



Recruitment of Black Identifying Young Adults into Clinical Trials: a Report from the Field

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Introduction

Recruitment for clinical studies in minority communities in the United States (U.S.) is difficult due to historic mistreatment of participants and their data [1]. Traditional power dynamics favoring the knowledge production mechanisms within academic institutions rather than knowledge generation by the members of minority communities persist due to the systemic racism that continues to shape and impact legislation, relations, and health outcomes in these communities [2, 3]. As a result of this power dynamic, researchers have excluded minority populations by labeling them as hard to reach, and are just recently beginning to create methods and strategies to meet the needs of people of color [4]. However, these methods are largely gleaned from Black adult women, and thus relegate youth and Black men even further into the margins.

We are primarily concerned with recruitment and retention strategies for marginalized populations because of the study's focus on chronic disease prevention in a high incidence population. Black—defined here as Hispanic and non-Hispanic Black—young adults suffer from higher rates of overweight and obesity in comparison with their White counterparts [5]. Being overweight

or obese can lead to chronic health conditions in life, including type 2 diabetes, heart disease, stroke, and even death [6]. The ASPIRE Study, with funding from the National Institute of Nursing Research, seeks to test an intervention using technology and individualized health coaching to achieve weight loss, increase exercise, and overall healthier nutrition habits in Black young adults aged 17 to 25. The long-term goal is to develop a personalized and culturally tailored intervention that can be disseminated across community colleges nationwide.

This paper describes the creation of culturally and environmentally responsive recruitment methods for a randomized controlled trial of 256 Black young adults for a weight loss intervention study. Approximately 50% of participants will be Black men. The onset of COVID-19 has particularly affected recruitment strategies, and we will describe the researchers' adjustments within both this context, and the context of the widespread declaration and acceptance of racism as a primary public health concern since June 2020. Though these adaptations are notable within the national context of the United States, we believe these strategies for online and community-based recruitment will provide significant guidance as researchers seek to maximize participant benefit while also increasing equitable knowledge production and interventions that can scale and be brought to market.

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Methods

To inform the development of our recruitment strategy, we reviewed literature for recruitment and retention

strategies for engaging Black young adults in weight management clinical trials. As Black participants are historically underrepresented in clinical trials, we identified no articles that exclusively analyzed recruitment strategies for engaging young Black adults in weight loss programs. Accordingly, we broadened our search criteria to identify research that could inform an intersectional recruitment strategy for this understudied population.

In identifying applicable sources to inform the development of a recruitment plan, criteria of interest included a significant portion of the paper dedicated to the explanation of successful recruitment strategies and emphasized the intersection of the Black identity with gender, age, or income of our target group. With an emphasis on young adults, the search also prioritized studies using multi-media images and marketing techniques and incorporated best practices from previous studies conducted in the specific community college population. Specific attention was given to community-based, rather than regional/national enrollment efforts, because of the context of the current project. There was also emphasis placed on studies that discussed specific enrollment strategies to engage Black men in research studies.

We considered three main aspects when identifying applicable and implementable tactics to fit the existing project constraints: community-based scope, research team capacity, and the onset of the novel coronavirus, COVID-19. First, the unique nature of the recruitment on a single community college campus resulted in the preference for community-based recruitment processes. Second, we kept the capacity of the research project, team, budget, and scope in mind when considering realistic and attainable recruitment methods. Third, the onset of COVID-19 prior to initial recruitment efforts resulted in the removal of specific tactics from consideration, and the alteration of recommended recruitment strategies to ensure compliance with health precautions.

Initial Findings and Applications

An initial review of relevant sources revealed two key findings that required further exploration before incorporating into our strategy. The first finding was the importance of community involvement in recruitment methods [7, 8]. To address this need, the research team identified potential student groups and local organizations within

the local community college network. To identify these groups, the research team pulled contact information from the college's student club list, looked for affiliated social network pages, and browsed upcoming events on the college website. Additionally, the project's Community Advisory Board (CAB), made up of students, faculty, and staff with the goal of appropriately informing research activities and data dissemination in the college community, has played an integral role in identifying clubs, initiatives, and resources that will expand the reach of recruitment efforts.

The second finding emphasized the use of culturally targeted and gender-specific frames in outreach material [9, 10]. In creating recruitment flyers, the project assistant looked at examples of successful research flyers, while also considering specific elements such as color, use of messaging, and photographs that would appeal to the target audience. These flyers were presented to the team of co-investigators, as well as the CAB, and have been modified according to feedback. The flyers are accompanied by one of eight possible gain-framed messages, inviting students to participate in the study for various beneficial reasons (see Table 1). Gain-framed messages incorporate the benefits of performing a specific behavior, whereas loss-framed messages focus on the negative consequences of not performing the behaviors and typically activate feelings of racial discrimination [4, 9]. Each gain-framed message incorporates a different theme of behavior change that has proven salient in research recruitment efforts with men and Black women respectively [11, 12]. Each week, the project assistant sends a flyer paired with a message to 100 Black students at the community college, as well as a different flyer-message pair to another group of 100 students. Additionally, the coordinator sends follow-up emails with new flyer-message pairings to approx. 200 students from the previous week(s).

In keeping the capacity of the research team in mind, the principal investigator and project coordinator reassessed project needs and readjusted the budget to allow for the hiring of an additional team member. Instead of hiring multiple research assistants to conduct enrollment and check-in visits, a single project assistant was hired with a background in minority youth outreach and service utilization to focus on participant recruitment and retention. The team was willing to accept reduced human resources capacity in light of the COVID-19 pandemic, which was expected to significantly reduce the number of participants enrolling per month.

Table 1 Gain-framed messages for ASPIRE Study virtual recruitment

	Frame	Message	Response rate
Female targeted	Physiological health	College is an important time to form habits that positively impact your long-term health. Healthy eating and exercise could help prevent the onset of long-lasting diseases such as type 2 diabetes and high blood pressure	1.2%
	General wellbeing	College can be a time of increased pressure and stress. Healthy eating and exercise could increase your energy levels and improve self-esteem while combating feelings of depression and anxiety	1.8%
	Social/family responsibility	Your family, friends, and community depend on you and your healthy eating and exercise can help you improve your overall health and wellbeing so that you can continue to care for your loved ones.	1.6%
	Physical appearance	You get to decide your own ideal body shape. Healthy eating and exercise can be a tool to help you work towards personal fitness and body goals.	2.1%
Male targeted	Muscular and bulk	Whether you want to gain muscle, bulk up, or tone your body, you can use healthy eating and exercise to obtain your ideal build.	1.3%
	Autonomy over health	You can take charge of your own health outcomes! The use of Fitbit allows you to monitor your fitness levels, set personal goals, and work towards improving your overall health	0.7%
	Empowerment through knowledge	Knowledge is power. By working with a world-record-seeking health coach, you can learn the best workout regimens and how to fuel your body to meet your personal fitness goals.	1.2%
	Community impact and empowerment through health knowledge	By participating in the ASPIRE study, you can help develop a wellness program for fellow Black and Hispanic community college students across the country, while learning the best workout regimens and how to fuel your body to meet your personal fitness goals.	1.3%

With regard to the COVID-19 pandemic, recruitment has occurred exclusively online. People of color have been disproportionately affected by the coronavirus, and thus, we prioritized minimizing disease risk through exclusively recruiting individuals through online, passive methods, and conducting eligibility screenings over the phone [13, 14]. Through convening our CAB, we developed online recruitment methods, such as engaging on social media accounts and delivering presentations at online meetings of student organizations. We have also amended subject lines in our emails to emphasize the accessibility of the study by labeling it as an “at home fitness program.”

Recruitment has been active since December of 2020. The team has emailed approx. 2300 students, and has yielded slightly above a 3% response rate, which is on par for similar direct mailing messaging campaigns [10]. Efforts have been made to stratify email lists by gender in an attempt to specifically target black males with flyers and messages that have been designed for them. These emails include images of black men participating in exercise and messages focusing on

building muscle and personal/community empowerment [15, 16]. Stratified by gender, the overall response rate for women is just over 2%, while the response rate for men is just above 0.5%. The most effective frames by perceived gender identity were Muscularity and Bulk (1.3%), and Community Impact and Empowerment through Health Knowledge (1.3%) for contacts that the research team perceived to be male. For contacts that the research team perceived to be female, the most effective frames to date are Physical Appearance (2.1%) and General wellbeing (1.8%).

Limitations

The onset of COVID-19 and the institutionalization of social distancing measures have severely limited our recruitment efforts. A preliminary study to assess the ability of the research team to recruit the target population in the college community was largely successful in that they were able to recruit over 400 Black young adults, mainly through word of mouth and in-person recruitment methods

[17]. Shifting our recruitment to solely online platforms demonstrated a significant shift for the research team, and took approximately three months to create, gain IRB approval, and deploy.

Another limitation arises in the attempted gender stratification of the email lists. The research team recognizes gender as a social construct to which not all of the potential participants will relate. Yet, the recruitment materials were constructed with the gender binary in mind, and the analytics conducted thus far are reflective of such as well. Recognizing this, the research team is planning additional studies that specifically investigate inclusion of gender minorities (GM) into clinical health and wellness research, with the hopes of further tailoring both recruitment materials and the text-message-based intervention piloted in the study.

Conclusion

To date, the research team has recruited over 20% of the target number in less than three months of active recruitment during the COVID-19 pandemic. Accordingly, we believe the culturally relevant adjustments, like including relatable images and multiple languages, have profoundly impacted study enrollment. We will continue to work with CAB members to iterate relevant recruitment materials and methods for our desired population. Designing, implementing, and cataloguing recruitment methods for Black youth is increasingly important due to their lack of representation in clinical studies despite bearing a higher burden of disease than their white peers. We will continue to document and publish findings from our recruitment efforts in order to build the literature so that both researchers and potential participants are able to engage in culturally competent, responsive, and necessary research.

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