Disparities in supportive care breast cancer clinical trial enrollment

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Background

- Supportive care clinical trials (CTs) are crucial for improving breast cancer (BC) survivorship. However, the representation of diverse demographic groups is insufficiently characterized.

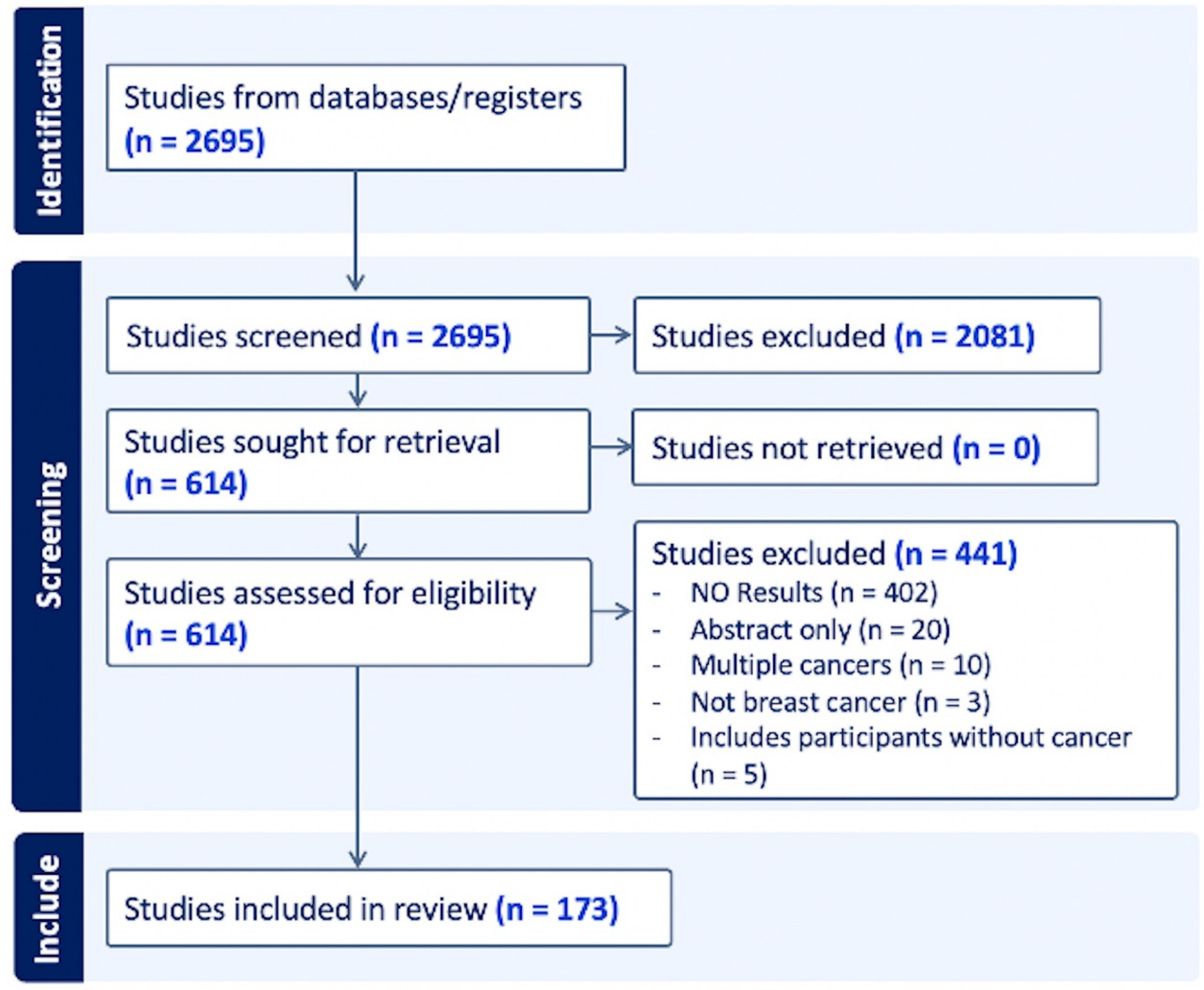
Aim

- Assess representation of Black, Asian, Hispanic, and older adults in supportive care BC CTs

Methods

- Systematic review of supportive care BC CTs registered on ClinicalTrials.gov with enrollment in the United States from January 2010 to September 2022.
- Exclusion Criteria:
    - CTs enrolling multiple cancer types or non-cancer patients
    - CTs limiting enrollment to specific demographic groups
- Data abstracted using Covidence software and following the PRISMA systematic review guidelines
- One-sample proportion tests were performed to compare representation of Black, Asian, Hispanic, and older adults (age ≥65) in BC CTs to incidence data from the SEER registry.
    - Secondary analyses by intervention and funding type

Figure 1. PRISMA flow of trial identification, screening, and inclusion



There is inadequate representation of Black, Asian, Hispanic, and older adult participants across breast cancer (BC) supportive care clinical trials (CTs).

Enhancing diversity representation in BC supportive care CTs is necessary to improve health equity and the generalizability of supportive care CTs.

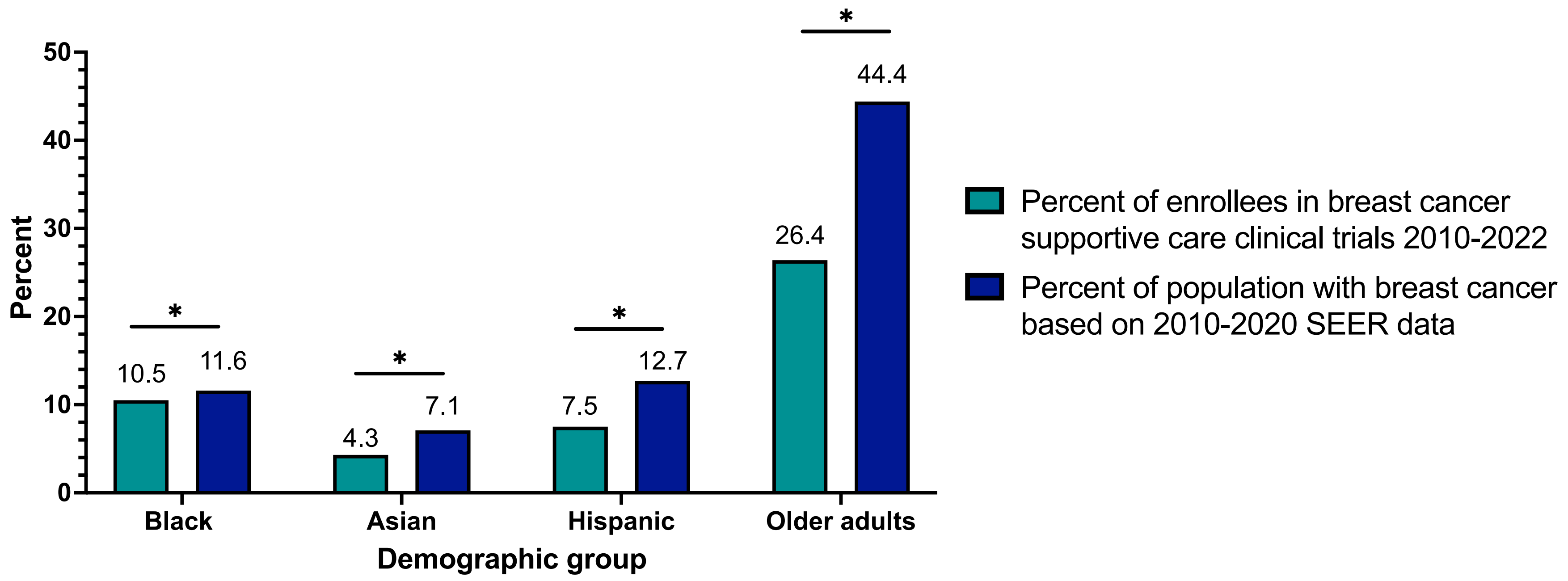
Results

Table 1. Black, Asian, Hispanic, and Older adult participants are underrepresented in BC supportive care CTs overall, with adequate representation of Black and Asian participants in a minority of trial subtypes

	CTs with race-specific data n(%)	Black n(%)	p-value (95% CI)	Asian n(%)	p-value (95% CI)	CTs with ethnicity-specific data n(%)	Hispanic n(%)	p-value (95% CI)	CTs with age-specific data n(%)	Older adult n(%)	p-value (95% CI)
Overall	128 (100%)	1764 (10.5%)	**<0.001 (0.100, 0.110)**	716 (4.3%)	**<0.001 (0.040, 0.046)**	99 (100%)	1044 (7.5%)	**<0.001 (0.070, 0.079)**	30 (100%)	1134 (26.4%)	**<0.001 (0.251, 0.277)**
By intervention											
Diet and/or physical activity	31 (24.2%)	471 (14.2%)	**<0.001 (0.131, 0.155)**	41 (1.2%)	**<0.001 (0.009, 0.017)**	22 (22.2%)	226 (9.1%)	**<0.001 (0.080, 0.103)**	1 (3.3%)	5 (13.2%)	**<0.001 (0.050, 0.289)**
Cognitive health	3 (2.3%)	17 (10.3%)	0.686 (0.063, 0.162)	9 (5.5%)	0.492 (0.027, 0.104)	2 (2.0%)	4 (3.8%)	**0.010 (0.012, 0.101)**	N/A	N/A	N/A
Symptom management	49 (38.3%)	648 (8.6%)	**<0.001 (0.080, 0.092)**	482 (6.4%)	**0.011 (0.058, 0.070)**	40 (40.4%)	488 (7.8%)	**<0.001 (0.071, 0.085)**	20 (66.7%)	853 (27.5%)	**<0.001 (0.259, 0.291)**
Psycho-oncology	11 (8.6%)	65 (7.2%)	**<0.001 (0.056, 0.091)**	32 (3.5%)	**<0.001 (0.025, 0.050)**	9 (9.1%)	43 (6.3%)	**<0.001 (0.047, 0.085)**	3 (10.0%)	47 (21.2%)	**<0.001 (0.161, 0.273)**
CAM	17 (13.3%)	137 (11.9%)	0.763 (0.102, 0.140)	46 (4.0%)	**<0.001 (0.030, 0.054)**	11 (11.1%)	81 (9.6%)	**0.007 (0.077, 0.118)**	2 (6.7%)	13 (25.5%)	**0.0099 (0.148, 0.399)**
Education/ Communication	11 (8.6%)	373 (11.8%)	0.832 (0.107, 0.129)	79 (2.5%)	**<0.001 (0.020, 0.031)**	9 (9.1%)	177 (5.8%)	**<0.001 (0.050, 0.067)**	3 (10.0%)	216 (24.5%)	**<0.001 (0.217, 0.275)**
Sexual Health	6 (4.7%)	53 (9.1%)	0.062 (0.069, 0.118)	27 (4.6%)	**0.022 (0.031, 0.067)**	6 (6.1%)	25 (4.5%)	**<0.001 (0.030, 0.066)**	1 (3.3%)	0 (0.0%)	**<0.001 (0, 0.690)**
By funding type											
NIH or similar	33 (25.8%)	477 (9.0%)	**<0.001 (0.082, 0.098)**	135 (2.5%)	**<0.001 (0.021, 0.030)**	27 (27.3%)	360 (7.5%)	**<0.001 (0.068, 0.083)**	4 (13.3%)	449 (36.2%)	**<0.001 (0.335, 0.390)**
Academic	67 (52.3%)	787 (12.8%)	**0.005 (0.120, 0.136)**	194 (3.1%)	**<0.001 (0.027, 0.036)**	48 (48.5%)	302 (6.5%)	**<0.001 (0.058, 0.073)**	17 (56.7%)	221 (30.5%)	**<0.001 (0.272, 0.341)**
Industry	21 (16.4%)	435 (8.9%)	**<0.001 (0.081, 0.097)**	361 (7.4%)	0.511 (0.067, 0.082)	18 (18.2%)	352 (8.6%)	**<0.001 (0.077, 0.095)**	9 (30.0%)	464 (19.9%)	**<0.001 (0.183, 0.216)**
Other	7 (5.5%)	65 (13.5%)	0.233 (0.106, 0.169)	26 (5.4%)	0.159 (0.036, 0.079)	6 (6.1%)	30 (6.6%)	**<0.001 (0.046, 0.094)**	N/A	N/A	N/A
SEER	—	11.6%	—	7.1%	—	—	12.7%	—	—	44.4%	—

Results Continued

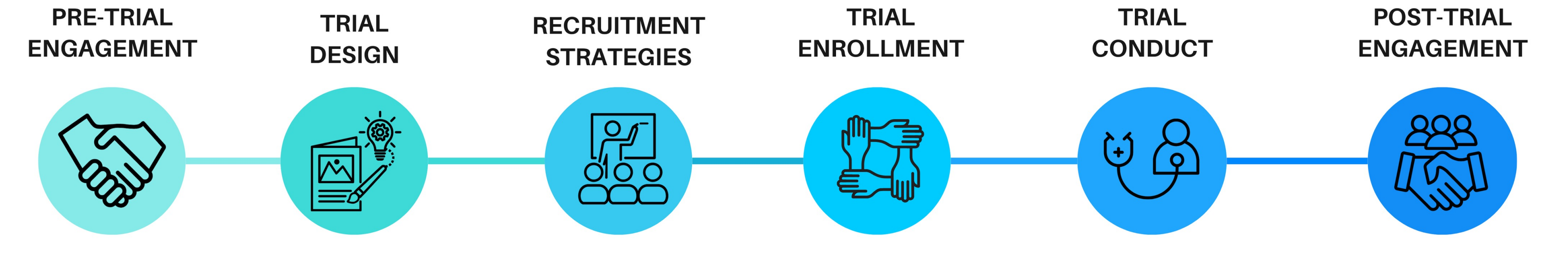
Figure 2. Representation of demographic groups in BC supportive care CTs overall compared to SEER incidence data



Conclusion & Future Directions

- The results of our study highlight differences in demographic representation in BC supportive care CTs.
- Continued efforts and tailored strategies are needed across the spectrum of CT development to enhance representation of diverse populations.

Figure 3. Pathway to enhancing diversity representation in BC Supportive Care CTs



PRE-TRIAL ENGAGEMENT

- Foster partnerships between stakeholders (e.g. trial sponsors, community/patient groups)
- Educate communities about clinical trial participation

TRIAL DESIGN

- Conduct trials medically underserved areas
- Use standard terminology for race and ethnicity for consistent reporting
- Broaden eligibility criteria and avoid unnecessary exclusions
- Use of tools such as artificial intelligence to evaluate eligibility criteria

RECRUITMENT STRATEGIES

- Use online resources and social media to recruit patients
- Hold education and recruitment events at convenient times in trusted locations, businesses, and public events (e.g. churches, salons, markets, festivals)

TRIAL ENROLLMENT

- Enroll participants that reflect the population of interest regarding age, sex, race, and ethnicity
- Share trial resources in multiple languages and use multilingual staff and/or interpreters
- Use patient navigators to facilitate trial education and enrollment

TRIAL CONDUCT

- FDA Diversity Plans
- Provide staff with recurring cultural education, training, and evaluation
- Reduce frequency of in-person study visits and increase flexibility of visit times
- Use of decentralized clinical trials and digital health to increase convenience (e.g. telehealth follow-up)
- Use of patient navigation to address social determinants of health barriers and increase care access (e.g. travel, lodging, food, child care)

POST-TRIAL ENGAGEMENT

- FDA post-marketing requirements or commitments regarding diversity
- Continued engagement with patients and communities and share trial updates