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ORIGINAL RESEARCH

Participant-Centered Insights on Clinical Trial Design: A Qualitative Study of Participant Engagement in Traditional and Decentralized Trial Designs

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Introduction: As clinical research transitions from traditional site-based models to decentralized clinical trials (DCTs), understanding participant experiences is essential. While DCTs promise improved accessibility and operational efficiency, empirical insights into how participants navigate these formats remain limited.

Objectives: This study explored participant experiences in both traditional and decentralized trials to identify factors influencing engagement, satisfaction, and retention. A secondary aim was to generate recommendations for participant-centered trial design.

Methods: We conducted online, semi-structured focus groups with individuals who had recently participated in either traditional or decentralized clinical trials. Transcripts were analyzed using inductive thematic analysis to identify key patterns of participant experiences.

Results: Five overarching themes emerged: *Navigating Trial Modalities*, *Drivers of Participation*, *Communication and Relational Dynamics*, *Structural and Psychological Gateways*, and *Technology in Practice*. Decentralized trials were valued for flexibility and integration into daily routines, while traditional trials offered supportive in-person interactions, but posed logistical burdens. Across both models, participants consistently identified communication quality, trust in clinical relationships, and feeling respected as the most salient influences on satisfaction and retention.

Conclusion: While trial modality shapes logistical aspects of the participant experience, relational and structural factors such as transparent communication, emotional readiness, and technology usability were more influential in determining engagement and retention. These findings underscore the importance of embedding participant-centered design principles in both traditional and decentralized trials. Enhancing relational engagement, clarifying expectations, and addressing digital and logistical barriers may not only improve participant satisfaction, but also optimize trial efficiency and data quality.

Keywords: Participant Engagement; Decentralized Clinical Trials; Clinical Trial Design; Qualitative Research; Participant Satisfaction; Focus Groups

Introduction

> "The incidence of patient availability sharply decreases when a clinical trial begins and returns to its original level as soon as the trial is completed."
> – Lasagna's Law (1979)

Clinical trial recruitment and retention have long been major challenges in drug development. While randomized controlled trials (RCTs) remain the gold standard for assessing an intervention's safety and efficacy, sustaining participant involvement throughout the study lifecycle is often more difficult than initial enrollment.[1-2] Participant dropout diminishes the quality and completeness of trial data, compromises statistical power and generalizability, and can jeopardize the study's validity and interpretability.[3] Attrition leads to prolonged timelines and increased costs. This, in turn, reduces market exclusivity and shortens patent protection, ultimately weakening the commercial incentive to innovate.[4] Delayed study results may also decrease clinical relevance due to evolving standards of care, impacting the drug's adoption. Additionally, the timing of financial returns affects the overall cost of development. As clinical research aims to yield generalizable and reliable results, overcoming the cost-effectiveness barriers that impede participant retention becomes essential.[5-6]

Traditional clinical trials are typically conducted in brick-and-mortar sites requiring participants to attend frequent in-person visits for assessments and procedures. While this model is favored by sponsors due to logistical

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considerations, it creates challenges in recruiting participants. Travel requirements, financial costs, and time commitments create barriers to participation. These logistical demands are particularly difficult for individuals who are in full-time employment, have caregiving responsibilities (such as caring for children, elderly parents, or dependent family members), have limited mobility, or live in rural areas. An estimated 70% of potential participants in the United States live more than two hours from the nearest trial site.[7] These challenges contribute to slow enrollment and high dropout rates, further exacerbating inefficiencies in drug development. In recent years, decentralized clinical trials (DCTs) have gained interest in addressing these challenges associated with traditional on-site visits, particularly during disruptions caused by the COVID-19 pandemic.[8]

The COVID-19 pandemic accelerated the adoption of DCTs, in which trial activities such as consent, data and sample collection, monitoring, and even intervention delivery occurred remotely through telehealth platforms, mobile apps, wearables, or home visits.[8-10] In response to public health restrictions, regulatory agencies issued emergency guidance permitting protocol flexibility, and enabling remote data collection and safety monitoring.[11-12] These adaptations highlighted the potential of DCTs to enhance participant access and continuity while reducing trial disruptions.

DCTs promise not only logistical convenience, but also greater inclusivity, particularly for traditionally underserved or geographically isolated populations. For example, in diabetes trials, continuous glucose monitors (CGMs) allow for passive, real-time data collection in a participant's home. This minimizes disruption to daily life while maintaining high-quality clinical data.[13] DCT models may also reduce participant burden and travel costs, both of which are frequently-cited barriers to trial retention.[14-15] However, decentralization introduces new concerns, including disparities in digital literacy, trust in technology, coordination of procedures, and the potential for data fragmentation across platforms.

Stakeholder perspectives, especially those of participants, are essential for evaluating the true impact of DCTs on engagement, satisfaction, and retention. While DCTs are frequently highlighted for their operational efficiency and scalability, a significant gap remains in understanding how participants perceive and experience these models compared to traditional site-based trials. As clinical research continues to shift toward more participant-centered approaches, addressing this knowledge gap is critical. It is not yet clear whether DCTs truly reduce perceived participant burden and enhance engagement, or whether they introduce new, less visible challenges such as technological barriers, fragmented communication, or reduced interpersonal support. Without a deeper understanding of participant experiences, trial designs may fail to address the most important factors influencing engagement, retention and adherence. Closing this gap is essential to ensuring that DCTs deliver on their promise of increased accessibility, inclusivity, and efficiency in the future of clinical research.

Emerging regulatory and methodological frameworks increasingly emphasize operational alignment with participant needs. The final ICH E6(R3) guideline (adopted January 2025) underscores proportionate risk approaches, data governance, and participant-centric trial design.[16] Additionally, risk-based quality management (RBQM) and its application to clinical data management are established in the literature as a comprehensive framework for proactively managing trial risk.[17] Yet few empirical studies integrate participants' lived experiences into these frameworks to inform operational design. The present study addresses that gap by exploring participant perspectives on traditional versus decentralized trials, with implications for data management and risk-based oversight.

Study Objectives

This qualitative study explored participant experiences and perspectives in both traditional and DCTs, with a focus on identifying the factors that influence engagement, retention, and trial completion. Using focus group interviews, the study aimed to uncover key themes, barriers, and facilitators that shape the participant experience across the continuum of trial operations, including recruitment, informed consent, enrollment, participation, and follow-up. By comparing participant experiences across trial formats and gathering participant-driven insights, the study sought to inform strategies that enhance generalizability, improve retention, and promote participant-centeredness in future clinical trial designs.

Methods

Study Design

This study employed a qualitative descriptive design to explore participant experiences in both traditional and DCTs. Focus group methodology was chosen to facilitate dynamic discussions and to capture a broad range of perspectives on trial engagement, burden, and retention. A semi-structured interview guide (**Table 1**) was developed to prompt conversation around participants' motivations, challenges, and suggestions for improving trial participation.

The study is reported in accordance with the Standards for Reporting Qualitative Research (SRQR)[18] and Consolidated criteria for reporting qualitative research (COREQ).[19] A completed COREQ checklist is provided in Supplement 1, with references to corresponding sections of the manuscript to support transparency and reproducibility.

Ethical Considerations

Ethical approval for this study was obtained from the Institutional Review Board (IRB) at the University of Jamestown (IRB Record #001CR). All participants provided informed consent prior to taking part in the study. Participants were informed of the voluntary nature of the study, their right to withdraw at any time, and the steps taken to protect their confidentiality. To acknowledge their time and contribution, participants were offered a $50 gift card as compensation upon completion of the focus group session.

Table 1: Focus Group Question Guide.

Semi-Structured Focus Group Questions
1. Can you describe your initial experience when you first learned about the clinical trial you participated in? How were you approached or informed?
2. What motivated you to join the clinical trial? Were there specific factors that influenced your decision?
3. For those who have participated in traditional clinical trials, what aspects did you find most challenging? What did you appreciate the most about the traditional setup?
4. For those who have participated in decentralized clinical trials, what aspects did you find most challenging? What did you appreciate the most about the decentralized setup?
5. Did you use any digital technologies to your knowledge during your participation? What was your experience with these? Describe.
6. How did you feel about the various activities in the trial, like tests and follow-up appointments?
7. Which parts of the trial made it easier for you to participate? Were there any specific supports or resources that were particularly helpful or conversely challenging? Describe.
8. What are the most significant benefits you experienced in traditional/decentralized clinical trials?
9. If you have experienced both types of trials, how would you compare your experiences? What were the key differences you noticed?
10. How satisfied were you with your overall experience in clinical trials? Describe specific factors that contributed to satisfaction or dissatisfaction.
11. Did you complete the trial all the way to your last visit? If not, what was the reason for leaving the trial or what motivated you to stay to the end?
12. Based on your experiences, what improvements would you suggest for future clinical trials to make them more participant-friendly?
13. How has participating in clinical trials impacted your overall view of clinical research? Would you participate in another clinical trial in the future? Why or why not?

Participant Recruitment

Participants were recruited using purposive sampling methods, with the goal of including individuals who had participated in either decentralized or traditional clinical trials. Recruitment was conducted between September and November 2024 through social media platforms (e.g., Facebook, LinkedIn) and professional research networks. Study advertisements described the research objectives, inclusion criteria, and how to participate. To be eligible, participants had to be 18 years or older, able to communicate in English, and currently or recently enrolled in a clinical trial involving either decentralized or traditional trial elements. Participants who had not taken part in a clinical trial were excluded.

Privacy and Confidentiality

To ensure privacy and confidentiality, each participant was assigned a unique identification code used throughout the study for data labeling. Personally identifiable information was removed from transcripts, and all digital files were stored in password-protected folders accessible only to authorized study personnel. No identifying information is included in the dissemination of findings.

Data Collection

Focus groups were conducted by the researchers SK and KKL via secure online conferencing software (Zoom Communications, Inc). A total of three focus group sessions were held, with each session attended by six to seven participants and lasting approximately 60 minutes. A semi-structured discussion guide (**Table 1**) was used to facilitate conversation, encouraging participants to share their experiences with clinical trial participation, including what motivated them to enroll, challenges faced, and reasons for discontinuation or continued engagement. All sessions were recorded and auto-transcribed verbatim. Field notes were taken during and immediately after each session to supplement transcript analysis.

Data Analysis

Consistent with a qualitative descriptive approach, we conducted inductive thematic analysis.[18,20–22] Two researchers (SK and KKL) independently reviewed transcripts to identify key phrases and patterns related to participant experiences in traditional and DCTs. Preliminary codes were developed and refined through iterative review of the data.

To support analysis, we incorporated AI tools following initial manual coding. QualiGPT, a large language model designed for open and axial coding, was used to confirm and refine initial codes.[23-24] ThemeWeave AI, a custom-built AI tool aligned with qualitative research literature including Braun and Clarke's framework for latent theme identification,[25] supported code clustering, theme refinement, and transparent documentation. Human researchers retained final interpretive authority throughout the analytic process, with AI-generated outputs functioning solely as supportive inputs rather than definitive analytic determinations. Large language

model outputs were archived within the study files, thereby establishing a transparent audit trail. Potential sources of bias were addressed through comparative checks between AI-assisted outputs and independently generated human codes, with any discrepancies adjudicated through consensus-based discussion among the research team.

Transcripts were dual-coded independently by two researchers (SK and KKL), with inter-coder agreement addressed through consensus-based adjudication. This process ensured consistency between the coders while preserving a level of flexibility appropriate for qualitative analysis.

Methodological rigor was further strengthened through adherence to established guidance on trustworthiness in thematic analysis,[26] and by aligning reporting practices with recognized standards, including SRQR[18] and COREQ.[19] Strategies employed to ensure analytic credibility and dependability included independent dual coding, iterative consensus discussions, and maintenance of comprehensive documentation. This integrated approach ensured that the incorporation of AI augmented the transparency, efficiency, and reproducibility, while preserving human interpretive judgment, in accordance with emerging best practices for ethical AI integration in qualitative research.[25,27–28]

Themes and subthemes were finalized following collaborative review and consensus ensuring analytic rigor and alignment with study objectives. Illustrative quotations from participants by theme and subtheme are provided in Supplement 4.

Results

Participant Demographics

A total of 19 individuals participated in three semi-structured focus group interviews conducted virtually via Zoom (Zoom Communications, Inc.) in October and November 2024. All participants were 18 years of age or older and able to communicate in English. Each had prior experience participating in at least one clinical trial. Participants reported experiences with traditional and DCTs models in various therapeutic areas and phases of development.

Participants reported involvement in trials that incorporated a range of decentralized modalities. Eighteen of the 19 participants reported using digital tools during their trial experience, including mobile health apps, wearable devices (e.g., Apple Watch or Fitbit), virtual visits, or telehealth services. Participants reported that data were captured through digital devices and transmitted via applications to electronic data capture (EDC) systems. These operational contexts provided the basis for participants' reflections on trial convenience, data privacy, and technological usability.

Overarching Themes and Subthemes

Analysis of the focus group transcripts revealed several overarching themes that provide a comprehensive view of participant experiences and perceptions in both traditional and DCTs. Inductive thematic analysis yielded five primary themes that captured participants' experiences across traditional and decentralized trial modalities. These were: (1) *Navigating Trial Modalities*, (2) *Drivers of Participation*, (3) *Communication and Relational Dynamics*, (4) *Structural and Psychological Gateways*, and (5) *Technology in Practice*. Each theme comprises distinct but interconnected subthemes that illuminate the various personal, relational, and structural factors influencing participant engagement, motivation, satisfaction, and retention (**Figure 1**). In total, 12 subthemes were identified, reflecting the hierarchical structure of the analysis (**Table 2**, Supplement 3). These themes not only reflect the logistical and operational realities of trial participation, but also capture the emotional, psychological, and interpersonal dynamics that shape how participants navigate through, and derive meaning from, their clinical trial involvement. This thematic structure serves as the foundation for understanding the diverse elements that contribute to a positive or challenging trial experience.

Major Theme #1: Navigating Trial Modalities

Participants compared decentralized and traditional clinical trial models, emphasizing the logistical ease of remote formats. Many described how DCTs allowed greater alignment with their daily routines, reducing the burden of participation.

Subtheme 1: Ease and Flexibility of Decentralized Participation

Participants valued the logistical simplicity and convenience offered by DCTs compared with traditional models, highlighting that remote access through apps, wearables, and virtual visits eliminated the need for travel, reduced time off work, and simplified routines. This convenience was central to both enrollment and sustained engagement. As Participant 2004 noted,

> "I really didn't have to go to any physical location... everything was done remotely,"

which was corroborated by participant 1004 as

> "What I appreciated the most [...] was just the fact I could complete that virtually and I did not necessarily have to, you know, pay out of pocket to go to a specific location to go to a clinic or anything like that."

Subtheme 2: Alignment of Trial Design with Everyday Life

Participants appreciated DCTs that integrated smoothly into their daily routines, minimizing disruption and stress. Flexible designs with virtual visits and wearable-based procedures made trial participation feel manageable and unobtrusive. Participant 3001 shares,

> "You know I didn't have to be anywhere. [...] If I wore the watch I just had to answer those surveys. I didn't have to leave work early. I didn't have to take up 3 hours of my time sitting in an office."

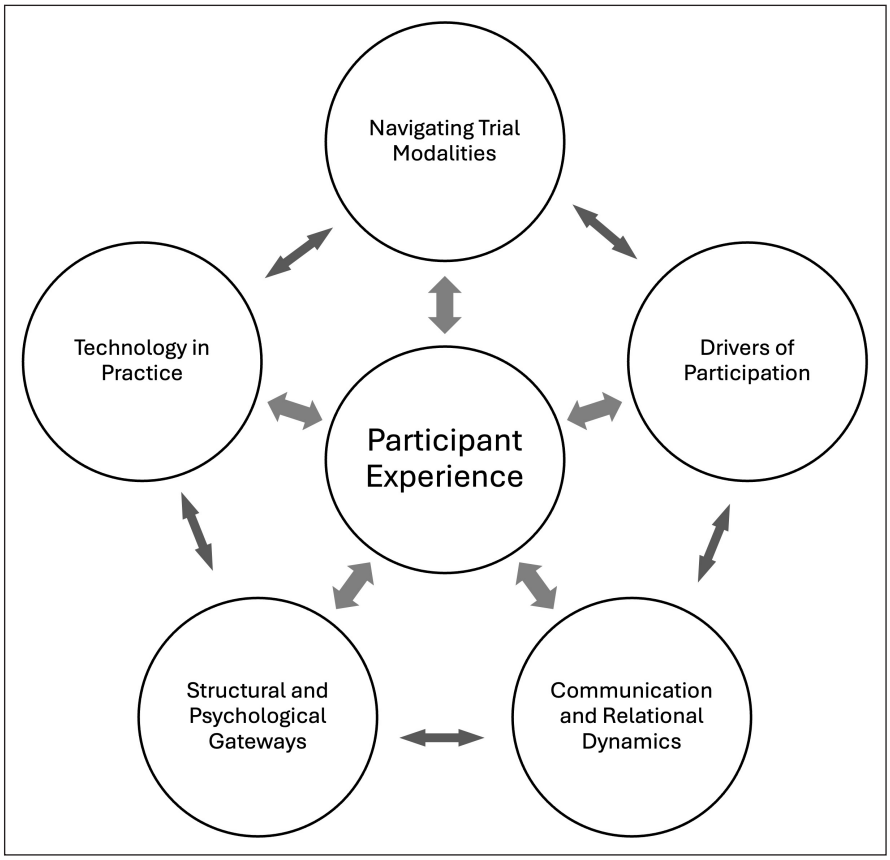

Figure 1: Thematic map of participant experiences across traditional and decentralized clinical trials.

This figure illustrates the five primary themes generated through inductive thematic analysis of focus group transcripts: *Navigating Trial Modalities, Drivers of Participation, Communication and Relational Dynamics, Structural and Psychological Gateways, and Technology in Practice*. These themes, while analytically distinct, are conceptually interconnected and collectively depict the relational, structural, and experiential factors shaping participant engagement, satisfaction, and retention across trial modalities. The central position of Participant Experience reflects the integrative nature of these influences and the dynamic relationship between logistical, interpersonal, and technological components of trial participation.

Table 2: Themes and Subthemes.

Theme	Theme Description	Subtheme	Subtheme Description
Navigating Trial Modalities	Explores participant comparisons between decentralized and traditional trials, focusing on logistical aspects and lifestyle compatibility.	Ease and Flexibility of Decentralized Participation	Remote visits and digital monitoring were viewed as reducing logistical burdens such as travel and scheduling.
		Alignment of Trial Design with Everyday Life	The extent to which trial procedures integrated seamlessly into existing routines was a key facilitator of engagement.
Drivers of Participation	Motivational underpinnings of participation encompassed personal health aspirations, altruistic intent, and financial considerations.	Self-Improvement and Personal Health Goals	Participants sought to manage their health more effectively or access innovative treatments.
		Altruistic Motives and Advancing Science	A desire to contribute to broader scientific knowledge or help future patients informed participation choices.
		Influence of Financial and Material Incentives	Compensation and material benefits served as notable, albeit variably interpreted, motivators.

(Contd.)

Theme	Theme Description	Subtheme	Subtheme Description
Communication and Relational Dynamics	The nature and quality of interpersonal communication with clinical staff significantly influenced participants' trust, comfort, and decision-making.	Building Trust and Setting Clear Expectations	Transparent, respectful, and empathetic communication enhanced trust and clarified participant roles.
		Influence of Clinical Relationships on Participation	Endorsements and rapport with trusted clinicians were pivotal in shaping willingness to enroll.
		Perceptions of Objectification and Interpersonal Disconnect	Some felt reduced to clinical subjects, which harmed engagement.
Structural and Psychological Gateways	Both tangible barriers and affective states shaped access to, and engagement with, clinical trials.	Practical Constraints and Access Barriers	Issues such as cost, transport availability, and time demands emerged as limiting factors.
		Emotional Readiness and Mental Hurdles	Psychological preparedness, including anxiety and role strain, influenced trial engagement.
Technology in Practice	Participants' experiences with digital tools used in decentralized trials were diverse, spanning enthusiastic adoption to cautious skepticism.	Adapting to and Engaging with Digital Tools	Participants varied in their digital fluency and receptiveness to technology-mediated interactions.
		Trust and Concerns around Data Use and Privacy	Concerns about the security, use, and potential misuse of personal data emerged as salient.

Similarly, Participant 1002 reflects,

> "It felt like just going about my daily activities and just incorporating this little tasks here and there, you know. So, it just felt like living my life with a few adjustments."

Major Theme #2: Drivers of Participation

Motivational drivers spanned personal, altruistic, and financial domains. Participants described joining trials to improve their health, contribute to science, or gain access to resources and compensation.

Subtheme 1: Self-Improvement and Personal Health Goals

Participants were motivated by a desire to improve their health, access alternative treatments, and feel more in control of their care. Trials were seen as a pathway to potential symptom relief and empowerment. Participant 1002 said,

> "It was about finding results... I wanted something convenient."

Participant 2003 reflected,

> "Joining the clinical trial left me empowered... I was taking control of my health."

Others, like Participant 3003, valued the access to free medical care as part of their motivation:

> "Going through a clinical trial [...] gave me access to free medical care at any time."

Subtheme 2: Altruistic Motives and Advancing Science

Many participants were driven by a desire to help others and advance medical research. Altruistic motives often outweighed personal benefits, with participants expressing pride in contributing to a greater cause. Participant 1003 shared,

> "I figured it's the right thing to do... if I could like, try to go up and help out other people and save lives... then I feel that was my obligation."

Participant 1005 remarked,

> "I feel like I want to do something so that I can contribute to the future of health care... even a minor role."

On the same note, they remark,

> "It would feel meaningful to me to be playing that role in helping people with those diseases, like it brings them hope."

Participant 2003 emphasized,

> "This prospect of finding a new treatment was incredibly enticing. I wanted to contribute to the advancement of medical science and hoping that my participation will not only improve my own life, but also the lives of others facing similar challenges as well."

Subtheme 3: Influence of Financial and Material Incentives

While not the primary motivator for most, compensation played a meaningful role in supporting participation. It helped offset logistical burdens and signaled appreciation for participants' time and effort. Participant 2005 acknowledged, "*Our time is being compensated*," while Participant 1006 recalled receiving "*a gas incentive*." Some participants reflected on the balance between altruism and reward, such as participant 1003:

> "I did it for the cause, not really for the compensation."

Participant 1004 elaborated,

> "You do this, and you get paid, and everyone wins, you contribute to a bigger cause."

These reflections illustrate that, although financial and material incentives were not the primary driver for many, they were often appreciated and contributed to a positive experience, particularly when paired with flexibility and a sense of contributing to something larger than oneself.

Major Theme #3: Communication and Relational Dynamics

The quality of communication from trial staff and health care providers shaped participants' trust and sense of agency. In both traditional and decentralized formats, understanding procedures, potential risks, and participant responsibilities was essential for building trust and facilitating informed consent. Positive relational experiences often enhanced engagement, while negative interactions left some feeling depersonalized.

Subtheme 1: Building Trust and Setting Clear Expectations

Participants emphasized that clear, transparent communication built trust and encouraged sustained engagement. Being informed about what to expect and having someone available to answer questions fostered confidence. Many described positive experiences when study staff and clinicians were proactive in explaining trial details, answering questions, and providing resources. Knowing what to expect, and having access to someone who could address concerns, made participants feel valued and informed. Participant 1004 shared,

> "I had someone over the phone who was willing to respond... to answer the fine details."

Participant 3003 recalled receiving videos and testimonies, saying,

> "I felt convinced... when I got [the information], I was excited."

Still, unmet expectations around clinic visit durations, as described by Participant 2005, highlighted the importance of setting clear logistical guidance from the outset:

> "We're supposed to only be at the clinic for an hour and 30 minutes. But there are days that we end up staying there for up to 2 hours, sometimes even more."

Subtheme 2: Influence of Clinical Relationships on Participation

Trusted relationships with health care providers played a key role in participants' decisions to join clinical trials. Many participants mentioned that their physicians' recommendations gave them the confidence to explore and enroll in studies. Participant 1002 shared,

> "I was actually told about it by my doctor. So I read up about it."

Participant 2003 described how their doctor's explanation of clinical trials as a

> "vital option for anyone seeking innovative treatments"

changed their perspective entirely. For some, like Participant 3001, health care providers served as direct points of contact, offering reassurance and guidance throughout the process. These insights highlight how strong physician-participant relationships are essential for recruitment and for shaping positive attitudes toward clinical trials.

Subtheme 3: Perceptions of Objectification and Interpersonal Disconnect

Several participants mentioned that their experience with clinical study staff was positive, built lasting relationships, and enhanced their experience of participating in a clinical trial. Conversely, some participants described experiences of feeling objectified in the clinical trial process. For some, the focus on procedures and protocol came at the expense of empathy and genuine connection. These feelings of being depersonalized affected overall satisfaction and willingness to engage fully.

Participant 3005 shares,

> "They pretty much treat you as a number, and it's like almost on a conveyor belt. And it's just like, Oh, do this, do this, do this this. They don't even seem to have compassion at all."

Participant 1006 echoes this feeling, saying,

> "What was most challenging honestly, was the fact [that you are], basically the guinea pig. And you didn't really know what was going to be the outcome."

The procedural nature of trial participation was described by Participant 3001,

> "I wasn't getting paid for people to be kind to me. I was getting paid to be a guinea pig."

Participant 1006 also expresses concern about the informed consent process, stating,

> "[About informed consent, you] read a little bit of it at the beginning, and then you just kind of like glaze all over or whatnot. No, I also start to feel like they do it intentionally to make it long, so you won't read it all."

Despite these challenges, some participants did find support and community in their trial experiences. Participant 1001 reports,

> "I was very satisfied. I had two clinical representatives that were working on the trial, and also the doctor, [...] at every meeting that I had with them

> in person. They came in, they asked me how I was doing, you know. Try to kind of get a little bit more of a rapport with me, and I felt like I wasn't [...] in this alone, like, you know, I could go to them with any questions, concerns, or so on and so forth."

Similarly, Participant 2002 shares,

> "I also appreciate the sense of community whereby you get to connect with some others in the trial, create the sense of purpose, meet new friends, talk to people that sometimes have the same problem with you, too."

These reflections highlight the wide range of interpersonal experiences in clinical trials, showing how both negative and positive social dynamics can shape participants' perceptions and satisfaction.

Major Theme #4: Structural and Psychological Gateways

Participation in traditional and DCTs was shaped by both practical constraints and emotional readiness. These gateways influenced not only whether individuals joined a trial, but also how they experienced it.

Subtheme 1: Practical Constraints and Access Barriers

Participants reported that travel, time demands, and complex procedures often made participation in traditional clinical trials difficult. Balancing trial tasks with daily life was a common struggle. Participant 1002 shared,

> "The most challenging thing was balancing my everyday activities... and making the visits."

Others described long appointments and tedious processes. Participant 3001 said,

> "It was very complicated... very tedious... a lot of work."

These barriers frequently led to frustration, reinforcing the appeal of DCTs for their greater flexibility and convenience.

The frequency and length of appointments also posed challenges, as described by Participant 2003:

> "The visits were pretty too frequent for me, and the appointments was kind of very lengthy, and doing a lot of extensive paperwork that was [...] really time consuming."

These accounts collectively demonstrate that logistical, procedural, and scheduling barriers can significantly affect participants' experience, often requiring considerable effort and persistence to overcome. This was particularly true for traditional clinical trials, with DCTs offering greater flexibility and control to participants.

Subtheme 2: Emotional Readiness and Mental Hurdles

Beyond practical challenges, participants described a range of emotional and psychological factors that influenced their experience in clinical trials. Some sought studies that would not exacerbate stress or emotional burden, while others encountered unexpected frustrations or anxieties during participation. Participant 2003 shared:

> "I'm thinking about the experience I had. It's actually a mix of emotions initially when I first joined the trial, I felt hopeful and excited, and I was eager to contribute to the medical research and the potential benefit for the innovative treatments like I said. However, in the course of the trial, technical glitches, connectivity problems really really got to me. I felt, frustrated."

Participants in blinded trials expressed disappointment over not knowing their treatment group, as noted by participant 1001:

> "I was in a blind study, so I didn't know if I would get a placebo or the actual study medication, so I was kind of disappointed in that. I know obviously, that a lot of clinical trials do that."

These reflections reveal how clinical trial participation is not only a rational, but also an emotional decision with psychological readiness and mental hurdles ranging from expectations, empowerment, and hopes to stress, anxiety and frustration with uncertainty. Emotional context, therefore, significantly shaped participants' experiences and engagement in clinical trials.

Major Theme #5: Technology in Practice

Digital tools such as mobile apps, smartwatches, and online platforms were central to participants' experiences in DCTs. This theme addresses both the benefits and challenges of engaging with technology during study participation. Many participants appreciated the structure, reminders, and real-time feedback provided by digital tools. However, some encountered usability issues, lack of technical support, or fatigue from continuous monitoring and data input. The theme reflects a nuanced engagement with technology, highlighting its role in enhancing trial accessibility while also requiring adaptability and digital literacy. While many appreciated its role in streamlining trial tasks, concerns arose regarding usability and data privacy.

Subtheme 1: Adapting to and Engaging with Digital Tools

Participants had varied experiences using digital tools in DCTs. Some found the technology intuitive and easy to adopt. Participant 1002 shared,

> "The app that I used... wasn't exactly difficult to use."

Others encountered frustrations with syncing devices or managing new technology. Participant 2003 described "technical glitches" and time lost troubleshooting, though also appreciated features like symptom and sleep tracking through wearables. Participant 3001 noted,

> "I didn't enjoy wearing [the watch] to bed,"

while participant 3002 found syncing Apple Watch data to the trial app "most challenging." Some suggested improving DCTs through more self-guided formats. As Participant 1005 proposed,

> "Just ship the items... so they can try and use it by themselves."

While digital tools enabled flexibility, comfort with technology and the presence of technical support influenced participants' overall experience in DCTs.

Subtheme 2: Trust and Concerns around Data Use and Privacy

Participants expressed concerns about data privacy when engaging in DCTs. Worries included potential data breaches, unauthorized access, and unclear data usage. Participant 2003 shared,

> "Data security is actually a great concern for me... I was skeptical."

The same participant added,

> "I worried about my data being breached [...] and unauthorized access and all that."

Others, like Participant 3002, were open to data sharing but wanted clearer communication:

> "I was comfortably sharing health data. [But] I would have appreciated that...the study provided clear guidelines on how my data would be used."

These insights show that while DCTs offer convenience and improved data capture, trust depends on transparent data policies and strong privacy protections.

Discussion

This study examined participant experiences across decentralized and traditional clinical trial formats, revealing that trial modality, while important, is secondary to relational and contextual factors in shaping participant engagement and satisfaction. The five overarching themes – *Navigating Trial Modalities*, *Drivers of Participation*, *Communication and Relational Dynamics*, *Structural and Psychological Gateways*, and *Technology in Practice* – articulate the multidimensional nature of trial participation and point toward key leverage points for enhancing trial design. This aligns with growing evidence that operational and relational factors, such as the quality of communication, trust, and empathy, often outweigh logistical conveniences when it comes to participant satisfaction and willingness to stay involved in research.[29]

Navigating Trial Modalities emphasized the logistical advantages of DCTs. Consistent with prior literature on digital health engagement, participants in DCTs praised the logistical flexibility and reduced burden associated with remote formats.[30] However, the convenience of virtual participation did not fully compensate for perceived losses in interpersonal connection, echoing findings from relational autonomy frameworks.[31] Conversely, while participants in traditional trials appreciated the emotional support provided by in-person staff, they also cited travel demands and time constraints as significant barriers, aligning with broader evaluation of conventional trial access inequities.[32] Their experiences reveal how traditional formats may unintentionally exclude or discourage potential participants, particularly those with health or resource constraints. This underscores the need for clinical trial operations that are not only technologically robust but also attentive to the lived realities and individual needs of participants.

Drivers of Participation identified in our focus groups were multifaceted, encompassing personal health goals, altruistic motives, and, less commonly, financial incentives. Notably, engagement was often rooted in intrinsic motivations and trust in clinical teams, rather than convenience or material compensation. Participants emphasized that the decision to remain engaged was driven by a sense of purpose and the quality of their interactions with study personnel. This is consistent with the existing evidence that intrinsic motivators and strong participant-researcher relationships are central to successful trials.[33–34]

Communication emerged as a foundational element in participant engagement. Conversely, lack of clarity or inadequate communication created hesitation or skepticism. Across both formats, communication quality and trust emerged as dominant influences on retention. Participants' narratives reflected that transparent expectations, relational warmth, and a sense of being valued were critical for sustained engagement. These insights support a growing consensus that participant-centered design, encompassing clear communication, responsiveness to individual contexts, and ethical attention to power dynamics, is essential for both recruitment and retention across trial modalities.

Relational Dynamics was represented by the centrality of human connection and provided one of the most powerful insights emerging from this study. Regardless of trial format, participants consistently underscored the importance of compassionate, accessible, and communicative trial staff. The presence of empathetic providers, whether in person or through virtual check-ins, was linked to participants' sense of safety, trust, and emotional comfort. Trials that lacked consistent or responsive communication risked participant disengagement or mistrust. A particularly salient theme was the experience of objectification or interpersonal disconnect, with some participants feeling like "just a number" or a "guinea pig." These accounts reveal that the absence of empathy, individual recognition, and genuine communication can undermine trust and deter future participation.[35] This underscores that a participant-centered redesign of trial operations, with deliberate attention to communication and relationship-building is fundamental to participant retention and adherence.

Structural and Psychological Gateways captured the layered barriers participants faced, including

transportation, scheduling, mental health, and emotional readiness. Our findings draw attention to emotional readiness and the psychological landscape in which participants join and remain in studies. Mental health, procedural anxiety, and uncertainty about randomization all contributed to challenges with engagement and retention. Participant-centered support, such as anticipatory guidance, check-ins, and clear explanations, may buffer these challenges and foster resilience.[36]

Technology in Practice highlighted the dual role of digital tools as both facilitators and barriers of participation. The expanding use of digital tools in clinical trials offers new opportunities for engagement, but also introduces unique barriers. While technology was broadly accepted and well-designed digital platforms were appreciated, participants voiced concerns about data privacy and use, underscoring the need for transparent and ethical data governance, user-centered interface design, and robust support structures in DCT platforms. This duality underscores the necessity of designing participant-centered digital systems that are intuitive, supportive, and adaptable to varying levels of digital literacy. As clinical research increasingly leverages digital modalities, ensuring ethical data use and designing for trust will be critical.

Study Strengths and Limitations

This study provides timely insights into participant experiences across both decentralized and traditional clinical trial models, offering comparative depth rarely explored in existing literature. Its strengths include the use of focus group methodology that captured nuanced first-person narratives, while the inclusion of participants from both trial formats allowed for meaningful contrasts. This study has several limitations. The sample was limited to English speakers, which may constrain applicability across more diverse populations. Recruitment via social media may have preferentially reached participants already comfortable with digital technologies. In addition, participants with higher digital literacy were likely overrepresented, introducing potential selection bias and limiting the generalizability of findings to groups with lower technology access or skills. Online data collection may have excluded those with limited digital access, and retrospective accounts are susceptible to recall and social desirability biases. Additionally, variability in trial designs and institutional contexts was not systematically controlled. Future research would benefit from broader sampling, inclusion of underrepresented groups, and mixed-method designs to triangulate findings and increase generalizability.

Recommendations

This qualitative study explored participant experiences across traditional and DCTs models to identify factors that shape engagement, satisfaction, and retention. The thematic findings provide actionable insights into redesigning clinical trial operations to prioritize participant-centeredness, foster relational trust, and enhance both participant outcomes and data quality. Our findings advocate for a deliberate shift toward recognizing participants as true partners in research. Accordingly, we propose recommendations that address technological, relational, and procedural aspects of trial design and conduct, aimed at optimizing engagement and satisfaction in all trial formats (**Table 3**).

By integrating these participant-centered strategies, trial sponsors and investigators can improve not only recruitment and retention, but also data integrity and trial efficiency. In a rapidly evolving research landscape, the future of clinical trials depends on models that respect, empower, and meaningfully engage participants throughout their journey.

Our findings also resonate with evolving international standards in clinical research. The final *ICH E6(R3) Guideline for Good Clinical Practice* emphasizes participant-focused trial design, proportionate risk management, and robust data integrity safeguards.[16] These principles align closely with participants' expressed needs for convenience, transparency, and trust across both traditional and decentralized contexts. Likewise, RBQM frameworks highlight proactive identification and mitigation of factors that may affect data quality and participant safety.[37] Insights from this study, such

Table 3: Recommendations for Enhancing Participant Experience in Clinical Trials.

Recommendation	Description
Invest in Intuitive, Supportive Technology	Digital tools should prioritize usability and accessibility, pre-trial orientations, and real-time support available.
Prioritize Relationship-Based Communication	Foster frequent, empathetic interactions; assign dedicated coordinators for regular, supportive contact and feedback.
Balance Convenience with Human Connection	Enhance accessibility via decentralized approaches, but maintain personal engagement through video calls and personalized check-ins.
Address Data Privacy Transparently	Communicate clearly about data use, storage, and protection; implement strong cybersecurity protocols to sustain participant trust.
Support Emotional and Motivational Needs	Recognize emotional factors and motivations; align incentives with personal values and perceived benefits, not just financial rewards.
Embed Participant Feedback into Trial Design	Involve participant advisory boards or feedback loops during protocol development to ensure responsiveness to participant needs and expectations.

as logistical burdens, digital literacy disparities, and the importance of relational trust, map directly to these risk domains and can inform practical RBQM strategies.

Implications for Data Management

Participant-centered insights translate into practical considerations for clinical data management (CDM). Each theme reported in this study highlights how participant experiences directly influence data quality, completeness, and reliability. By aligning CDM practices with these insights, data managers can strengthen trial workflows, mitigate risks to data integrity, and ensure that participant-centered trial designs yield high-quality evidence (**Table 4**).

Together, these implications underscore the essential role of data managers in bridging participant-centered insights with operational excellence. By embedding these considerations into daily workflows, CDM professionals can advance both data integrity and participant-centered trial conduct.

From a practical standpoint, incorporating participant perspectives into CDM planning and oversight improves the resilience and relevance of data processes. Aligning data capture methods across decentralized and traditional settings ensures consistency, while streamlined query design reduces participant burden and improves response accuracy. Centralized monitoring can help identify experience-related data trends, guiding targeted quality interventions.

Structured feedback channels among data managers, clinical operations, and site teams keep data oversight responsive to participant needs. As trials increasingly incorporate remote and hybrid elements, these approaches position CDM professionals as key partners in delivering risk-based, high-quality, and participant-centered research.

Future Research

This study highlights key factors shaping participant experiences in clinical trials, suggesting further research to advance a truly participant-centered approach. Future studies should include larger, more diverse populations to evaluate how operational strategies influence engagement, retention, and satisfaction across different clinical contexts. Quantitative research could shed light on how experiences change over time during a clinical trial and identify which aspects of communication, support, or digital integration most strongly impact outcomes. Additionally, intervention studies are needed to test the effectiveness of strategies such as enhanced relationship-building, tailored participant education, and improved digital support in both decentralized and traditional trials. It will also be important to explore participants' evolving concerns about data privacy and technology use, and to assess how collaborative design processes involving participants, researchers, and technology developers can optimize trial models. Ultimately, building an evidence base for participant-centered best practices will support the ongoing evolution of clinical trial design and operations.

Conclusion

Taken together, these findings emphasize that trial success is less a function of operational format than of participant experiences. While decentralized and technology-enabled trials increase convenience and accessibility, a truly positive experience requires empathy, transparency, and robust privacy protections. Addressing both practical

Table 4: Themes and Implications for Data Management.

Theme	Implications for Data Management
Navigating Trial Modalities	Data managers should anticipate variability in data flow depending on whether participants engage through site-based or decentralized modalities. Integration of eConsent, telehealth, remote monitoring, and eSource data into EDC systems is essential to reduce missing data and ensure accuracy across hybrid or decentralized models.
Drivers of Participation	Participant motivations such as altruism, health goals, and financial incentives influence participant engagement and retention, which directly influences longitudinal data quality. Data managers should implement proactive tracking of missing data and align retention strategies with data collection milestones.
Communication and Relational Dynamics	Trust and clear communication with participants are relationship-building factors that directly affect data accuracy and reliability. Data managers can support this by developing communication logs, metadata standards, and structured documentation that ensure participant concerns and clarifications are consistently captured across sites or platforms.
Structural and Psychological Gateways	Practical barriers (e.g., transportation, scheduling) and psychological readiness shape participation and engagement over time. Data managers should account for these potential challenges in risk-based quality management (RBQM) plans, with contingency strategies for anticipated missingness or dropout patterns.
Technology in Practice	Digital literacy and data privacy concerns affect participant willingness to engage with digital tools. Data managers should ensure user-friendly platforms, robust cybersecurity protections, and maintain transparent audit trails to preserve both participant trust and data integrity.

and emotional needs, and ensuring participants feel valued, and not objectified, is essential for enhancing trial retention, data quality, and trust. A reorientation toward participant-centered operations, grounded in the lived experiences of trial participants, is therefore critical for designing trials that are not only efficient and scientifically rigorous, but ethical, inclusive, and sustainable.

Additional Files

The additional files for this article can be found as follows:

- **Supplement 1:** COREQ Checklist. DOI: https://doi.org/10.47912/jscdm.441.s1
- **Supplement 2:** Researcher Contributions and Credentials. DOI: https://doi.org/10.47912/jscdm.441.s2
- **Supplement 3:** Thematic Hierarchy. DOI: https://doi.org/10.47912/jscdm.441.s3
- **Supplement 4:** Participant Experiences in Traditional and Decentralized Clinical Trials—Selected Quotations by Theme and Subtheme. DOI: https://doi.org/10.47912/jscdm.441.s4

Competing Interests

The authors have no competing interests to declare.

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