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

Webinar 3 – Thursday, March 17, 2022 1 PM ET
Using WebEx and webinar logistics

- All lines will be in listen-only mode
- Submit questions at any time using the Q&A or Chat Panel and select *All Panelists*
- You may need to activate the appropriate box using the floating navigation panel. Found on the bottom of your screen
- This webinar is being recorded
Welcome to Webinar 3

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ICF, Outcomes Research Branch, Healthcare Delivery Research Program
Division of Cancer Control and Population Sciences
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Webinar Outline

• **Presentation 1: Drs. Prigerson and Lichtenthal** – “Enhancing and Mobilizing the POrential 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

Holly G. Prigerson, PhD
Irving Sherwood Wright Professor in Geriatrics
Professor of Sociology in Medicine
Director, Cornell Center for Research on End-of-Life Care
Department of Medicine
Weill Cornell Medicine

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Holly G. Prigerson, PhD
Wendy G. Lichtenthal, PhD, FT

“Enhancing and Mobilizing the POTential 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

Holly G. Prigerson, Ph.D.
Irving Sherwood Wright Professor in Geriatrics
Professor of Sociology in Medicine,
Weill Cornell Medicine
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NCI Cancer Caregiver Webinar
March 17, 2022
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
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
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
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

So what is EMPOWER?
Enhancing & Mobilizing the POTential for Wellness & Emotional Resilience
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.

**Conceptual Model:**

**EMPOWER Improves Mental Health by Reducing Experiential Avoidance**

- **EMPOWER**
  - Acknowledge potentially traumatic situation
  - Engage in mindfulness, breathing, & grounding exercises
  - Provide psychoeducation re: pre-loss grief, peritraumatic stress & experiential avoidance
  - Review cognitive-behavioral and acceptance-based strategies to build distress tolerance
  - Invoke patient’s values and perspective to aid in surrogate decision-making

**Timeline**

- Patient ICU Admission
- Surrogate Mental Health: 1, 3, 6, 12 Months from T1/Baseline

- **Experiential Avoidance**

**Improved Mental Health**

- Family Surrogate
  - < PGD symptoms
  - < PTSD symptoms
  - < Decisional Regret

**EMPOWER = Enhancing & Mobilizing the Potential for Wellness & Emotional Resilience**

**PGD = Prolonged Grief Disorder**
<table>
<thead>
<tr>
<th>In ICU/Telehealth</th>
<th>Delivered in single or multiple sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 1</td>
<td>Nurturance, Understanding, and Joining</td>
</tr>
<tr>
<td>Module 2</td>
<td>Breathing Retraining, Grounding Exercises, and Mindfulness Meditation</td>
</tr>
<tr>
<td>Module 3</td>
<td>Psychoeducation about Trauma, Grief, and the Cognitive-Behavioral Model</td>
</tr>
<tr>
<td>Module 4</td>
<td>Increasing Acceptance and Sense of Permission to Experience Challenging Emotions</td>
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<tr>
<td>Module 5</td>
<td>Connecting with the Patient’s Voice</td>
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<tr>
<td>Module 6</td>
<td>Using the EMPOWER Toolbox and Coping Rehearsal</td>
</tr>
<tr>
<td>Phone/Telehealth</td>
<td>2 weeks post-Module 6</td>
</tr>
<tr>
<td>Phone/Telehealth</td>
<td>4 weeks post-Module 6</td>
</tr>
</tbody>
</table>
## Preliminary Results

<table>
<thead>
<tr>
<th>Measure</th>
<th>Post-intervention</th>
<th>One-month Follow-up</th>
<th>Three-month follow-up</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Cohen’s d</td>
<td>n</td>
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<tr>
<td>Grief Intensity (PG-12/13)</td>
<td>20</td>
<td>-1.39</td>
<td>16</td>
</tr>
<tr>
<td>State Anxiety (STAI)</td>
<td>16</td>
<td>-0.58</td>
<td>11</td>
</tr>
<tr>
<td>Depression (PHQ-9)</td>
<td>-</td>
<td>-</td>
<td>17</td>
</tr>
<tr>
<td>Peritraumatic Distress (PDI)</td>
<td>17</td>
<td>-0.16</td>
<td>12</td>
</tr>
<tr>
<td>Traumatic Stress (IES-R)</td>
<td>11</td>
<td>-0.45</td>
<td>10</td>
</tr>
<tr>
<td>Experiential Avoidance (BEAQ)</td>
<td>25</td>
<td>-0.25</td>
<td>18</td>
</tr>
<tr>
<td>Decision Regret (DRS)</td>
<td>8</td>
<td>-1.38</td>
<td>8</td>
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</tbody>
</table>

Note. Between-groups Cohen’s d comparing EMPOWER to EUC.
## Preliminary Results

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

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

**Reduced Experiential Avoidance May Mediate Changes**

- **Timeline**
  - **Patient ICU Admission**
  - **Surrogate Mental Health**
    - 1, 3, 6, 12 Months from T1/Baseline

**Experiential Avoidance**
- Acknowledge potentially traumatic situation
- Engage in mindfulness, breathing, & grounding exercises
- Provide psychoeducation re: pre-loss grief, peri-traumatic stress & experiential avoidance
- Review cognitive-behavioral and acceptance-based strategies to build distress tolerance
- Involve patient’s values and perspective to aid in surrogate decision-making

**EMPOWER**
- Enhancing & Mobilizing the PC tential for Wellness & Emotional Resilience
- PGD = Prolonged Grief Disorder
“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
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

This work is supported by the National Cancer Institute (NCI) grant R21 CA218313 (Prigerson/Lichtenthal) and the American Cancer Society (ACS) grant 130534-PEP-17-053-01-PCSM (Prigerson/Lichtenthal). Clinicaltrials.gov Registration # NCT03276550
Thank you!

For questions or suggestions, please contact Holly Prigerson at hgp2002@med.cornell.edu or Wendy Lichtenthal at lichtenw@mskcc.org.
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

Kathrin Milbury, PhD
Associate Professor
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

Whisenant….Milbury, under review
## Parenting Intervention Study

<table>
<thead>
<tr>
<th>Format and Topics</th>
<th>Key Elements</th>
</tr>
</thead>
</table>
| **1** Dyadic: Illness-Communication | Assessment of:  
- children's current knowledge and exposure  
- children's coping styles  
Psychoeducation on:  
- developmentally appropriate language of diagnosis and treatment  
- children's illness comprehension  
- typical age-dependent child responses |
| **2** Dyadic: Family Ritual and Legacy Making | Identifying:  
- 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** Caregiver: Self-Care | Supporting the caregiver in:  
- identifying barriers and facilitators to self-care  
- activating the social network and accessing other resources  
- addressing emotions of guilt and anxiety |
| **4** Caregiver: Preparedness for Death | Psychoeducation on:  
- 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.

NCI R21CA256694
Trial Design and Eligibility

N=50 patient-caregiver dyads

<table>
<thead>
<tr>
<th>Patient</th>
<th>Patient and Caregiver</th>
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</thead>
<tbody>
<tr>
<td>• Metastatic or locally recurrent solid malignant tumor</td>
<td>• ≥18 years old</td>
</tr>
<tr>
<td>• ≥1 dependent child(ren) between the ages of 4 and 16</td>
<td>• Share joint custody</td>
</tr>
<tr>
<td>• Have a spousal caregiver</td>
<td>• Speak and read English</td>
</tr>
<tr>
<td></td>
<td>• Access to the internet</td>
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</table>
## Assessments

<table>
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<tr>
<th>Measures</th>
<th>Baseline</th>
<th>6-Week FU</th>
<th>12-Week FU</th>
<th>24-Week FU</th>
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<tbody>
<tr>
<td>Feasibility Indicators</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Hospital Anxiety and Depression Scale</td>
<td>X</td>
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<td>X</td>
<td></td>
</tr>
<tr>
<td>Parenting Concern Questionnaire</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Cancer-Related Parenting Self-Efficacy Scale</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>National Quality Forum metrics</td>
<td>P</td>
<td>P</td>
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<td>P</td>
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<tr>
<td>Semi-Structured Interview</td>
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<td></td>
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<td>X</td>
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<tr>
<td>MD Anderson Symptom Inventory</td>
<td>P</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Prognosis and Treatment Perceptions Questionnaire</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Dyadic Adjustment Scale</td>
<td>X</td>
<td></td>
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</table>
### Progress to Date

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Dyads, N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approached</td>
<td>22</td>
</tr>
<tr>
<td>Consented</td>
<td>8 (67% consent rate)</td>
</tr>
<tr>
<td>Ineligible</td>
<td>6: Children &gt;16</td>
</tr>
<tr>
<td></td>
<td>2: Lack of coparent</td>
</tr>
<tr>
<td>Declined</td>
<td>3: Not interested</td>
</tr>
<tr>
<td></td>
<td>1: Busy with other research</td>
</tr>
<tr>
<td>Pending Consent</td>
<td>2</td>
</tr>
<tr>
<td>Baseline Completed</td>
<td>7</td>
</tr>
<tr>
<td>Started Intervention</td>
<td>4</td>
</tr>
</tbody>
</table>
With Gratitude

Study Co-Investigators

Sujin Ann-Yi, MFT, PhD
Meagan Whisenant, PhD, APRN
Eduardo Bruera, MD
Yisheng Li, PhD

Research Team
- Stella Snyder, MS
- Victoria Necreto, LPC
- Morgan Jones, MA
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
Acknowledgment & Disclosures

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

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Rod Rezaee, MD
Ethen Singer, PhD
Kate Sandstron, APRN-BC

Nurse Interventionists:
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- Emily Hayden, RN
- Debby Hornick, RN
- Claudia Shipman, RN

Research Assistants:
- Pat Brandt, BS
- Barbara Boveington-Molter, MS
- Sumin Park, MSN, RN
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

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

**Processes**

- Caregiver Intervention
  - Simulation for skills training
  - Support
  - Education

**Proximal Outcomes**

- Cognitive Mediator
  - Self-efficacy for Caregiving

**Distal Outcomes**

- Caregiver Outcomes
  - Anxiety, Depression, HRQOL, Fatigue
- Patient Care Events & Healthcare Utilization Outcomes
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
<table>
<thead>
<tr>
<th>Treatment Planning Phase</th>
<th>Treatment Phase</th>
<th>Posttreatment Survivorship Phase</th>
</tr>
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<tbody>
<tr>
<td>Present study &amp; obtain informed consent</td>
<td><strong>T0</strong> Randomization</td>
<td>T1</td>
</tr>
<tr>
<td><strong>Intervention Group</strong></td>
<td>1&lt;sup&gt;st&lt;/sup&gt; week of XRT</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; week of XRT</td>
</tr>
<tr>
<td><strong>Control Group</strong></td>
<td></td>
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</table>

| Measures | 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 1<sup>st</sup>, 3<sup>rd</sup>, and 6<sup>th</sup> weeks of XRT
Telephone booster 2 weeks after XRT
# Measures

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Instrument</th>
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<tbody>
<tr>
<td>Caregiver Anxiety, Depression, HRQOL, &amp; Fatigue</td>
<td>PROMIS measures</td>
</tr>
<tr>
<td>Patient HRQOL Interrupted XRT course</td>
<td>FACT disease-specific measures Treatment record</td>
</tr>
<tr>
<td>Health Care Utilization Hospital admissions, emergency room visits, IV fluid use</td>
<td>Medical record</td>
</tr>
</tbody>
</table>

## Cognitive Mediator

<table>
<thead>
<tr>
<th>Caregiver Self-efficacy for caregiving</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caregiver</td>
<td>CG Inventory (Merluzzi) &amp; Self-efficacy scale for managing side effects &amp; specific skills</td>
</tr>
</tbody>
</table>

## 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

- Patients screened for eligibility (n = 1189)
- Patients approached (n = 237)
- Eligible Caregivers approached (n = 134)
- Randomized (n = 87)
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
References


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