



Published in final edited form as:

*J Geriatr Oncol.* 2020 March ; 11(2): 347–349. doi:10.1016/j.jgo.2019.07.019.

## Behavioral, Psychological, and Supportive Care Interventions in Geriatric Oncology: The Cancer and Aging Group Infrastructure Core

Rawad Elias<sup>a,1,\*</sup>, Kah Poh Loh<sup>b,1</sup>, Valerie Targia<sup>c</sup>, Mary Whitehead<sup>c</sup>, Beverly Canin<sup>c</sup>, Aminah Jatoi<sup>d</sup>, Matthew Loscalzo<sup>e</sup>, Supriya Mohile<sup>b</sup>

<sup>a</sup>Hartford Healthcare Cancer Institute, 85 Retreat Ave, Hartford, CT, 06103, United States

<sup>b</sup>James P. Wilmot Cancer Institute, University of Rochester Medical Center, 601 Elmwood Avenue, Box 704, Rochester, NY, 14620, United States

<sup>c</sup>SCOREboard Advisory Group

<sup>d</sup>Department of Oncology, Mayo Medical School, Rochester, MN, 55905, United States

<sup>e</sup>Department of Supportive Care and Department of Population Sciences, City of Hope Comprehensive Cancer Centre, 1500 E Duarte Rd, Duarte, CA, 91010, United States

### Abstract

Current research efforts focusing on improving outcomes of older adults with cancer lack the appropriate infrastructure to support this growing need. The Cancer and Aging Group R21/33 National Institute of Health (NIH)/National Institute of Aging (NIA) grant aims to support development of geriatric oncology research through dedicated cores. The mission of the Core on Behavioral, Psychological, and Supportive Care Interventions will be to provide guidance in the field of non-pharmacological interventions. The Core will provide investigators with expertise, advocacy, and support in study design, development, and execution.

### Keywords

Geriatric Oncology; Research Infrastructure; Interventions

---

\*Corresponding author at: Hartford HealthCare Cancer Institute, 85 Retreat Ave, Hartford, CT 06106. rawad.elias@hhchealth.org.

Author contribution:

Conception and Design: Rawad Elias and Kah Poh Loh

Data Collection: Rawad Elias and Kah Poh Loh

Analysis of Interpretation of Data: Rawad Elias and Kah Poh Loh

Manuscript writing: All authors

Approval of Final Article: All authors

<sup>1</sup>Rawad Elias and Kah Poh Loh contributed equally to this manuscript.

**Publisher's Disclaimer:** This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

## 1. Introduction

The Cancer and Aging Research group (CARG) is a pan-disciplinary, collaborative network of investigators whose primary focus is to improve the care of older adults with cancer through research and other scholarly activities. CARG has expanded greatly since its formation under the leadership of Dr. Arti Hurria. It is now comprised of researchers from more than 70 institutions and has enrolled over 1500 patients in research studies.

Aging is associated with multiple changes that manifest as various impairments in the older adult.<sup>1</sup> These impairments vary widely among older patients based on the interaction of multiple factors such as comorbidity, functional status, psychologic, socioeconomic, and cognition.<sup>2</sup> Although older adults constitute the majority of patients with cancer, they have been historically underrepresented in oncology clinical trials. Therefore, many older adults are treated based on data derived from a younger or fitter patient population.<sup>3</sup> With the increasing number of older adults, it is important to address the challenges of treating older patients with cancer.

A comprehensive geriatric assessment (CGA) identifies vulnerabilities in older patients that are not detected by routine examination, predicts potential treatment-related complications, estimates survival, and facilitates treatment decisions in older adults with cancer.<sup>4</sup> Impairments identified by the assessment can guide implementation of supportive care interventions with the goal of improving outcomes in older adults with cancer.<sup>5</sup> These interventions were associated with improved survival in older adults, however data specific to older patients with cancer is lacking.<sup>6</sup> This is particularly true for behavioral, psychological and supportive care interventions.

## 2. The CARG R21/33 Infrastructure Grant

Older patients with cancer are at increased risk for treatment-related complications. Despite significant efforts, such as the development of chemotherapy toxicity prediction tools, limited information is available to guide the management of older adults.<sup>3,7,8</sup> Interventions focused on supportive measures are critical to improve outcomes of older patients receiving cancer treatment. However, little data is available regarding the development and implementation of these interventions.<sup>5</sup> This research gap will become more notable with the increase in the aging population and the advent of treatments that pose new challenges, as in the case of immunotherapeutic agents and targeted therapies. Therefore, a more robust geriatric oncology research infrastructure is needed to address this age-related healthcare disparity. Early investigators interested in pursuing research on cancer and aging are often under-supported and isolated within their institutions. In fact, only a limited number of institutions offers training in geriatric oncology or has faculty dedicated to investigating cancer in older adults.<sup>9,10</sup>

Although CARG has been successful in enhancing geriatric oncology evidence, its current structure is based on personal initiative and collaborations. The goal of the CARG infrastructure R21/33 grant in partnership with the National Institutes of Health (NIH) / Aging (NIA) is to foster geriatric oncology research efforts leading to improvement in the

clinical care of older adults with cancer. This infrastructure through the cores aims to support investigators exploring questions related to cancer and aging by providing expertise and resources, including pilot funding, that will help facilitate individual's research and career development. The broad mission is to encourage early investigative efforts and accelerate transition into large studies that will lead to high-impact contributions to the geriatric oncology evidence repository.

### **3. The CARG R21/33 Core: behavioral, psychological and supportive care interventions.**

Several Cores constitute the foundation of the CARG infrastructure. The areas of expertise covered by these Cores are: 1) Clinical and biological measures of aging, 2) Behavioral, psychological and supportive care interventions, 3) Care delivery and comparative effectiveness research, 4) Biostatistics and 5) Dissemination and communications.

Behavioral interventions generally refer to non-pharmacological procedures that aim to understand, modify, or change patient behaviors. These interventions can target various domains such as physical activity, nutrition, psychosocial, and cognition. Supportive care, as defined by the National Cancer Institute (NCI), refers to care provided to improve the quality of life of patients who have a serious or life threatening illness.<sup>11</sup> Supportive care interventions aim to prevent or treat symptoms, side effects, and psychological, social, spiritual problems related to a disease or its treatment. Behavioral and supportive care interventions may often overlap.<sup>11</sup>

The design and conduct of behavioral and supportive care interventions for older adults with cancer have a unique set of challenges. These include frequent exclusion of older patients with poor baseline physiologic capacity, complexity of the health of older adults, and high attrition due to factors associated with aging.<sup>12</sup>

Several white papers from the U13 conference, "Geriatric Oncology Research to Improve Clinical Care", highlighted areas of highest research priority and gaps: 1) Develop and test interventions tailored for older patients with cancer (e.g., based on needs, capacity, barriers, and specific outcome), 2) Consider pragmatic and alternative trial designs to facilitate recruitment, 3) Incorporate outcomes relevant to older adults (e.g., function and quality of life instead of aerobic capacity for exercise trials), 4) Incorporate stakeholder involvement, and 5) Consider dissemination and implementation strategies.<sup>12-16</sup>

To help illustrate strategies to address the aforementioned gaps, we describe several ongoing and recently completed studies. Nelson et al. conducted a pilot randomized trial of a psychotherapy intervention specific to older adults with cancer.<sup>17</sup> The telephone-facilitated psychotherapy intervention [Cancer and Aging: Reflections for Elders (CARE)] allowed enrollment of older patients who are frail and those who have difficulty with transportation (Gap 1). In addition, the investigators sought feedback from stakeholders in its early development (Gap 4). Pergolotti et al. also conducted a randomized controlled trial of occupational and physical therapy that incorporated endpoint relevant to older adults with cancer (i.e., activities of daily living and patient-reported measures; Gap 3).<sup>18</sup> Mohile et al.

conducted a cluster randomized controlled trial on whether providing a geriatric assessment (GA) summary and GA-driven recommendations to patients, their caregivers, and oncologists improve communication and patient/caregiver satisfaction.<sup>19</sup> This national study illustrated the use of a pragmatic trial to facilitate recruitment of older adults with cancer seen in their community oncology setting (Gap 2) and patient stakeholders to inform the conduct of the trial (Gap 4), which will guide future dissemination and implementation strategies (Gap 5). While not exclusive to older adults, the Healthy Living after Cancer (HLaC) is a dissemination and implementation study on a multicomponent behavioral intervention and incorporated endpoints related to implementation and effectiveness.<sup>20</sup> Such design will promote the dissemination and implementation of the intervention, thereby promoting its uptake (Gap 5).

The mission of this Core is to support investigators in the design and conduct of studies that are evaluating interventions in behavioral, psychological, and supportive care domains in order to improve the outcomes of older adults with cancer. The Core's broad function will be to serve as a point of contact for researchers and support them by providing direct input through consultation services or connecting them to outside expertise when not available within the Core. The Core will advocate for researchers by linking them to existing resources and, particularly in the case of young investigators, provide them with adequate support within and outside their institutions. Recruitment of older adults to studies is essential for high-impact geriatric oncology research, and therefore the Core will provide investigators with expertise in recruitment strategies. A substantial component of the Core's function includes regular mentoring of the investigators and linking them with members from other cores as needed. Table 1 illustrates the potential areas in need and how the Core can support investigators in these areas. The Core will provide recommendations and guidance in various areas including study design, eligibility criteria, intervention development and adaptation, intervention quality and fidelity, outcomes, and assessment tools. In addition, the Core will develop a repository that house commonly used conceptual and theoretical framework, study measures, assessment tools, and active behavioral placebo controls, where investigators can access to.

To achieve these goals, we will create standard operating procedures that will help to ensure that investigators can work efficiently with the Core. The creation of an on-line platform located on [www.mycarg.org](http://www.mycarg.org) is going to be essential for the Core workflow. This platform will offer investigators a portal to connect with the Core and place requests electronically for assistance in the Core's area of expertise. In addition, it will allow Core members to triage these requests. It will be important, in this process, to implement follow-up procedures for tracking purposes. A principal feature of this platform will be a library of resources, either already existent or created by the Core, that will facilitate to investigators access to relevant data and established expertise. We will also create a structure to ensure regular communication with the other Cores to establish best practices for the larger program and to identify investigators whose work spans multiple areas. Finally, the Core will identify innovative approaches to allow for the sustainability of the group and its mission following the end of the parent grant. Among the potential sources for funding could be through senior investigators in CARG using the Cores for their R01 studies, or by being a potential resource for researchers in other collaborative groups, or through NIH mechanisms.

## 4. Conclusion

Advancement of geriatric oncology research is critical to improve the care of older adults with cancer. However, current research efforts dedicated to cancer and aging lack robust infrastructure to support this growing need. Through dedicated infrastructure Cores, the CARG R21/33 NIH/NIA grant will aim to support investigators and facilitate their research development. The mission of the Core on Behavioral, Psychological, and Supportive Care Interventions is to provide expertise and guidance in the field of non-pharmacological interventions. Over the last years, CARG members have continued their passion and commitment to the field of geriatric oncology. The R21/33 grant will allow CARG members to structure their dedication and expertise leading to an impactful growth in geriatric oncology research.

## References

1. Soto-Perez-de-Celis E, Li D, Yuan Y, et al.: Functional versus chronological age: geriatric assessments to guide decision making in older patients with cancer. *Lancet Oncol* 19:e305–e316, 2018 [PubMed: 29893262]
2. Inouye SK, Studenski S, Tinetti ME, et al.: Geriatric syndromes: clinical, research, and policy implications of a core geriatric concept. *J Am Geriatr Soc* 55:780–91, 2007 [PubMed: 17493201]
3. Hurria A, Levit LA, Dale W, et al.: Improving the Evidence Base for Treating Older Adults With Cancer: American Society of Clinical Oncology Statement. *J Clin Oncol* 33:3826–33, 2015 [PubMed: 26195697]
4. Rittmeyer A, Barlesi F, Waterkamp D, et al.: Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicentre randomised controlled trial. *Lancet*, 2016
5. Mohile SG, Velarde C, Hurria A, et al.: Geriatric Assessment-Guided Care Processes for Older Adults: A Delphi Consensus of Geriatric Oncology Experts. *J Natl Compr Canc Netw* 13:1120–30, 2015 [PubMed: 26358796]
6. Soubeyran P, Terret C, Bellera C, et al.: Role of geriatric intervention in the treatment of older patients with cancer: rationale and design of a phase III multicenter trial. *BMC Cancer* 16:932, 2016 [PubMed: 27908282]
7. Hurria A, Togawa K, Mohile SG, et al.: Predicting chemotherapy toxicity in older adults with cancer: a prospective multicenter study. *J Clin Oncol* 29:3457–65, 2011 [PubMed: 21810685]
8. Extermann M, Boler I, Reich RR, et al.: Predicting the risk of chemotherapy toxicity in older patients: the Chemotherapy Risk Assessment Scale for High-Age Patients (CRASH) score. *Cancer* 118:3377–86, 2012 [PubMed: 22072065]
9. Maggiore RJ, Dale W, Buss MK, et al.: Survey of geriatric oncology (geri our) training among hematology/oncology (hem/onc) fellows. *Journal of Clinical Oncology* 32, 2014
10. Maggiore RJ, Gorawara-Bhat R, Levine SK, et al.: Perceptions, attitudes, and experiences of hematology/oncology fellows toward incorporating geriatrics in their training. *J Geriatr Oncol* 5:106–15, 2014 [PubMed: 24484724]
11. Van Allen EM, Wagle N, Sucker A, et al.: The genetic landscape of clinical resistance to RAF inhibition in metastatic melanoma. *Cancer Discov* 4:94–109, 2014 [PubMed: 24265153]
12. Kilari D, Soto-Perez-de-Celis E, Mohile SG, et al.: Designing exercise clinical trials for older adults with cancer: Recommendations from 2015 Cancer and Aging Research Group NCI U13 Meeting. *J Geriatr Oncol* 7:293–304, 2016 [PubMed: 27197916]
13. Mohile SG, Hurria A, Cohen HJ, et al.: Improving the quality of survivorship for older adults with cancer. *Cancer* 122:2459–568, 2016 [PubMed: 27172129]
14. Nipp RD, Yao NA, Lowenstein LM, et al.: Pragmatic study designs for older adults with cancer: Report from the U13 conference. *J Geriatr Oncol* 7:234–41, 2016 [PubMed: 27197914]

15. Presley CJ, Dotan E, Soto-Perez-de-Celis E, et al.: Gaps in nutritional research among older adults with cancer. *J Geriatr Oncol* 7:281–92, 2016 [PubMed: 27197919]
16. Loh KP, Janelins MC, Mohile SG, et al.: Chemotherapy-related cognitive impairment in older patients with cancer. *J Geriatr Oncol* 7:270–80, 2016 [PubMed: 27197918]
17. Nelson CJ, Saracino RM, Roth AJ, et al.: Cancer and Aging: Reflections for Elders (CARE): A pilot randomized controlled trial of a psychotherapy intervention for older adults with cancer. *Psychooncology* 28:39–47, 2019 [PubMed: 30296337]
18. Pergolotti M, Deal AM, Williams GR, et al.: Older Adults with Cancer: A Randomized Controlled Trial of Occupational and Physical Therapy. *J Am Geriatr Soc* 67:953–960, 2019 [PubMed: 31034594]
19. Mohile SG, Epstein RM, Hurria A, et al.: Improving communication with older patients with cancer using geriatric assessment (GA): A University of Rochester NCI Community Oncology Research Program (NCORP) cluster randomized controlled trial (CRCT). *Journal of Clinical Oncology* 36:LBA10003–LBA10003, 2018
20. Eakin EG, Hayes SC, Haas MR, et al.: Healthy Living after Cancer: a dissemination and implementation study evaluating a telephone-delivered healthy lifestyle program for cancer survivors. *BMC Cancer* 15:992, 2015 [PubMed: 26690258]

**Table 1:**

Potential areas of needs and examples of how the Core can support investigators in these areas

Areas	Examples of how the Behavioral, Psychological, and Supportive Care Interventions Core can support investigators
Mentorship and collaboration in behavioral and supportive care intervention for older adults	<ul style="list-style-type: none"> <li>• The core will pair junior investigators who need mentorship in behavioral and supportive care intervention research with senior investigators (in collaboration with the Mentorship Core). The senior investigators may subsequently serve as a mentor or an advisor.</li> <li>• The core will facilitate collaborations among investigators interested in behavioral and supportive care interventions for older adults, ultimately leading to multiple principle investigator grants.</li> </ul>
Grant and protocol development	<ul style="list-style-type: none"> <li>• The investigators will present their grant proposal and protocol to the core and senior investigators for feedback.</li> <li>• The core will identify reviewers to assist with grant and protocol development.</li> <li>• The core will provide resources on grant funding mechanisms that are relevant to behavioral and supportive care interventions.</li> </ul>
Study design	The core will provide recommendations and resources on various study designs relevant to behavioral and supportive care interventions (e.g., mixed-method design, factorial design, multiphase optimization strategy; in collaboration with the Care Delivery and Comparative Effectiveness Research Core).
Eligibility criteria	The core will provide recommendations on appropriate eligibility criteria, striking the balance between the ability to meet the target accrual vs. excluding frail patients who may benefit the most from the intervention.
Recruitment and retention strategies for older adults	<ul style="list-style-type: none"> <li>• The core will provide examples of recruitment materials that are tailored to older adults (e.g., flyers, brochures).</li> <li>• The core will provide recommendations on optimal recruitment and retention strategies when enrolling older adults (e.g., appropriate incentives, assessment interval).</li> </ul>
Intervention development and adaptation	<ul style="list-style-type: none"> <li>• The investigators will be able to obtain feedback from patient advocates and stakeholders early during the development and adaptation process.</li> <li>• The core will provide develop a repository of active behavioral placebo controls and conceptual and theoretical framework relevant to behavioral and intervention research.</li> </ul>
Intervention quality and fidelity	The core will provide recommendations, guidance, and strategies to ensure that intervention is delivered in a high quality and consistent manner.
Study outcomes	<ul style="list-style-type: none"> <li>• The core will provide recommendations on study outcomes that are relevant to older adults (e.g., ability to perform activities at home).</li> <li>• The core will provide guidance on relevant study measures that will promote subsequent effort in dissemination and implementation (in collaboration with the Dissemination and Communications Core).</li> </ul>
Assessment tools	The core will develop a repository of commonly used assessment tools in studies of behavioral and supportive care interventions for older adults, to assist investigators (in collaboration with the Clinical and Biological Measures of Aging Core).
Statistical support	The Core will assist with statistical and power analyses for studies of behavioral and supportive care interventions (in collaboration with the Biostatistics Core).