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Incorporating health literacy principles into the adaptation of a methods motivational interviewing approach for enrolling black adults in a pilot randomized trial

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Suboptimal enrollment and retention efforts can compromise the quality of clinical trials. Barriers to enrolling marginalized populations include low awareness/education about clinical trials. Methods-Motivational Interviewing (MMI) is a patient-centered process that integrates education in providing trial information and engages participants in discussions about the trial before enrollment. Though the MMI approach is effective in enhancing trial recruitment and retention, limited studies have incorporated evidence-based health literacy approaches, especially for underrepresented individuals. In this study, prior to the informed consent process, Black adults completed an interactive orientation followed by a small group discussion. The content used health literacy principles including plain language, infographics, and a pictorial roadmap to guide participants about the purpose of a trial, the randomization process, the study objectives, and timeline. Thereafter, two focus groups explored participants' perceptions of the enrollment process. Fifteen participants attended the orientation with 14 enrolled in the trial after the orientation, (93% enrollment rate). Retention was 93% (control) to 100% (intervention) at the end of 6 months. Participants reported positive orientation experiences due to a better understanding of the study information, expectations, and rationale behind randomization. Implementing an adapted MMI approach focused on health literacy principles may improve trial enrollment and retention rates among Black adults.

Keywords Health literacy, Clinical trials, Enrollment, Retention, Black adults, Motivational interviewing

Clinical trials are the foundation for advancing scientific knowledge and innovative treatment approaches in healthcare and medicine[1]. Suboptimal participant enrollment and engagement can compromise the quality of randomized controlled trials including diminishing the validity and rigor of trial results. To address disparities in trial outcomes, it is of particular importance for clinical trials to have enrollment of diverse populations. To do this, there is a need to address disparities in clinical trial participation and engagement[2].

Though it has been nearly 30 years since NIH declared that members of racial and ethnic minority groups, and women must be included in clinical trials[3], we continue to see underrepresentation of these individuals in trials[4]. The average enrollment rate of underrepresented populations in clinical trials have ranged from less than 5–11% compared to non-Hispanic white participants whose enrollment rates are as high as 80%[5–7].Barriers to enrollment and engagement have included a lack of awareness of trials, limited referrals to clinical trials, fear and mistrust of clinical research, and reduced access to clinical trial opportunities[8–11].

Many efforts have been made to address the disparities in representation of racial and ethnic minority groups. Several proposed approaches have included reducing the time spent to travel to the clinical trial site enrollment location, using professional interpreters in communicating trial information[12], providing enrollment sites within the community, using patient navigators and research coordinators to help with barriers to enrollment such as transportation, and providing flexible hours for participants to enroll[13].

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Engaging community members from the population of interest in developing the study design, protocols, and intervention implementation plan has been shown to be successful[14]. As well, the time spent engaging with community partners, allowing them to be involved in recruitment efforts, has been worthwhile in enrolling marginalized populations[9,11,15]. Other studies have shown that reducing participant constraints to participation such as providing flexibility for when and where to discuss trial enrollment may enhance enrollment efforts[13]. Despite the numerous approaches implemented in prior literature, barriers continue to exist in enrolling underrepresented populations in trials, which is a critical factor to consider since they are disproportionately at a higher risk for chronic diseases[16].

An important factor in clinical trial enrollment, especially for marginalized populations, is health literacy. According to Healthy People 2030, health literacy is categorized as both personal health literacy and organizational health literacy. While personal health literacy emphasizes the individual's "ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others;"[17]organizational literacy emphasizes the roles of organizations in allowing individuals to find, understand and use the information to inform their health actions and decisions[18].

Health literacy is a vital component to participant recruitment in clinical trials because if an individual does not have sufficient understanding of the clinical trial process, they are likely to not enroll in a clinical trial[19]. Improving personal health literacy can help in addressing the gap in insufficient recruitment of underrepresented groups in clinical trials. Similarly, organizational equity efforts to advance health literacy may include actions by researchers and research institutes to make sure clinical trial materials are understandable and accessible to audiences.

Several other proposed strategies on how to incorporate health literacy principles into clinical trials[20,21]include using simple and plain language in informed consent forms and trial materials, confirming understanding of trial procedures using teach back, getting feedback from end users on trial materials, and limiting the use of numbers, where possible[20].

A systematic review showed that health literacy principles can be successfully incorporated into different stages of the clinical trial process[21]. However, there are limited efforts in utilizing health literacy principles to educate underrepresented individuals about clinical trials and trial information, especially before the informed consent process begins. Incorporating ways to enhance health literacy about trials before an informed consent process may support autonomy in the decision-making about trial participation, lead to better engagement in trials and reduce suboptimal trial enrollment.

According to Goldberg and Kiernan[22], the use of prerequisite orientations, purposefully held before participants enroll in a trial may increase enrollment. This innovative patient-centered approach called Methods-Motivational Interviewing (MMI), integrates interactive and educational sessions in providing trial information and engages participants in discussions about participating in a clinical trial before enrollment in the trial[22,23].

These prerequisite orientations involve participants actively learning about clinical trials, the rationale behind methods used in clinical trials, and the study research questions. In addition, ambivalence towards participating in the trial is diffused via discussions of the pros/cons regarding study participation. The orientation encourages potential trial participants to consider a commitment to the study methods, i.e., completing all study assessments irrespective of their randomization status or successful engagement in the study, and one other commitment to themselves, i.e., changing their health behaviors[23].

Previous studies have used the MMI approach in several randomized behavioral trials across various chronic conditions and diverse populations, including adults with asthma[24], adolescents with type 1 diabetes[25], lifestyle promotion programs for families[26], fitness programs for Latino adults[27], etc. It has been suggested that the MMI approach with the integrated prerequisite orientation sessions, may increase the rigor of trials, due to an improvement of participant retention in a trial and attendance at an intervention[23]. The MMI approach has been adapted for use in varied delivery formats such as in-person, virtual, and conference calls[25–27]. In this study, the MMI approach used evidence-based health literacy principles to enhance enrollment and retention of Black/African American adults. There is a growing move towards the engagement of racial and ethnic minority groups in clinical trials[28], by enhancing their understanding of trial information. Hence, this study investigated the use of an adapted MMI approach in enrolling Black adults into a trial, investigating their facilitators and barriers to trial enrollment.

Methods

Sample

The inclusion criteria for participation included the following (1) Black/African American adults aged 18 to 90 years old diagnosed with type 2 diabetes, (2) can speak and/or read English, (3) currently have a prescription for one oral or injectable diabetes medication, (4) living in the geographical area during the study, (5) having an A1C value of 7.5% or greater, and (6) self-reporting they have medication nonadherence. Participants were excluded if they were (1) currently participating in another diabetes management program focused on medication adherence, (2) an older adult with a prior episode of hypoglycemia that required medical assistance or administration of glucagon, and (3) self-reported schizophrenia, dementia, untreated bipolar disorder, or active substance use disorder.

Recruitment

Purposive sampling, and passive and active approaches was used to recruit participants in a midwestern city in the US. The passive approaches included posting IRB-approved flyers in food pantries and community centers, radio and newspaper advertisements, and word of mouth. The active approaches included community presentations about the study by the PI, and inviting participants from prior studies to inform others about the current study.

Methods motivational interviewing approach

This innovative approach includes the use of prerequisite orientations to increase retention in randomized trials. The process includes meaningfully involving participants in active learning about the research question, the trial process, the scientific rationale for the methods used in the trial, and to diffuse ambivalence about the pros/cons they might have about enrolling in the study. This interactive session is held prior to participants enrolling the study, and provides detailed information about the trial, so that potential participants can consider if they want to commit to changing the targeted behavior and completing the trial, irrespective of their personal success in the trial[22].

Adaptation of methods-motivational Interviewing approach

An adapted Methods-Motivational Interviewing (MMI) approach, incorporating a prerequisite orientation, was implemented in the recruitment stage of a pilot trial assessing the feasibility and exploratory outcomes of a culturally tailored diabetes self-management intervention versus a standard diabetes program for Black adults. This clinical trial was registered at https://clinicaltrials.gov/ct2/show/NCT05527847. The first day of registration was 09/01/2022. The clinical trial study design, details and results are not presented in this paper. For this adapted MMI approach, the prerequisite orientation took place before the informed consent process, featuring a 20-minute in-person interactive presentation led by the principal investigator and a 15-minute small group discussion led by the study coordinator. Informed by the core constructs of the MMI approach by Jake-Schoffman et al.[23], we tailored our interactive presentation to include: (1) the meaning of research and the purpose of clinical trials, (2) an introduction to randomization and the process of randomization, (3) an overview of the study clinical trial and differences between the two trial arms, (4) the study timeline including assessments, time involvement, and incentive schedule, and (5) an explanation about the scientific rationale for completing assessments.

Following the interactive presentation, the principal investigator left the meeting room the orientation was held to mitigate power dynamics. Thereafter, the study coordinator facilitated group discussions with potential participants using motivational interviewing principles. Specifically, the facilitated group discussions prompted potential participants to think of two pros and cons for participation in the trial. Since our trial comprises two trial arms, each receiving one type of diabetes self-management program, the study coordinator also asked the potential participants to generate an additional two pros and cons for 'being in the 6-week group' and 'being in the 8-week group'. After the brainstorming session, the study coordinator allocated an equal amount of time to allow potential participants to share their opinions on each scenario (e.g., pros of being in the trial, cons of being in the trial, etc.) to sustain neutrality regarding trial participation.

Health literacy principles

Health literacy involves providing information to people so that they can make well-informed health decisions. As a social determinant of health, it can influence equity, especially in the enrollment of underrepresented individuals in clinical trials. Some general guidelines for communicating health information include using clear communication, plain language and relevant graphics which highlight the objectives; offering health information that is easy to find, understand, and use; sharing accurate, accessible, and actionable information to guide well-informed health decisions, and asking for feedback through 'teach-back' methods[29–31].

Applications of health literacy principles in designing an interactive orientation

The prerequisite orientation (total time of 45–50 min) was developed following health literacy principles in engaging with potential trial participants[32]. The visual aids and key strategies we used in the initial 20-minute interactive presentation is demonstrated in Table 1. The interactive presentation incorporated five main topics, including (1) an introduction to research and trial, (2) an introduction to randomization, (3) an overview of the program, (4) the study timeline and expectation, and (5) explanation of scientific rationale for completing assessments.

In the first topic of the presentation, we began by defining 'research' to our potential participants, introducing synonymous terms such as clinical trials and clinical studies. We explicitly mentioned that we could use the terms interchangeably throughout the entire study. Additionally, we explained the purpose of conducting various types of research, providing examples and visual aids to enhance participant understanding of the topics. Our presentation specifically introduced behavioral research and illustrated how this type of research would be conducted in a community setting for our audience, and how it differed from other type of trials.

Following the introduction to research and variation in clinical trials, the second topic explained 'randomization' to our potential participants. In this segment, we elucidated the process, beginning with potential feelings (e.g., feeling unfair) that participants might experience. We clarified how researchers handled the assignment of participants in a study, outlining methods such as using flip coins or computer-generated programs. Additionally, we provided the rationale behind this process[35]. To ensure simplicity, we used plain language, visualized the procedure, and illustrated how human choices could introduce bias into trial results, offering a straightforward example for better understanding. Finally, we connected how randomization allows for trustworthy results that would minimize bias in the final study outcomes.

In delivering the main content of study information, we provided potential participants with relevant background information about the prevalent health-related issues in the Black community. For cultural appropriateness, we acknowledged possible mistrust experienced in healthcare/research settings when introducing the purpose of this study. With well-designed visual aids, we presented only the essential information about the intervention components. For instance, we organized group education sessions and support by diabetes self-management topics. Throughout the presentation, we aimed to remain neutral regarding the effectiveness of the two trial arms. We avoided emphasizing culturally tailored support in one of the trial arms, instead focusing

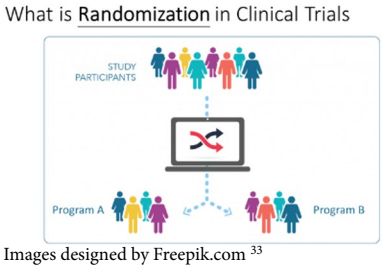
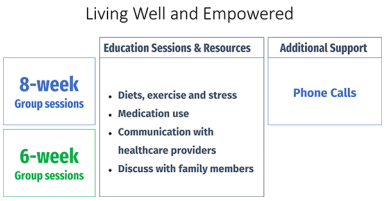
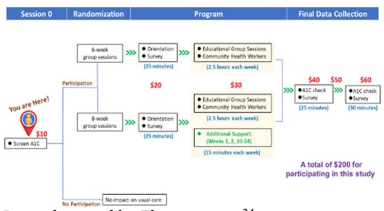
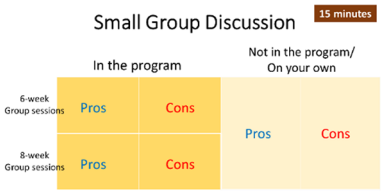
Topics	Example slides	Key points and principles of health literacy applied
1. Introduction to research and trials	 Images designed by Freepik.com [33]	• Define 'research' and introduce similar terms • Explain the meaning of research, different types of research, behavioral research in clinical trials using simple, plain language • Use pictures and examples
2. Introduction to randomization	 Images designed by Freepik.com [33]	• Explain the rationale behind randomization • Visualize the process • Avoid academic and medical jargon
3. An overview of the program		• Account for cultural considerations • Informative headings, and sections shaded with different colors to break up content. • Numbers in numeric form • Provide an overview of the two arms in the study • Neutrally explain the similarities and differences between trial arms
4. The study timeline and expectation	 Icons designed by Flaticon.com [34]	• Use a pictorial roadmap to visualize the study timeline, including study assessments, time involved, and payment/incentive schedule • Clear design by retaining the study timeline structure and adding a layer of information each time
5. Explanation of scientific rationale for completing assessments	 Icons designed by Flaticon.com [34]	• Use an infographic to explain the scientific rationale for a "true" picture, provide transparency and value of their contribution • Use the trial arms as an example
6. Small group discussions to diffuse ambivalence		• Ask open-ended questions to encourage participant engagement • Visualize different scenarios of trial participation to avoid confusion • Interactive discussion to ensure understanding of the study information and create a safe space to express concerns

Table 1. The visual aids and key points and principles of health literacy applied. # Images 1 and 2 were designed by Freepik. https://www.freepik.com/. Icons 4 and 5 were designed by Flaticon https://www.flaticon.com/. All other pictures were generated by us (Authors of the manuscript).

on the format of support participants would receive in the intervention group. To enhance clarity, we used colors to highlight the similarities and differences between the two trial arms, ensuring that the information was easily understandable for potential participants.

Following the general overview of the study information, the next topic delved into more detailed study procedures by specifying the expectations associated with each study event. To enhance understanding, we employed a pictorial roadmap that mirrored the structure of the study timeline while incorporating layers of information. This included details such as the number and types of study assessments, the time involved in each assessment or intervention, and the payment or incentive schedule provided at different phases. Importantly, we

emphasized to potential participants that they still had the option not to participate in the trial. It was crucial for them to understand that this decision would not impact their usual care.

The final topic of the presentation focused on elucidating the scientific rationale for retaining participants during the overall study. An infographic design informed by Kiernan et al.[36] was applied to enhance knowledge of the scientific rationale, provide transparency, and share the value of its scientific contribution. Adapting the visualization to the two trial arms in our study, we explained how different scenarios could impact the 'true' study results. Our goal was to demonstrate the importance of participant retention in obtaining meaningful and accurate data. Additionally, we wanted to establish trust with potential participants by being transparent about our purpose to only accept unbiased results of the study.

Subsequently, we implemented several strategies to diffuse ambivalence about study participation. We intentionally used open-ended questions at the end of each topic (e.g., What questions do you have for me? What part of the procedure needs more explanation?) to encourage potential participants to engage in the discussion. An interactive group discussion about the pros and cons of participating in a trial enhanced potential participants' understanding of the study's key information of the study but also fostered a safe environment to share their concerns. Informed consent was obtained from all participants. All methods were carried out in accordance with approval of the Health Sciences Institutional Review Board of the Principal Investigator's prior University (2022 – 0879), approved on 9/18/2023. The study was carried out in accordance with the principles of the Declaration of Helsinki.

Data collection

As part of the 45–50 min prerequisite orientation, there was 15-minute small group discussion, to discuss the pros and cons of participating in the trial. Potential participants in the groups took turns sharing their thoughts with the whole group. About 5–10 min were used to answer questions they might have about the trial. Discussion notes were documented by two research assistants and summarized across three different screening/orientation days. At least 4–5 potential participants participated in each orientation across the screening/orientation days, for a total of 15 individuals. After the trial started, two 30-minute focus groups – one with the intervention group and one with the control group, were conducted by the study coordinator to gather participants' feedback on the prerequisite orientation and explore their perceptions of the enrollment process. The coordinator has extensive experience in facilitating focus groups and maintained a neutral stance in gathering participants' feedback on the prerequisite orientation. We also collected quantitative measures, including trial enrollment and retention rates using study documents review. While there are no standard criteria for enrolling and retaining participants in Black adult populations, we set the target based on our previous work – enrollment rate of 80% and retention rate of 75%[37]. The attrition rate was set as 20% after randomization. Our anticipated time from the initial screening to enrollment was 60 days.

Data analysis

Participant demographic information, recruitment and retention rates for the trial were analyzed using descriptive statistics. Discussion notes, gathered from each screening day, were summarized through document review. Focus group transcripts were analyzed by one research assistant using inductive content analysis[38]. For qualitative analysis, NVivo 10 (Lumivero) was used to organize the codes and themes from the focus group transcript and keep audit trails. Data triangulation with observations and focus groups at different time points was implemented to ensure the credibility of this qualitative study[39].

Results

Fifteen potential participants attended a 30-minute prerequisite orientation prior to providing informed consent. Fourteen participants, comprising six males (43%) and eight females (57%) enrolled in the trial after the orientation. The majority of participants had some college degree or a more advanced degree (10, 77%) and the majority resided in an urban or suburban area (11, 85%). The average number of years since diabetes diagnosis was 14.7 years (SD = 9.6), and the average number of oral diabetes medicines was 2.0 (SD = 1.2).

The enrollment rate was 93% (14/15) of all eligible participants, representing a 13% increase over our target (80%). The time from screening to enrollment was 13 days, indicating a 47-days acceleration compared to the anticipated timeline, and there were no dropouts (0%, 0/14) after randomization. The retention rate in this 6-month trial was 93% (13/14), with 100% in the intervention group and 86% in the control group. The overall retention rate was 18% higher than our set target.

The findings from the discussion notes over five screening days are summarized in Table 2. In discussing the advantages of participating in the trial, potential participants expressed value in adopting healthier lifestyles, having accountability in managing diabetes, supplementing provider information with intervention educational content and having the ability to share diabetes self-management information with family members. Participants perceived time commitment, conflicts with schedules, and attending in-person sessions as drawbacks of participating in the trial. When reflecting on the pros and cons of not participating in the trial, potential participants identified no time commitment as a positive aspect. However, they acknowledged that not participating would mean missing the opportunity to acquire skills for managing their diabetes. Additionally, two potential participants had experience being in a prior program and expressed interest in attending again but had concerns about potential repetitive content.

In the discussion of the pros and cons of the 8-week group sessions versus 6-week group sessions, both positive and negative perspectives were reported. Some potential participants preferred to have additional education and support to help maintain their routine after the group sessions. However, they also perceived the longer time commitment as a disadvantage. In contrast, regarding the 6-week group sessions, some potential participants felt

Discussion topics	Pros	Cons
Participating in the trial	▪ Learning about diabetes self-management skills (nutrition, exercise, and treatment) ▪ Accountability for managing diabetes ▪ Opportunities to meet with others living with diabetes ▪ Access to support and resources from the program ▪ Learning new information and meeting with providers ▪ Learning how to talk about diabetes with family members ▪ Learning healthy eating styles to inform other family members	▪ Time commitment ▪ Attending can affect their normal work schedule ▪ Concerns about being unable to attend the sessions due to bad weather or not having access to virtual meetings. ▪ Repetition for people who may have participated in the program before ▪ Having to attend the sessions in person ▪ Not being able to choose which intervention group to participate in
In the **8-week** group sessions	▪ Having longer sessions to get more information ▪ Having additional phone call support ▪ Preference of having follow-up calls after the program ▪ Maintaining knowledge by talking about it with someone else	▪ Longer time commitment
In the **6-week** group sessions	▪ Get done with the program faster ▪ Receive maximum benefit from just 6 weeks ▪ A shorter time commitment required	▪ Don't have additional support ▪ Too short
Not participating in the trial	▪ No time commitment	▪ Missed opportunity for a person with diabetes to learn about the condition and have better control ▪ Not learning about how to get into a better routine for diabetes management

Table 2. Pros and cons of participating in the trial vs. not participating in the trial – information reported by potential participants in small group discussions.

that completing the program in a shorter time frame might be a more efficient choice to get similar content. They reported shorter duration and no access to additional phone call support as negatives. (Table 2)

Positive experiences of the prerequisite orientation were reported in the two focus groups because of a better understanding of the study information and expectations and rationale behind the randomization process. Participants appreciated the opportunity to have the research team explain the study information and the interventions before the trial.

"It was a great introduction to the program, just letting us know what we're getting involved in and what is expected of us and what resources or …information you all would give." – Participant 3 (control group).

Participants also commented on the efforts taken to clearly explain the distinctions between research terms. As well, one participant expressed a preference for going through all the details regarding the study timeline and program schedule to make them understand what a weekly schedule would entail if they chose to attend the program.

> "She [The principal investigator] took the time, and she went through what the weeks would look like. She explained, which I didn't realize that people may not understand the difference between study … and the clinical trials." – Participant 4 (intervention group).

Another point of feedback reported from the participants was they wanted the research team to be explicit about the study expectations. One participant perceived that being transparent from the beginning when discussing the time involved in the program, and maintaining a space for them to make the final decision were crucial aspects.

"She [the principal investigator] made it perfectly clear what they [the research team] will expect in the study. It made a big difference. Because it gave you the choice to decide whether you wanted to stay or not. And after hearing everything, all the expectations. Because you might have thought it sounded good at first, but then you found out, it's going to be six to eight weeks. No, that's too long for me, and then decided not to do it." – Participant 1 (intervention group).

Implementing the prerequisite orientation had a positive impact on creating a safe and welcoming environment for potential participants to raise concerns at the beginning of the program. One participant noted that the prerequisite orientation helped address their questions and appreciated the time the research team dedicated to answering those questions.

"This [the prerequisite orientation] should clear up any questions that people may have. And if not, she [the principal investigator] is still here for them [the potential participants] to ask her questions. I just thought it was a good thing." – Participant 4 (intervention group).

Regarding the explanation about conducting a randomization procedure in a clinical trial, participants reported that they understood the rationale behind the process and agreed with the idea of assigning trial participants. One participant reflected on the thoughts about randomization,

"The explanation [about randomization] was clear, and it was helpful. And I understood more about what and how randomization works. It's not like, with different programs of things that happen, they always select the same ten people, the same whichever…I like the idea of the randomization because it's putting us up in different groups where we're not all together." – Participant 3 (control group).

Most of the participants further expressed they have no group preferences for a specific trial assignment group. They just wanted any kind of education, regardless of whether it was a six-week group session or an eight-week group session.

Discussion

This study employed an adapted MMI approach incorporating health literacy principles into a prerequisite orientation for Black adults enrolled in a pilot behavioral clinical trial. The health literacy principles highlighted the definition and explanation of all research terms using simple plain language instead of academic and medical jargon, the use of infographics, pictures, and examples, using visualizations and pictorial road maps, chunking information, using information headings, and accounting for cultural considerations. Our results show that participant enrollment and retention rates exceeded our target, and the qualitative findings suggest that the adapted MMI approach proactively supported participants in understanding and accepting the scientific rationale of the randomized trial. Participants reported that the approach provided them with a transparent and comprehensive view of the commitment involved in trial participation prior to enrolling.

The MMI approach has been used in behavioral clinical trials examining various health conditions and across diverse populations[24–27], but has not been widely used in studies involving Black adults. This trial is one of the few studies that have used the MMI approach in Black adults, and especially adapted it for increased understanding of clinical trials, and cultural relevance to a historically excluded group in trials. A behavioral trial aimed at helping Black and Latino adults lose weight employed multiple strategies to enhance recruitment and retention, including elements of an MMI approach conducting group orientation sessions[40]. However, they did not explicitly report on outcomes related to the MMI approach[41]. Our study explores trial enrollment and retention outcomes, related to the use of this approach, and methodologically uses both qualitative and quantitative methods to further gain insight into the influence of the adapted MMI approach among Black adults. This analysis is critical for understanding the impact of MMI approaches on addressing Black and other minoritized groups' fears and mistrust of clinical research. Through examining and refining these MMI approaches, researchers can more successfully engage with Black participants in the clinical trial process. Ultimately, the increased participation of Black adults in clinical trials will enhance progress towards reducing health disparities.

Addressing health literacy is essential for successful clinical trial recruitment to ensure that prospective participants have a sufficient understanding of the clinical trial process and to enhance the likelihood that they are comfortable enrolling[19]. Enhancing health literacy is particularly critical for addressing the gap in insufficient enrollment of underrepresented groups in clinical trials[21]. In contrast with prior studies evaluating MMI approaches to enhance enrollment and retention, our study is the first to incorporate health literacy principles into the MMI approach. While addressing health literacy throughout the clinical trial process is feasible to do, few studies have incorporated health literacy principles for underrepresented individuals, particularly before the informed consent process[21].

Our results suggest that using an adapted MMI approach with embedded health literacy principles enhanced the clinical trial process in three ways. First, it enhanced the understanding of clinical trial information prior to the informed consent process. Using a prerequisite orientation incorporating active learning and opportunities for discussion of pros and cons of trial participation, fostered a deeper understanding of information about the trial and helped to address ambivalence about the decision to participate in the trial. Second, our findings are consistent with studies demonstrating that the use of health literacy principles can enhance clinical trial enrollment and retention among marginalized groups[42–44]. Utilizing this approach supports autonomy in the decision-making process and may help to build trust among underrepresented groups[21]. Third, our findings show promise that using an adapted MMI approach with embedded health literacy principles may increase attendance rates for intervention sessions for marginalized groups. Presenting clear information about the activities and time commitments involved in trial participation during the prerequisite orientation allowed for individuals to carefully consider the commitment and make an informed decision about their availability to participate. Presenting study information using an understandable and accessible approach and providing an opportunity to discuss with the research team prior to informed consent, enhanced understanding of clinical trial information. As well, study participant feedback may guide future study processes including how to recruit and retain participants in clinical trials. For example, results from the discussion highlight the rationale for trial participation which can be leveraged in motivating underrepresented individuals during recruitment, and their challenges with intended participation, informing how to reduce barriers to trial participation.

This research had several limitations. First, this was a pilot trial with a small sample size, which limits the validity and generalizability of the findings. Acknowledging this reality, the authors report the findings as suggesting or showing promise regarding certain outcomes. The inclusion of both qualitative and quantitative data strengthens the analysis, despite the small sample. Second, while this was a randomized clinical trial, the MMI approach was applied prior to randomization for all participants. All potential participants were a part of the adapted MMI approach and there was no comparison group which did not experience the adapted approach. It is not possible to know whether the enrollment and retention outcomes reflect the adapted MMI approach or some other contextual factors in patient engagement. Third, there is limited generalizability of the study results as the majority of Black adults enrolled in the study had some college degree or a more advanced degree and may have higher health literacy than Black adults with less education. Future studies should consider the inclusion of individuals with diverse characteristics including education levels.

Future studies should explore adapted MMI approaches incorporating health literacy principles in larger trials with underrepresented populations to demonstrate whether it leads to enhanced trust in trials and improves enrollment and retention outcomes. Additionally, future studies should employ randomized or optimization study designs in which some potential participants receive the adapted MMI approach and others do not, to reduce potential confounders and isolate the effects of the adapted MMI approach on trial enrollment and retention outcomes.

Data availability

I don't have any research data outside the submitted manuscript file. The corresponding author should be contacted for data requests.

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Author contributions

O.S conceptualized and designed the study, contributed to data acquisition, and interpretation, drafted the original manuscript; M.W contributed to the study design, data acquisition, analysis, and interpretation, and substantially revised the manuscript; M.M contributed to the conceptualization and design of the study, data acquisition, analysis, and interpretation, and substantially revised the manuscript. All authors reviewed the manuscript.

Declarations

Competing interests

The authors declare no competing interests.

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