# Emerging From the Haze<sup>™</sup>: Pilot Feasibility Study Comparing Two Virtual Formats of a Cognitive Rehabilitation Intervention

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**OBJECTIVES:** To gather feasibility and preliminary data comparing two virtual delivery methods for providing Emerging From the Haze™ (Haze) to cancer survivors compared to waitlist control (WLC).

**SAMPLE & SETTING:** Eligible participants (N = 93) reported cancer-related cognitive impairment following chemotherapy for stage I–III solid tumors, Hodgkin lymphoma, or non-Hodgkin lymphoma.

METHODS & VARIABLES: A three-arm randomized design was used to compare virtual live group presentation of Haze sessions, virtual prerecorded Haze group sessions, and WLC. Data were collected at baseline, week 10, and week 14.

**RESULTS:** Feasibility was demonstrated. Significant cognitive function improvement at week 10 versus WLC was reported for the live group, and clinical improvement was reported for the prerecorded group. The prerecorded group reported significant improvement at week 14 versus WLC in physical activity, sleep, and health-related quality of life.

IMPLICATIONS FOR NURSING: Additional pilot and feasibility evidence for cognitive rehabilitation interventions was demonstrated. Prerecorded Haze delivery shows potential for clinical effectiveness and scalability. Future multisite research is warranted.

KEYWORDS cognition; cognitive rehabilitation; telemedicine; cancer survivors
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he cognitive sequelae of cancer and cancer-related treatment for noncentral nervous system malignancies, referred to as cancer-related cognitive impairment (CRCI), occur in as many as 75% of patients with cancer during treatment and continue for years post-treatment in about 35% of these patients (Ahles & Root, 2018; Ahles & Saykin, 2007; Henneghan et al., 2021, 2023; Janelsins et al., 2014; Koppelmans et al., 2014; Wefel et al., 2004). CRCI can be extremely distressing and may profoundly affect health-related quality of life (HRQOL), occupational achievement, social reintegration, and identity (Ahles et al., 2012; Boykoff et al., 2009; Crouch et al., 2022; Henderson et al., 2019; Myers, 2012; Von Ah et al., 2012). Research designed to mitigate the cognitive effects of cancer and cancer therapy is a key component of the Oncology Nursing Society Research Agenda's priority area of palliative care and psychosocial oncology, particularly regarding the need to "determine the most effective interventions to improve patient and caregiver HRQOL" (Von Ah et al., 2019, p. 660)

Effective, evidence-based options for managing or treating CRCI that can be widely disseminated are extremely limited and urgently needed. Research to address this knowledge gap is crucial to promote HRQOL for cancer survivors. The efficacy of pharmacologic treatments has been inconclusive in this population, and these treatments are unlikely to address the wide-ranging and multifaceted concerns related to CRCI (Allen et al., 2018; Asher & Myers, 2015). Cognitive rehabilitation is an umbrella term that encompasses cognitive training, strategy training, and cognitive behavioral therapy (Dos Santos et al., 2020; Fernandes et al., 2019; Lange et al., 2019). Research indicates that cognitive rehabilitation and interventions targeting improvements in physical activity, sleep disturbance, mindfulness, and reduction of loneliness may improve cognitive function (Cacioppo & Hawkley, 2009; Chiesa et al., 2011; Jaremka et al., 2014; Johns et al., 2016; Lange et al., 2019; National Comprehensive Cancer Network, 2023; Von Ah & Crouch, 2020).

Emerging From the Haze<sup>™</sup> (Haze) is a standardized, multidimensional cognitive rehabilitation intervention developed for cancer survivors experiencing CRCI. Haze consists of psychoeducational and experiential content and has been provided regularly within the cancer survivorship program at Cedars-Sinai Medical Center (CSMC) in Los Angeles, California, since 2010. Haze content is provided in a group setting by an interprofessional team with oncology rehabilitation, neuropsychology, and group facilitation expertise. Haze has shown promising results for improving patient-reported cognitive function in patients with a variety of cancer types who report CRCI following primary therapy for cancer (Asher et al., 2019; Liang et al., 2018; Myers et al., 2020, 2022). Haze initially was designed for only live, in-person delivery in six weekly 2.5-hour sessions. Retrospective analyses (N = 110) demonstrated significant improvements in perceived cognitive function (PCF) for participants (Asher et al., 2019). Positive results from previous waitlist-controlled pilot work demonstrated improvements in PCF for in-person groups of breast cancer survivors (N = 61) receiving Haze content live via videoconferencing (Myers et al., 2020). Subsequent positive results also were demonstrated from a single-arm investigation of virtual live delivery resulting the need for social distancing during the COVID-19 pandemic (N = 37) (Myers et al., 2022). Participants attended Haze in virtual groups instead of in-person groups. Based on participant feedback from the single-arm pilot, Haze was revised to provide the content in 10 shorter weekly sessions (60-90 minutes). However, virtual live delivery of Haze is restricted to the day of the week and time of day that the program is being delivered, which limits access. Development of a prerecorded format for Haze was of significant interest as a potential mechanism to increase scalability and facilitate eventual broad dissemination across settings and locations.

The purpose of this pilot study was to gather preliminary data comparing two telehealth virtual delivery methods to waitlist control (WLC) for the Haze standardized cognitive rehabilitation intervention for cancer survivors. The primary aim was to demonstrate the feasibility of a three-arm study design comparing the following groups: (a) virtual live Haze group sessions, (b) virtual prerecorded Haze group sessions, and (c) WLC. Secondary aims were to assess between-group differences for changes in PCF and to explore between-group differences for changes in health behaviors (physical activity, sleep, mindfulness), psychosocial outcomes (mood, loneliness), a determinant of behavior change (intention to change), and HRQOL.

## Methods

#### **Theoretical Framework**

Two conceptual models guided this study. The Revised Conceptual Model of Chemotherapy-Related Changes in Cognitive Function based on the theory of unpleasant symptoms incorporates the impact of situational factors related to lifestyle and personal experiences, as well as the concurrent experiences of multiple symptoms, on changes in cognitive function in cancer survivors (Hess & Insel, 2007; Myers, 2009). This model depicts the potential relationships among the following study variables: physical activity (exercise), mood (anxiety and depression), loneliness (social support), PCF (self-reported), and the potential confounding variables of age, education, hormone status (e.g., menopause), and ongoing endocrine therapy. The study also was undergirded by the theory of planned behavior (TPB). The TPB indicates that the following four constructs are key determinants of behavioral change: (a) instrumental and affective attitudes toward the desired behavior, (b) perceived behavioral control, (c) subjective norms, and (d) intention to change the behavior (Ajzen, 1991, 2006; Ajzen & Fishbein, 1980). Intention to change has been shown to be the most proximal determinant of behavior change (Rhodes & Courneya, 2004) and was measured for the following three aspects of the cognitive rehabilitation intervention content: strategies to facilitate exercise, sleep quality, and mindfulness.

#### Study Design, Setting, and Sample

This prospective, randomized, waitlist-controlled, three-arm pilot study was conducted at the University of Kansas Cancer Center (KUCC) in Kansas City and CSMC. Eligible participants were adults (aged 18 years or older) diagnosed with stage I–III solid tumors, Hodgkin lymphoma, or non-Hodgkin lymphoma who were within six months to five years of completing chemotherapy (and radiation therapy if received) and who reported changes in cognitive function. These time frames were selected to be consistent with the researchers' previous work (Myers et al., 2020, 2022) and to allow resolution of most acute treatmentrelated side effects, while still capturing shorter- and longer-term issues with cognitive function. Ongoing treatment with endocrine, anti-HER2, or other stable maintenance therapies (e.g., rituximab) were allowed. Patients were excluded for known history of other neurologic conditions involving impaired cognitive function (e.g., Parkinson disease, multiple sclerosis, Alzheimer disease or related dementia). Patients also were excluded for previous receipt of intrathecal chemotherapy or nonautologous marrow or stem transplantation (autologous transplantation cell was allowed). Feasibility was defined as successful recruitment (more than 95% of target sample), a greater-than-70% retention rate per group, 85% session attendance adherence, and positive participant satisfaction ratings. To achieve the primary aim for demonstration of feasibility, a planned sample size of 90 with 30 participants per group allowed for an attrition rate of as much as 20%. This sample size is consistent with recommended parameters for pilot studies (Browne, 1995; Julious, 2005; Teare et al., 2014). Twenty-four participants per group provided 80% power (95% confidence intervals estimated within 0.8 SDs) to detect a large between-group effect size (Cohen's d = 0.83) using a two-sided, two-sample t test at the 0.05 level of significance.

# Intervention

The intervention was designed and implemented by members of the study team. An overview of the Haze content is depicted in Table 1. The content is based on recommendations from the National Comprehensive Cancer Network (2023) for cancer survivorship and includes evidence-based information regarding behaviors related to brain health. Behaviors associated with the reduction of inflammatory cytokines and increase of markers of brain health like brainderived neurotrophic factor are emphasized (Di Liegro et al., 2019; Lange et al., 2019). In particular, participants are encouraged to find sustainable ways to increase physical activity (target 150 minutes of moderate weekly exercise), decrease intake of processed foods and added sugars, increase intake of foods rich in omega-3 fatty acids, practice mindfulness strategies, and incorporate elements of sleep hygiene to reduce sleep disturbance and fatigue. Participants are led through a series of exercises and strategies to help increase concentration and focus, minimize distractions, and boost short-term memory. Content also is devoted to the management of negative thoughts that can exacerbate issues with cognitive function. All

participants in the intervention group received paper and electronic copies of the program slides, handouts, and homework exercises.

The virtual live and prerecorded groups were facilitated concurrently. Presenters of the virtual prerecorded program content included a physical medicine and rehabilitation physician (i.e., physiatrist) specializing in cancer rehabilitation and a neuropsychologist, thus ensuring content fidelity. Four cohorts of 10-week sessions were provided. Secure telehealth conferencing platforms were used for the live and prerecorded audio and video delivery of the intervention. The virtual live group webinar presentations (group 1) were broadcast in real time from CSMC. This same content was video recorded and stored on a secure shared drive provided by CSMC for this study. The prerecorded group sessions (group 2) were accessed from the shared drive and hosted in real time by the telemedicine and telehealth systems coordinator at the University of Kansas Medical Center, the umbrella academic association under which the KUCC operates. These prerecorded videos were synchronously watched by group 2 participants. Group 2 discussion was facilitated by one advanced practice oncology nurse to ensure intervention consistency. Participants in both virtual groups were able to ask questions in real time and take part in group discussions regarding the content. Participants in the WLC (group 3) were invited to attend their preferred delivery method after completing the study assessment time points for data collection.

To additionally ensure intervention fidelity, make any midstream study adjustments, and inform future study design, the study team met during and after each cohort to discuss participants' satisfaction survey responses and troubleshoot any challenges related to technology, participants' questions, or issues with data collection.

#### Recruitment

Following University of Kansas Medical Center Institutional Review Board approval, several recruitment strategies were employed. Individuals on the CSMC waitlist to attend the Haze program were approached regarding interest in study participation. In addition, patients reporting cognitive issues to the healthcare teams at CSMC and KUCC were provided information about the study. External referrals were received from other institutions (e.g., Swedish Cancer Institute, University of Michigan, Masonic Cancer Alliance membership). The Curated Cancer Clinical Outcomes Database was used to identify eligible

TABLE	<b>1. Emerging From the Haze™ Content</b>	1	
Week	Session Focus	Key Content	Homework
1	Introduction and program overview, neuroplasticity, and understanding CRCI	<ul> <li>Learn the state of the science regarding CRCI.</li> <li>Understand the principles of neuroplasticity.</li> <li>Understand the various sources of CRCI.</li> </ul>	<ul> <li>Start a daily log of cognitive problems.</li> </ul>
2	Stress management, relaxation techniques, mindfulness, and meditation	<ul> <li>Understand the physiologic correlates of stress and its effect on physical and psychological health.</li> <li>Learn stress management techniques, incorporating relaxation and mindfulness approaches.</li> </ul>	<ul> <li>Listen to a relaxation CD or engage in mindfulness meditation practice at least once a day for 15 minutes.</li> </ul>
3	Lifestyle and cognition: exercise	<ul> <li>Understand the role of exercise in potentially improving cognitive function.</li> </ul>	-
4	Mood and negative/automatic thoughts	<ul> <li>Understand the symptoms of depression and anxiety.</li> <li>Learn techniques for managing mood.</li> <li>Learn techniques for countering negative thinking.</li> </ul>	<ul> <li>Monitor mood via a depression or anxiety inventory.</li> <li>Fill out an automatic thought record for a situation that elicits strong emotions.</li> </ul>
5	Lifestyle and cognition: sleep hygiene	<ul> <li>Recognize the effect of chronic insomnia on cognitive function and review nonphar- macologic strategies for improving sleep.</li> </ul>	-
6	Lifestyle and cognition: nutrition	<ul> <li>Highlight the possible effect of poor nutrition on cognitive function and mood.</li> </ul>	-
7	Cognitive strategies to enhance attention	<ul> <li>Understand the different subtypes of attention.</li> <li>Learn strategies for improving attention.</li> </ul>	-
8	Cognitive strategies to enhance memory	<ul> <li>Understand the different aspects of memory.</li> <li>Learn strategies for improving memory via memory mnemonics.</li> </ul>	<ul> <li>Apply 1 of the memory mnemonic strate- gies learned to a daily situation.</li> </ul>
9	Cognitive strategies: problem-solving, pacing, balancing lifestyle	<ul> <li>Learn steps for effective problem-solving.</li> <li>Learn strategies to improve coping and adjustment.</li> <li>Learn how to pace and balance.</li> </ul>	-
10	Cognition: social support and overall program review	<ul> <li>Recognize the link between chronic loneliness and cognitive symptoms.</li> <li>Review major themes of the Emerging From the Haze curriculum.</li> </ul>	-

CRCI–cancer-related cognitive impairment **Note.** From "Emerging From the Haze: A Multicenter, Controlled Pilot Study of a Multidimensional, Psychoeducation-Based Cognitive Rehabilitation Intervention for Breast Cancer Survivors Delivered With Telehealth Conferencing" by J.S. Myers, G. Cook-Wiens, R. Baynes, M.-Y. Jo, C. Bailey, S. Krigel, ... A. Asher, 2020, *Archives of Physical Medicine and Rehabilitation*, 101(6), p. 952 (https://doi.org/10.1016/j.apmr.2020.01.021). Copyright 2020 by Elsevier. Adapted with permission. patients receiving care at KUCC who had opted in or not opted out for being contacted about clinical trials.

# **Data Collection and Study Procedures**

Informed consent was obtained prior to any data collection. In-person or virtual consent was allowed. Block randomization (blocks of six) was used via REDCap at the time of consent to ensure relatively equal group size for comparison (Harris et al., 2009, 2019). Data were collected at baseline (T1), immediately postintervention (week 10, T2), and week 14 (T3). Commensurate assessment time points were employed for WLC participants. Because this study

was unblinded, participants were informed of their group assignment following informed consent and completion of the T1 study questionnaires to minimize any expectancy effect. Participants received a small payment incentive after completing all three sets of study questionnaires. Study questionnaires were administered electronically via REDCap. Cellular data plan–enabled, password-protected study tablets were loaned to participants who did not have internet access, videoconferencing-compatible devices, or reliable cellular service to ensure broad study access. Only deidentified data were extracted from REDCap for analyses. All data were stored on a secure, dedicated



CONSORT–Consolidated Standards of Reporting Trials; Haze–Emerging From the Haze™ cognitive rehabilitation intervention

# TABLE 2. Sample Characteristics (N = 92)

		_,						
	lotal (	N = 92)	Live (I	N = 31)	Prerecord	ed (N = 31)	Waitlist Con	trol (N = 30)
Characteristic	X	Range	X	Range	X	Range	X	Range
Age (years)	52.45	23-77	51.52	23-77	51.52	28-75	54.3	33-73
Years of education	16.33	7-26	16.29	7-20	16.58	11-26	16.1	8-22
Months since chemotherapy	22.19	6-66	19.59	6-66	25.72	6-66	21.5	6-66
Months since radiation therapy	21.35	1-61	20.32	2-53	19.15	1-43	23.89	6-61
Characteristic		n		n		n		n
Sex								
Female		89		31		31		27
Male		3		-		-		3
Gender								
Female		89		31		31		27
Male		3		-		-		3
Ethnicity								
Hispanic or Latino		11		3		3		5
Not Hispanic or Latino		81		28		28		25
Race								
American Indian or Alaska Native		1		-		1		-
Asian		5		2		1		2
Black or African American		6		2		3		1
White		73		26		23		24
2 or more races		3		1		1		1
Prefer not to answer		4		-		2		2
Relationship status								
Married		56		20		15		21
In a relationship		15		4		8		3
Not in a relationship		12		2		6		4
Divorced		6		3		2		1
Widowed		1		-		-		1
Prefer not to answer		2		2		-		-
Employment status								
Full-time		30		10		12		8
Not employed		26		8		8		10
Retired		16		3		6		7
Part-time		15		7		4		4
Medical leave		5		3		1		1
Menopause status								
Premenopause		10		1		5		4
Perimenopause		4		3		1		-
Postmenopause		66		24		24		18
Not applicable		10		2		1		7
Prefer not to answer		2		1		-		1
Cancer type								
Breast		63		25		19		19
							Continued on t	he next page

TABLE 2. Sample Characteristi	cs (N = 92) (Continued	)		
	Total (N = 92)	Live (N = 31)	Prerecorded (N = 31)	Waitlist Control (N = 30)
Characteristic	n	n	n	n
Cancer type (continued)				
Non-Hodgkin lymphoma	6	1	4	1
Colorectal	4	2	2	-
Ovarian	4	1	1	2
Head and neck	3	-	-	3
Endometrial	2	1	1	-
Hodgkin lymphoma	2	-	2	-
Lung	2	-	2	-
Cervical	1	-	-	1
Gastric	1	-	-	1
Other	4	1	-	3
Disease stage				
I	23	8	8	7
II	31	15	8	8
III	28	7	9	12
IV	8	1	4	3
Other	2	-	2	-
Received radiation therapy				
Yes	51	19	13	19
No	41	12	18	11
Received endocrine therapy				
No	64	19	21	24
Yes	28	12	10	6
Endocrine therapy ongoing				
No	67	20	23	24
Yes	25	11	8	6
Received surgery				
Yes	72	26	23	22
No	20	5	8	8

research drive at the University of Kansas Medical Center.

# Instruments

Information from patient health records provided type and stage of cancer, treatment regimen(s), and pertinent medications. Study instruments required about 20 minutes to complete. The demographics questionnaire yielded data on age, sex, gender, race and ethnicity, years of education, menopause status, relationship status, and employment status. Other instruments were the Patient-Reported Outcomes Measurement Information System (PROMIS) Cognitive Function

Short Form (CF), version 2.0; PROMIS Cognitive Function-Abilities Short Form (CF-A), version 2.0; Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ); Pittsburgh Sleep Quality Index (PSQI); Mindful Attention Awareness Scale; PROMIS Emotional Distress-Anxiety, version 1.0; PROMIS Emotional Distress-Depression, version 1.0; University of California, Los Angeles (UCLA), Loneliness Scale, version 3.0; determinants of behavior change (intention) based on the TPB; PROMIS Global Health, version 1.2; and a satisfaction survey.

PROMIS CF and PROMIS CF-A: The PROMIS CF and CF-A were derived from the Functional

TABLE 3. Weekly Session Attendance by Intervention Group												
	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10		
Cohort	n	n	n	n	n	n	n	n	n	n		
Live group (N = 31)	27	29	24	28	28	26	26	26	22	22		
Cohort 1 (n = 8) Cohort 2 (n = 8) Cohort 3 (n = 6) Cohort 4 (n = 9)	7 7 4 9	7 8 6 8	7 8 3 6	8 7 6 7	8 7 6 7	8 6 5 7	7 6 5 8	8 6 5 7	7 6 3 6	6 5 4 7		
Prerecorded group (N = 30)	23	28	23	25	23	23	26	23	23	23		
Cohort 1 (n = 6) Cohort 2 (n = 9) Cohort 3 (n = 7) Cohort 4 (n = 9)	6 4 5 8	6 7 6 9	5 6 4 8	6 7 4 8	5 6 4 8	6 6 4 7	6 7 5 8	5 6 5 7	5 6 5 7	4 7 4 8		

wk-week

Note. Mean attendance for the virtual live group was 25.8 participants, and mean attendance for the virtual prerecorded group was 24 participants.

Assessment of Cancer Therapy-Cognition item bank and designed to elicit self-reporting of cognitive function from cancer survivors. These instruments have been recommended for use in CRCI research by the Cancer Neuroscience Initiative Working Group (Henneghan et al., 2021, 2023). The PROMIS CF items are framed in a negative way (e.g., "My thinking has been slow"), and the PROMIS CF-A items are framed as positive statements (e.g., "My mind has been as sharp as usual"). The PROMIS CF is recommended (Henneghan et al., 2021) as the primary instrument of choice to harmonize data across studies and is the primary measure of PCF in this study. However, evidence has shown that use of the PROMIS CF-A as the secondary measure of PCF in this study may be of benefit because the two forms may measure two different constructs (Henneghan et al., 2021; Lai et al., 2014). Both instruments contain eight items. Items are ranked on a five-point Likert-type scale, with scores on the PROMIS CF ranging from 1 (very often) to 5 (never) and scores on the PROMIS CF-A ranging from 1 (not at all) to 5 (very much). Higher scores on each instrument reflect better cognitive function. Raw scores are rescaled into T scores with a mean of 50 and an SD of 10. Test-retest analyses from a single-arm pilot study indicated high reliability ratings for the PROMIS CF (Cronbach's alpha = 0.946) and CF-A (Cronbach's alpha = 0.952) (Myers et al., 2022).

GSLTPAQ: The GSLTPAQ, also called the Godin Leisure-Time Exercise Questionnaire, is one of the most frequently used instruments to measure self-recall of physical activity in cancer survivors (Amireault et al., 2015b). This succinct four-item questionnaire is recommended by the National Cancer Institute Division of Cancer Epidemiology and Genetics research program for oncology clinicians and researchers. The GSLTPAQ ranks survivors as either active (score of 24 or higher) or inactive (i.e., insufficiently active) (score of 23 or lower) on a validated leisure score index. Correlations with physical activity as measured by accelerometer or pedometer range from 0.31 to 0.57, and agreement between GSLTPAQ scores and accelerometer measurement was 70.8% in a sample of 199 breast cancer survivors (Amireault et al., 2015a, 2015b).

PSQI: The PSQI is a validated instrument commonly used for measuring sleep quality in cancer-related studies. A study with 474 breast cancer survivors demonstrated strong internal consistency (Cronbach's alpha = 0.7), test-retest reliability (intraclass correlation coefficient = 0.76), and correlation with subjective sleep complaints ( $r \ge 0.60$ ) (Fontes et al., 2017). The PSQI contains seven component scores calculated from 18 items and yields a global score. Higher scores indicate greater difficulty sleeping.

Mindful Attention Awareness Scale: The Mindful Attention Awareness Scale is a six-point, 15-item Likert-type scale with scores ranging from 1 (almost always) to 6 (almost never). Higher scores indicate higher levels of mindfulness (Brown & Ryan, 2003). The instrument is used to assess the core characteristic of mindfulness and has good internal consistency (Cronbach's alpha = 0.82-0.87) and divergent validity

TABLE 4. Satisfaction S	Survey Result	ts (N = 54)	
	Total (N = 54)	Live (N = 28)	Pre (N = 26)
Response	n	n	n
Weekly session length			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	1 1 11 17 24	- - 3 9 16	1 1 8 8 8
Overall course length			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	1 - 9 11 20	- - 3 7 11	1 - 6 4 9
Week 1			
0–Not satisfied at all 1–Slightly satisfied 2–Moderately satisfied 3–Very satisfied 4–Exceptionally satisfied	- - 8 23 20	- 2 11 13	- 6 12 7
Week 2			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	- 4 21 29	- - 1 11 16	- - 3 10 13
Week 3			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	- 1 6 24 23	- 2 11 15	- 1 4 13 8
Week 4			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	1 - 7 18 28	- - 4 8 16	1 - 3 10 12
Week 5			
0–Not satisfied at all 1–Slightly satisfied 2–Moderately satisfied 3–Very satisfied 4–Exceptionally satisfied	- 2 6 21 24	- 1 12 13	- 1 5 9 11
	C	continued in the	next column

TABLE 4. Satisfaction S	urvey Resul	ts (N = 54) (C	ontinued)
	Total (N = 54)	Live (N = 28)	Pre (N = 26)
Response	n	n	n
Week 6			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	- 1 7 20 25	- 2 10 16	- 1 5 10 9
Week 7			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	- 5 18 18	- - 9 11	- - 9 7
Week 8			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	1 1 6 15 19	- 1 1 8 12	1 - 5 7 7
Week 9			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	- 1 6 15 19	- - - 10 11	- 1 6 5 8
Week 10			
0-Not satisfied at all 1-Slightly satisfied 2-Moderately satisfied 3-Very satisfied 4-Exceptionally satisfied	- 2 5 15 19	- - 1 8 13	- 2 4 7 6
Homework assignments			
0–Not satisfied at all 1–Slightly satisfied 2–Moderately satisfied 3–Very satisfied 4–Exceptionally satisfied	1 6 16 18 12	- 2 8 11 7	1 4 8 7 5
Completion online			
0–Not satisfied at all 1–Slightly satisfied 2–Moderately satisfied 3–Very satisfied 4–Exceptionally satisfied	- 5 8 20 21	- 3 4 11 10	- 2 4 9 11
		Continued on a	the next page

TABLE 4. Satisfaction 3	burvey Result	15(11 - 34)(0	onunueu)
	Total (N = 54)	Live (N = 28)	Pre (N = 26)
Response	n	n	n
Number and length of study questionnaires			
0-Not satisfied at all	-	-	-
1–Slightly satisfied	5	3	2
2-Moderately satisfied	12	7	5
3-Very satisfied	24	11	13
4-Exceptionally satisfied	12	7	5
Preferred delivery meth- od if taking course again			
Virtual group setting watching live broadcast	23	15	8
In-person group setting	14	6	8
Virtual group setting watching pre broadcast	10	2	8
Individuals watching pre videos	6	4	2
No preference	1	1	-

TABLE 4. Satisfaction Survey Becults (N = E4) (Continued)

pre-prerecorded

**Note.** Values may not add up to the total N because not all participants answered every question.

with the Beck Depression Inventory and State–Trait Anxiety Inventory (Dehghan et al., 2020).

**PROMIS Emotional Distress-Anxiety and PROMIS Emotional Distress-Depression Short Forms:** These PROMIS instruments are four-item, five-point Likerttype scales with scores ranging from 1 (never) to 5 (always). Higher scores indicate greater anxiety or depression. Raw scores are rescaled into T scores with a mean of 50 and an SD of 10. These instruments have been extensively validated in multiple populations, including cancer survivors. Individual PROMIS negative affect domains for anxiety and depression were validated with more than 300 cancer survivors in addition to other populations. Validity of these subscales was found to be excellent (Cronbach's alpha = 0.97) (Schalet et al., 2016).

**UCLA Loneliness Scale:** This instrument has been used extensively in the cancer survivor population to assess subjective feelings of loneliness and isolation. The UCLA Loneliness Scale, version 3.0, consists of 20 items ranking loneliness from 1 (never) to 4 (often) and yields a total score, with higher total scores indicating greater self-reported loneliness (Russell, 1996). Internal consistency reports are high, with Cronbach's alpha ranging from 0.89 to 0.94 and test-retest reliability during a 12-month period reported as r = 0.73 (Deckx et al., 2014).

**Determinants of behavior change (intention):** This researcher-designed measure was developed according to established procedures for the design of questionnaires based on the TPB (Ajzen, 1991, 2006). Intention to change was selected because it is the most proximal determinant of behavior change according to the TPB. Two items are ranked on a seven-point Likert-type scale. The scores of both items are summed to yield the intentions construct score. Test–retest analysis in a previous single-arm pilot study found high reliability (Cronbach's alpha  $\geq$ 0.7) across three behaviors (exercise, sleep, and mindfulness) (Myers et al., 2022).

**PROMIS Global Health:** This 10-item measure of HRQOL yields global physical and mental health scores and is scored in the same manner as other PROMIS instruments. Internal consistency (0.81) and reliability (0.86) are excellent (Hays et al., 2009).

Satisfaction survey: This 20-item survey was created by the researchers and used to assess participants' satisfaction with the length of the intervention, class session duration, and weekly program content. Items were scored from o (not satisfied at all) to 4 (exceptionally satisfied). Participants also were asked to rank their satisfaction with the homework assignments, number and length of study questionnaires, and completion of study questionnaires online, as well as to indicate their preferred method for Haze delivery if they were to take part in the Haze program again. Three narrative response questions were included to gather qualitative data about aspects of the Haze program that participants found to be most helpful, strategies gleaned from the program they planned to use regularly, and any other feedback they wished to share with the team about the Haze program or the study experience. This instrument was administered only at T2, and these data were not collected from participants in the WLC group.

#### **Statistical Analyses**

Descriptive statistics (counts, means, and SDs) were used to summarize results for aim 1 (feasibility measures: enrollment, retention, and satisfaction), and within- and between-group differences for study outcomes at T2 and T3 were used for aim 2 (primary and secondary measures of PCF) and aim 3 (changes in health behaviors, psychosocial

outcomes, intention to change, and HRQOL). Linear mixed models also were used to test the within-group changes (T3 versus T2) and betweengroup differences in changes in study outcomes for aims 2 and 3. The following potential confounding factors were controlled in these models: baseline study questionnaire scores, age, years of education, and total types of treatment. Two contrasts of interest were tested. One contrast was used to compare differences in scores between the WLC and the two intervention groups combined; the other contrast was used to compare differences in scores between the live and prerecorded groups. Because all analyses were conducted based on changes in scores between time points, only participants for whom data were available for all time points were included in the between-group comparisons of changes. Results of the analyses were compared using the last observation carried forward missing data computation method. Consistency between these results confirmed the robustness of the findings.

Participants' responses to the narrative questions on the satisfaction survey were reviewed using deductive content analysis with the goal of gaining feedback to inform future development of the intervention. Themes were developed based on the satisfaction survey items to describe aspects of the Haze program that participants found to be most helpful, as well as any action plans for implementation of strategies learned from Haze content.

### FIGURE 2. Satisfaction Survey: Selected Participant Responses to Narrative Questions

# Most Valuable Components of Emerging From the Haze™ Program

- "Giving us the tools to deal with our haze and memory issues. Explaining how health, exercise, and emotional well-being are interconnected and how we have to work on all 3 to help heal. Giving us homework to practice the techniques discussed. Using real-life examples of using the tools."
- "I learn not to multitask and do 1 thing at a time. I learn memory tricks to remember people's names or events. Using [colored sticky notes] to rate the level of deadline that is needed for the tasks. Using tools on the [smartphone] like the microphone and the reminders to do a better job remembering things."
- "Thank you very much for allowing me to participate. It was great to find out there were others like me going through very similar circumstances. I definitely felt less alone when it came to dealing with the effects of chemo[therapy]."
- "How to better deal with stress, anxiety, and being mindful. I had already put into place some of the workarounds, and this study gave me better ways to use them. I learned a great deal about myself and realized most of my anxiety and stress comes from physical limitations of chemo[therapy] and radiation [therapy], more so than the 'chemobrain.""
- "The fact that [there] are several other natural or selfcontributing factors that contribute to chemobrain and the detailed content to explain how and why. It was also very helpful to have presenters that were easy to listen to. It was good to understand the reasons behind some of the struggles. It was also encouraging to see that the recommendations were in alignment with some of the steps I had already begun taking toward dealing with some of

these issues. Being in a group and hearing others share their experiences was also very helpful."

"Where to begin? Seeing with my own eyes and hearing with my own ears that I was not alone. Learning about just how important exercise is, and that not very much exercise can have a huge impact. Mindfulness and meditative and visionary techniques. Learning to be more deliberate in my thinking. Hearing from others what has worked for them."

#### **Action Plans for Implementation**

- "Truthfully, all 10 sessions are beneficial. I am glad that it's not about pushing medicine but a doable lifestyle change. This class helped me to relieve stress and restore a relationship with members of my family. I am watching what I purchase now for groceries and intentionally getting outside for exercise. I am establishing a routine for better sleep as well as mindfulness."
- "The sessions on exercise and nutrition were most helpful to me. I knew those were important, but the emphasis on just how important they are really hit home and made me actually take some actions to improve those areas of my life."
- "Exercise more. Engage socially and stay connected. Meditate regularly. Focus on good sleep. Make healthy food choices. Avoid overly stressful aspects of life, but be reminded that a healthy amount of good stress is effective. Be present. Slow down and utilize my senses more. Focus on accepting and not resisting."
- "I have been using the many attention, memory, and problem-solving exercises and plan to continue. Understanding 'being busy versus being productive' has helped me plan my days more effectively with the task lists. I start each day with the breathing and mindfulness techniques we discussed, which continue to be helpful."

# Results

One hundred and thirty-eight patients were referred and/or screened for participation (see Figure 1). Target enrollment (N = 90) was exceeded; 93 participants provided consent. Participants were geographically diverse, with representation across three time zones (Pacific, Central, and Eastern). One participant withdrew prior to completion of the baseline questionnaires and randomization, providing an initial evaluable sample of 92 participants. Participants primarily were White (n = 73), non-Hispanic (n = 81), female (n = 89), and diagnosed with breast cancer (n = 64) (see Table 2). The majority were married (n = 56) and well educated ( $\overline{X}$  years of education = 16.33). Slightly more than half (n = 51) had received radiation therapy. About one-third (n = 28) had received endocrine therapy, 25 of whom were receiving this treatment at the time of the study. No significant demographic differences were noted between groups at baseline. However, baseline scores on the PROMIS CF and CF-A instruments measuring PCF were higher for both intervention groups than for the WLC (p < 0.05).

Weekly attendance for each cohort is reflected by group in Table 3. Mean weekly attendance was 25.8 of 31 for the live group and 24 of 31 for the prerecorded group. Overall retention was 82 of 93, with 26 of 31 for the live group, 27 of 31 for the prerecorded group, and 27 of 30 for the WLC.

Participant satisfaction ratings for length of the intervention, class session duration, and weekly program content after completion of the live and prerecorded group Haze sessions were high (see Table 4). Across 10 weekly sessions, overall satisfaction ratings of 2 or higher on a 0–4 scale ranged from 83% to 100% ( $\overline{X} = 95\%$ ), and satisfaction ratings of 3

or higher ranged from 76% to 93% ( $\overline{X}$  = 83%). Similar results were noted for the completion of study questionnaires online. Average satisfaction ratings across 10 weekly sessions of 2 or higher were 91%, and satisfaction ratings of 3 or higher were 76%. Satisfaction ratings with the homework assignments and number and length of study questionnaires were slightly lower. Across these two items, ratings of 2 or higher ranged from 87% to 91%, and ratings of 3 or higher ranged from 57% to 68%. Satisfaction ratings for the live and prerecorded groups were comparable across all the measures. Participants were asked to indicate their preferred method of Haze delivery if they were to take part in the program again. Of 54 participants, 23 preferred the virtual live group, 14 preferred an in-person group setting, 10 preferred the virtual prerecorded group, 6 preferred individual viewing, and 1 expressed no preference. When the responses were calculated by intervention group, 15 of 28 participants in the virtual live group indicated that they would choose that delivery method again. Participants in the virtual prerecorded group were evenly distributed at 8 of 26 each for choosing in-person, live, and prerecorded delivery if they were to take part in the program again.

Narrative responses on the satisfaction survey were provided by 43 participants. Of the 28 who responded to the question about what components of the Haze program they planned to implement, the most common answer was mindfulness (n = 28), followed by diet (n = 19), exercise (n = 18), sleep (n = 17), and experiential strategies to enhance memory and concentration (n = 14).

Positive comments were provided about the strength of the presenters, empathy of the group facilitator, and experience of feeling heard. Participants in both intervention groups mentioned appreciating

		Live (	Group			Prerecord	led Group		Waitlist Control				
Baseline (N = 31) Week 10			(N = 28)	= 28) Baseline (N = 31) Week			Week 10 (N = 27)		(N = 30)	Week 10 (N = 28)			
Outcome	X SD		x	SD	x	SD	x	SD	x	SD	x	SD	
PROMIS CF	33.5	7.2	39.2	7.5	33.3	5.4	39	4.1	30.9	6.3	34.3	7.5	
PROMIS CF-A	CF-A 36.8 7.4 42.8 7.9		36.3	5.8	40.3	5.2	35.3	6.2	37.4	8.1			

# TABLE 5. Perceived Cognitive Function Mean Scores at Baseline and Week 10

CF–Cognitive Function Short Form; CF-A–Cognitive Function–Abilities Short Form; PROMIS–Patient-Reported Outcomes Measurement Information System

**Note.** The PROMIS CF and CF-A instruments contain 8 items. Items are ranked on a 5-point Likert-type scale, with scores on the PROMIS CF ranging from 1 (very often) to 5 (never) and scores on the PROMIS CF-A ranging from 1 (not at all) to 5 (very much). Higher scores on each instrument reflect better cognitive function. Raw scores are rescaled into T scores with a mean of 50 and an SD of 10.

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ABLE 6. Perceived Cognitive Function Between-G	oup Change and Effect Size Differe	ences From Baseline to Week 10
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	Live Group (N = 28)		Pre G (N =	roup 27)	WL (N = 1	.C 28)	Live-	-Pre	Live-	-WLC	Pre-	WLC
Outcome	e X̄ Chg SD X̄ Chg SD		X Chg	SD	р	d	р	d	р	d		
PROMIS CF	4.92	6.5	5.56	5.1	3.12	5.9	0.689	0.108	0.279	0.293	0.107	0.443
PROMIS CF-A	6.25	6.7	3.86	5.5	1.63	6.4	0.155	0.389	0.011*	0.707	0.172	0.374

# \*p < 0.05

CF—Cognitive Function Short Form; CF-A—Cognitive Function–Abilities Short Form; chg—change; pre—prerecorded; PROMIS—Patient-Reported Outcomes Measurement Information System; WLC—waitlist control

**Note.** The PROMIS CF and CF-A instruments contain 8 items. Items are ranked on a 5-point Likert-type scale, with scores on the PROMIS CF ranging from 1 (very often) to 5 (never) and scores on the PROMIS CF-A ranging from 1 (not at all) to 5 (very much). Higher scores on each instrument reflect better cognitive function. Raw scores are rescaled into T scores with a mean of 50 and an SD of 10.

the ability to ask questions about the Haze content. Several participants mentioned enjoying the group interaction and the validation they experienced from knowing they were not alone regarding the experience of CRCI. Direct quotes demonstrating participants' descriptions of what they found most valuable about the Haze program and what they intend to implement are listed in Figure 2.

Descriptive statistics (means and SDs) for the variables used to measure PCF (PROMIS CF and CF-A) are listed in Table 5. Two-sample t tests indicated that the only statistically significant between-group difference demonstrated was in PROMIS CF-A scores for the virtual live group compared to WLC at T2 (p = 0.011, d = 0.707) (see Table 6). No differences were seen in the CF (p = 0.689, d = 0.108) or CF-A (p = 0.155, d = 0.389) scores between the live and prerecorded groups. Clinically meaningful improvement in the CF-A score was demonstrated for the prerecorded group (p = 0.107, d = 0.413) between T1 and T2 compared to WLC in congruence with the minimally important change defined for PROMIS measures (between 2 and 6 T scores).

Descriptive statistics (means and SDs) for the measures of health behaviors, psychosocial outcomes, determinants of behavior change, and HRQOL are listed in Table 7. Two-sample t tests or Wilcoxon rank sum tests were conducted to compare the between-group difference in change from baseline for each outcome depending on whether the normality of data assumption was satisfied. The only significant between-group change scores were demonstrated between T1 and T3 for the prerecorded group compared to the WLC. The mean change in physical activity (GSLTPAQ scores) for the prerecorded group was 11.6 (SD = 15.1) compared to a mean change of -0.73 (SD = 27.7) for the WLC (p = 0.002) (see Table 8). In addition, an improvement in mental HRQOL (PROMIS Global Health score) was demonstrated between T1 and T3 for the prerecorded group ( $\overline{X}$  change = 5.6, SD = 5) compared to the WLC ( $\overline{X}$  change = 2.16, SD = 4.3) (p = 0.01).

Because of the lack of between-group difference for the live and prerecorded groups, linear mixed models (random intercept) were used to analyze changes in scores between time points (T2-T1 and T3-T1) for repeated measures after controlling for baseline scores, within-group effects (T3 versus T2), and between-group effects (randomized group). Univariate analyses of associations of potential confounding factors (age, years of education, total types of treatment) for each outcome were performed prior to conducting linear mixed-model analyses. Significant results are reported in Table 9. Significant modeling estimates for the two intervention groups combined were obtained for PCF (PROMIS CF and CF-A, higher scores indicate better cognition), sleep quality (PSQI, lower scores indicate better sleep quality), intention to change exercise behavior, and physical and mental HRQOL (PROMIS Global Health, higher scores indicate greater HRQOL).

#### Discussion

The original Haze intervention was delivered in person during six weekly 2.5-hour sessions (Myers et al., 2020). Following the onset of the COVID-19 pandemic, the Haze intervention was piloted live via secure videoconferencing (Myers et al., 2022). Although satisfaction survey results did not indicate the need for change, feedback gleaned from interviews conducted with participants in the earlier pilot informed the revision of the Haze intervention from six weekly 2.5-hour sessions to 10 weekly 60to 90-minute sessions to minimize "Zoom fatigue" (Myers et al., 2022). Results from the current threearm pilot study demonstrated that the shift to a 10-week duration and shorter weekly sessions was acceptable to participants. Intervention group participants rated satisfaction with overall course length and weekly session length as "very satisfied" (17 of 54 for overall course length, 18 of 54 for weekly session length) or "exceptionally satisfied" (both 24 of 54). Satisfaction with the weekly session content also was high. On average across 10 weeks, slightly more than 84% rated satisfaction with weekly session content (weekly sessions were attended by differing numbers of participants) as "very satisfied" (39%) or "exceptionally satisfied" (45%). Only 14 of 54 participants indicated a preference for in-person group Haze delivery if they were to take part in the program again. Satisfaction with completing the study questionnaires online also was high, with the majority (41 of 54) having reported being "very" or "exceptionally" satisfied. These results appear to reflect participants' comfort with the shift to virtual programming and research participation.

Overall participant retention was high (n = 82 of 93), as was retention in the live group (n = 26 of 31) and prerecorded group (n = 27 of 31). As with previous studies, the researchers believe that the WLC design

ABLE	7. 9	Second	lary C	)utc	ome l	Vlean	Scores	for In	tervent	ion (	Groups a	t Bas	seline,	Week	10,	and	Week	14
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			Live C	Group			Prerecorded Group						
	Base (N =	Baseline (N = 31)		Week 10 (N = 28)		Week 14 (N = 26)		eline 31)	Week 10 (N = 27)		Week 14 (N = 27)		
Outcome	x	SD	x	SD	x	SD	x	SD	x	SD	x	SD	
GSLTPAQ	25.8	21.4	32.5	18.2	32.9	19.5	21.4	17	27.9	18.2	31.2	19.4	
Intention to change (exercise)	5.3	1.7	6.3	1.2	5.9	1.5	4.9	2.1	6	1.5	5.7	1.6	
Intention to change (mindfulness)	5.7	1.4	5.9	1.2	5.9	1.3	5.8	1.3	6.1	1.3	5.7	1.4	
Intention to change (sleep)	6	1.8	6.5	1	6.5	0.9	6.3	1.1	6.3	1.3	6.3	1.1	
MAAS	3.9	0.9	4.2	0.9	4.3	0.8	3.7	0.8	4	0.8	4	0.9	
PROMIS Emotional Distress-Anxiety	58.6	9	55.9	6.9	55.1	7.3	61	7.6	55.6	8.9	56.9	8.7	
PROMIS Emotional Distress-Depression	53.8	9.2	49.7	7.9	51	8.4	56	7.4	52.3	8.1	50.1	8.5	
PROMIS Global mental HRQOL	43.1	8.2	46	7	48	7	40.6	7.7	44.1	6.8	46.8	7.5	
PROMIS Global physical HRQOL	41.7	8.1	44.6	8.2	44.7	8.4	41.5	7.1	44.1	5.4	44.6	5	
PSQI	8.7	3.4	7.7	3.2	6.5	2.8	9.8	4.4	7.9	4.1	7.4	4.2	
UCLA Loneliness Scale	39.7	12.4	36.4	11.2	36.3	9.7	41.5	13.7	38.7	13.5	37.5	12.2	

GSLTPAQ–Godin–Shephard Leisure-Time Physical Activity Questionnaire; HRQOL–health-related quality of life; MAAS–Mindful Attention Awareness Scale; PROMIS–Patient-Reported Outcomes Measurement Information System; PSQI–Pittsburgh Sleep Quality Index; UCLA–University of California, Los Angeles

**Note.** The GSLTPAQ is a 4-item questionnaire measuring self-recall of physical activity that rates survivors as active (score of 24 or higher) or inactive (score of 23 or lower) on a validated leisure score index. The researcher-designed measures of intention to change, which is the most proximal determinant of behavior change according to the theory of planned behavior, employs 2 items ranked on a 7-point Likert-type scale to measure exercise, mindfulness, and sleep. The scores of both items are summed to yield intentions construct scores for intention to change exercise, mindfulness, and sleep behavior, with higher scores indicating greater intention to change. The MAAS is a 6-point, 15-item Likert-type scale with scores ranging from 1 (almost always) to 6 (almost never). Higher scores indicate higher levels of mindfulness. The PROMIS Emotional Distress–Anxiety and Emotional Distress–Depression Short Form instruments are 4-item, 5-point Likert-type scales with scores ranging from 1 (never) to 5 (always). Higher scores indicate greater anxiety or depression. The PROMIS Global Health instrument, which yields mental health and physical health subscores, is a 10-item, 5-point Likert-type scale, with scores ranging from 1 (never) to 5 (always). Higher scores indicate greater mental or physical HRQOL. Raw scores for all PROMIS instruments are rescaled into T scores with a mean of 50 and an SD of 10. The PSQl contains 7 component scores calculated from 18 items and yields a global score. Higher scores indicate greater difficulty sleeping. The UCLA Loneliness Scale consists of 20 items ranking loneliness from 1 (never) to 4 (often) and yields a total score, with higher total scores indicating greater self-reported loneliness.

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TABLE 8. Secondary Outcome Mean Scores for Intervention Groups at Baseline, week 10, and week 14												
	Live Group			Prerecorded Group			Waitlist Control					
	Basel Wee	ine to k 10	Basel Wee	ine to k 14	Basel Wee	ine to k 10	Basel Weel	ine to k 14	Baseline to Base Week 10 We		Baseli Weel	ine to k 14
Outcome	X Chg	SD	X Chg	SD	X Chg	SD	X Chg	SD	X Chg	SD	X Chg	SD
GSLTPAQ	4.58	14.8	4.58	14.6	8.33	14.7	11.6ª	15.1	-1.12	16.7	-0.73	27.7
PROMIS Global mental HRQOL	2.4	5.7	4.07	5.9	2.79	4.1	5.6 <sup>b</sup>	5	0.27	4.9	2.16	4.3

TABLE 9. Secondary Outcome Mean Second for Intervention Orauna at Becaline, Weak 40, and Weak 44

 $^{\rm a}\,p$  = 0.002 significant difference from waitlist control  $^{\rm b}\,p$  = 0.01 significant difference from waitlist control

chg-change; GSLTPAQ-Godin-Shephard Leisure-Time Physical Activity Questionnaire; HRQOL-health-related quality of life; PROMIS-Patient-**Reported Outcomes Measurement Information System** 

Note. The GSLTPAQ is a 4-item questionnaire measuring self-recall of physical activity that rates survivors as active (score of 24 or higher) or inactive (score of 23 or lower) on a validated leisure score index. The PROMIS Global Health instrument, which yields mental health and physical health subscores, is a 10-item, 5-point Likert-type scale, with scores ranging from 1 (never) to 5 (always). Higher scores indicate greater mental or physical HRQOL. Raw scores for the PROMIS Global Health instruments are rescaled into T scores with a mean of 50 and an SD of 10.

contributed to the retention rate for the WLC group (n = 27 of 30) in addition to having a positive influence on recruitment because all participants were able to eventually attend the Haze program. Additional elements of feasibility were demonstrated through successful recruitment of the desired sample size and weekly session attendance ranging from 22 to 29 of 31 for the live group ( $\overline{X}$  = 25.8 of 31) and 23 to 26 of 30 for the prerecorded group ( $\overline{X}$  = 24 of 30) (some group participants dropped out of the study over time, affecting weekly attendance rates).

Very few participants required the loaned cellular data plan-enabled tablets (n = 3). However, this pilot study provided the opportunity to further develop and test a system for provision and return of the tablets to inform future work. Of note, referring healthcare providers shared that the availability of the tablets contributed to being able to offer the program to patients living in rural areas and patients without internet access. This practice should be continued in future research to facilitate efforts to increase sample diversity. Participants in this pilot primarily were non-Hispanic (n = 81) and White (n = 73). Efforts are ongoing to translate the Haze intervention and related materials for Spanish-speaking participants. These revisions will facilitate future targeted recruitment among the Hispanic population.

In addition to meeting the primary end points for feasibility, the study results contributed to the growing body of evidence in support of cognitive rehabilitation interventions to address CRCI for cancer survivors. Improvements in PCF, as measured by the PROMIS CF and CF-A, were demonstrated for both

intervention groups. Statistically significant difference in the PROMIS CF-A score between the live group and WLC was observed (p = 0.011). In addition, clinically meaningful difference in the PROMIS CF-A score was demonstrated for the prerecorded group compared to the WLC (Cohen's d = 0.443), which supports findings from earlier pilot studies (Myers et al., 2020; Terwee et al., 2021). However, no between-group differences were noted for the two intervention groups. Improvements were observed for sleep quality, intention to change exercise behavior, and physical and mental HRQOL in the intervention groups compared to WLC. In contrast to previous studies, reduction in loneliness did not reach statistical significance for the intervention groups (Myers et al., 2020, 2022). One potential explanation may be that participants had developed effective strategies for coping with loneliness and isolation during the COVID-19 pandemic. Another explanation may be that virtual programming is not a consistently ideal way to mitigate loneliness.

#### Limitations

Study limitations include the relatively small numbers of participants for each of the three groups. The study was powered to detect only a large effect size, and this limitation may have blunted the detection of between-group differences. Despite broad geographic representation, participant racial and ethnic diversity was limited primarily to White, non-Hispanic survivors, minimizing generalizability of results to a broader population. The fact that some participants were recruited from the Haze waitlist at CSMC may have more heavily weighted participant distribution

#### Variable Coefficient 95% CI Perceived cognitive function PROMIS CF (Intercept) 18.05 [11.83, 24.26] -2.961 WLC and [-5.44, -0.48] groups differencea Between-group -0.636 [-3.47, 2.2] differenceb Mc ak 10

**TABLE 9. Linear Mixed Models** 

Week 10	-	-	-		
Week 14	1.366	[0.4, 2.33]	0.006		
Baseline score	-0.409	[-0.6, -0.22]	-		
PROMIS CF-A					
(Intercept)	19.1	[11.39, 26.81]	-		
WLC and	-3.551	[-6.3, -0.8]	0.012		
groups					
difference <sup>a</sup>					
Difference	-2.764	[-5.98, 0.45]	0.091		
between					
groups⁵					
Week 10	-	-	-		
Week 14	0.456	[-0.51, 1.42]	0.35		
Baseline score	-0.414	[-0.62, -0.2]	-		
Secondary outcomes					

р

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0.02

0.657

Change inten- tion (exercise)			
(Intercept) WLC and groups difference <sup>a</sup>	3.921 -0.653	[3.15, 4.69] [-1.2, -0.1]	0.021
Between-group difference <sup>b</sup>	-0.093	[-0.74, 0.55]	0.78
Week 10	-	-	-
Week 14	-0.123	[-0.43, 0.19]	0.431
Baseline score	-0.624	[-0.76, -0.49]	-
PROMIS Global mental HRQOL			
(Intercept)	10.75	[4.69, 16.82]	0.001
WLC and groups difference <sup>a</sup>	-3.105	[-5.21, -1]	0.004
Between-group difference <sup>b</sup>	0.303	[-2.13, 2.74]	0.805
Week 10	-	-	-
Week 14	2.36	[1.51, 3.21]	-
Baseline score	-0.217	[-0.36, -0.07]	0.004
		Continued in	the next colum

TABLE 9. Linear Mixed Models (Continued)						
Variable	Coefficient	95% CI	р			
Secondary outcomes (continued)						
PROMIS Global physical HRQOL						
(Intercept)	19.68	[12.11, 27.25]	-			
WLC and groups differenceª	-20.45	[-4.02, -0.07]	0.042			
Between-group difference <sup>b</sup>	-0.132	[-2.42, 2.16]	0.909			
Week 10	-	-	-			
Week 14	0.416	[-0.52, 1.35]	0.379			
Baseline score	-0.234	[-0.37, -0.1]	0.001			
Years of edu- cation	-0.479	[-0.85, -0.11]	0.011			
Pittsburgh Sleep Quality Index						
(Intercept)	-1.753	[-4.81, 1.31]	0.258			
WLC and groups differenceª	1.027	[0.13, 1.93]	0.026			
Between-group difference <sup>b</sup>	-0.225	[-1.28, 0.83]	0.673			
Week 10	-	-	-			
Week 14	-0.577	[-1.05, -0.11]	0.017			
Baseline score	-0.252	[-0.37, -0.14]	-			
Years of edu-	0.172	[0.01, 0.34]	0.041			
cation						

<sup>a</sup> Average difference from WLC to intervention groups <sup>b</sup> Average difference from prerecorded to live group CF–Cognitive Function Short Form; CF-A–Cognitive Function– Abilities Short Form; CI–confidence interval; HRQOL–healthrelated quality of life; PROMIS–Patient-Reported Outcomes Measurement Information System; WLC–waitlist control

to the West Coast, but the researchers do not believe that this distribution had an impact on feasibility or participant satisfaction. Patient-reported outcomes were chosen as the primary measure of cognitive function and abilities for this pilot study. Evidence would suggest that subjective (patient-reported) and objective (neurocognitive testing) measures of cognitive function may measure different constructs, and the psychological impact of CRCI may be most associated with effects on HRQOL (Gutenkunst et al., 2021; Hermelink et al., 2010; Oerlemans et al., 2022). The sensitivity of neurocognitive testing for non-central nervous system CRCI remains a subject of some debate, particularly with relatively short intervals of time before and after an intervention and related to ecologic validity shortfalls germane to several psychometric measures. The search for accessible, undemanding testing to evaluate day-to-day neurocognitive performance in a nonclinical testing environment continues (Savard & Ganz, 2016). Results from a concurrently conducted substudy of a mobile digital assessment tool will be reported separately.

Findings from the satisfaction survey were limited because feedback was gleaned from participants who had experienced only a single Haze delivery method. Those who were in the virtual live group indicated a preference for virtual live group delivery again if they were to repeat the Haze program. Interestingly, those in the prerecorded group indicated equal preference among in-person, virtual live, and virtual prerecorded group delivery. Having a positive experience with the prerecorded delivery method, as evidenced by the high satisfaction ratings, may have influenced responses to this question. The flexibility for dissemination and scheduling provided by the prerecorded Haze delivery format, combined with the lack of between-group differences in outcomes from the live group, warrant additional study in a larger, well-powered, randomized study. Of note, during recruitment, some potential and actual participants expressed the desire for individual viewing of the prerecorded content. This option was requested because of timing conflicts between work schedules and the study cohorts (day of week, time of day), as well as because some participants wanted to "make up" content that they missed because of being absent during the 10 weekly sessions. Of the 54 intervention participants, 6 indicated that individual viewing would be their preferred option if they were to participate in the program again. Future research is needed to compare virtual delivery in a group setting and virtual delivery to individuals.

The goal for future development and testing of the prerecorded version will be to increase the strength and ability of the intervention to be broadly disseminated to a wider range of geographically diverse and under-resourced populations. The current pilot was conducted by members of the study team to lay the necessary groundwork for larger-scale testing with multiple group facilitators across multiple settings.

# **Implications for Nursing**

CRCI is a prevalent sequela to cancer and cancer treatment and has a significant negative impact on

#### **KNOWLEDGE TRANSLATION**

- Feasibility was demonstrated for two telehealth virtual delivery methods for 10 weekly group sessions of a cognitive rehabilitation program for cancer-related cognitive impairment.
- High participant satisfaction and retention were demonstrated for live and prerecorded cognitive rehabilitation content and delivery.
- Intervention group participants reported improvements in cognitive function, physical activity, sleep quality, intention to change exercise behavior, and physical and mental health-related quality of life.

HRQOL for cancer survivors. The results of this study add to the evidence in support of cognitive rehabilitation programs to address the cognitive issues reported by survivors and therapeutic lifestyle interventions. Cognitive rehabilitation programs blend experiential exercises to improve memory and concentration with strategies for coping with changes in cognitive function. Nurses play a key role in identifying patients who are experiencing these changes. Nurses' awareness of available cognitive rehabilitation programs and eligibility requirements for ongoing clinical trials is critical for providing cancer survivors with access to appropriate care.

# Conclusion

Limited resources are available to meet the rehabilitation needs of the broader community, and numerous barriers still exist for individuals with functional difficulties or disabilities that interfere with access to rehabilitative interventions (Bright et al., 2018). Demonstrating feasibility (recruitment, retention, and satisfaction) for two forms of telehealth virtual delivery (live versus prerecorded) of the Haze program compared to WLC was a critical step to inform the design of a larger confirmatory study, which could demonstrate the evidence necessary to support the program's accessibility and wide dissemination to a broad and underserved population of cancer survivors. An important next step toward this goal will be to test implementation of the prerecorded version across multiple sites and group facilitators to test feasibility and intervention fidelity on a broader scale in preparation for a large confirmatory trial. Future research is needed to examine the potential impact of the prerecorded cognitive rehabilitation content that may be viewed individually (i.e., outside of a group setting). Culturally appropriate translations for non-Englishspeaking participants also are of interest to facilitate health equity for survivors experiencing CRCI.

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