



Supporting the Science of Informal Cancer Caregiving: Highlights of NCI-Funded Research

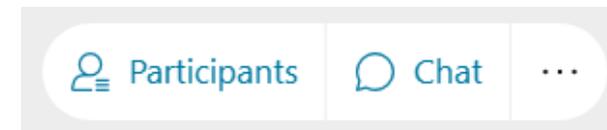
Webinar 3 – Thursday, March 17, 2022 1 PM ET

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Welcome to Webinar 3



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Webinar Outline

- **Presentation 1: Drs. Prigerson and Lichtenthal** – “Enhancing and Mobilizing the POtential for Wellness and Emotional Resilience of Surrogate Decision-Makers of ICU Patients” (EMPOWER)ing Cancer Patient Caregivers
- **Presentation 2: Dr. Milbury** – Supporting Caregivers Who Parent a Young Child While Caring for a Spouse with an Incurable Cancer: A Pilot Trial of a Dyadic Parenting Intervention
- **Presentation 3: Dr. Mazanec** – Building Family Caregiving Skills Using a Simulation-Based Intervention for Care of Patients with Cancer
- **Dr. Mollica:** Questions and Answers

Presenters



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Holly G. Prigerson, PhD
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“Enhancing and Mobilizing the P*O*tential for Wellness and Emotional Resilience of Surrogate Decision-Makers of ICU Patients” (EMPOWER)ing Cancer Patient Caregivers

EMPOWER: Addressing Distress to Improve Outcomes in Critically Ill Cancer Patients & Their Surrogates

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NCI Cancer Caregiver Webinar

March 17, 2022



Weill Cornell Medicine



New York-Presbyterian



**Memorial Sloan Kettering
Cancer Center**

Surrogates of critically ill patients are ...



- at increased risk of posttraumatic stress disorder (PTSD) & prolonged grief disorder (PGD)
- often asked to make life-and-death decisions about the patient's care when extremely upset
- **grief, anxiety, and peritraumatic stress** undermine end-of-life (EoL) decision-making by— resulting in suboptimal EoL decisions and care for patients, and guilt and regret for their surrogates
- COVID-19 has made this bad situation worse

Mental health interventions needed to target mental health outcomes

- Prior trials targeting surrogate PTSD, anxiety, and depression have proven ineffective; some > PTSD rates
- But, while prior trials targeted mental health outcomes, they weren't mental health interventions
- Mental health interventions are needed to help surrogate decision-makers to improve EoL decisions on the patient's behalf and, thus, reduce surrogate decisional regret while promoting their mental health



A close-up photograph of a person's hands held up in a gesture of prayer or distress. The hands are positioned palm-to-palm, with fingers spread. The person is wearing a dark brown sweater. The background is blurred, suggesting an outdoor setting.

What should a mental health intervention in the critical care setting target?

- Surrogates may experience symptoms of grief, anxiety, stress, dissociation, & hyperarousal
- These experiences are associated with experiential avoidance-- efforts to “get away from” difficult thoughts and feelings
 - May manifest as distraction, ruminative worry, reassurance-seeking, avoidance of decisions-making, and/or pursuit of life-prolonging care given lack of awareness that the patient is very unlikely to survive
- Avoidance is negatively reinforcing, bringing short-term relief but maintaining distress in the long-run
- **Experiential avoidance** is a predictor of **PGD** and **PTSD**

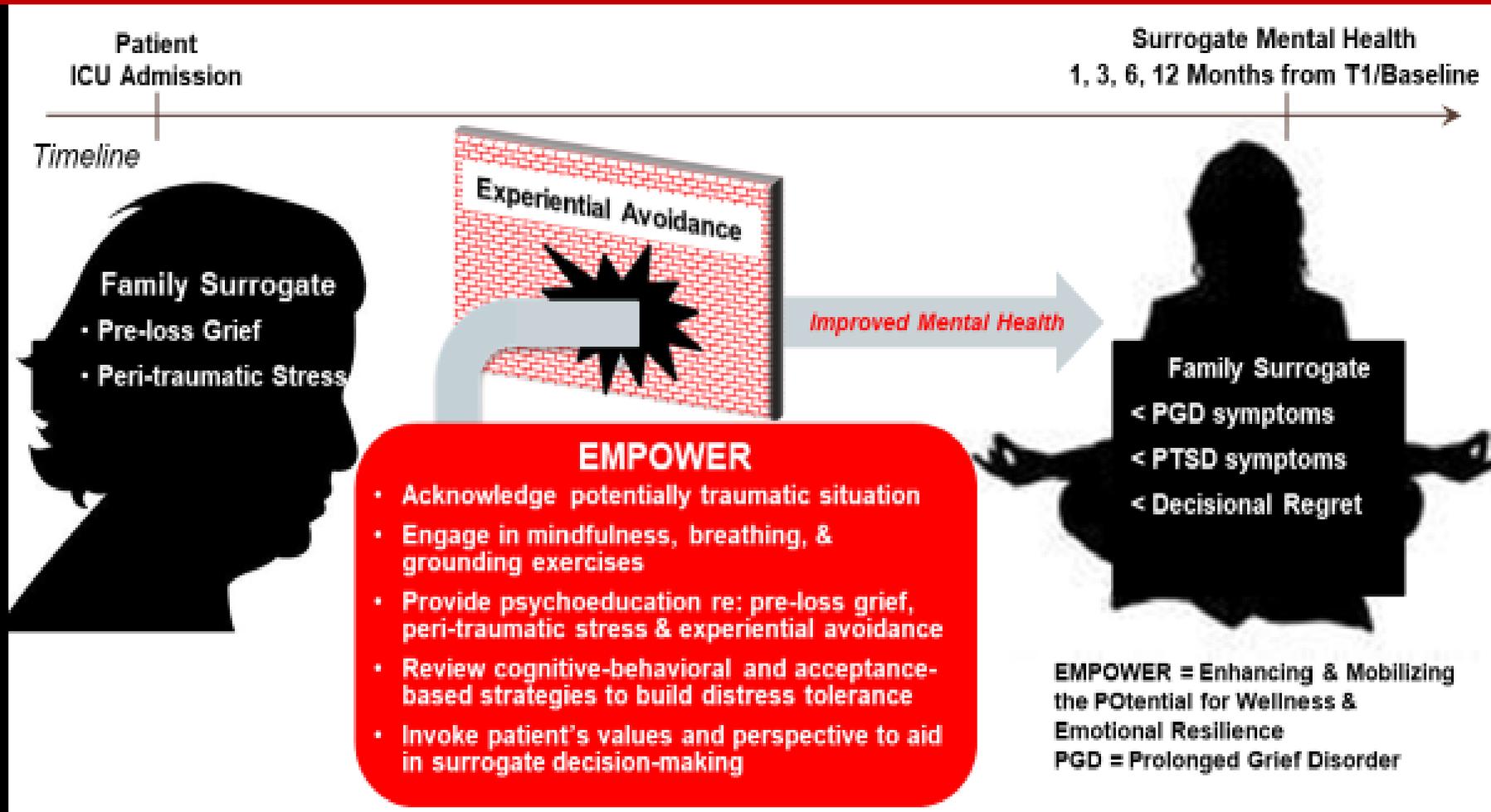
So what is EMPOWER?

Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience

- An intervention to empower surrogates with tools, psychoeducation, and experiential exercises
- Six ultra-brief (~15- to 20-minute) modules (total time: ~1.5 – 2 hours) **administered flexibly** to accommodate interruptions and crises during the patient's ICU stay
- May be delivered in a single session or 2-3 briefer sessions, with 2 booster calls
- Incorporates cognitive-behavioral, acceptance-based, and grief therapy techniques to assist with coping



Conceptual Model: EMPOWER Improves Mental Health by Reducing Experiential Avoidance



The goal is not to eliminate grief, anxiety, and peritraumatic stress reactions, but rather to empower surrogates to respond to these reactions adaptively and compassionately.

The EMPOWER Intervention

In ICU/ Telehealth	Delivered in single or multiple sessions	Module 1	Nurturance, Understanding, and Joining
		Module 2	Breathing Retraining, Grounding Exercises, and Mindfulness Meditation
		Module 3	Psychoeducation about Trauma, Grief, and the Cognitive-Behavioral Model
		Module 4	Increasing Acceptance and Sense of Permission to Experience Challenging Emotions
		Module 5	Connecting with the Patient's Voice
		Module 6	Using the EMPOWER Toolbox and Coping Rehearsal
Phone/ Telehealth	2 weeks post-Module 6	Booster Call 1	Check-in and review of psychoeducation and coping skills
Phone/ Telehealth	4 weeks post-Module 6	Booster Call 2	Check-in and review of psychoeducation and coping skills

Preliminary Results

Measure	Post-intervention		One-month Follow-up		Three-month follow-up	
	n	Cohen's d	n	Cohen's d	n	Cohen's d
Grief Intensity (PG-12/13)	20	-1.39	16	-1.57	15	-1.20
State Anxiety (STAI)	16	-0.58	11	0.93	10	0.12
Depression (PHQ-9)	-	-	17	-0.89	17	-0.74
Peritraumatic Distress (PDI)	17	-0.16	12	0.04	11	-0.22
Traumatic Stress (IES-R)	11	-0.45	10	-1.40	10	-0.99
Experiential Avoidance (BEAQ)	25	-0.25	18	-0.89	18	-1.20
Decision Regret (DRS)	8	-1.38	8	-0.73	6	-1.57

Note. Between-groups Cohen's d comparing EMPOWER to EUC.

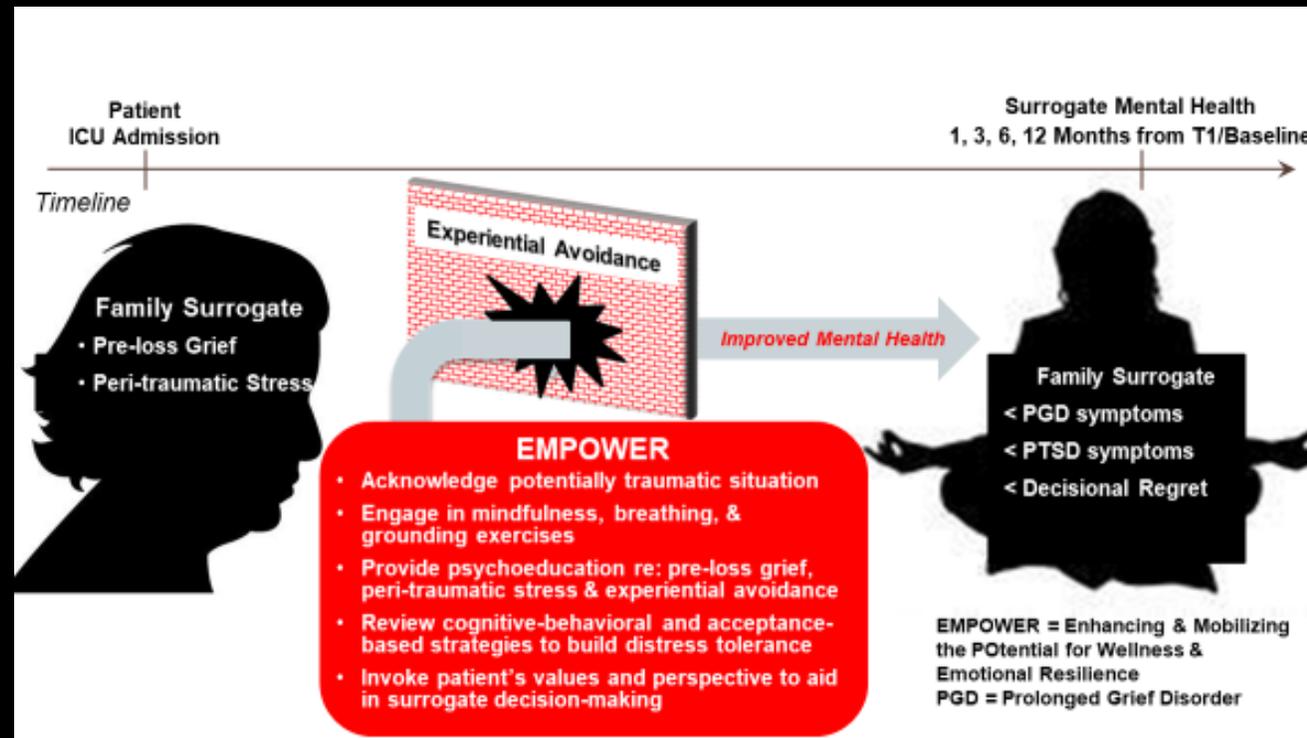
Preliminary Results

Measure	Post-intervention		One-month Follow-up		Three-month follow-up	
	n	Cohen's d	n	Cohen's d	n	Cohen's d
Grief Intensity (PG-12/13)	20	Large	16	Large	15	Large
State Anxiety (STAI)	16	Moderate	11	Not maintained	10	Not maintained
Depression (PHQ-9)	-	-	17	Large	17	Moderate-Large
Peritraumatic Distress (PDI)	17	No effect	12	No effect	11	Small
Traumatic Stress (IES-R)	11	Small-Moderate	10	Large	10	Large
Experiential Avoidance (BEAQ)	25	Small	18	Large	18	Large
Decision Regret (DRS)	8	Large	8	Moderate-Large	6	Large

Note. Between-groups Cohen's d comparing EMPOWER to EUC.

Reduced Experiential Avoidance May Mediate Changes

Reductions in posttraumatic stress symptoms were associated with reductions in experiential avoidance from baseline to 3 months post-intervention ($p < .01$), suggesting the mediating role of experiential avoidance



Participant Exit Interview Feedback

“It wasn't something I was really looking forward to or looking to when I didn't think it was going to be helpful for me at the time because there's so much on my mind. But after being placed in the room and having to actually talk about it when I barely had time - - to eat or - - let alone think about oh I should get to therapy. It wasn't something I was actually thinking of. But at the end of the day it really--I don't want it to feel overdramatic in saying, like, it saved my sanity. But it really did, you know, really did give me a support that I didn't really think I needed until everything--until I actually did it and then I realized what a weight off my shoulders it felt like to be able to talk about it... So, you know, I sat down and asked questions about things right in the hospital - - kind of if I had to I just go out and take care of something with my mother. So it was very helpful. I can't express how helpful it was.” -EMPOWER1

Preliminary Conclusions & Next Steps

- While recruitment has been challenging, EMPOWER shows promise in reducing symptoms of **grief, posttraumatic stress, experiential avoidance, depression, and regret**, with positive qualitative feedback
- Results are consistent with our hypothesis that experiential avoidance drives improvements in outcomes
- Will be conducting a multi-site RCT to determine EMPOWER's efficacy (NINR R01, funding pending), to explore cultural sensitivity and mechanisms of action, and as well as facilitate implementation
- Adaptations of EMPOWER are currently underway, including for versions tailored for Latinx surrogates and parents of children in the PICU



Our Team & Acknowledgements

- Multiple Principal Investigators: Holly G. Prigerson, PhD, Wendy G. Lichtenthal, PhD
- Co-Investigators: David Berlin, MD, Lindsay Lief, MD, Janna Gordon-Elliott, MD, Cynthia X. Pan, MD, Stephen Pastores, MD, Neil Halpern, MD, William Breitbart, MD, Allison Applebaum, PhD
- Consultants: Kailey Roberts, PhD, Christopher Brewin, PhD, Christopher Cox, MD, Susan Vaughan, MD
- Lead Interventionist: Maddie Rogers, LMSW
- Current RAs/CRCs: Martin Viola, MS, Daniel Ouyang, MD, Shayna Rabin, BA, Hillary Winoker, BS, Taylor Coats, MA, Carol Fadalla, BA
- Biostatistician: Paul Maciejewski, PhD, Cici Jiehui Xu, MA

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Thank you!

For questions or suggestions,
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Kathrin Milbury, PhD

Supporting Caregivers Who Parent a Young Child While
Caring for a Spouse with an Incurable Cancer: A Pilot Trial
of a Dyadic Parenting Intervention



Supporting Caregivers who Parent a Young Child while Caring for a Spouse with an Incurable Cancer: A Pilot Trial of a Dyadic Parenting Intervention

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Department of Behavioral Science

Parenting and Cancer

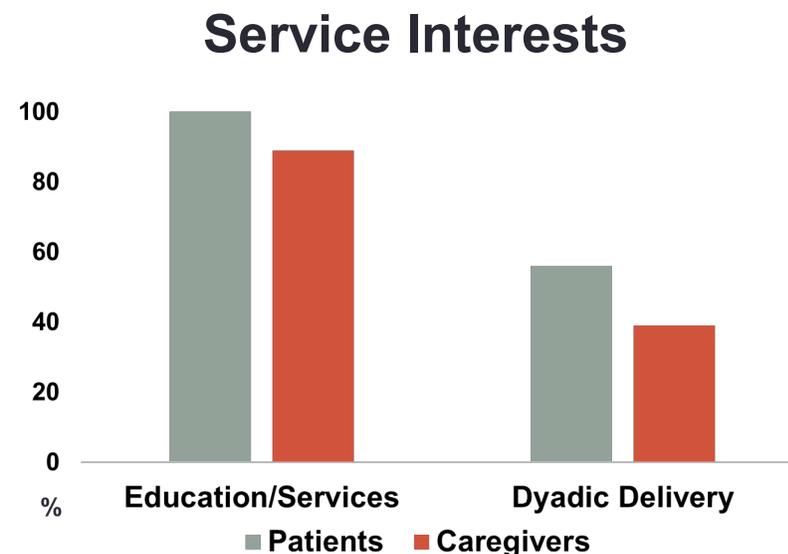
- ~ 18.3% of newly diagnosed cancer patients parent at least one minor child.
- Parental cancer poses unique challenges to patients and their spousal caregivers/coparents.
- Parents with advanced cancer are particularly vulnerable to reporting parenting concerns.
- Spousal caregivers/coparents tend to experience substantial distress due to the competing tasks of caring for their ill partner as well as their child(ren).

Dual Caregiving

- In the aging literature, dual caregiving (“sandwich generation”) has been recognized as a particularly stressful role.
- In the cancer setting, dual caregiving remains largely unaddressed.
- Existing intervention studies are typically focused on the parenting concerns of caregivers of pediatric patients.
- In the adult setting, many families report that their parenting concerns are not addressed by their oncology teams and desire advice and guidance.

Intervention Needs

- Formative research (n=25 patient-caregiver dyads)
- Themes identified through qualitative interviews included:
 - Deciding how to disclose the cancer diagnosis
 - Sharing important information related to treatment and symptoms
 - Concerns about discussing prognosis
 - Difficulty accessing mental health services for the entire family
 - Accessing support network to meet day-to-day family needs
 - Support and communication between spouses



Parenting Intervention Study

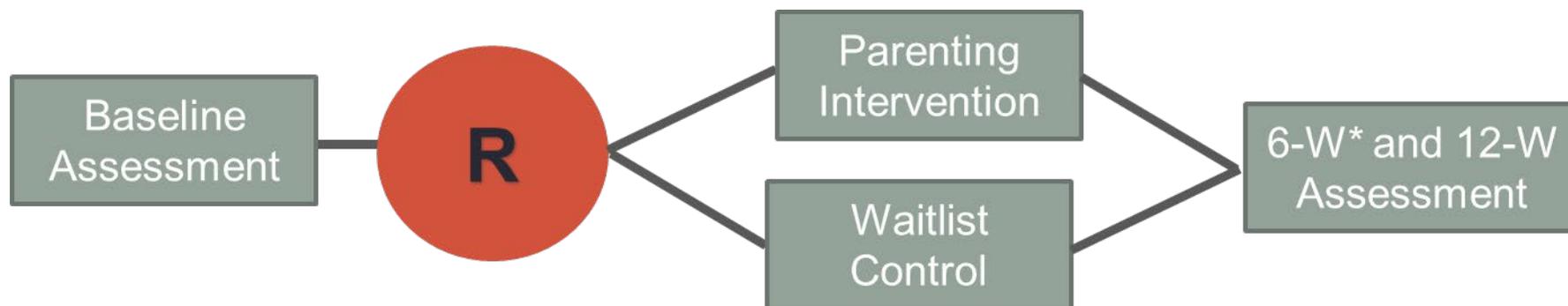
	Format and Topics	Key Elements
1	<u>Dyadic:</u> Illness-Communication	<p>Assessment of:</p> <ul style="list-style-type: none"> • children's current knowledge and exposure • children's coping styles <p>Psychoeducation on:</p> <ul style="list-style-type: none"> • developmentally appropriate language of diagnosis and treatment • children's illness comprehension • typical age-dependent child responses
2	<u>Dyadic:</u> Family Ritual and Legacy Making	<p>Identifying:</p> <ul style="list-style-type: none"> • key areas of family life that have been disrupted • possible solutions to maintaining family routines/rituals • activities that keep the child(ren) connected to the ill parent now and after death
3	<u>Caregiver:</u> Self-Care	<p>Supporting the caregiver in:</p> <ul style="list-style-type: none"> • identifying barriers and facilitators to self-care • activating the social network and accessing other resources • addressing emotions of guilt and anxiety
4	<u>Caregiver:</u> Preparedness for Death	<p>Psychoeducation on:</p> <ul style="list-style-type: none"> • preparing the child(ren) for the parent's death and funeral • typical age-dependent child grief behaviors • identifying complicated grief in children • resources for bereaved children

Current Pilot RCT

- **Aim 1**: Examine the feasibility of implementing a parenting support intervention in patients with an incurable cancer and their spousal caregivers.
- **Aim 2**: Evaluate the initial evidence for intervention efficacy relative to a WLC group regarding patient and spousal caregiver psychological symptoms, parenting concerns and parenting efficacy, and patient EOL healthcare utilization.
- **Aim 3**: Understand the patients' and caregivers' experiences using qualitative methods regarding participation in this study.



Trial Design and Eligibility



N=50 patient-caregiver dyads

Patient	Patient and Caregiver
<ul style="list-style-type: none">• Metastatic or locally recurrent solid malignant tumor	<ul style="list-style-type: none">• ≥18 years old
<ul style="list-style-type: none">• ≥1 dependent child(ren) between the ages of 4 and 16	<ul style="list-style-type: none">• Share joint custody
<ul style="list-style-type: none">• Have a spousal caregiver	<ul style="list-style-type: none">• Speak and read English
	<ul style="list-style-type: none">• Access to the internet

Assessments

Measures	Baseline	6-Week FU	12-Week FU	24-Week FU
Feasibility Indicators	X	X	X	
Hospital Anxiety and Depression Scale	X	X	X	
Parenting Concern Questionnaire	X	X	X	
Cancer-Related Parenting Self-Efficacy Scale	X	X	X	
National Quality Forum metrics	P	P	P	P
Semi-Structured Interview		X		
MD Anderson Symptom Inventory	P			
Prognosis and Treatment Perceptions Questionnaire	X			
Dyadic Adjustment Scale	X			

Progress to Date

- Award 10/01/2021
- Trial activated 1/18/2022
- Enrollment started 2/4/2022

Activity	Dyads, N
Approached	22
Consented	8 (67% consent rate)
Ineligible	6: Children >16 2: Lack of coparent
Declined	3: Not interested 1: Busy with other research
Pending Consent	2
Baseline Completed	7
Started Intervention	4

With Gratitude

Study Co-Investigators



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Building Family Caregiving Skills Using a Simulation-Based Intervention for Care of Patients with Cancer

Supporting the Science of Informal Cancer Caregiving

Building Family Caregiving Skills Using a Simulation-Based Intervention for Care of Patients with Cancer

Susan Mazanec, PhD, RN, AOCN, FAAN
March 17, 2022



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Acknowledgment & Disclosures

- Funding by the National Cancer Institute of the National Institute of Health (R37CA240707)

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-Barbara Boveington-Molter, MS

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Problem

The Caregiving Gap

- Caregiving in the US 2020 (N=1,392)
 - 58% of the surveyed caregivers were performing complex medical/nursing tasks
- Caregivers of Individuals with Cancer – 2016 report from the National Alliance for Caregiving (N = 111)
 - High burden of care; more intense caregiving
 - Varied CG activities: ADLs, IADLs, Communication, Advocate, Monitor
 - 72% assist with medical/nursing tasks
 - 43% performing tasks without any preparation
- **50% - 58% of cancer caregivers report unmet training needs**
(vanRyn et al., 2011; Mollica et al., 2017)

Background

Significance

- Caregiver Physical & Psychological Health
 - Reduce stress to reduce downstream health issues
- Patient Outcomes
 - Positive relationship between CG and Patient psychological distress (Hodges et al., 2005)
 - Systematic review by Griffin et al. (2014): cancer CG interventions improve patient outcomes related to pain & symptom management

Recommendations:

- Tailored, proactive approach
- Address skills training, but also communication & self-care
- Early intervention during the care trajectory
- Reassessment & training at transitions & prn

Background

Simulation

- Student-centered, active learning technique that is effective in training healthcare professionals



Caregiver Intervention



- Designed with interdisciplinary team; manualized intervention
- Delivered to the CG by a research nurses in the clinic
- 3 sessions with Caregiver during XRT at **1st, 3rd, and 6th weeks of XRT**

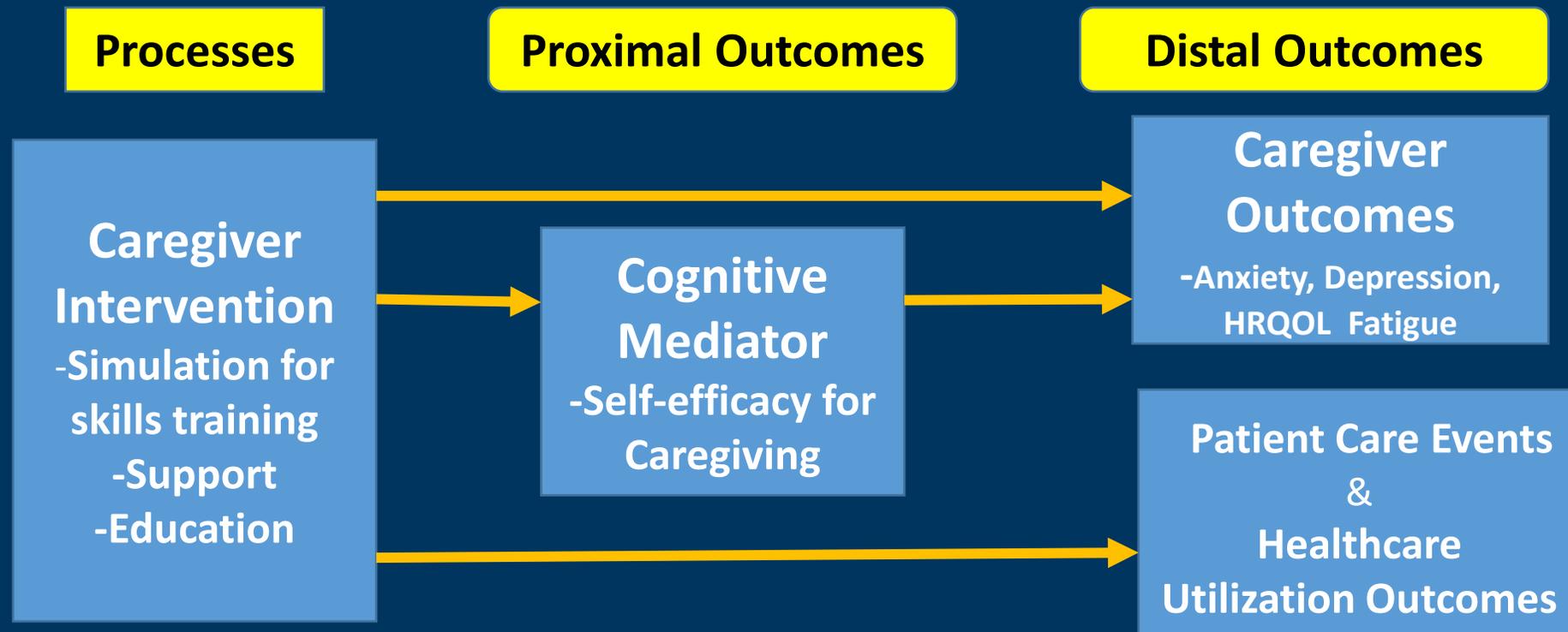
	Theme	Educational Focus	Simulation
1	The Patient's Experience	5 most common symptoms & management	Skills – Tubes, Suctioning, Oral assessment, Skin care
2	The Caregiver & Dyad Experience	5 most common caregiver concerns & self-care; Roles, communication, emotions, intimacy	Role play – health promotion & communication
3	Transition to Survivorship	Common patient and caregiver issues during the immediate transition	Repeat simulations as needed
	Telephone booster	Patient care issues; self-care strategies for caregiver	

Study Aims

- Evaluate the effect of the caregiver intervention, compared to a control group, on
 - CG outcomes:** anxiety, depression, fatigue, HRQOL, self-efficacy for caregiving
 - Patient outcomes:** HRQOL, interrupted radiation therapy
 - Healthcare Utilization outcomes:** Emergency room visits, hospital admissions, & use of IV fluids
- Examine mediators and moderators
- Compare costs between groups & describe costs associated with the intervention

Theoretical Frameworks & Model

- **Design of Intervention**: Self-efficacy & Social Cognitive Theory (Bandura, 1977)
- **Study Model**: Revised Self-and Family Management Framework (Gray et al., 2015)



Methods

- Design: Two-group, randomized controlled trial; RAs blinded
- Setting: University Hospitals Seidman Cancer Center
- Sample: Convenience sample of 180 patients & their caregivers
- **Inclusion Criteria for Patients:**
 - 18 years of age or older, receiving Radiation Therapy for:
 - Stage I-IV A/B Head and Neck cancer, Stage I-III Anal or Rectal cancer, Stage I-IV A Esophageal cancer, or Stage II-III NSCLC
 - Has an identified caregiver who is willing to participate
- **Inclusion Criteria for Caregivers:**
 - 18 years of age or older; Family member or friend of a patient described above
 - Identified by the patient as their primary caregiver
- **Exclusion Criteria:**
 - Hospice & CGs who are themselves undergoing cancer treatment

Treatment Planning Phase		Treatment Phase			Posttreatment Survivorship Phase		
T0	Randomization	T1		T2		T3	T4
Present study & obtain informed consent		1 st week of XRT	3 rd week of XRT	End XRT 6 th -8 th week	2 weeks post XRT	4 weeks post XRT	20 weeks post XRT
	Intervention Group	X	X	X	X		
	Control Group						
Measures M				M		M	M

Control Group: Usual care + NCI booklet, *When Someone you Love is Being Treated for Cancer*, given at enrollment

Intervention Group: Usual care + NCI booklet +
 3 sessions with nurse at 1st, 3rd, and 6th weeks of XRT
 Telephone booster 2 weeks after XRT

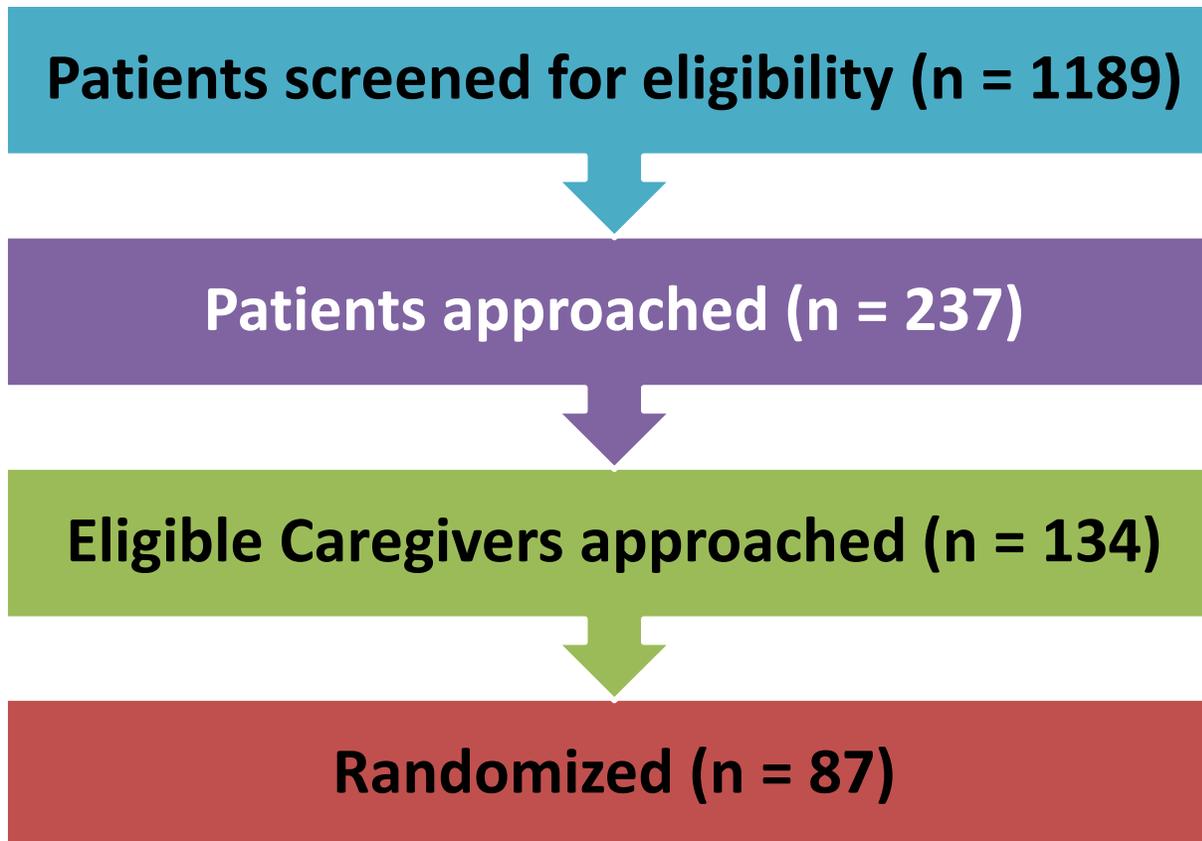
Measures

Outcomes		Instrument
Caregiver	Anxiety, Depression, HRQOL, & Fatigue	PROMIS measures
Patient	HRQOL Interrupted XRT course	FACT disease-specific measures Treatment record
Health Care Utilization	Hospital admissions, emergency room visits, IV fluid use	Medical record
Cognitive Mediator		Instrument
Caregiver	Self-efficacy for caregiving	CG Inventory (Merluzzi) & Self-efficacy scale for managing side effects & specific skills
Potential Moderators		
Illness factors, performance status, use of services, care demands		



Progress

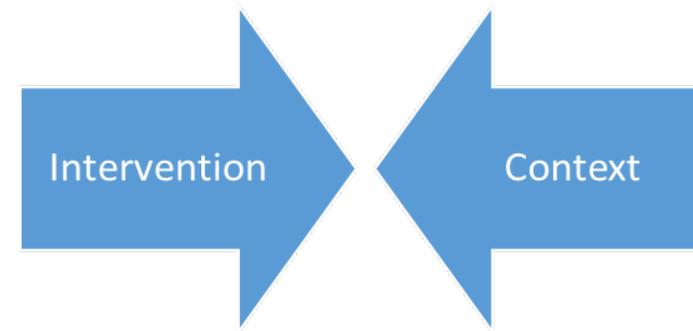
- Awarded July 2019; opened to enrollment Dec. 2019
- Recruitment is ongoing at 2 sites



Challenges

- **Pandemic pivot**
 - Intervention
 - Retained all sessions and content
 - Kept first session, including simulations, as in-person with COVID-19 safety procedures
 - Conducted Session 2 and 3 with role play simulations remotely
 - Recruitment & consent procedures – hybrid approach
 - Changes will be evaluated for impact on study validity
- **Timing of enrollment & challenge of consenting dyads**
 - Primary refusal reasons:
 - PT = “CG does not need intervention”
 - CG = “Overwhelmed/busy”
 - Strategies: (1) Collaboration with physicians and clinical staff in introducing study, and (2) Training of RAs

Lessons Learned



- **Flexibility of complex clinical intervention**

- Caregivers often have needs beyond scope of study
- Need for comprehensive fidelity measures to monitor delivery, receipt, & enactment of the intervention

- **Screening for health literacy**

- 37% have limited to marginal health literacy scores
- Training of all staff to use universal health literacy strategies

- **Next Steps:** Expansion to other clinical sites with goal of sample diversification



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Questions?

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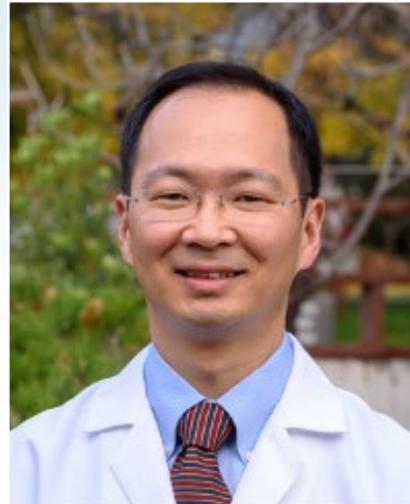


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**Supporting the Science of Informal Cancer Caregiving:
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