smoking.

#### 6.0 Statistical Considerations

Wake Forest School of Medicine will be the Coordinating Center for the study and will conduct all data analysis.

#### 6.1 Analysis of Primary Objective

Accrual will be estimated as the number of patients accrued divided by the number of months of accrual. A 95% confidence interval for the monthly accrual rate will be calculated based on the Poisson distribution. The refusal rate will be estimated as the number of patients who refuse to participate divided by the number eligible. Retention will be primarily defined as the proportion of patients who provide 8 week and 12 week data. Patients who discontinue the intervention (refuse phone calls) but complete the outcome assessments will be counted in the numerator for calculating retention. Retention estimates will be calculated overall and by site. Adherence to the intervention will be calculated as the number of intervention sessions completed, the frequency of completing exercises, and number of website visits. We will calculate and report the mean adherence across all individuals as well as the proportion of patients who completed three or more sessions. Several measures will be used to quantify acceptability, including quantitative measures and interview. Means and the proportion responding affirmatively to the highest two responses for each question will be combined and exact 95% CIs will be calculated for these estimates. In addition, Dr. Salsman and Dr. Moskowitz will review open-ended (written) feedback and audio-recordings of phone interviews to identify meta-themes and determine saturation of concepts.<sup>78</sup>

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#### 6.2 Analysis of Secondary Objective

Quantitative outcomes will be assessed by a covariance pattern model for repeated measures to examine change in PA and PROMIS scores over time.

#### 6.2 Power and Sample Size

While this is a pilot study and we will not be testing the efficacy of the intervention, we do want to be able to estimate feasibility, acceptability, and changes in PA and PROMIS scores with a fair degree of precision. With a total of 60 patients we can estimate confidence intervals around means to within ±0.25 SD, and proportions within ±12.7%, with 95% confidence. Assuming that 20% of the patients may drop out, we could estimate confidence intervals for means within ±0.28 SD and proportions within ±14.1% for measures evaluated at the end of the study. Furthermore, the sample size of N=60 should permit us to achieve data saturation, or the point at which successive information serves only to replicate previous content themes and no new information is obtained.<sup>79</sup> Past research reveals that saturation often occurs within the first 12 interviews.<sup>78</sup>

#### 6.3 Estimated Accrual Rate

It is anticipated that 3.2 patients a month will be accrued to this trial, meeting the target of 60 in 19 months. To date, we have recruited 18 patients in 6 months at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University.

#### 6.4 Estimated Study Length

Patients will complete their participation in 12 weeks, for an estimated study length of 15 months.

### 7.0 Data Management

The web intervention is delivered via a customized website built on Moodle, a courseware platform that is used by schools and universities worldwide. Moodle allows delivery of text or video instruction as well as interactive activities such as journals and adaptive quizzes. Moodle is recognized as secure and well-tested software, and HIPAA-compliant. All communications with the website will use industry-standard TLS/SSL encryption. Another layer of security will be provided by avoiding any use of personally identifiable information, medical information, or other sensitive information in the context of the intervention. Patients' Moodle accounts will not be linked to their real name or email address. The design of our intervention website has been refined through a number of iterations based on user testing and feedback from study patients (e.g., simplifying the interface,

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clearly labeling new material and exercises). We have also ensured that material is viewable on handheld, tablet, and laptop devices.

Informed consent document	ORIS
Protocol registration form	ORIS
Pre-, post- and follow-up test	Qualtrics
Questionnaires (Qualtrics)	
Intervention Sessions 1-5	Moodle
Phone Interview	Audio-recorded and stored among password protected study files

### 8.0 Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed (state the anticipated time the data will be destroyed, e.g. three years after closure of the study, and the method of destruction), consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual patient will appear in reports, presentations, or publications that may arise from the study.

### 9.0 Data Safety and Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study patients. The principal investigator will be assisted by other members of the study staff.

The risks of this study are low; however staff will be trained to handle situations with sensitivity and empathy. The study coordinator will be trained to monitor for significant patient distress or depressive symptoms and will be instructed on the appropriate courses of referral is a patient is considered to be at risk for a safety concern.

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# **10.0** Reporting of Unanticipated Problems, Adverse Events or Deviations

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.

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### Appendix A – Subject Eligibility Checklist

IRB Protocol No.	CCCWFU Proto	ocol No.			
Study Title:					
Principal Investigator:					
Inclusion Criteria (as outlined in study pro		Criteria is met	Criteria is NOT met	(Plea	Source Used to Confirm * use document dates and lab results)
Exclusion Criteria (as outlined in study pro		Criteria NOT present	Criteria is present	(Plea	Source Used to Confirm * se document dates and lab results)
This subject is	ineligible for	r participat	tion in this st	tudy.	
ORIS Assigned PID:					
Signature of research profession	al confirming el	igibility:			Date:
Signature of Treating Physician*	k. 				Date:

<sup>\*</sup> 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"

<sup>\*\*</sup>Principal Investigator signature can be obtained following registration if needed

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#### APPENDIX B: REDUCED REGISTRATION FORM

# Comprehensive Cancer Center of Wake Forest University REDUCED REVIEW\*\* REGISTRATION FORM

Protocol #:		_			*Required Fields
Protocol Title: (optional)					
DEMOGRAPHICS					
Name (last, first): (or initials)				_	
UNIT # (MRN): (required if exists) Zip Code: (required if no Notes and the content of the content		(required if no MRN			
*SEX O MALE	○ FEMA	LE			
*ETHNICITY (choose one):	O HISPA	ANIC	O NON-HIS	SPANIC	
*RACE (choose all that apply):	□ WHIT	TE	AFRICA	N-AMERICAN	
	ASIA	N.	PACIFIC	C ISLANDER (HAWAIIAN	)
	NATI	IVE AMERICA	AN (ALASKA	AN)	
*DIAGNOSIS:					
BIRTH DATE:	(i	include if no N	MRN is provi	ded)	
*MD Name (last, first):					
*DATE CONSENT WAS SIGNE	ED				
Date of Registration (if differ	ent)				
PID #:	(to be cor	mpleted by Re	egistrar)		
The Comprehensive Cancer Ce Registrar the day the patient is communicated to the Centralize	consented;	; if this is not	possible we	require that all registration	
**Reduced review means eligib	ility and oth	her review are	not perforn	ned by CRM registrar.	
Questions: call 713-6767					
	Submit	t by Email***	Prin	t Form	

<sup>\*\*\*</sup>If not using the full wfubmc.edu outlook client (full outlook, not web outlook), save this file and attach to an email to registra@wfubmc.edu

Submitter of this form is responsible for insuring that all regulatory and eligibility requirements are met for this registration.

### **Appendix C – Study Measures**

Variables	Construct/Measures
Demographics	Age, gender, ethnic, edu, income, job & mar. status, insurance, etc.
Clinical	Cancer dx, stage, adj. tx, etc.
Quality of Life	Global Impact Items PROMIS PROMIS Global 10 PROMIS-29 + 4 additional PROMIS physical function items PROMIS Anger SF
Psychological Well-Being	NIH PROMIS General Sell-Efficacy Scale SF NIH Toolbox Life Satisfaction SF NIH PROMIS Meaning & Purpose SF NIH Toolbox Positive Affect SF
Health Behaviors	Diet Alcohol Use & Smoking Leisure Time Exercise Questionnaire

### **EMPOWER Sociodemographic Questions**

SDC01	What is your current age?		
SDC02	Are you of Hispanic origin, such as Lati	n American,	, Mexican, Puerto Rican, or Cuban?
		01	Yes, of Hispanic origin
		02	No, not of Hispanic origin
		09	Decline to answer
SDC03	Do you consider yourself?		
		01	White or Caucasian
		02	Black or African American
		03	Asian
		04	Native Hawaiian/Other Pacific Islander
		05	Native American or Alaska Native
		06	Mixed racial background
		07	Other race
		09	Decline to answer
SDC04	What is your gender?	01	Female
		02	Male
SDC05	What is your marital status?		
	,	01	Single, never married
		02	Married
		03	Divorced
		04	Separated
		05	Widowed
		06	Living with partner
SDC06	Do you currently live alone or with ot	hers?	
	, , , , , , , , , , , , , , , , , , ,	01	Live alone
		02	Live with others (e.g., parent, roommate,
			spouse/partner, brother, sister, children)
SDC07	Are you now responsible for raising an	•	<del>-</del>
		01	No
		02	Yes

SDC08 taxes?	Which of the following income categories	best describes your total household income before
	01	Less than \$15,000
	02	\$15,000 to \$24,999
	03	\$25,000 to \$34,999
	04	\$35,000 to \$49,999
	05	\$50,000 to \$74,999
	06	\$75,000 to \$99,999
	07	\$100,000 to \$124,999
	08	\$125,000 to \$149,999
	09	\$150,000 to \$199,999
	10	\$200,000 to \$249,999
	11	\$250,000 or more
	994	Decline to answer
SDC09	What is the highest level of education you hav	e completed?
	01	Grade school – between 1 and 8 years
	02	Some high school
	03	High school diploma or equivalent (e.g., GED) – 12 years
	04	Some college, vocational or training school
	05	College graduate
	06	Some graduate school
	07	Graduate degree
SDC10	What was your school/employment status <u>right</u> mark all that apply.	t before you were diagnosed with cancer? Please
	01	Part-time student
	02	Full-time student
	03	Working part-time
	04	Working full-time
	05	Unemployed
	06	Full-time homemaker or family caregiver
	07	Other (please describe in box below)

SDC11	How did your school/employment stamark all that apply.	atus <u>cha</u>	nge because of your cancer or its treatment? <i>Please</i>
		01	It has not changed because of my cancer or its treatment
		02	I quit working completely
		03	I quit going to school completely
		03	I changed my work status from full-time to part-
		04	time
		05	I changed my school status from full-time to part- time
		06	I took more than 2 weeks total time off from work
		07	I took more than 2 weeks total time off from school
		08	Other (please describe in box below)
SDC12a	Are you now covered by any type of	of health	insurance?
		01	No
		02	Yes
	Yes, GO TO QUESTION SDC12b SDC12b. How is this health insurar	nce prov	ided? MARK ALL THAT APPLY.
		01 Th	nrough your employer/school
		02 Th	rough your spouse's employer/school
			nrough your parent
			edicaid or other public assistance program
			ther State Program (for example, Medi-Cal, SCHIP)
			ilitary or Veteran's Benefits
		07 Ot	ther (please describe in the box below)
		09 I d	lon't know

### **Disease and Treatment Information**

SDC13	Please circle which statement best describes your current activity level:					
		0= Normal activity, without symptoms 1= Some symptoms, but do not require bed rest during waking day 2= Require bed rest for less than 50% of waking day 3= Require bed rest for more than 50% of waking day 4= Unable to get out of bed				
SDC14	What is your height? (feet/inches)					
SDC15	What is your weight? (lbs)	<u> </u>				
SDC16	What was the date of your cancer diagno	osis? (month and year)/				
SDC17	Please select one of the boxes below the your cancer). If none of the boxes is con Basal cell skin cancer Bladder cancer	nt reflects your "primary" cancer diagnosis (e.g., original location of rrect, please select "Other" and explain.   Leukemia				
	Bone tumor	Lung cancer				
	Brain cancer	☐ Melanoma (skin cancer)				
	Breast cancer	☐ Myeloma				
	Central Nervous System tumor	☐ Non-hodgkin lymphoma				
	Cervical cancer	Ovarian cancer				
	Colorectal cancer	Prostate cancer				
	Esophageal cancer	Sarcoma (bone or soft tissue)				
	Head and neck cancer	Stomach cancer				
_ bi	Hepatobiliary cancer (liver, pancreas, le duct)	☐ Testicular cancer				
	] Hodgkin lymphoma	☐ Thyroid cancer				
	] Kidney cancer	Other:(explain)				

SDC18 Has your cancer spread to any lymph nodes:	
	0=No
	1=Yes
	2=Not sure
SDC19a. Has your cancer spread to another part of your bod	y (other than to any lymph nodes)?
	0=No
	1=Yes
	2=Not sure
SDC19b. If yes, please check all that apply:	
22 0 15 0 11 you, produce one on the three uppry.	□ Bone
	□ Brain
	☐ Lung
	□ Liver
	☐ Other: (please specify)
SDC20a Are you currently receiving treatment? (check al	l that apply)
chemotherapy	
radiation treatment	
I am not currently receiving treatment.	
CDC201 IC 1: 11 1 1:1	4 4 10
SDC20b If applicable, when did you complete your cance	r treatment(s)?  ☐ I did not receive surgery for my cancer.
<u> </u>	☐ I did not receive surgery for my cancer.
	☐ I did not receive enchrotherapy for my cancer
c. radiation(month and year) OK	- I did not receive radiation for my cancer
SDC21a Where did you receive most of your primary activity radiation therapy)?	e cancer treatment (surgery, chemotherapy,
107	01 Academic medical center
	22 Community-based hospital or health center
	Office-based private practice
SDC21b List the name of the institution where you receive	rad most of your primary active concer
treatment (surgery, chemotherapy, radiation therapy).	ed most of your primary active cancer
(Surgery, enemotilerapy, radiation therapy).	
SDC22 A survivorship care plan (SCP) is a document that it	
	g healthy. Following completion of your primary active
treatment for cancer, did you receive a SCP from you	
	01 No
	22 Yes
	3 I don't know
SDC23 Do you now (within the past month), or have yo	ou ever had any of the following conditions?
(please check all that apply)	2. 2. 2. had any of the following conditions.

AIDS/HIV	Hypertension
Acid Reflux (heartburn)	Insomnia
Anemia	Multiple Sclerosis (MS)
Anxiety	Migraine/Headaches
Arthritis	Ulcers
Asthma	Other (specify below)
Back Pain	
Depression	
Diabetes	
Fibromyalgia	
Heart Disease	
Hepatitis	

### **Global Impact**

		Completely positive	Mostly positive; a little negative	A little more positive than negative	Equally positive and negative	A little more negative than positive	Mostly negative; a little positive	Completely negative
1	How positive or negative has the overall impact of your illness been on your views about yourself and your life?			0		0		

		Not at all	A little bit	Somewhat	Quite a bit	Very much
2	Overall, how much has having your illness affected your views about yourself and your life?	0		0	0	

#### Positive Affect

Positive	Allect		Positive Affect						
	Item ID For the next set of questions, please tell us								
			how true each statement was of you in the past 7 days.						
1	PA001	In the past 7 days:	I felt cheerful.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
2	PA002	In the past 7 days:	I felt attentive.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
3	PA006	In the past 7 days:	I felt delighted.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
4	PA010	In the past 7 days:	I felt happy.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
5	PA014	In the past 7 days:	I felt joyful.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
6	PA019	In the past 7 days:	I felt enthusiastic.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
7	PA020	In the past 7 days:	I felt determined.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
8	PA021	In the past 7 days:	I felt interested.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					
9	PA025	In the past 7 days:	I was thinking creatively.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much					

10	PA026	In the past 7 days:	I liked myself.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much
11	PA030	In the past 7 days:	I felt peaceful.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much
12	PA037	In the past 7 days:	I felt good-natured.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much
13	PA039	In the past 7 days:	I felt useful.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much
14	PA042	In the past 7 days:	I felt understood.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much
15	PA044	In the past 7 days:	I felt content.	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much

### General Life Satisfaction

		(	General Life Satisfaction	
	Item ID		For the next set of questions, please indicate how much you agree or disagree with each statement.	
35	PA045m	Indicate how much you agree or disagree:	In most ways, my life is close to perfect.	1 = Strongly disagree 2 = Disagree 3 = Slightly disagree 4 = Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
36	PA046	Indicate how much you agree or disagree:	If I could live my life over, I would change almost nothing.	1 = Strongly disagree 2 = Disagree 3 = Slightly disagree 4 = Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
37	PA047	Indicate how much you agree or disagree:	I am satisfied with my life.	1 = Strongly disagree 2 = Disagree 3 = Slightly disagree 4 = Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
38	PA048	Indicate how much you agree or disagree:	So far I have gotten the important things I want in life.	1 = Strongly disagree 2 = Disagree 3 = Slightly disagree 4 = Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
39	PA049m	Indicate how much you agree or disagree:	My life situation is excellent.	1 = Strongly disagree 2 = Disagree 3 = Slightly disagree 4 = Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree

### **Meaning and Purpose**

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
PA203_ C	I have a good sense of what makes my life meaningful.			_		
PA205_ C	I generally feel that what I do in my life is valuable and worthwhile.					
PA210_ C	I have very clear goals and aims for my life.					

### Not at all A little bit Somewhat Quite a bit Very much

	•	· <u> </u>	, , ,,,,,,,	 <u> </u>	vory macr
PA221_ C	My life has meaning.				
PA224_ C	My life has significance.				
PA227_ C	I have a clear sense of direction in life.				
PA232_ C	I experience deep fulfillment in my life.			_	
PA237_ C	My life has purpose.				

### **General Self-Efficacy**

For the next set of questions, please read each sentence and rate your level of confidence in managing various situations, problems, and events.

		I am not At all Confident	I am a a little confident	I am somewhat confident	I am quite confident	I am very confident
GSE11_C	I can manage to solve difficult problems if I try hard enough.					
GSE14_C	I am confident that I could deal efficiently with unexpected events.					
GSE19_C	If I am in trouble, I can think of a solution.					
GSE20_C	I can handle whatever comes my way.					

# PROMIS-29 (+4 additional PROMIS physical functioning items and PROMIS Anger SF)

### Please respond to each question or statement by marking one box per row.

	Physical Function	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
1	Are you able to do chores such as vacuuming or yard work?					
2	Are you able to go up and down stairs at a normal pace?					
3	Are you able to go for a walk of at least 15 minutes?					
4	Are you able to run errands and shop?					
		Not at all	Very little	Somewhat	Quite a lot	Cannot do
5	Does your health now limit you in doing two hours of physical labor?					
6	Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries?					
7	Does your health now limit you in lifting or carrying groceries?					
8	Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?					
	Anxiety In the past 7 days	Never	Rarely	Sometimes	Often	Always
9	I felt fearful					
10	I found it hard to focus on anything other than my anxiety					
11	My worries overwhelmed me					
12	I felt uneasy					

	Depression In the past 7 days	Never	Rarely	Sometimes	Often	Always
13	I felt worthless					
14	I felt helpless					
15	I felt depressed					
16	I felt hopeless					
	Anger During the past 7 days	Never	Rarely	Sometimes	Often	Always
17	I was irritated more than people knew					
18	I felt angry					
19	I felt like I was ready to explode					
20	I felt grouchy					
21	I felt annoyed					
	Fatigue During the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
22	I feel fatigued					
23	I have trouble <u>starting</u> things because I am tired					

	Fatigue In the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
24	How run-down did you feel on average?					
25	How fatigued were you on average?					
	Sleep Disturbance In the past 7 days	Very poor	Poor	Fair	Good	Very good
26	My sleep quality was					
	In the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
27	My sleep was refreshing					
28	I had a problem with my sleep					
29	I had difficulty falling asleep					
	Ability to Participate in Social Roles and Activities	Never	Rarely	Sometimes	Usually	Always
30	I have trouble doing all of my regular leisure activities with others					
31	I have trouble doing all of the family activities that I want to do					
32	I have trouble doing all of my usual work (include work at home)					
33	I have trouble doing all of the activities with friends that I want to do					
	Pain Interference In the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
34	How much did pain interfere with your day to day activities?					
35	How much did pain interfere with work around the home?					
36	How much did pain interfere with your ability to participate in social activities?.					

### **PROMIS Global Items**

Please respond to each item by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
3lob <b>a1</b> 01	In general, would you say your health is:	5	4	3	2	1
Slobal02	In general, would you say your quality of life is:	5	4	3	2	1
5lob <b>s</b> 103	In general, how would you rate your physical health?	5	□ 4	3	2	1
Slobal04	In general, how would you rate your mental health, including your mood and your ability to think?	<u> </u>		3	2	1
5lob <b>a</b> 105	In general, how would you rate your satisfaction with your social activities and relationships?	<u> </u>	4	3	2	
Sloba109	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	<b>_</b> 5		3	2	1

Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	1	2	3	4	5
Global08	How would you rate your fatigue on average?	1	2	3	4	5
Global07	How would you rate your pain on average? 0 1 2  No pain	3 4	5	6 7	8 9	10 Worst imaginable pain

#### Diet

- 1. About how many cups of fruit (including 100% pure fruit juice) do you eat or drink each day?
  - a. None
  - b. ½ cup or less
  - c. ½ cup to 1 cup
  - d. 1 to 2 cups
  - e. 2 to 3 cups
  - f. 3 to 4 cups
  - g. 4 or more cups

- 1 cup of fruit could be:
- 1 small apple
- 1 large banana
- 1 large orange
- 8 large strawberries
- 1 medium pear
- 2 large plums
- 32 seedless grapes
- 1 cup (8 oz.) fruit juice
- ½ cup dried fruit
- 1 inch-thick wedge of watermelon
- 2. About how many cups of vegetables (including 100% pure vegetable juice) do you eat or drink each day?
  - a. None
  - b. ½ cup or less
  - c. ½ cup to 1 cup
  - d. 1 to 2 cups
  - e. 2 to 3 cups
  - f. 3 to 4 cups
  - g. 4 or more cups

- 1 cup of vegetables could be:
- 3 broccoli spears
- 1 cup cooked leafy greens
- 2 cups lettuce or raw greens
- 12 baby carrots
- 1 medium potato
- 1 large sweet potato
- 1 large ear of corn
- 1 large raw tomato
- 2 large celery sticks
- 1 cup of cooked beans
- 3. About how often do you drink regular pop/soda or other sugar sweetened beverages (not diet or calorie-free) in a typical week?
  - a. Every day
  - b. 5 6 days a week
  - c. 3 4 days a week
  - d. 1 2 days a week
  - e. Less often than 1 day a week
  - f. I don't drink any regular soda/pop or other sugar sweetened beverages
- 4. How many times per week do you eat fast food meals or snacks?
  - a. Every day
  - b. 5 6 days a week

- c. 3 4 days a week
- d. 1 2 days a week
- e. Less often than 1 day a week
- f. I don't drink eat any fast food meals or snacks

<u>Alcohol</u>	
5. Do you drink alcohol?	☐ Yes ☐ No
a. If yes, how many days per week do you drink alcohol?	
b. How many drinks containing alcohol do you have on a typical day when you are drinking?	
Smoking	
6. Do you currently smoke?	□ Yes □ No
a. If yes, how many packs a day do you smoke?	<del></del>
7. Did you smoke previously?	□ Yes □ No
a. If you are a former smoker, how many years has it been since you quit?	

### **Current Physical Activity**

For this questionnaire, we want you to recall your <u>current</u> leisure time physical activity (do not include work or household activities) during a **typical week**. When considering the number of times per week, please only include those times that you were physically active for **more than 15 minutes**.

	ample: You typically swim vigorously for 20 minutes 2 times	per week and run for 4	0 minutes 3 times per
		Times per Week	Average Duration Each Time You Exercised (in minutes)
1)	Strenuous Exercise (Heart Beats Rapidly) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	<u> </u>	
		Times per Week	Average Duration Each Time You Exercised (in minutes)
1)	<b>Strenuous Exercise</b> (Heart Beats Rapidly) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)		
2)	<b>Moderate Exercise</b> (Not Exhausting) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)		
3)	Mild Exercise (Minimal Effort) (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snowmobiling, easy walking,		

Date:								1.D.	#	
		Interv	ention	Evalu	ation (	Phone	Interv	iew So	cript)	
Thank you for telephone con conversation of RA] as a re	versati will be	on is b brief, ı	eing reander 3	corded 1 0 minut	for quales. The	ity assu en in on	rance p	urposes 1 you'll	. I expe	
****** ****	****	*****	****	*****	*****	*****	*****	*****	*****	*******
First, I'd like	to ask	you a f	ew que	stions a	bout the	ese sess	ions and	d the stu	ıdy so f	ar.
Let's go back	throug	the s	kills w	e've cov	ered:					
1. Please	c. Grad. For e. Inf f. Pos g. Per h. Go	atitude rmal M formal N sitive R rsonal s als s of Ki	Journa indfulr Mindfu eappra strength	ness (bre lness (m isal ns	eath awa	areness ess in o	) laily life		avorite	(9):
10 1100000				tive Eve			(1) (0	. 10000 1		(2)*
				italizing						
				itude Jo						
			Min	dfulness	s Forma	l (Brea	th Awar	reness)		
			Min	dfulness	s Inform	nal (Min	ndfulnes	ss in Da	ily Acti	vities)
			Posi	tive Rea	appraisa	.1				
			Pers	onal str	engths					
			Atta	inable (	Goals					
			Acts	of Kind	dness					
what	extent		you re	comme	_		ly not" i s to a fri		eing "d	efinitely yes", to
0 Definitely no	1 t	2	3	4	5	6	7	8	9	10 Definitely

		hat extent would ged with cancer?	•		on to someon	e newly
De	0 1 finitely not	2 3	4 5	6 7 8	8 9	10 Definitely
*	******	*******	******	******	*****	******
Ho		you to practice the your response)	e following ski	lls over the next (	6 months?	
4.	Positive	Event:				
	0 Not at all	1 Once a month	2 Once a week	3 2-3 times/week	4 Daily	Other
5.	Capitaliz	zing:				
	0 Not at all	1 Once a month	2 Once a week	3 2-3 times/week	4 Daily	Other
6.	Gratitud	le Journal:				
	0 Not at all	1 Once a month	2 Once a week	3 2-3 times/week	4 Daily	Other
7.	Mindful	Breath Awarene	ss:			
	0 Not at all	1 Once a month	2 Once a week	3 2-3 times/week	4 Daily	Other
8.	Mindful	ness in Daily Acti	vities:			
	0 Not at all	1 Once a month	2 Once a week	3 2-3 times/week	4 Daily	Other

9.	Positive	Reappraisal:				
	0	1	2	3	4	Other
	Not at all	Once a month	Once a week	2-3 times/week	Daily	
10.	Personal	Strengths:				
	0	1	2	3	4	Other
	Not at all	Once a month	Once a week	2-3 times/week	Daily	
11.	Attainab	le Goals:				
	0	1	2	3	4	Other
	Not at all	Once a month	Once a week	2-3 times/week	Daily	
12.	Acts of I	Kindness				
	0	1	2	3	4	Other
	Not at all	Once a month	Once a week	2-3 times/week	Daily	
***	******			******	******	******
		Pla	anning for cont	inued practice		
Foi	premise of Again the	of these coping ski ese skills are like r	lls is that they on the conscience of the constant of the cons	d practice of the sk only work if you con don't exercise them to you, you need to	ntinue to pra , they aren't	ctice them. likely to work
It	frequentl practice l	y) but are less like ess). First let's ta	ly to continue (lk about the one	n above participant XX skill from abov that you plan to co t into your day and	e participant ntinue. Wha	is going to at about it is

How about your least favorite skill? Can you tell me what about that one makes you less likely to try and incorporate it into your life?

One of	the interesting things about any new skill is that after a while you might get bored with it
	or it may stop having the same impact that it had initially. If (skill participant rates as
	most likely to continue) starts getting old for you, you should go back to the skills and
	choose another one and increase your practice of that one. Let's talk about (XX skill that
	participant rated the second most likely to practice) and ways you might be able to
	incorporate that into your daily life.

\*

#### Questions about website usage:

Can you talk about your experience using the intervention website?

Probe: What features did you like?

What could have been clearer?

What did you think of the at home practice exercises?

*If the participant did not progress through all the lessons* Why did you stop at lesson X?

In about four weeks (cite specific dates), I will email you the final online questionnaire for the study. This will mark the end of your participation in the study.

Are there any questions I can answer for you now?

Thank you again for your time and participation in this study. We really appreciate it!

Hang up.