Understanding Preferences for Clinical Trial Participation in Representative Patient Populations

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Background

- Patient characteristics may affect how a patient responds to medicines and medical devices.[1-3]
- Ensuring that patients enrolled in clinical trials (the term "clinical trials" includes medical device clinical trials or studies) are representative of the intended patient population is vital to support the interpretability of findings and ensure the entire population benefits from subsequent medical product development.
- Clinical trials often face challenges in enrolling sufficient numbers of participants, and certain patient groups are frequently underrepresented, limiting the ability to draw meaningful conclusions regarding the generalizability of clinical trial findings across patient subgroups.[3]
- By including participants who more accurately represent those living with the condition, researchers can better understand how treatments may perform across different patient groups, including potential differences in effectiveness, safety, and side effects.

Objectives

- Identify barriers and enablers to clinical trial participation from the perspective of patients with peripheral vascular disease (PVD) or other cardiovascular disease (CVD).
- Explore the impact of patient characteristics on preferences for participating in clinical trials.
- Identify clinical trial characteristics that are most important to patients when deciding whether to participate.

Methods

- Forty semi-structured, one-on-one, web-assisted interviews were conducted with participants with PVD or other CVD and who had/did not have previous clinical trial experience (**Figure 1**).
- Interview audio recordings were transcribed and analyzed using content analysis to identify common themes. Code frequency and illustrative quotes were used to analyze qualitative data.
- Sociodemographic and clinical characteristics of interview participants were collected quantitatively. Descriptive statistics (e.g., N, mean, SD, and frequency) were used to characterize the sample.

Figure 1. Interview Structure

SECTION 1	Treatment Experience	Participants shared their treatment history, reasons for switching treatments, levels of satisfaction with treatments received, and perceived needs for the development of new treatments.
SECTION 2	Clinical Trial Experience	Participants described their level of familiarity with clinical trials, prior participation in clinical trials, opportunities to participate, factors that made trials appealing or unappealing, and motivations for accepting or declining participation.
SECTION 3	Clinical Trial Participation	Participants shared whether they would participate in a clinical trial for their CVD/PVD, their motivations for participating, and factors that would deter them from participation.
SECTION 4	Clinical Trial Features	Participants shared their perspectives on specific clinical trial features through a ranking exercise, provided feedback on a mock recruitment flyer for a hypothetical trial, discussed views on sham procedures, and described their tolerance for invasive procedures.

Abbreviations: CVD = cardiovascular disease; PVD = peripheral vascular disease

Disclosures

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Results

Participant Characteristics

- Approximately half (57.5%) of participants had previously taken part in one or more clinical trials. The sample included White (27.5%) and non-White participants (72.5%) (**Table 1**).

Table 1. Participant Characteristics

Characteristic	Total (N=40)	CT-experienced (n=23, 57.5%)	CT-inexperienced (n=17, 42.5%)
Age, mean (SD)	52.4 (16.6)	52.0 (16.9)	52.9 (16.7)
Sex, n (%)			
Male	11 (27.5)	5 (21.7)	6 (35.3)
Female	29 (72.5)	18 (78.3)	11 (64.7)
Race/Ethnicity[a], n (%)			
White[b]	17 (42.5)	13 (56.5)	4 (23.5)
Black or African American	17 (42.5)	9 (39.1)	8 (47.1)
Asian	1 (2.5)	1 (4.3)	0 (0.0)
Native Hawaiian or other Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
American Indian or Alaska Native	5 (12.5)	2 (8.7)	3 (17.6)
Hispanic or Latino	7 (17.5)	4 (17.4)	3 (17.6)
Middle Eastern or North African	1 (2.5)	1 (4.3)	0 (0.0)
Location, n (%)			
Rural	5 (12.5)	2 (8.7)	3 (17.6)
Suburban	20 (50.0)	12 (52.2)	8 (47.1)
Urban	14 (35.0)	8 (34.8)	6 (35.3)
Prefer not to state/missing[b]	1 (2.5)	1 (4.3)	0 (0.0)
Diagnosis[a], n (%)			
High blood pressure	20 (50.0)	8 (34.8)	12 (70.6)
Coronary or ischemic heart disease	9 (22.5)	8 (34.8)	1 (5.9)
Arrythmias	14 (35.0)	11 (47.8)	3 (17.6)
Heart attack	4 (10.0)	4 (17.4)	0 (0.0)
History of cerebrovascular disease	1 (2.5)	0 (0.0)	1 (5.9)
Heart failure	10 (25.0)	7 (30.4)	3 (17.6)
Peripheral vascular disease	16 (40.0)	4 (17.4)	12 (70.6)
Other cardiovascular disease	8 (20.0)	7 (30.4)	1 (5.9)

[a] Multiple responses allowed; [b] Eleven (27.5%) reported White only; Abbreviation: CT = clinical trial

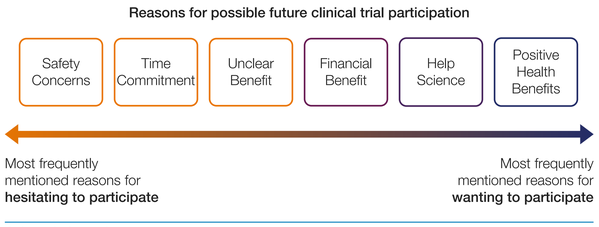
Clinical Trial Perceptions

- When asked about their previous clinical trial experience, almost all participants with experience described it positively.

> *"I felt very listened to and informed and taken care of, even though I was young they made sure to explain to me, and I really appreciated that […] It was very relaxed. I felt very safe."*
>
> —Clinical trial-experienced, Hispanic/Latino

- Participants wanted to participate in clinical trials to help science and have positive health benefits but were worried about the unknown risks and time commitment (**Figure 2**).

Figure 2. Factors influencing trial participation/hesitation



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- No major differences were found regarding preference for clinical trial staff race/ethnicity or community background. Non-White and White participants expressed that having clinical trial staff from their same community was important (n=5/29, 17.2%; 3/11, 27.3%, respectively).
- Non-White participants appeared to be less trusting than White participants of a government-run clinical trial. Overall, knowing the trial sponsor was important (57.5%).

> *"I know there's some companies out there that don't have a very good reputation in what they do and how they handle patients in general, right, and I want to make sure that if I am handing something over that the sponsor company is, is an ethical company – right, and that isn't just using that data for their own profit."*
>
> —Clinical trial–experienced, Asian American/Pacific Islander

- When presented with details of a hypothetical 12-month clinical trial requiring a surgically implanted medical device, regular check-ups, and monitoring:
  - Forty-five percent said they would be willing to participate, 32.5% were unsure, and 22.5% were not willing to participate. More non-White participants indicated they would participate (n=15/29; 51.7%) than White (n=3/11; 27.3%), and a slightly higher proportion of those without clinical trial experience (n=9/17, 52.9%) were willing to participate than those with clinical trial experience (n = 9/23, 39.0%).

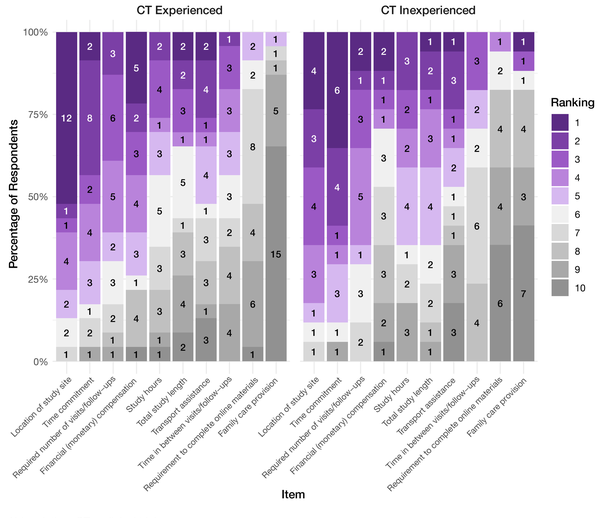
Investigational Treatment: Surgically Implanted vs. Daily Orals

- Around 77.5% indicated that they would be more likely to participate if the trial required less invasive procedures (e.g., a wearable device), although 5.0% mentioned that a clinical trial requiring a device that "required upkeep" or that they "had to carry" would decrease their likelihood of participating.
- A clinical trial requiring treatment administered as a daily oral pill increased participants' willingness to take part in a trial for most participants (n=24, 60.0%) but decreased it for others (n=3, 7.5%), who cited dysphagia or dislike of pills.
- Most (60.0%) would want to know the exact probability of receiving placebo in a trial requiring treatment administered as a daily oral pill. Participants viewed the possibility of sham procedures to be important (67.5%) and as a possible deterrent to participation.

Ranking of Clinical Trial Features

- **LOGISTICS:** Clinical trial-experienced participants most often rated location of study site as most important in influencing their decision to participate in a trial, while clinical trial-inexperienced participants most often rated time commitment as the most important and found study site location to be less important than clinical trial-experienced patients (**Figure 3**).

Figure 3. Ranking of Logistics-related Trial Features



Abbreviation: CT = clinical trial

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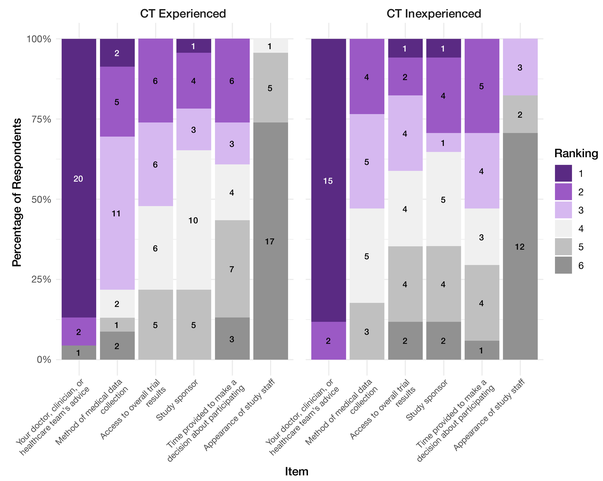
- **INFORMATION:** Clinical trial-experienced and inexperienced participants found their doctors' advice to be the most important information-related clinical trial feature in influencing their decision to participate (**Figure 4**).

Figure 4. Ranking of Information-related Trial Features



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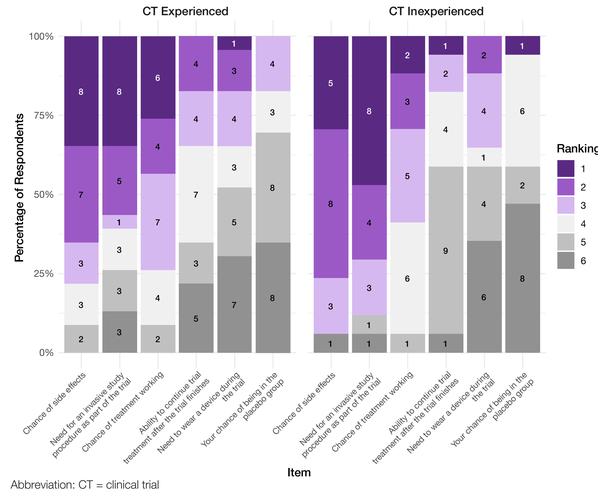
- **TREATMENT:** Clinical trial-experienced participants more often ranked the chance of side effects as the most important, while clinical trial-inexperienced participants most often ranked the need for an invasive study procedure as most important in influencing their decision to participate (**Figure 5**).

Figure 5. Ranking of Treatment-related Trial Features



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Conclusions

- Results were generally consistent irrespective of participants' individual characteristics. However, some differences were observed across clinical trial experience and race/ethnicity.
- Participants were open to participating in future clinical trials, but clear information on side effects, study duration, and required procedures are important to decision-making.
- Clinical trial features such as referral source, study location, and financial compensation would influence decisions to participate and may be modifiable to enhance recruitment.

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