A Geriatric Assessment (GA) intervention to reduce treatment toxicity in older patients with advanced cancer: A University of Rochester Cancer Center NCI Community Oncology Research Program cluster randomized controlled trial (CRCT)

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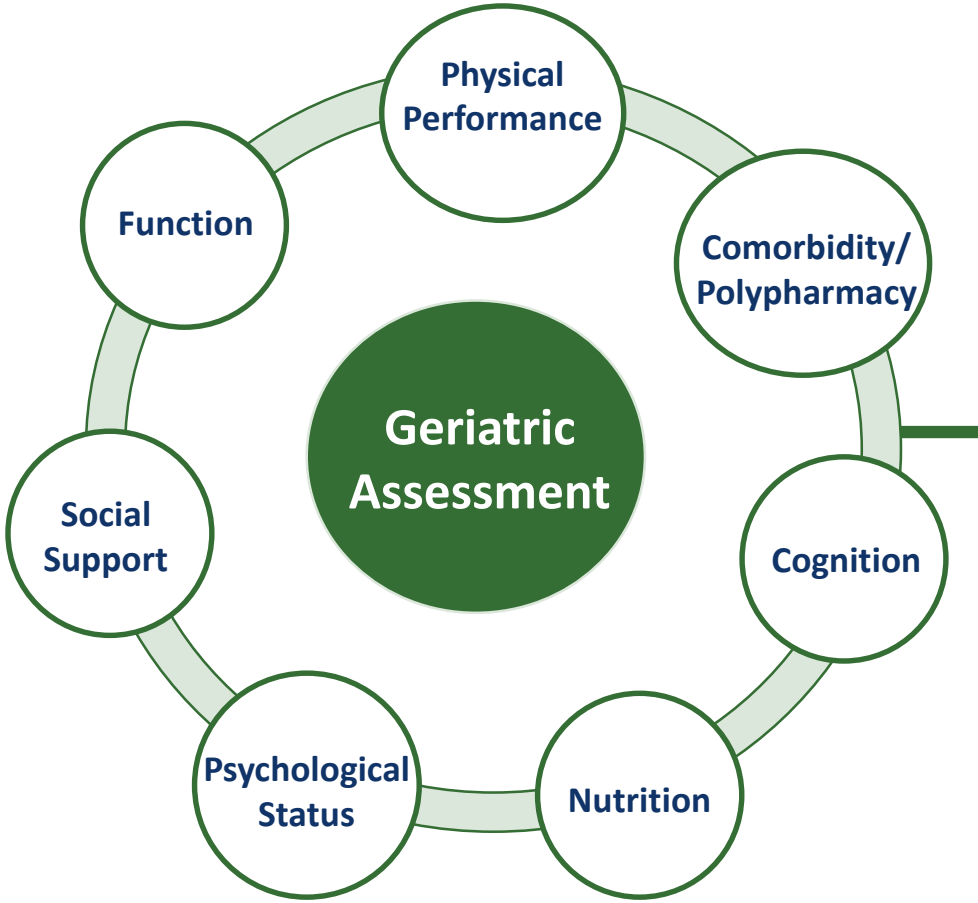
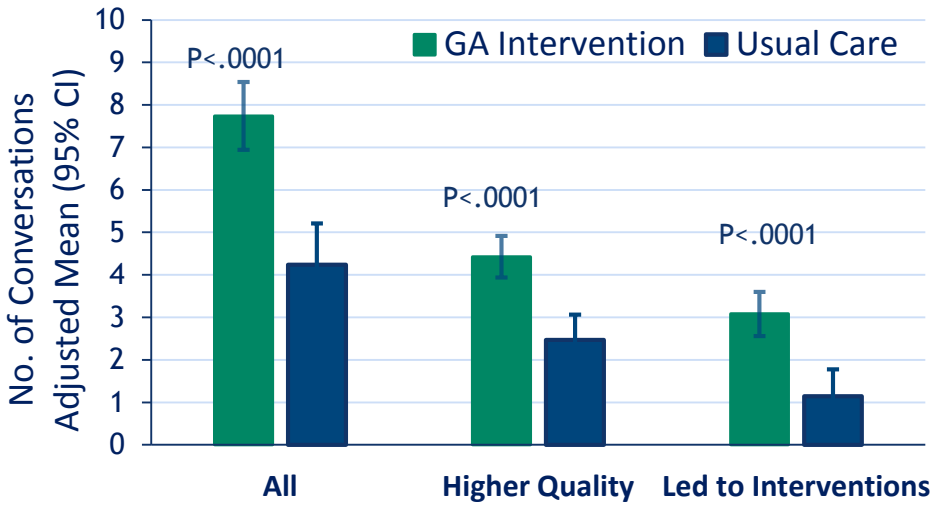
Benefits of the Geriatric Assessment



- Predicts toxicity and mortality
- Guides decisions and care management
- Fosters communication
- Improves clinical outcomes

Improves Communication About Age-Related Concerns

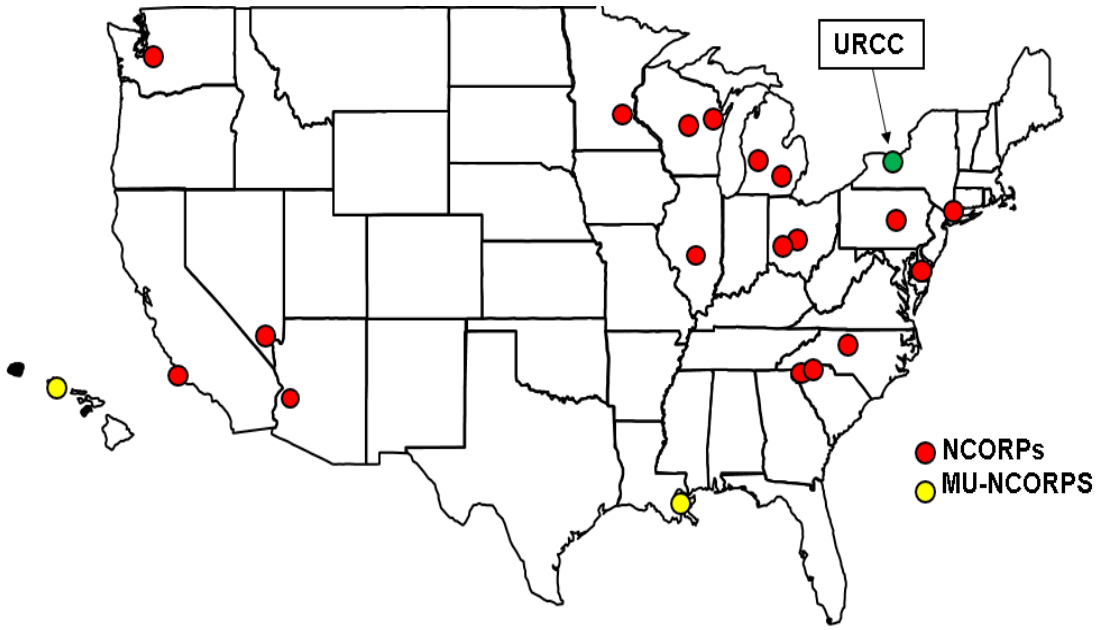


Soto-Perez-de-Celis et al. The Lancet 2018;Hurria et al. JCO 2016
Mohile et al. JAMA Onc 2019

Aims of this University of Rochester NCI Community Oncology Research (NCORP) Study

- **Primary Aim:**
  - To evaluate if providing a GA summary with recommendations for management to oncologists reduces **grade 3-5 toxicity** (CTCAE v4) in patients aged 70+ starting a new regimen with chemotherapy and/or other agents which cause toxicity for advanced cancer

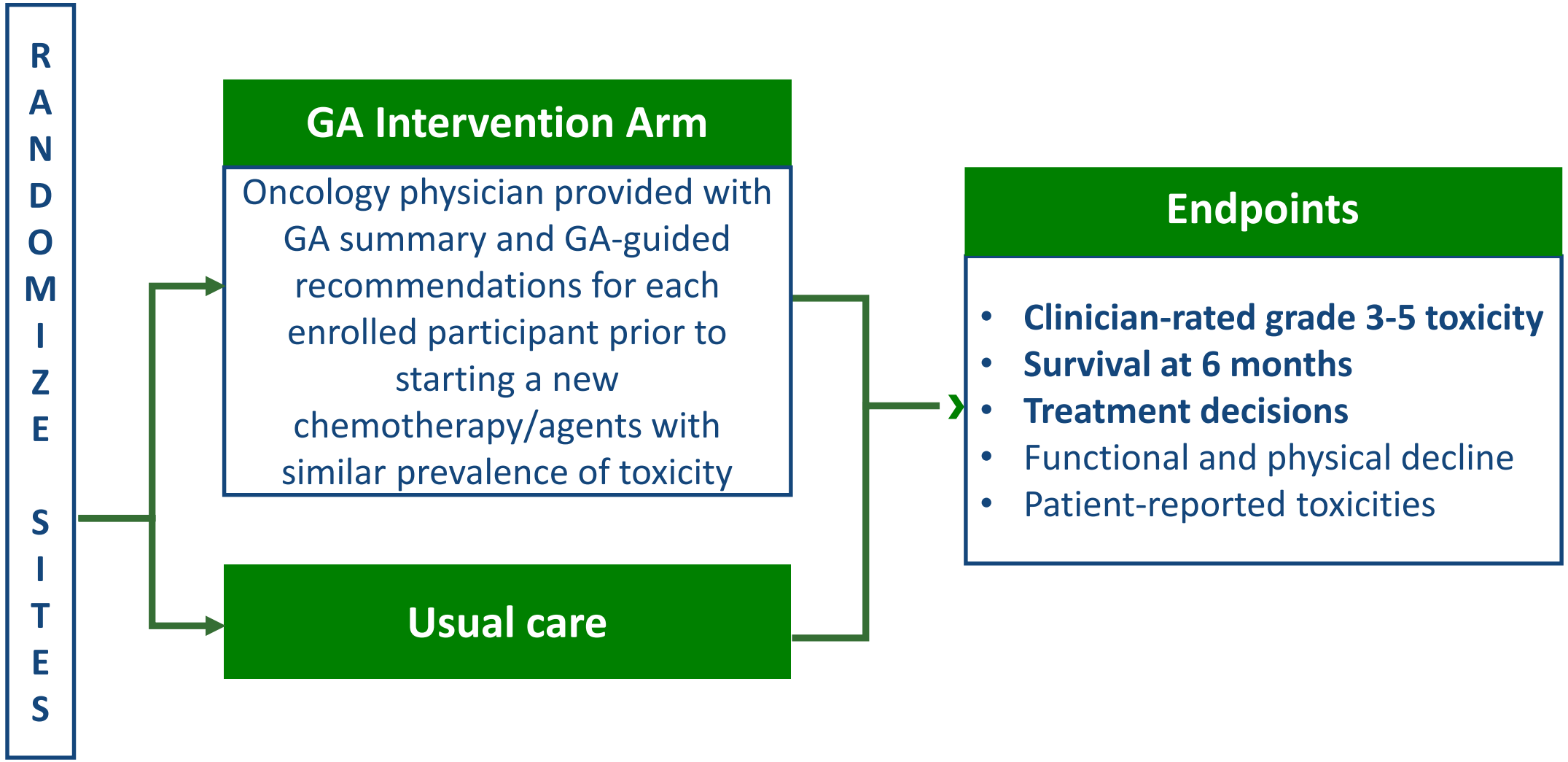
- **Secondary Aims:**
  - **Survival** at 6 months
  - **Treatment decisions**



Aurora NCORP	Greenville NCORP of the Carolinas	Nevada Cancer Research Foundation NCORP
Cancer Research Consortium of West Michigan	Gulf South MU NCORP	Northwell Health NCORP
Columbus NCORP	Hawaii MU NCORP	Pacific Cancer Research Consortium
CROWN NCORP	Heartland Cancer Research NCORP	SCOR NCORP
Dayton Clinical Oncology Program	Kaiser Permanente	Upstate Carolina NCORP
Delaware/Christiana Care NCORP	Metro-Minnesota NCORP	Wisconsin NCORP
Geisinger Cancer Institute NCORP	Michigan Cancer Research Consortium	

Study Schema

Geriatric Assessment for Patients 70+



GA Intervention

GA-Guided Communication

- Intervention prompted for communication about impairments
  - Weigh risks and benefits of treatment in the context of GA domain impairments
  - Consider less aggressive therapy or less complex regimens
  - Consider safety for treatment

- Treating oncologist ultimately made the decision for treatment plan
  - Treatment plan was captured prospectively
  - A blinded oncology team reviewed if intensity of treatment was reduced

Mohile et al. JNCCN, 2015; Mohile et al. JAMA Oncol, 2019

GA Intervention Summary Example

Domain	Description	GA Results
Physical Performance	Recent falls have been shown to predict toxicity from cancer treatment. Physical performance concerns and falls are associated with morbidity, mortality, compromised quality of life, and considerable economic burden. Falls occur in approximately 1/3 of all people over age 65 and in 1/2 of all people over age 80. Physical performance concerns and falls promote the loss of independence and are primary reasons for admission to extended-care facilities. Older patients who fall may experience fracture, head injury, infection and delirium (if occurs after surgery), exacerbated bleeding, and prolonged hospitalizations. Recent falls have been shown to predict toxicity from cancer treatment.	Your patient has a high risk of future falls as demonstrated by the scores on the following: Short Physical Performance Battery Score: N/A Timed Up and Go score: >13.5 seconds History of fall(s): ≥1 OARS Physical Health - Number of “a lot” response(s): ≥1

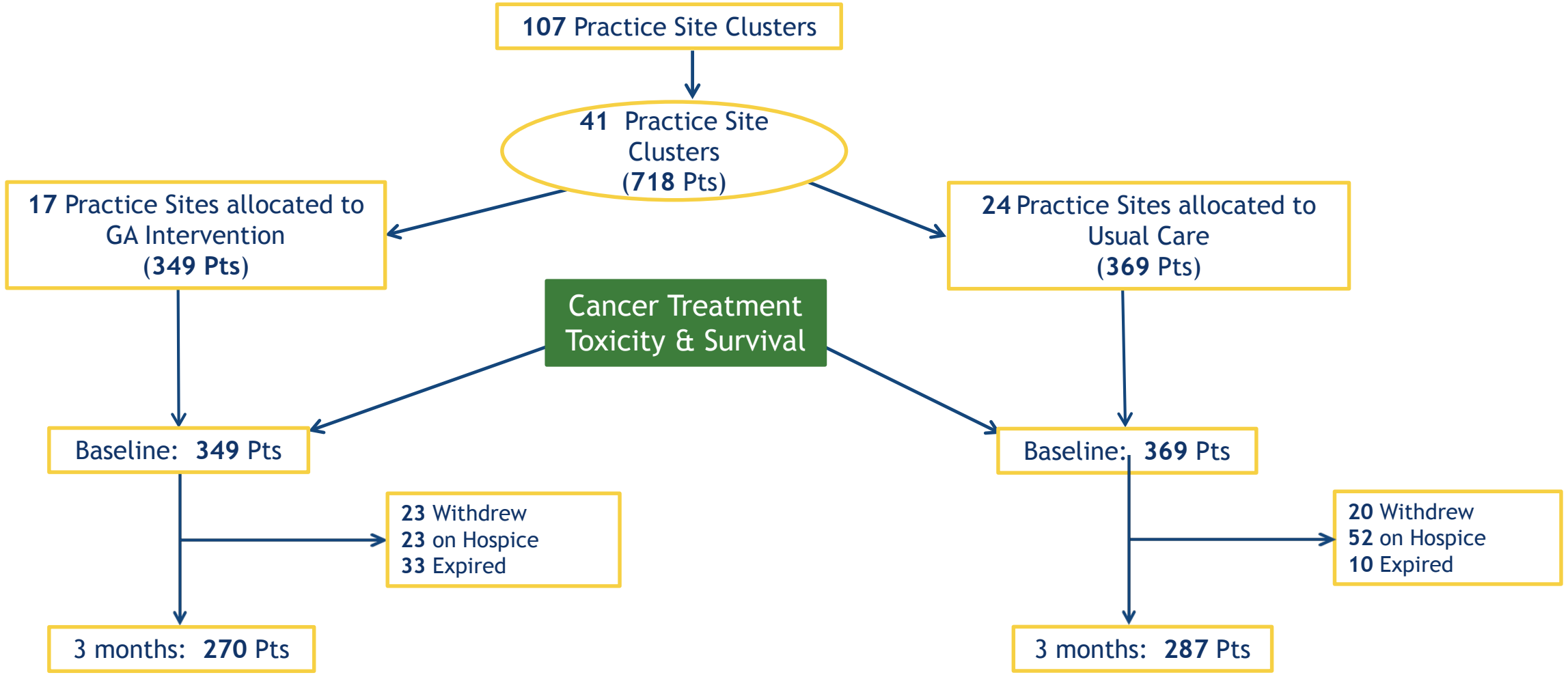
GA Intervention

Management Recommendations Example: Physical Performance

Did you or your staff complete any of the following with the patient during the clinic consultation (study visit)?
1. Weigh risks and benefits of treatment options incorporating information about the patient's physical performance.
2. Address possible impact of treatment on falls and physical performance.
3. Address impact of treatment on function and independence.

Recommendations	Recommended		Implemented?	Implemented by	
	Yes	No	Enter Reason Code	Physician	Staff
1. Referrals:					
A. Physical Therapy (outpatient or home-based depending on eligibility for home care): request gait/assistive device evaluation, strength and balance training.	☐	☐	☐	☐	☐
B. Occupational therapy (if eligible for home care, OT referral to do safety evaluation).	☐	☐	☐	☐	☐
C. Aide services (SW may be able to assist).	☐	☐	☐	☐	☐
D. Personal Emergency Response information (PERS) especially if alone at any time while receiving treatment (SW may be able to assist).	☐	☐	☐	☐	☐

GAP70: CONSORT Diagram



Patient Eligibility

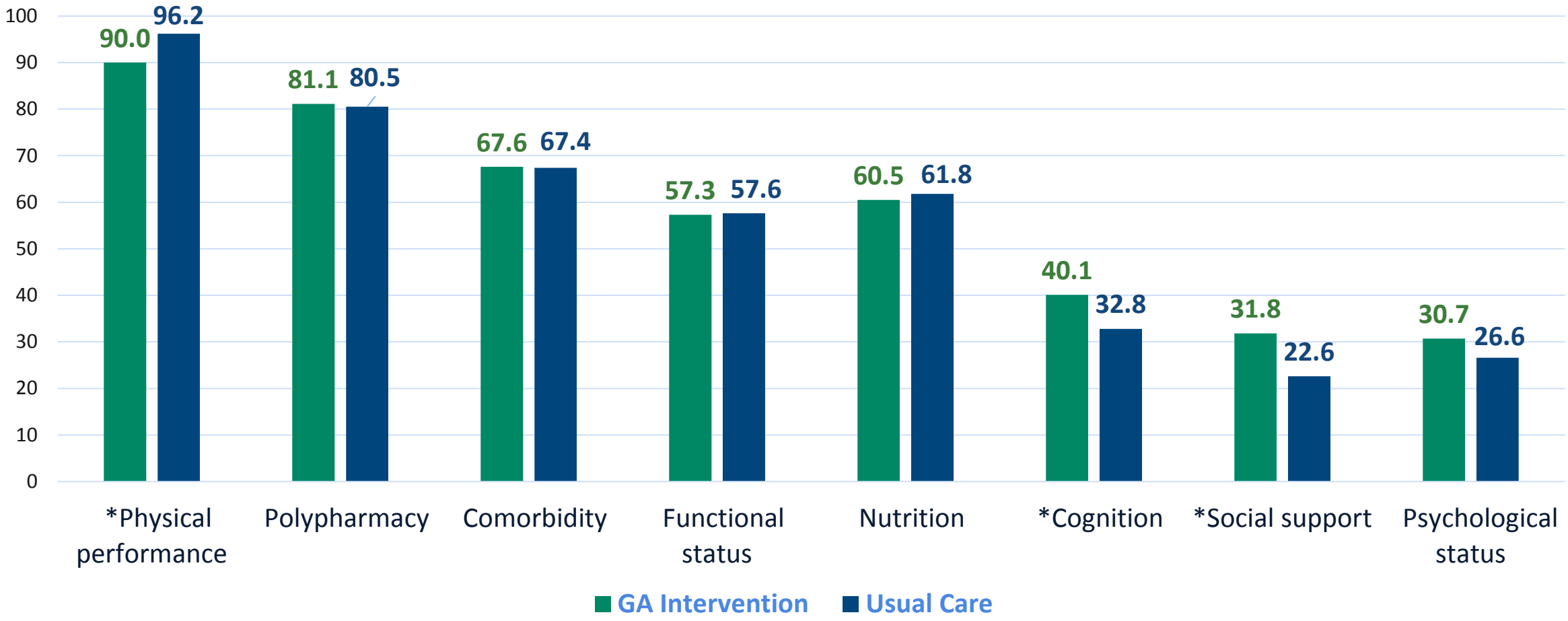
- Aged 70+
- Incurable stage III or IV cancer
- >1 GA domain impaired other than polypharmacy
- Starting a new regimen chemotherapy or other agents with similar prevalence of toxicity
- Not on 'best supportive care' or hospice

	GA Intervention	Usual Care	
	N or Mean (% or SD)	N or Mean (% or SD)	P value
Age	77.2 (5.7)	77.2 (5.2)	0.98
Female	145 (41.5%)	166 (45.0%)	0.35
Race/Ethnicity			<0.01
Non-Hispanic White	281(80.5%)	347 (94.0%)	
African American	40 (11.5%)	12 (3.3%)	
Cancer Type			<0.01
Gastrointestinal	133 (38.1%)	114 (30.9%)	
Genitourinary	56 (16.0%)	53.0 (14.4%)	
Lung	63 (18.1%)	116 (31.4%)	
Stage IV	304 (87.1%)	324 (87.8%)	0.11
Cancer Treatments			0.53
Chemotherapy	305(87.4%)	328 (88.1%)	
Non-chemotherapy	44(12.6)	41(11.1%)	
Prior chemotherapy	104 (30.8%)	81 (22.7%)	0.02

Prevalence of Adverse Outcomes (n=718)

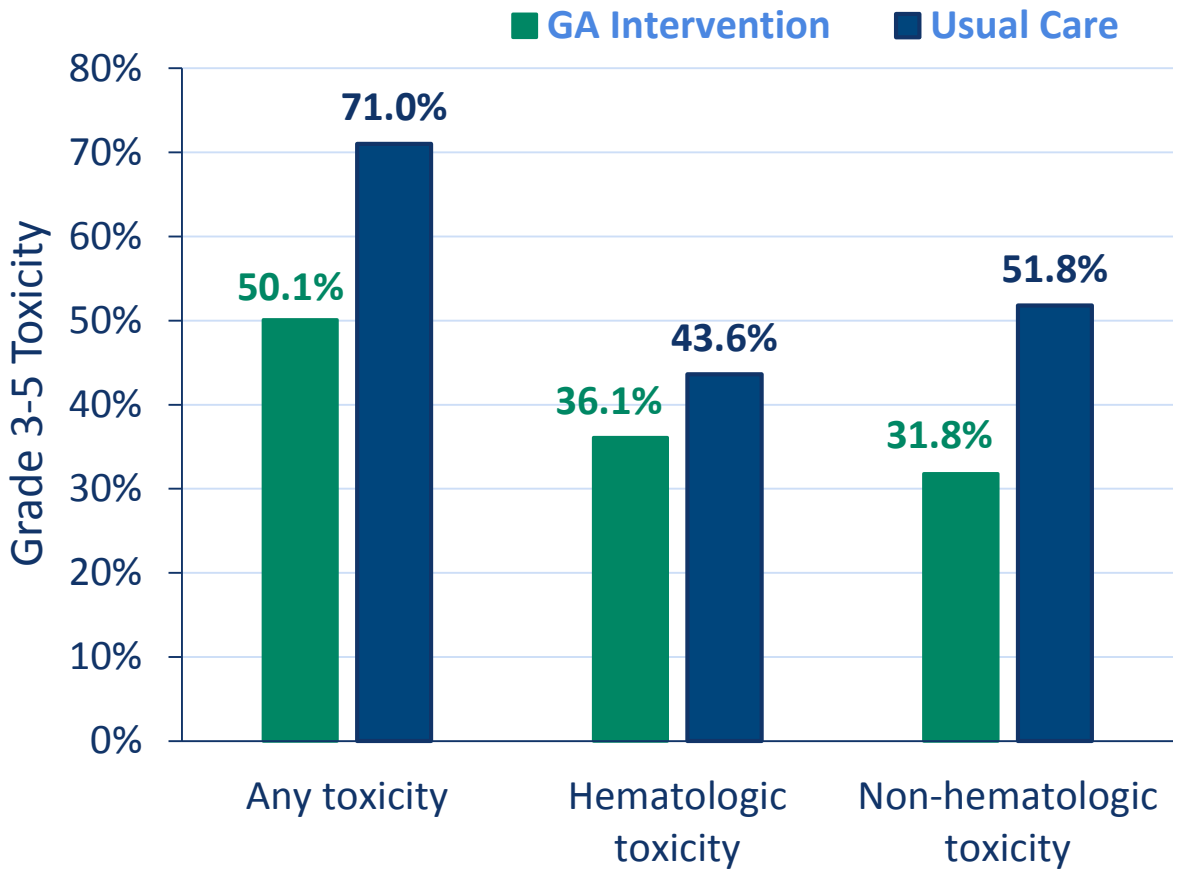
Adverse Outcome	Prevalence
Grade 3-5 toxicity within 3 months	60.9%
Dose modification within 3 months	50.0%
Discontinuation of treatment within 3 months	17.7%
Entered into Hospice within 3 months	15.9%
Death (due to all causes) within 6 months	26.5%

Prevalence of GA Domain Impairments by Study Arm



*P value <0.05 for Physical performance, Cognition, and Social Support.

Any Grade 3-5 CTCAE Toxicity in 3 Months



- **Any Grade 3-5 Toxicity**

  Adjusted Risk Ratio: 0.74

  95% CI: (0.63-0.87), P < 0.01

  Clustering effect: P = 0.15

- **Any Grade 3-5 Hematologic Toxicity**

  Adjusted Risk Ratio: 0.85

  95%CI: (0.69-1.05), P = 0.13

  Clustering effect: P = 0.30

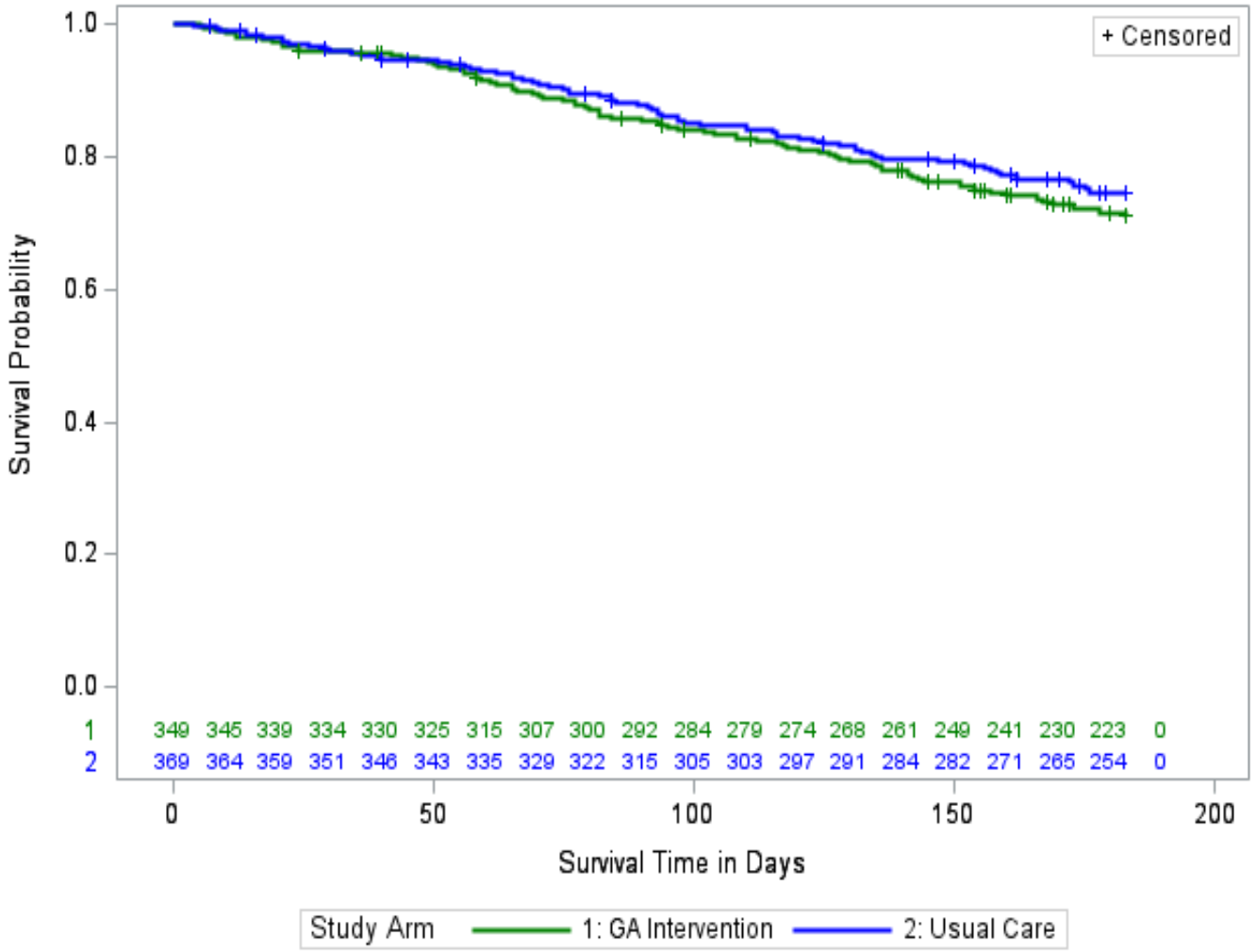
- **Any Grade 3-5 Non-hematologic Toxicity**

  Adjusted Risk Ratio: 0.73

  95% CI: (0.53-0.996), P = 0.047

  Clustering effect: P < 0.01

Survival at 6 Months



- **Survival at 6 month based on Kaplan Meier Estimates**

  GA Intervention: 71.3% (66.2%- 75.9%)

  Usual Care: 74.3% (69.5%-78.6%)

  P = 0.33

- Adjusted Hazard Ratio: 0.87

  95% CI: (0.65-1.15), P = 0.33

  Clustering effect: P = 0.04

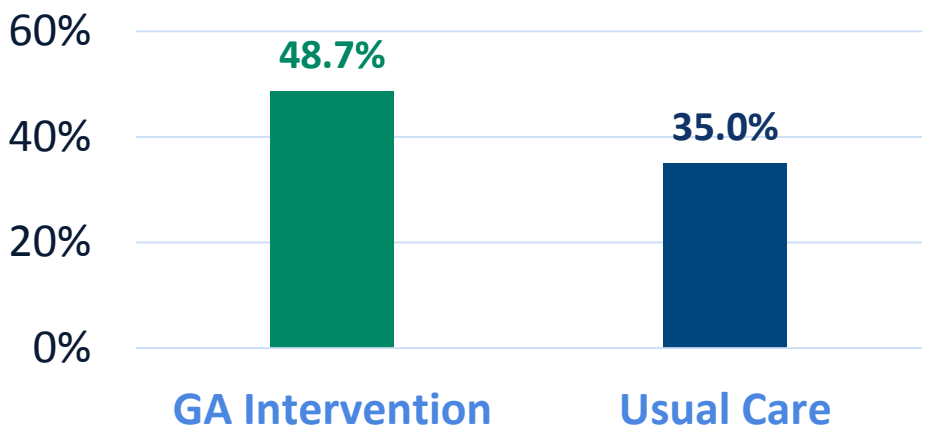
Treatment Intensity

- Adjusted Risk Ratio=1.37

  95% CI: (1.06-1.76), P=0.016

  Clustering effect: P=0.03

Reduced Dose Intensity at Cycle 1

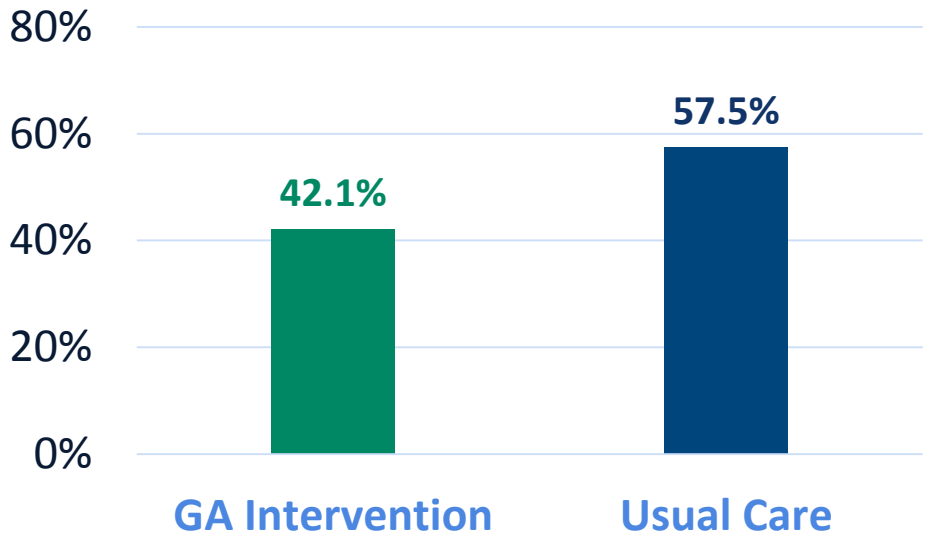


- Adjusted Risk Ratio=0.85

  95% CI: (0.67-1.08), P=0.190

  Clustering effect: P<0.01

Dose modification at 3 months Related to Toxicity



Conclusions

- A GA summary with management recommendations provided to the oncologist prior to the start of a new treatment regimen
  - reduces clinician-rated grade 3-5 toxicity over 3 months
  - without significantly lowering survival at 6 months
- May be due to reduced treatment intensity provided at cycle 1
  - Effect of GA-guided management recommendations will be further evaluated
- This large cluster randomized study is the first show that a GA intervention for patients aged 70+ with advanced cancer and ≥1 GA domain impairment improves clinical outcomes
  - Lends further support to the ASCO geriatric oncology guideline which recommends GA for older adults undergoing chemotherapy
  - PRO outcomes will be presented in the future