Title

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Journal

Journal of Racial and Ethnic Health Disparities, 7(5)

ISSN

2197-3792

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Publication Date

2020-10-01

DOI

10.1007/s40615-020-00724-8

Peer reviewed

Published in final edited form as:

J Racial Ethn Health Disparities. 2020 October ; 7(5): 996–1002. doi:10.1007/s40615-020-00724-8.

The problem of underrepresentation: Black participants in lifestyle trials among patients with prostate cancer

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Conflicts of Interest

Kyle B Zuniga has no conflicts of interest to disclose. Hala Borno has a family member with employment, leadership, and stock and other ownership interests in Collective Health. June M Chan has a family member with employment; travel, accommodation, and expense payments; stock and other ownership interests; and research funding from GRAIL; a family member with employment; travel, accommodation, and expense payments; and research funding from Myriad Genetics; institutional affiliation that has research funding from Genomic Health; and research funding from GenomeDx. Erin L Van Blarigan has no conflicts of interest to disclose. Terrence Friedlander has a consulting/advisory role in Genentech; a consulting/advisory role in AstraZeneca; a consulting/advisory role and travel, accommodations, and expense payments in Clovis Oncology; a consulting/advisory role in Foundation Medicine; a leadership role in Med BioGene; a speakers' bureau role in Sanofi; a speakers' bureau role in Dendreon; a speakers' bureau role in Astellas Medivation; travel, accommodations, and expenses payments in AstraZeneca/MedImmune; travel, accommodations, and expenses payments in Genentech/Roche; honoraria in EMD Soreno; research funding from Janssen; research funding from ImClone Systems; research funding from Aragon Pharmaceuticals; and research funding from GlaxoSmithKline. Sunny Wang has institutional affiliation that has research funding from Clovis Oncology. Li Zhang has no conflicts of interest to disclose. Stacey A Kenfield has research funding from GenomeDx and has a consulting/advisory role at Mojo Enterprises, Inc.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee of the University of California San Francisco and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was deemed unnecessary as de-identified data was gathered retrospectively from publicly available sources or in aggregate from corresponding authors.

Data Availability

The datasets generated during and analyzed during the current study for the reference population are publicly available in the Surveillance, Epidemiology, and End Results (SEER) repository, https://seer.cancer.gov/seerstat/. The datasets generated during and analyzed during the current study for the study population were obtained from trial publications, ClinicalTrials.gov, and corresponding author request, and aggregate data can be found in Online Resource 2.

Abstract

Introduction—Healthy lifestyle behaviors are an essential component of prostate cancer survivorship; however, it is unknown whether Black participants are adequately represented in randomized controlled trials (RCTs) on lifestyle interventions. The goal of this study was to identify types of lifestyle RCTs that may require improved recruitment resources to enhance generalizability of lifestyle recommendations to Black patients.

Materials and Methods—ClinicalTrials.gov was used to identify lifestyle RCTs among patients with prostate cancer. Using racial distribution data from the Surveillance, Epidemiology, and End Results (SEER) program as a reference, one-sample proportion tests were performed to assess adequate recruitment of Black participants.

Results—Of 31 lifestyle trials, one trial reported race-specific results. Proportion of Black participants was acquired from 26 trials. Compared to the US population, Black participants were overrepresented in the overall study population (17% versus 15%, $p = 0.019$). Black participants were underrepresented in trials exploring exercise interventions (9% versus 15%, $p = 0.041$), trials among patients with advanced disease (9% versus 16%, $p < 0.001$), and in university-funded trials (12% versus 15%, $p = 0.026$).

Conclusions—The reporting of race data, and race-specific results when feasible, is essential for clinicians to accurately generalize findings from lifestyle trials. Additional resources may be necessary to aid in strategic recruitment of Black participants for trials on exercise interventions, trials among patients with advanced disease, and in university-funded trials.

Keywords

African Americans; Prostatic Neoplasms; Exercise; Diet; Randomized Controlled Trial

Introduction

As with many cancers, the burden of prostate cancer is greater among Black patients compared to White patients [1]. Black patients are diagnosed with prostate cancer at a younger age, tend to have more aggressive disease, and have poorer survival outcomes [2–4]. Multiple biological and socioecological reasons for this disparity have been proposed. Some studies have suggested that genetic susceptibility and differences in androgen biology predispose Black patients to worse outcomes independent of socioeconomic variables [5, 6]. Still, psychosocial determinants of health such as socioeconomic status, education level, perceptions of healthcare recommendations, and quality of healthcare received affect Black communities in a disproportionately negative way compared to White communities [7–9].

Despite the increased disease burden among Black communities, cancer mortality rates are on the decline [10]. As a result, prostate cancer survivorship has become an essential component of long-term cancer care. As multiple studies have demonstrated their benefit, the American Cancer Society has recommended specific evidence-based lifestyle factors as a key component of survivorship [11, 12]. For example, pelvic floor muscle training has been repeatedly shown to reduce incontinence secondary to radical prostatectomy [13]. Exercise alone or in combination with a plant-based, whole food diet may mitigate the adverse effects

of androgen deprivation therapy, including decreasing bone mineral density loss, increasing muscle strength, and reducing body mass index [14, 15].

Although these findings are promising, racial inclusivity in research is imperative to ensure that accurate generalizations can be made regarding survivorship care. Given the differences that exist in tumor biology between races, lifestyle factors may have varying magnitudes of effect or even opposing directions of effect [16, 17]. For example, Layne et al. reported that people of White race who reported the highest intake of dietary vitamin D had a slight increase in prostate cancer risk (HR 1.05, $p = 0.003$), whereas people of Black race trended toward a statistically significant decrease in risk (HR = 0.84, $p = 0.09$) [16]. Thus, further research is necessary to determine which individuals would benefit most from vitamin D supplementation. Clearly, adequate recruitment of Black participants and reporting of race-specific results is essential for accurate generalizations of findings.

The goals of this study were to describe reporting of race and race-specific analyses of Black participants in randomized controlled trials (RCTs) on lifestyle interventions in patients with prostate cancer. This study also sought to compare the distribution of Black participants in trials with the distribution of Black patients with prostate cancer in the US. The Surveillance, Epidemiology, and End Results (SEER) database was used as a suggested enrollment target for trials, as it contains data on a large proportion of the population with cancer and is designed to accurately reflect sociodemographic data from the US census [18].

Materials and Methods

Data Collection

RCTs were identified through the US National Library of Medicine ClinicalTrials.gov database beginning February 2000 (creation of ClinicalTrials.gov) through February 2019 by combining the term “prostate cancer” with a variety of lifestyle interventions (see Online Resource 1 for details). According to ClinicalTrials.gov, clinical trials are defined as studies in which participants are assigned to groups that receive a specific intervention or no intervention for the purpose of determining the effect of that intervention on a clinical outcome [19]. Lifestyle interventions were defined as any behavioral modification including dietary interventions (e.g., single-item to multifactorial interventions), exercise interventions (e.g., aerobic/resistance exercise, yoga), and mindfulness interventions (e.g., meditation, hypnosis). This study was approved by the Institutional Review Board at the University of California San Francisco.

Full trial selection criteria can be seen in Figure 1. Trials without full-text publications of trial outcomes available on Pubmed (including those with feasibility results only) were excluded. Trials without a placebo/usual care control arm and those conducted outside the US were also excluded. For those trials not reporting complete race data (i.e., data on the number of White, Black, and Other participants) either through a publication or on ClinicalTrials.gov, corresponding authors were contacted electronically with a request for aggregate race distribution data up to three times. Those trials without available race data identified through any of these methods were excluded. Intentional recruitment of Black

participants was assessed via the Recruitment Information section of ClinicalTrials.gov and the Methods section of the publication.

In order to identify enrollment targets for Black participants, prostate cancer data from the SEER registry on prostate cancer incidence was utilized. As the trials included in this study began between 2001–2015, incidence data on 813,928 patients diagnosed with prostate cancer with known race data during this time period was extracted using SEER*Stat, version 8.3.5 (https://seer.cancer.gov/seerstat/). SEER records were categorized by White, Black, and Other race.

Data Analysis

To determine adequate study representation (i.e., racial distribution similar to that of the US population), one-sample proportion tests were performed comparing the SEER prevalence (reference distribution) to the overall study population as well as study subcategory populations based on intervention type and primary funding source (identified on ClinicalTrials.gov under “Sponsor”). For the subcategory of disease severity, trials were categorized as “localized disease” trials if they only included patients with T3a disease or less without nodal disease or metastasis. Trials were categorized as “advanced disease” trials if they contained patients with greater than T3a disease, nodal disease (N1), metastasis (M1), or biochemical recurrence. The American Joint Committee on Cancer 6th edition TNM staging data was used to identify 608,006 incident prostate cancer cases with known staging data between 2004–2015. This was used as a reference group because its data covered a period closest to the range of years covered by the included trials. The localized disease reference group was calculated from the proportion of those with T3a disease or less without nodal disease or metastasis. The advanced disease reference group was calculated from the proportion of those with greater than T3a disease, nodal disease (N1), or metastasis (M1).

Differences were considered statistically significant at $p < 0.05$. Representation of Black participants was considered adequate if the proportion was not statistically significantly different from SEER data. Black participants were considered overrepresented if the study proportion was statistically significantly higher than SEER prevalence data and underrepresented if statistically significantly lower than SEER data. Analyses were performed with STATA®, version 15.

Results

Race reporting in lifestyle trials among patients with prostate cancer

Fifty-six registered trials were identified that investigated a lifestyle intervention among patients with prostate cancer with full-text publications on trial outcomes (Figure 1). 31 of these trials had a placebo/usual care control arm and were conducted in the US. Of these trials, 23 (74%) reported the number of Black participants. Race data was obtained via electronic request from 5 trials, 3 of which did not report proportion of Black participants and 2 of which reported proportion of Black participants with various cancer types. The final analysis included 26 trials beginning between 2001–2015. Of 31 studies, one (3%)

study reported race-specific results. No study mentioned intentional recruitment of Black participants.

The characteristics of the reviewed trials can be found in Table 1. 14 (54%) trials investigated dietary factors (2 on green tea, 1 on a low-fat diet, 2 on lycopene, 1 on milk thistle, 2 on omega-3 fatty acids, 2 on pomegranate, and 5 on soy), 3 (12%) investigated exercise, 7 (27%) investigated combined diet and exercise interventions, and 2 (8%) investigated pelvic floor muscle training (PFMT). There were 19 (73%) localized disease trials and 7 (27%) advanced disease trials. A detailed description of included trials can be found in Online Resource 2.

Representation of Black participants in lifestyle trials in patients with prostate cancer

Per SEER data, distribution of incident prostate cancer between 2001–2015 was 80% White, 15% Black, and 5% other. The results of the analyses comparing the proportion of Black patients in the pooled study population, comprised of the included trial populations, versus in the SEER population can be seen in Figure 2. The overall pooled study population overrepresents Black participants (17%, $p = 0.019$). Black participants were underrepresented in exercise trials (9%, $p = 0.041$), but were adequately represented in diet (14%, $p = 0.339$) and combined diet and exercise trials (13%, $p = 0.278$). Black participants were overrepresented in trials on PFMT (30%, $p < 0.001$). Black participants were underrepresented in university-funded trials (13%, $p = 0.030$). Black participants were also underrepresented in the single industry-funded (9%, $p = 0.026$) and non-profit organization-funded trial (4%, $p = 0.038$). Black participants were overrepresented in government-funded trials (24%, $p < 0.001$).

According to SEER, 15% of patients with localized disease and 16% of patients with advanced disease were Black. In the study population, Black participants were underrepresented in advanced disease trials (9%, $p < 0.001$) and overrepresented in localized disease trials (19%, $p < 0.001$).

Discussion

Difficulties in enrollment of Black participants in clinical trials is a historical problem. The NIH Revitalization Act of 1993 sought to improve involvement of underrepresented groups by mandating the inclusion of representation of women and racial/ethnic minorities in publicly-funded clinical trials. Regardless, representation remains persistently low [20]. The reporting of race ranges from 1.5% to 58%, with only 20% of RCTs in “high-impact” oncology journals analyzing results by race [21, 22]. In this analysis, a slightly higher proportion of lifestyle trials reported race data compared to the aforementioned statistics. Regardless, the ideal is that all trials report race data in their descriptive tables in order to determine to whom conclusions can be generalized. Furthermore, only 1 of 31 publications on lifestyle trials in this study reported race-specific results. For many trials, this may have been due to inadequate numbers of Black participants precluding race-specific analyses. If one is hypothesizing that there is a true difference in causal effect among White versus Black patients (e.g., effect modification), a much greater proportion of Black enrollment would be required, and thus perhaps overrepresentation rather than adequate representation

of Black participants is a better recruitment goal. For example, although the proportion of Black patients with prostate cancer in combined diet and exercise trials was similar to that of the US population, the overall study population included only 71 patients across seven trials. This reinforces the idea that reporting of race-specific results (or acknowledging that trials are underpowered for race-specific analyses) is critical for accurate translation of conclusions into clinical practice.

In this analysis, it was also demonstrated that, although Black participants were adequately represented in lifestyle trials overall, Black participants were underrepresented in trials exploring exercise interventions, trials in patients with advanced disease, and in university-funded trials. There have been multiple previous reports of underrepresentation in trials among patients with advanced disease. For example, over the last 10 years, the development and approval of new drugs such as sipuleucel-T, abiraterone, enzalutamide, cabazitaxel, and radium-223 chloride has dramatically advanced the treatment of castrate resistant prostate cancer. The landmark trials investigating these drugs demonstrated improvements in overall survival; however, only 240 of the 7,275 patients (3.3%) enrolled in these trials were Black [23]. Balakrishnan et al. reported that enrollment of Black patients with prostate cancer in therapeutic trials has increased since 2003; however, they continue to under-enroll patients with metastatic disease [24]. This is particularly concerning given that Black patients are more likely to present with and subsequently succumb to metastatic disease [4].

Difficulty in recruitment in university-funded trials may be because Black patients are less likely to be cared for at academic institutions compared to White patients [25]. This may be due to Black patients having limited access to these facilities relative to their White counterparts. Acknowledgement of this systemic barrier is the first step in ameliorating the institutional factors that, if rectified, may reduce racial outcomes disparities.[26] Underrepresentation may also be a product of the demographics around certain academic institutions. For example, although the proportion of Black participants was low in their trial, Winters-Stone et al. acknowledged that their study population was reflective of the primarily Caucasian demographic of their sample population in Oregon [27]. As this and one other trial made up two of the three exercise trials, this may also explain the underrepresentation found in this subcategory [28, 29]. Thus, additional funding may need to be directed towards these institutions to support targeted recruitment efforts and interinstitutional collaboration.

Notably, no study in our sample mentioned intentional recruitment of Black participants. Still, many lifestyle trials have recognized that adequate recruitment of Black participants requires targeted planning and outreach to Black communities. For example, in an attempt to strategically recruit minority participants, the Selenium and Vitamin E Cancer Prevention Trial (SELECT) investigators lowered the eligibility criteria for age from 55 to 50 for Black patients based on higher disease risk, formed the Minority and Medically Underserved Subcommittee, provided Minority Recruitment Enhancement Grants (MREGs) to sites with high minority-recruitment potential, and coordinated with leaders of Black organizations such as the National Association for the Advancement of Colored People. Their ambitious recruitment strategies helped achieve a study population that was 15% Black; however, this fell short of their goal of 20% [30]. Heiney et al. described a model for recruitment

of minority participants into a diet, exercise, and meditation intervention referred to as the Eating, Activity, and Stress Education (EASE) trial. Their model combined recruiter-participant relationship building with social marketing strategies such as identifying target groups, assessing media availability, and gathering feedback on the content and design of behavior change materials. Their resulting study populations was 22% Black [31]. The PATH study: A multi-site pilot study to understand Preferences, Attitudes, and Health behaviors related to diet and lifestyle among men with advanced prostate cancer and family caregivers, is being developed to improve understanding of diet, lifestyle, and technology use preferences among Black and Hispanic patients to develop culturally relevant behavior change materials. This study has prospects for not only improving recruitment in lifestyle trials but also the implementation of findings from said lifestyle trials.

The goal of this study was not to suggest that certain lifestyle trials are flawed or that their results are invalid. On the contrary, the results of these trials have emphasized the importance of behaviors like exercise and healthful diet among patients with prostate cancer and have inspired further investigation into the benefit of lifestyle interventions. Rather, the goal was to identify specific types of trials in which additional resources may need to be allocated for recruiting Black participants. The strengths of this study include our broad search of lifestyle factors and large overall sample of patients. Still, some subcategories had too few trials (e.g., industry-funded trials) to draw definitive conclusions. It is recognized that the comparison for advanced disease trials is imperfect, as some of these studies included a mix of patients with localized disease. However, these trials consisted of participants in advanced stages of their disease (e.g., on androgen deprivation therapy). Thus, this was considered to be a reasonable classification, and the SEER advanced disease distribution was considered to be a more accurate comparison group. Furthermore, underrepresentation remained statistically significant when compared to the general population distribution ($p < 0.001$). There is also the potential for selection bias, as those trials that were excluded due to lack of reporting of racial data may have done so due to inadequate representation of Black participants. Thus, these results may falsely report overrepresentation of Black participants. Furthermore, given that non-White, non-Black patients were grouped as “Other,” representation among other groups could not be explored (e.g., Hispanic patients, Asian patients, mixed race patients, etc.)

Conclusions

In order to identify resource allocation needs and to accurately generalize lifestyle recommendations, the reporting of race data, as well as race-specific results when feasible, in lifestyle trials among patients with prostate cancer is essential. Although this pooled analysis suggests that Black participants were adequately represented overall, there is a need for improved recruitment efforts of Black participants in trials exploring the effect of exercise, among patients with advanced disease, and in university-funded trials.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The investigators would like to thank Karen Basen-Engquist, Janet Cowan, Wendy Demark-Wahnefried, Mark Magbanua, Richard Sloan, Denise Snyder, and Kerri Winters-Stone for their assistance with the preparation of this article.

Funding

This work was funded in part by the National Center for Complementary and Integrative Health (T32AT003997), the National Cancer Institute (R01CA207749, R21CA184605, R01CA181802, K07CA197077), the UCSF Integrative Cancer Pilot Award, the Steven & Christine Burd-Safeway Distinguished Professorship, and the Helen Diller Family Chair in Population Science for Urologic Cancer.

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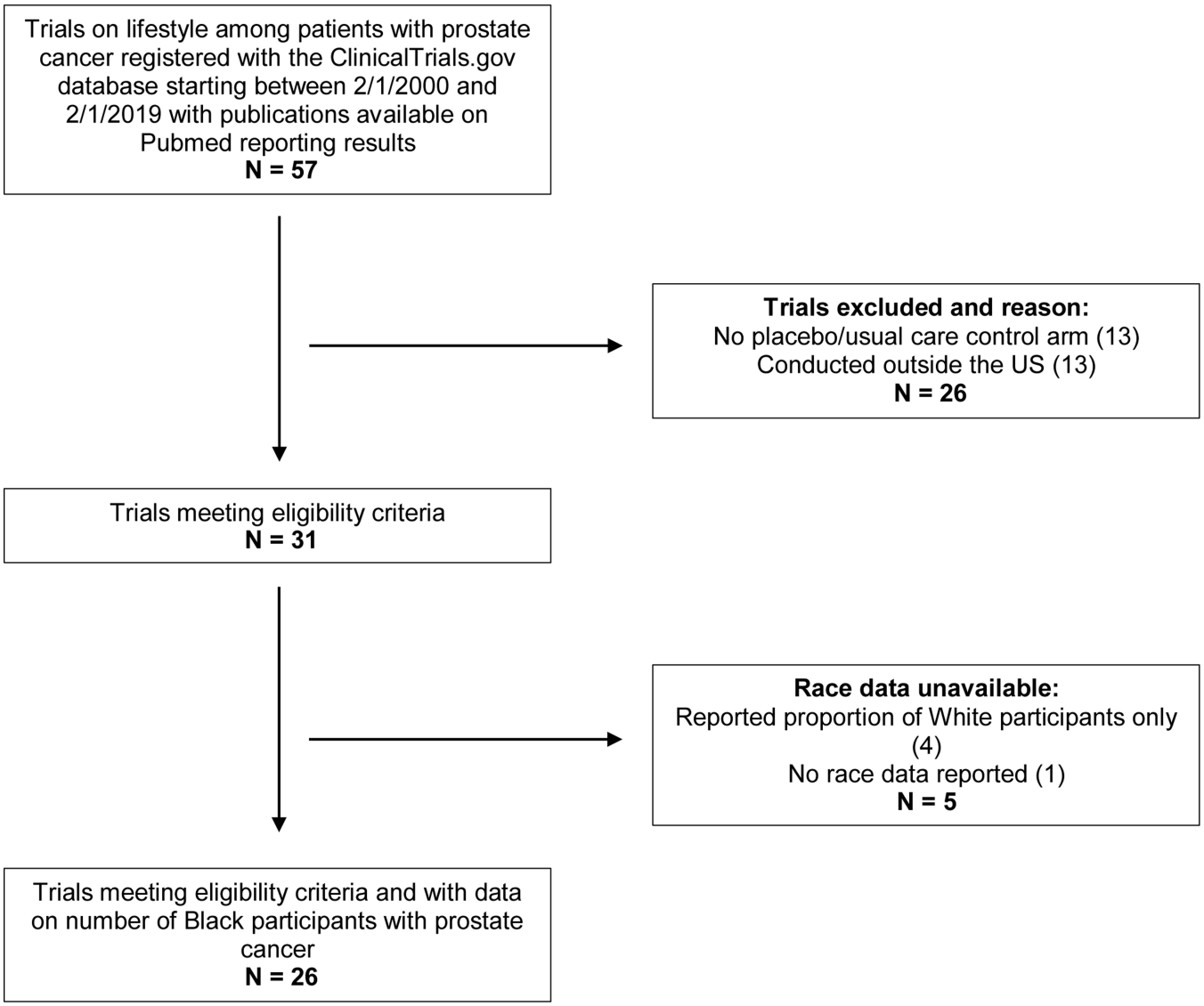

Figure 1:
Flow diagram showing trial identification, eligibility, and inclusion.

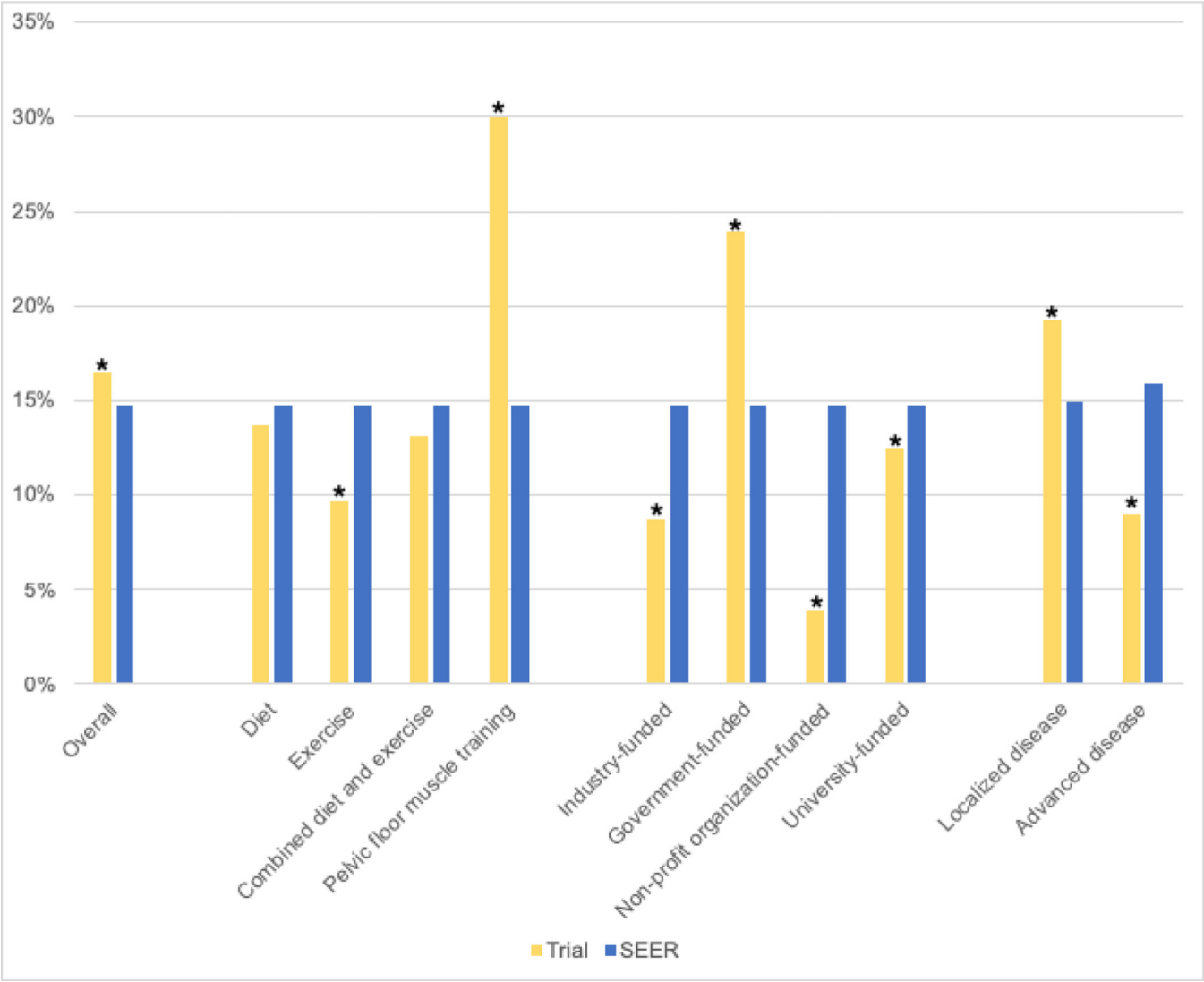

Figure 2:

Comparison of the proportion of Black participants in US randomized controlled trials on lifestyle among patients with prostate cancer versus the proportion of Black patients with prostate cancer in the US as per SEER data.

*Statistically significant difference

Table 1.

Characteristics of trials and trial population included in the analysis. For each racial category, the first column reports the study population. The second and third columns report descriptive statistics on the racial distribution across trials overall and within subcategories

	Trials	White participants			Black participants			Other participants*		
	n (%)	n (%)	Mean (SD)	Range	n (%)	Mean (SD)	Range	n (%)	Mean (SD)	Range
Overall	26 (100%)	1,843 (80%)	80% (13%)	54% −100%	381 (17%)	15% (11%)	0%−38%	92 (4%)	5% (7%)	0%−37%
Intervention										
Diet	14 (54%)	943 (81%)	82% (12%)	65% −100%	159 (14%)	14% (11%)	0%−33%	56 (5%)	4% (4%)	0%−14%
Exercise	3 (12%)	142 (86%)	85% (13%)	70% −94%	16 (10%)	11% (14%)	2%−26%	7 (4%)	4% (2%)	2%−6%
Combined diet and exercise	7 (27%)	448 (83%)	76% (14%)	54% −90%	71 (13%)	17% (11%)	8%−38%	24 (4%)	7% (13%)	0%−37%
Pelvic floor muscle training	2 (8%)	310 (69%)	69% (7%)	64% −75%	135 (30%)	30% (8%)	24% −35%	5 (1%)	1% (0.4%)	0.8% −1%
Primary funding source										
Industry	1 (4%)	155 (85%)	-	-	16 (9%)	-	-	12 (7%)	-	-
NIH or other US government agency	8 (31%)	643 (71%)	72% (12%)	54% −94%	217 (24%)	19% (11%)	0%−35%	47 (5%)	9% (12%)	0.8% −37%
Non-profit organization	1 (4%)	48 (94%)	-	-	2 (4%)	-	-	-	-	-
University	16 (62%)	997 (85%)	82% (12%)	63% −100%	146 (12%)	15% (12%)	0–38%	32 (3%)	3% (3%)	0%−8%
Disease stage										
Localized	19 (73%)	1,300 (78%)	79% (12%)	63% −100%	323 (19%)	18% (12%)	0%−38%	52 (3%)	4% (4%)	0%−14%
Advanced	7 (27%)	543 (85%)	83% (14%)	54% −94%	58 (9%)	8% (5%)	2%−19%	40 (6%)	8% (13%)	0%−37%

*Other races reported include Hispanic, Asian/Pacific Islander, Native American/Alaskan Native, and Multi-racial