Co-Developing a Patient-Centered Clinical Trial Summary Tool to Improve Communication and Access

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INTRODUCTION

Despite various efforts, cancer clinical trials often face low enrollment, with the latest national study reporting an estimated patient participation rate of 7.2%.[1]

Additionally, prostate cancer trials struggle with low enrollment among racial and ethnic minorities. African American, Latino and Asian men remain consistently under-represented in these trials compared to their incidence rates.[2;3]

While clinical trial consent forms provide comprehensive and essential information, their length and complex language may create barriers to patient understanding, further impeding participation.

OBJECTIVE

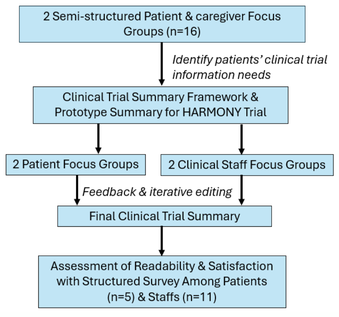
This study outlines the co-development process of a patient-centered clinical trial summary tool, created in collaboration with prostate cancer patients, their caregivers, community stakeholders, and cancer clinical staff.

By actively involving patients and their support networks in the development process, the tool aims to provide tailored information that meets patients' needs, and support informed decision-making in trial participation, particularly among underrepresented populations.

METHOD

This development process involved six semi-structured focus groups with patients, caregivers, and cancer clinical staff. The first 2 focus-groups with patients and caregivers identified key information needs, which informed the creation of a trial summary framework and a prototype for the HARMONY prostate cancer trial. Two additional focus groups with patients, caregivers, and 2 groups with cancer clinical staffs refined the prototype summary through iterative feedback on content, structure, and language. The final version's readability and participant satisfaction were assessed.

A summary of the study is presented in Figure 1.



RESULTS

1. Participants

The study included 29 participants: 18 patients & caregivers and 11 clinical research staff. Among patients and caregivers, 61% were White, 27% African American, and 11% Asian. Most had no prior clinical trial experience. (Table 1).

Characteristics	Patients or caregivers (n=18)	Staffs (n=11)
Age		
Under 50	0 (0 %)	6 (54 %)
50 to 64	5 (27 %)	4 (36 %)
65 to 74	9 (50 %)	0
75 or above	2 (11 %)	0
Gender		
Male	13 (72 %)	3 (27 %)
Female	5 (27 %)	7 (63 %)
Ethnicity		
Asian	2 (11 %)	2 (18 %)
Black or African American	5 (27 %)	3 (27 %)
Hispanic	0 (0 %)	1 (9 %)
White	11 (61 %)	3 (27 %)
Education Level		
High school diploma or GED	6 (33 %)	0
College degree	5 (27 %)	7 (63 %)
Graduate degree or higher	5 (27 %)	3 (27 %)
Prostate Cancer Disease Status		
Stages 1-3	8 (66 %)	N/A
Stage 4 or metastatic	2 (16 %)	N/A
Prior Clinical Trial Experience		
Yes	2 (17 %)	N/A
No	10 (83 %)	N/A

***Table 1**: **Participant Demographics** Note: Percentages may not total 100% due to missing data for 2 patients and 1 staff member.*

2. Key themes from focus groups with prostate cancer patients and caregivers.

In the initial two focus groups, patients and caregivers identified information they considered as important to know, before deciding to participate in a clinical trial (Table 2).

Key Themes	Explanation	Frequency
Study Summary	Phase, Study Design, Population, Research Team	7 times
Study Purpose	Research objectives and expected outcomes	6 times
Study Design	Comparison of Standard Treatment vs. Experimental Treatment	9 times
Side effects	Concise potential adverse effects	6 times
Health Benefits	Potential health benefits for participants	10 times
Logistics	Time Commitment, Travel, Ride Arrangements, Location, Compensation, Extra Blood Tests and Appointments	5 times
Staff Support	Additional Medical Staff Support	2 times

***Table 2**: Key themes and frequencies from patient focus groups.*

RESULTS (Cont.)

3. Prototype generation and iterative feedback

The prototype trial summary for the HARMONY trial was created, including the sections mentioned above.

For each section, three different versions were developed, varying in length and depth of information (short, medium, long). Feedback was collected from both patients and staff on the prototype, as well as their version preferences.

Sections	Preference	
	Patient (n=5)	Staffs (n=11)
Study Summary	**Long**	**Medium**
Goal	**Long**	**Long**
Design (experimental vs control)	**Long**	**Short**
Health Benefits	**Long**	**Medium**
Side Effects	**Long**	**Long**
Logistics	**Long**	**Long**
Staff Contact Information	**Long**	**Short**

prototype sections.

4. Assessment of readability and satisfaction

The final document was rated as 'very easy to read' by 100% of patients (n=5) and 90.1% of clinical research staff (n=11) surveyed, with "high satisfaction" reported by 92% of patients and 91% of staff (Figure 2).

CONCLUSION

Our study demonstrated the feasibility of co-developing a patient-centered clinical trial summary with patients and stakeholders, offering a replicable framework to enhance trial diversity. The tool is now being implemented in the HARMONY trial.

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