Adapting to Decentralised Clinical Trials: Analysis of Trial Clinician's Experiences and Impacts on the Patient-Centred Experience

Eoin Gamble, Conor Linehan, Ciara Heavin

Submitted to: Journal of Medical Internet Research
on: June 12, 2024

Table of Contents

Original Manuscript **5**
Supplementary Files **32**
Figures **33**
Figure 1 ..... **34**
Multimedia Appendixes **35**
Multimedia Appendix 1 ..... **36**

Adapting to Decentralised Clinical Trials: Analysis of Trial Clinician's Experiences and Impacts on the Patient-Centred Experience

Eoin Gamble[1]; Conor Linehan[2]; Ciara Heavin[1]

[1]University College Cork Cork IE
[2]School of Applied Psychology Cork IE

Corresponding Author:
Eoin Gamble
University College Cork
School of Applied Psychology University College Cork North Mall, Kilbarry Enterprise Centre,
Cork
IE

Abstract

Background: Industry, academic experts, and governing bodies emphasise the importance of prioritising the patient-centred experience in clinical trials to enhance retention, adherence, and trial participation. Concurrently, there has been a notable rise in the adoption of technology-mediated decentralised trial methodologies for conducting clinical trials.

Objective: Our study aims to understand clinicians' perceptions of this transition and its impact on delivering a patient-centred experience.

Methods: Fifteen clinicians with experience in facilitating decentralised trials (DCT) were interviewed and transcripts were analysed through reflexive thematic analysis [1].

Results: Our findings reveal one superordinate theme: the quality and frequency of interactions with patients and clinicians are limited, and six main themes (1) increased clinician demands, (2) the difficulties created for patients, (3) challenges knowing the patient and understanding their experiences, (4) impacts on forming and maintaining clinician-patient relationships, (5) difficulty in delivering desired support and care, and (6) effects on trial conduct. While DCTs offer advantages in improving accessibility, they introduce new complexities that can negatively impact patient engagement, retention, and the clinician-patient relationship. Implications for clinicians include taking on increased technical support roles, adapting to evolving working conditions, and reimagining their responsibilities, necessitating enhanced training programs. Implications for technology design include shifting the focus from solely data collection to creating patient-centred experiences and conditions, employing user-centred design principles and fostering collaboration among stakeholders.

Conclusions: One of the primary goals of clinical trials is to collect patient data while navigating several complex challenges, such as regulatory compliance, patient burden, study objectives, safety, scalability, protocols, and ethical considerations. Despite the many benefits of a remote approach, such as improved accessibility and data collection, DCTs have changed the dynamics for patients and clinicians. Approaches that work in traditional face-to-face trials may be less effective in the context of DCTs. As workplaces evolve with increasing technological mediation, clinicians face challenges that inevitably impact their working dynamics and potentially impact overall performance. Clinicians are crucial in navigating DCTs, acting as essential intermediaries between patients, support systems, and trial protocols. To adapt effectively to DCTs and the evolving trial dynamics, clinicians need adequate support and resources. The emphasis on patient technologies in DCT that focus on data collection, understandably vital for clinical trials, and the remote, reduced frequency and types of clinician-patient interactions to minimise patient burden, introduce new expectations and repercussions that impact the overall patient trial experience. Relying on clinicians to support the patient experience without adequately understanding each patient's unique experiences undermines their abilities to fulfil this role. Despite DCTs being presented as a patient-centred approach to trials, our research suggests that significant progress is still needed to realise this vision fully. While DCTs and the technology solutions employed show promise, they often fall short of adequately supporting important components of a patient-centred trial experience, potentially even detracting from it. A patient-centred experience requires a perspective that extends beyond convenience and reduced travel; it involves a complex interplay of personal, emotional, health, environmental, cultural, design, and contextual factors. Refocusing DCTs and how technology enhances these trials is necessary to support patients' diverse needs, recognising them as individuals with unique, personalised requirements backed with clear evidence of benefits. Prioritising conditions and technology that

enhance the patient experience in DCTs while maintaining rigorous data collection standards can create a more balanced and effective approach to DCT, ultimately benefiting both patients and clinicians.

(JMIR Preprints 12/06/2024:62947)
DOI: https://doi.org/10.2196/preprints.62947

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

Original Paper

Adapting to Decentralised Clinical Trials: Analysis of Trial Clinician's Experiences and Impacts on the Patient-Centred Experience

Abstract

Background:
Industry, academic experts, and governing bodies emphasise the importance of prioritising the patient-centred experience in clinical trials to enhance retention, adherence, and trial participation. Concurrently, there has been a notable rise in the adoption of technology-mediated decentralised trial methodologies for conducting clinical trials.

Objective:
Our study aims to understand clinicians' perceptions of this transition and its impact on delivering a patient-centred experience.

Methods:
Fifteen clinicians with experience facilitating decentralised trials (DCT) were interviewed, and transcripts were analysed using the reflexive thematic analysis outlined by Braun and Clarke [1].

Results:
Our findings reveal one superordinate theme: the quality and frequency of interactions with patients and clinicians are limited, and six main themes (1) increased clinician demands, (2) the difficulties created for patients, (3) challenges knowing the patient and understanding their experiences, (4) impacts on forming and maintaining clinician-patient relationships, (5) difficulty in delivering desired support and care, and (6) effects on trial conduct. While DCTs offer advantages in improving accessibility, they introduce new complexities that can negatively impact patient engagement, retention, and the clinician-patient relationship. Implications for clinicians include taking on increased technical support roles, adapting to evolving working conditions, and reimagining their responsibilities, necessitating enhanced training programs. Implications for technology design include shifting the focus from solely data collection to creating patient-centred experiences and conditions, employing user-centred design principles and fostering collaboration among stakeholders.

Keywords:
Decentralised trials; DCT; Remote trials; Clinical research technology; Site experience; Patient centeredness; Patient experience; Participant-centric trials; Human centred

Introduction

Clinical trials play a crucial role in testing new treatments and advancing medical knowledge [2] by

evaluating specific interventions on human subjects [3], and are traditionally conducted through in-person visits to healthcare sites [4]. However, developments in the USA, such as the 21st Century Cures Act (Public Law 114-255), demonstrate increasing legislative support for utilising technology for facilitating clinician-patient interactions in pharmaceutical research [5], [6] Clinical trials are undergoing a shift, with a growing emphasis on adopting technologically mediated approaches [7], [8]. Terms such as decentralised [9], remote [10], direct-to-participant, and virtual studies [11] have emerged to describe this approach to trial design and execution. In addition to the fully remote approach, hybrid trials incorporate decentralised and site-based elements [12]. Decentralised clinical trial (DCT) has emerged as the unified term to describe these trials [13]. For conceptual clarity, this research uses “DCTs” to refer to these types of trials.

DCTs utilise digital technologies to enable remote patient access to research, data gathering, and communication [14]. Data collection and assessments are now often carried out in participants' homes through technology [15], replacing traditional on-site data collection, minimising physical site attendance and emphasising participant-technology interactions over site staff interactions [16]. Integrating technologies such as smart devices, wearables, and sensors for data collection and processing [17]. Electronic patient-reported outcomes (PROs) capture health data through mobile apps or web interfaces [18], while telehealth technology facilitates remote exchanges, reducing or eliminating the need for in-person visits [19].

The concept of patient-centeredness has become paramount in drug development and clinical trials [20], with patient-focused drug development receiving significant attention from governing bodies[21]. Patient-centeredness is defined as addressing the needs of the patient throughout the design, activation, enrolment, data collection, completion and outcome reporting of a trial [22]. This concept emphasises the patient's experience during a trial [23], and stresses that the trial design supports the needs and preferences of participants [13]. Concepts such as person [24] and patient centeredness [25] are directly linked to various components of the delivery of care that contribute to the patient's overall needs and experience. Key aspects such as different forms of patient well-being [26], satisfaction [27], relationships [28], autonomy [29], support and organisational systems [30], personalisation [31], trust [32], communication and education [33] are interconnected within the centeredness definitions, contributing to a deeper understanding of expected patient centred experiences.

DCT and patient-centred concepts converge as decentralised methods are increasingly suggested as supporting patient-centeredness [5], contributing to a patient-centred experience [19], with the aim of reducing patient burden and enhancing experience [34]. DCT technology vendors promote DCT methods and technology as patient first, human centred, built for patients, meeting the needs of the patient, and centred around patient needs. Nevertheless, trial participant attrition has reportedly been a common problem in remote technology studies [35], indicating there is still work to be done to enhance the patient-centred experience during these technology trials. As the field progresses, there is an increasing demand for additional research to delve into stakeholders' perspectives on DCT [36]. Further investigation has been recommended to explore the effects of decentralised methods on stakeholders' challenges and patient participation experiences [16], [37]. Therefore, it is imperative to evaluate the effectiveness of current practices in achieving this goal. Our study uses semi-structured interviews to capture clinicians’ perspectives (principal investigators, study coordinators and site nurses i.e. individuals who play integral role in the patient experience during a DCT) on the impact of DCT on the experience of coordinating and carrying out trials and their impressions on how it affects the patient experience. The research investigates challenges in supporting patients, the clinician-patient relationship, and patient engagement during DCTs. The study aims to enhance our understanding of the practical implications and clinicians' perceptions regarding the transition to DCT and identify the implications for delivering a patient-centred experience.

Methods

Research Design

We undertook a qualitative study using semi-structured interviews to understand the perceptions of clinicians transitioning to decentralized technology-mediated methods for trial conduct and their impact on delivering a patient-centred experience. Data were gathered via semi-structured interviews, allowing clinicians to share their perspectives [38], and provide first-hand accounts [39].

Ethical Considerations

The study was approved by the University Social Research Ethics Committee (SREC) on 20th January 2023. Participation was voluntary, and upon recruitment, participants were provided with electronic information sheets and consent forms outlining the study's purpose and procedures. Personal details were anonymised, and sensitive data were removed from the transcripts. Participants were informed of their right to withdraw from the study.

Data collection

The research was conducted between February 2023 and June 2023. Each interview lasted approx. one hour. The interview guide was developed following examining the literature to address the research question posed (Appendix 1). The interview featured questions drawn from the literature [40] and focused on the patient experience, the relationship between clinician and patient, and keeping patients engaged during a trial. The interviews followed a conversational approach, mixing open-ended [41] and follow-up probe questions [42]. Interviews were conducted online via MS Microsoft Teams.

Data Analysis

Reflexive Thematic Analysis (RTA) was used to identify meaningful patterns within the transcripts. The author followed the process outlined by Braun and Clarke [1]. The first phase involved becoming familiar with the data and noting initial ideas by listening to the recorded interviews and reading and re-reading the transcripts. During phase 2, initial codes were generated using an open coding methodology, followed by reflection and refinement of the codes. Phase 3 involved identifying themes for clarity and specificity through discussions on overarching themes and sub-themes and one superordinate theme encompassing several themes. Further refinement took place to ensure the accuracy and representation of the data. Phase 4 entailed an examination and evaluation of themes to ensure alignment with the data. Phase 5 consisted of continued analysis and refinement and a final defined set of themes with clear definitions and names generated for each theme.

Participants

Table 1 presents a summary of interviewees, selected based on their professional knowledge and experience in conducting various forms of remote, hybrid and DCT [43]. Participants were recruited from diverse sites, roles, and countries to ensure a diverse range of experiences were captured. Each clinician had previously

conducted some form of remote trial, directly interacted with patients, and used a range of technologies, including patient apps and diaries, patient monitors, and telehealth.

Table 1. Summary of Study Participants

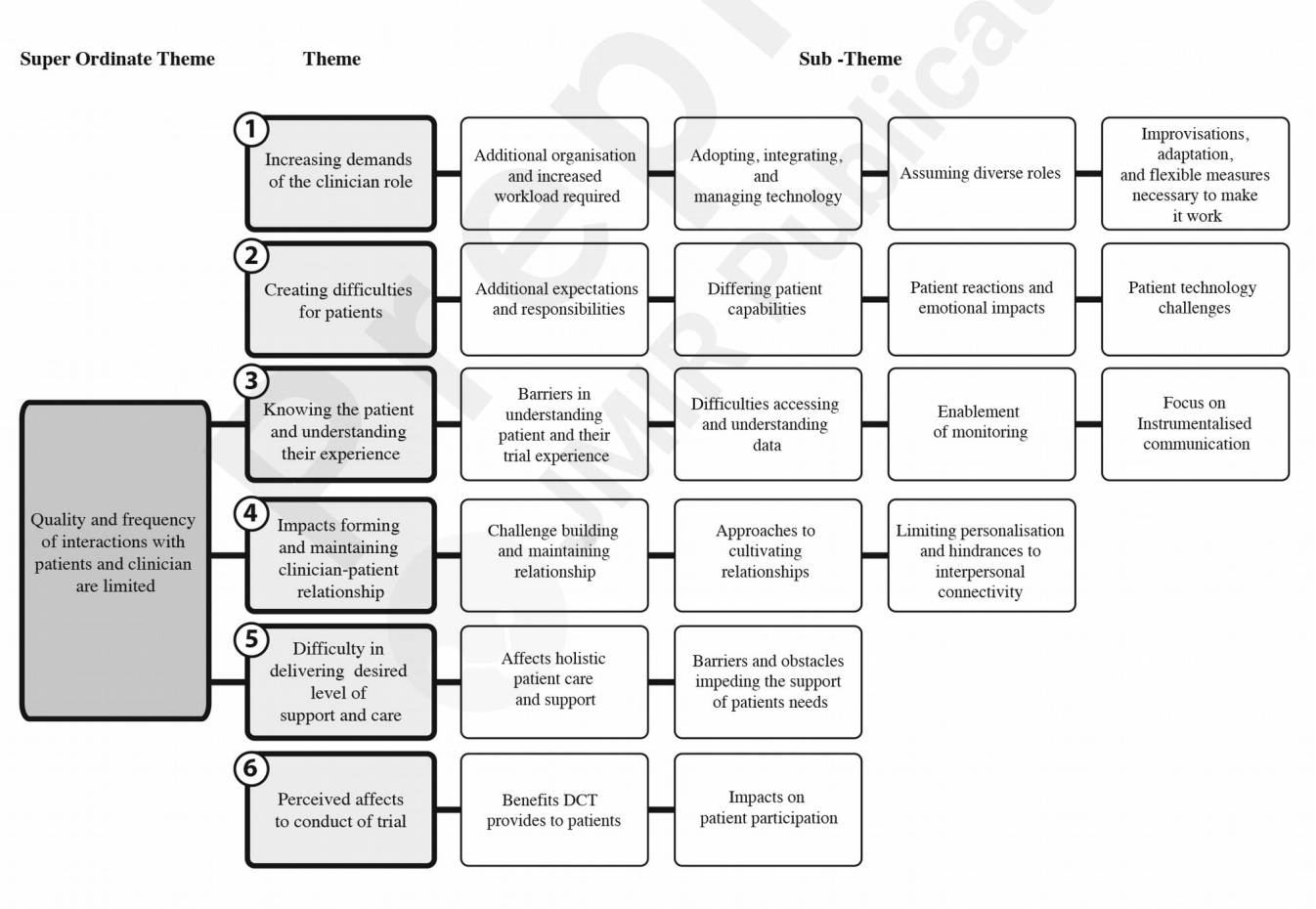
Role	ID	Facility	Experience	Location
Senior Research Nurse	SRN1	Research Centre	20 years	Ireland
Principal Investigator	PI1	Research Centre	20 Years	USA
Senior Research Nurse	SRN2	University Hospital – Research Centre	5 Years	Ireland
Clinical Research Coordinator	CRC1	Research Centre	13 Years	Spain
Clinical Research Coordinator	CRC2	Research Centre	12 Years	USA
Clinical Research Coordinator	CRC3	Research Centre	4 Years	USA
Clinical Research Nurse	CRN1	University Hospital – Research Centre	3 Years	Ireland
Clinical Research Coordinator	CRC4	Research Centre	3 Years	USA
Principal Investigator	PI2	Research Centre	25 Years	Belgium
Principal Investigator	PI3	Academic Med Centre	15 Years	USA
Clinical Research Coordinator	CRC5	Research Centre	4 Years	USA
Clinical Research Coordinator	CRC6	Research Centre	3 Years	USA
Clinical Research Coordinator	CRC7	Research Centre	5 Years	Canada
Study Coordinator	SC1	Research Centre	3 years	Canada

Research Assistant	RA1	Research Centre	3 Year	USA

Findings

Our findings are structured around six themes: (1) Increasing demands of the clinician role, (2) creating difficulties for patients; Themes 3 to 5 are placed within a superordinate theme that identifies how the quality and frequency of interactions between patients and clinicians are limited in DCTs; (3) knowing the patient and understanding their experience, (4) impacts forming and maintaining clinician-patient relationship, (5) difficulty in delivering desired level of support and care, and (6) perceived effects to conduct of a trial. Each theme has several sub-themes, as illustrated in Figure 1.

Figure1. Findings - Theme and Sub themes



Theme 1 - Increasing demands of the clinician role

This theme reveals the increased demands placed on clinicians due to the nature of DCTs. It highlights an increased need for organisation and workload management. When discussing their roles, participants highlighted the expanding scope of responsibilities, requiring them to assume diverse roles and implement improvisations, adaptations, and flexible measures to effectively support patients.

Additional organisation and increased workload required

Clinicians noted that remote trials create new tasks and additional effort compared to face-to-face trials. Impacts also include the need to work overtime and late-night calls to address patient issues, at times disrupting staff work-life balance. Participants highlighted the need for heightened organisation for successful DCT implementation. Increased efforts are needed during initial visits, addressing scheduling issues, aligning site visit resources, coordinating patient contact, and managing appointments. Sustaining communication with remote patients necessitates extensive follow-up and relies on clinicians organising frequent communication via phone, text, and email. With a DCT, general patient support requires a more conscious effort to be made by clinicians, with challenges particularly evident in supporting older demographics requiring additional assistance adapting to the technology. Furthermore, there is a need for the clinician to supplement the technology experience with human interaction to bridge the technology and remote gap.

> *"There have been evenings where my days supposed to be 8 to 5 and I have a call at 9-10 o'clock at night with the patient, because their diaries aren't working and it is important for them to do it to start the study drug the next day and they literally cannot, and it is very impactful for us, because we try to have that healthy work life boundary"* - SC1

> *"We try and educate them here as best we can, and sometimes we could be two or three hours going over the same thing."* – CRN1

Assuming diverse roles

A notable shift is seen in the clinician's role, which now includes patient technology training and education, providing comprehensive device instructions. The evolved role involves offering technology support and follow-up support for seamless technology use. Clinicians also serve as the primary point of contact for addressing patient issues within the trial setting. Patients directly contact clinicians rather than relying on trial support services, and clinicians act as an intermediary between patients, sponsors, and trial technology vendors. This expanded responsibility includes addressing technology support, device-related issues, software challenges, and phone and password problems.

> *"I think clinical trials are changing and adapting to technology and so that's kind of changed our role in clinical trials and following up with patients and doing phone calls and texting and emails, that's just part of being a study coordinator now and it can be like very scattered braining for coordinators"* – CRC6

Adopting, integrating, and managing technology

Participants emphasised the need for additional technical skills to support patients when conducting a DCT. Clinicians point to an increased workload, exacerbated by trial technology's manual and laborious nature, the

lack of standardisation, and the need to engage with diverse, complex technologies used across the trial portfolios.

> *"So, we have to be very versatile, and we have to know all these systems because these vendors don't provide us with all that information."* – PI2

Clinicians emphasised the difficulties of misalignment between technology vendors, sponsors, and the practical needs of the site. They stressed the importance of vendors being aware of site-specific challenges and integrating site feedback to effectively address technological issues. Furthermore, some clinicians felt technology solutions had an emphasis on administrative processes that overlook the perspectives and needs of sites and patients, hindering trial efficacy.

Improvisations, adaptation, and flexible measures necessary to make it work

Clinicians discussed the importance of an adaptive and improvised problem-solving approach to ensure the smooth operation of decentralised clinical trials. Their approach included proactive engagement with patients beyond established trial protocols, such as unscheduled calls, check-ins, tailored email support, and providing handwritten instructions on device usage. Additionally, clinicians proactively utilised patient diary entries and data to initiate meaningful conversations in remote interactions. They highlighted flexibility and adaptability as crucial, adjusting protocol expectations, providing additional phone support, and scheduling remote visits based on patient availability. Clinicians indicated they had to rely on instinct and intuition, drawing upon their professional background and experience in their approach to patients. They felt that the limitations of technologies meant they had to develop an awareness of patient patterns and trial-related behaviours.

> *"I'd say it's mostly my personal approach. Every coordinator works their trials in a different way. I've been in research for a few years now, and so I've kind of developed that on my own……I think instincts is a good word. It is challenging. You never know. Officially, I use my background and research to kind of gauge when I may need to reach out to patients."* – CRC5

At times, clinicians indicated that they must use workarounds to overcome the challenges of provided technologies, remote interactions and DCT limitations, including patient literacy and connectivity complications. They circumvent the help desk by directly addressing patient needs, acting as intermediaries, and assuming help desk responsibilities, all to ensure continued patient trial participation.

> *"I tried to be a savvy as I can about all the technology that I can be to help desk. I'm not being paid for the help desk are being paid for it, helpdesk should be doing it. But I don't want to put that burden on a patient saying you know, wait and call the help desk. and they don't have help desk in the local language, and they have to wait for translator and it's taking away time from them, which might mean that they will back out. I know that."* – PI2

Theme 1 Discussion

Remote tools and methods can improve trial efficiency and reduce burdens [44]. However, our findings echo [16], highlighting the extra burden on trial staff using DCT technologies. Our study underscores how the introduction of DCTs has heightened demands on clinicians, necessitating additional responsibilities, burdens, and organisational efforts. Our research further underscores how clinicians grapple with burdens throughout

trials, similar to findings from [36], which also identify challenges clinicians face in providing technical support to patients during DCTs. Our study outlines how clinicians' roles are evolving in response to DCT, necessitating the acquisition of additional skills to ensure trial success and effectively support patients. Clinicians face new challenges and must adapt to the technology focus and remote nature of these trials, at times assuming roles for which they may not be formally qualified to do. Rodgers et al.[36] review how clinicians face challenges in learning to manage trials using new technologies [5] suggest that site teams may not have the skills to support digital clinical trials. Our findings suggest clinicians are adjusting to the demands of DCT, which requires additional time and effort to ensure the trial's success. Clinicians demonstrate adaptability and resourcefulness to inadequate existing structures, employing workarounds and instinctive strategies. Suggesting that DCT does not fully cater to the clinicians' needs during the trial and may restrict their ability to perform their roles as they envision. However, these necessary adaptations may bring about negative consequences and disruptions to workflow, have unintended side effects, change trial approaches, and may have potential adverse impacts.

Theme 2 - Creating difficulties for patients

Theme two focuses on clinicians' perceptions of the challenges encountered by patients participating in DCT. This theme discusses the additional expectations placed on DCT participants, their varying capabilities, the emotional impact of being part of a DCT, technology challenges, and the multifaceted nature of challenges within the decentralised setting.

Additional expectations and responsibilities

Clinicians discussed the growing expectation that patients assume more responsibilities in DCT compared to traditional trials. Participants discussed how patients are expected to undertake tasks such as frequent diary entries, which can become overwhelming. Patients are expected to manage their trial technology tools, with technology vendors assuming patients have a comprehensive understanding of the technical hardware and software.

> *"To just give them a few a little bit of information and give them a little bit of training like, hey, this is on you now we'll just check on you every now and then. That's very much like we just push you out there to the wolves and we're going to just let you sink or swim. Even though that's not the case. But that's how they may feel and that's how it feels to us as well."* – CRC3

Differing patient capabilities

Clinicians noted challenges in supporting patients from specific demographic groups, particularly regarding their varying comfort levels with technology. They observed a lack of familiarity and technological literacy challenges, especially among older demographics, which posed barriers during a DCT. The disparity between technology solutions and patients' technical proficiency impacted their ability to operate devices and participate effectively in DCT.

> *"Some of our patients have a lot of difficulties using technology. It's insane. The challenges that they face. and I have been on the phone with one person for around 45 minutes trying to walk that person through how to get back into that application on their study device because they had no idea what they were looking at…. …...it's challenging for them, and they don't understand how to use it."* – RA1

Patient reactions and emotional impacts

Participants described the emotional impacts on patients due to the decentralised and technologically mediated nature of DCTs. Frustration with DCT influences the overall patient trial experience and can even lead to withdrawal of consent. Patients, particularly older demographics facing demands due to DCT, experience emotional tolls, leading to feelings of overwhelm, diminished confidence, anxiety, and increased stress.

> *"We have had patients, if they become frustrated with their piece of technology, specifically the example that comes to mind is an electronic diary like patient reported outcomes. If they do become frustrated with that, for whatever reason, if they have technical issues that they have to contact support a lot or have to contact the site a lot, they withdraw consent."* – CRC2

Clinicians noted that the nature of DCT could undermine patient trust. The limitations and absence of interpersonal interactions in technology-mediated communication can hinder the trust-building process between clinicians and patients, contrasting with on-site experiences. Consequently, patients may feel more like trial subjects than individuals receiving personalised care. Clinicians highlighted how some patients had indicated that they preferred conventional trial methods, which exacerbates the challenges sites face.

> *"You wouldn't have the same level as trust as, say, patients that are coming on site, because obviously they don't build or develop a relationship with the research nurse and the same with the doctor."* – SRN1

Conversely, some clinicians highlighted how DCT experiences with more comprehensive remote monitoring technologies can reassure patients, positively impacting their well-being during the trial. Patient perception and awareness of efficient clinician monitoring provide reassurance. Regular informed data reviews with clinicians can also reassure patients, boosting their confidence and trust in the clinicians and technology used as part of a DCT.

> *"But with the patients with the digital devices, they know they're being watched every day. They know they're being monitored every day. So, they have this assurance that they feel confident that they're OK. There's somebody watching them, someone looking out for them…..I think primarily, the patient feels looked after and has great reassurance of being monitored."* – SRN2

Patient technology challenges

Clinicians discussed the challenges patients face with trial technology, which makes the DCT process harder. These include device utilisation, connectivity problems, malfunctions, usability, and Wi-Fi-related issues, leading to increased burdens and hindrances for patients and clinicians during the trial experience.

> *"I have a patient that we did so much calling back and forth and emailing back and forth over weeks with IT before the resolution was that she just had to drive into town every day. Twice, a day to do her Diaries to be compliant."* – SC1

> *"It's the layout on the screen and the buttons themselves that have been a slight problem as well. ……. it doesn't always transform from a desktop to a mobile screen properly which also is a huge confusion for patients."* – CRC7

Theme 2 Discussion

Advocates for DCT tools and techniques promise that the method can alleviate patients' burdens in trials [44]. For example, [45] suggest that data collection becomes passive for patients using DCT technologies. Technologies can allow clinicians to monitor patients' symptoms and provide informed feedback, which can reassure patients. However, similarly to Cummins et al. [46], our study suggests that DCTs impose additional expectations and responsibilities on patients participating in trials. Previously, Moser & Doring [47] suggested that personal, emotional, and psychosocial factors significantly influence patient attrition in clinical trials. Trust is a pivotal component of both person-centred care [48] and patient-centred care[32]. It facilitates patient participation in research [49] and enhances retention [16], [50], [51] . Our study's findings indicate several adverse emotional impacts observed in patients during DCT, including feeling overwhelmed and frustrated and a notable impact on patient trust. Our findings challenge the suggestions that DCTs reduce patient burden, promote a patient-centred experience and indicate the potential for impacting patient retention.

Super Ordinate Theme - Quality and frequency of interactions with patients and clinicians are limited

We have included an overarching superordinate theme (see Figure 1) based on consistent observations made by clinicians during our interviews. The limited quality and frequency of interactions between patients and clinicians, stemming from DCT's remote technology-mediated nature, was observed as a central organising concept in our analysis. This limitation impacts several important components of patient-clinician interactions, serving as a primary obstacle to effective patient management, support, understanding, and care. Three main themes are identified within this superordinate theme, and these are outlined below.

Theme 3 - Knowing the patient and understanding their experience

The third theme discusses how carrying out a trial in a remote or decentralised manner has implications for how clinicians understand patients and their experiences. It highlights the efforts needed to overcome barriers to comprehending patient experiences, accessing relevant data, enabling effective monitoring, and the instrumentalising of communication.

Barriers in understanding patient and their trial experience

Clinicians noted that the lack of direct patient oversight in DCTs limits their ability to monitor and understand patients throughout the trial. The constraints imposed by DCTs contribute to challenges in understanding the patient's experience beyond protocol adherence and hinder timely assistance and support. Unlike on-site interactions, DCTs provide fewer insights into patient experiences, and clinicians face challenges in monitoring medication adherence, which they perceive may be done more effectively during traditional visits.

> *“it’s very difficult, to be honest, you don't have the same visibility of how compliant a patient is either. It's not only around compliance with study, if they were taking medication or that kind of thing it's easier for them to come into clinic to have oversight of that as well.”* – SRN1

Remote interactions in DCTs present challenges in obtaining important patient information and understanding.

Prompts from the patient are needed to understand when they are having issues. The absence of informal dialogues and in-person interactions hinders clinicians' awareness of pertinent patient details, affecting the evaluation of patient conditions and timely recognition of changes in patient conditions.

> *"You're able to pay attention to the little things in a patient when they come into the office. They may seem a little bit more tired than the last time you saw, or you may notice that their skin may look different, or they're veins when you normally you blood draw that their veins don't look the same as they did, you know. So you pay attention to the very little things that can possibly save a patient's life."* – CRC3

Clinicians depend on patient questionnaires to identify issues and comprehend patient needs. However, the types of data collection compromise clinicians' awareness of patient conditions and hinder informed discussions, evaluations, and individualised feedback, posing challenges in tailoring support. The limitations in technology-driven reports diverge from traditional site insights, impacting the depth of support provided. The remote and technological nature of DCTs delays clinicians' recognition of patients' needs and the comprehensive patient support needs. Clinicians also encounter challenges determining when to initiate patient contact and providing timely support beyond trial protocol expectations and data collection requirements. Establishing communication with remote patients is challenging and complicates the clinician's role, leading to additional stress. It requires concerted efforts to connect and coordinate schedules between clinicians and patients, and it is common for patients to be unresponsive to calls or messages.

Difficulties accessing and understanding data

The participants highlighted the complexity involved in analysing, identifying, and understanding the collected trial data, which made related tasks laborious. Limitations in technologies for data observation and analysis in DCT can lead to delayed issue observation, burdensome data processes, and insufficient reports or insights to support patients. Some clinicians resort to informal systems, such as using MS Excel, to analyse patient data and identify changes or symptom patterns. They also spoke of a time gap in patient compliance awareness and challenges in acquiring real-time data.

> *"Every vendor portal is very different, for some of them you literally have to click into every single diary to see that data and then go back and refilter. And it's a very cumbersome process. Even to get a week's worth of data, especially when you're looking at multiple and different results from patients there's no easy way to export that data."* – SC1

Enablement of monitoring

Clinicians praised the advancements in DCT technology for remote patient monitoring, which enables tracking patient progress, medication adherence, and symptom monitoring. This capability empowers clinicians to identify concerns and manage patients. Additionally, technology centralises data and documentation, streamlining access and facilitating longitudinal comparison of the patient. Furthermore, some technology enhances clinician-patient interaction by providing insights into patient patterns, informing and enabling more effective communication. Notifications enable timely interventions, and data readings enable analysis, both ensuring patient safety and well-being through remote monitoring.

> *"The person you're ringing can see your blood pressure can see your oxygen level, can see your weight can see pulmonary artery pressure So when they tell you, No. You know your blood pressure is OK. Your weight is OK. You're basing it on fact, so and they know you can see it so that it. They've confidence in what you say, and they reassured by what you say."* – SRN2

Focus on Instrumentalised communication

Clinicians highlighted how contacting patients in a DCT is primarily triggered by formal problems such as compliance concerns, irregular diary entries, compliance or data discrepancies which then trigger the need to follow-up by the site. Remote visits focus solely on a business-only and data-collection approach. Structured assessments during remote visits, centring around specific questions, reinforce the formal and data-centric approach. Resulting in a lack of casual conversation and personal connection opportunities and restricts the interpersonal dynamic between clinicians and patients.

> *"You know, you talk about business, and you get through what you need to get through and then the visit is usually terminated …… Usually the visit concludes at that point as opposed to an ongoing banter back and forth about whatever."* – PI1

> *"But when you're on the phone, you have exact questions that you're going to ask them. They're really isn't any time for chitchat."* – CRC6

Theme 3 Discussion

Research has shown that effective patient care requires understanding and responsiveness to individual experiences [52]. Fogel [53] outlines the significance of the trial staff's ability to maintain awareness of participants' feelings throughout the trial process. Our research suggests that DCTs pose barriers for clinicians in understanding the patient and their trial experiences, stemming from the absence of direct patient oversight and the limitations of technology support. This limitation hampers the clinician's ability to fully understand the patient's needs. The crucial role of clinicians in supporting patients' experiences and the gap in understanding patients' experiences in DCT leads to a disparity in effectively supporting patients throughout such trials. Clinicians discussed how DCT necessitates a business-oriented, data-collection approach during remote patient interactions, particularly during communication driven by trial protocols. They noted how a lack of patient compliance is the primary trigger for reaching out to patients outside established protocols. These instrumentalised communication approaches may diminish their sense of autonomy, and this depersonalisation can adversely affect patient satisfaction, motivation, trust, and patient outcomes, and impact participation. It is important to note that our study emphasised how some DCT technologies can genuinely facilitate enhanced monitoring of patients. These findings resonate with Coravos et al. [54], showcasing how DCT technologies enable real-time symptom alerts [55], [56] and provide pertinent patient data and information on study activities.

Theme 4 - Impacts forming and maintaining clinician-patient relationship

The fourth theme discusses the impacts of DCT on forming and maintaining clinician-patient relationships. It examines the dynamics surrounding clinician-patient relationships during DCT, addressing challenges in connection-building, interpersonal bonds, and the various ways relationships are cultivated.

Challenge building and maintaining relationship

Several challenges were identified in building and maintaining relationships, including limitations in developing connections with patients due to the workings of the remote settings. The absence of face-to-face interactions poses hurdles in establishing meaningful connections. Unlike traditional site trials, DCT trials present more significant challenges due to limited interactions, removing opportunities for positive rapport and impeding the formation of typical bonds developed onsite. Participants discussed issues with DCT technology functionality, pointing to a lack of dedicated mechanisms to support the interpersonal dynamic between the clinician and the patient.

> *"My biggest challenge is just being able to form that relationship and letting the patient know, making them feel comfortable enough to talk to us as often as they would need to and to be open with us."* – CRC5

Approaches to cultivating relationships

Clinicians noted the positive impact of shared technology challenges with patients, fostering camaraderie through increased interaction during remote technological issues. Increased patient interaction during patient health challenges allows clinicians to provide assistance, strengthening the clinician-patient relationship. Furthermore, collected trial data and readings provided by patient trial technology give clinicians patient insights and serve as a focal component, contributing to personalised insights and calls and, in turn, supporting relationship development. Relationships are further enhanced by personalising patient information, proactively providing tailored support notes, engaging in conversations about personal matters, staggering interactions and showing genuine interest.

> *"You'd have a bond with all the patients, but it would be stronger, with the patients that would be in bigger trouble because the readings are gone off. But because you sort out that, and you either sort out their medication or get them into hospital. They trust you and therefore the bond it is stronger."* – SRN2

Limiting personalisation and hindrances to interpersonal connectivity

Clinicians discussed how patient interactions and technology limited personalisation and hindered interpersonal connectivity, resulting in an impersonal and generic patient experience. They discussed various issues affecting the connection and bond between them and their patients, potentially leading to attrition from the trial. They highlighted the limited opportunities to build rapport, develop lasting connections, and enhance interactions, particularly due to the challenges of maintaining a connection remotely without past interactions or shared experiences with patients. DCT and technology-driven experiences, by removing in-person engagement, may leave patients feeling a lack of human care, fostering a perception of trials as cold and impersonal. At the same time, text and phone interactions, prioritising efficiency, may further diminish emotional understanding due to their brevity.

> *"Ideally, we want to provide the best medical care possible, whether we're around or not, so we want patients have a good experience with the technology. We want them to have a good experience with the medication that we're providing to them and with whatever telehealth visits that we are providing. But it is challenging because we don't have a chance to form that sort of bond that we would with our*

traditional patients that we see more often." – CRC5

DCT can lead to estrangement for clinicians and patients. Remote patients' risk being reduced to numbers in the system, and clinicians may overlook them due to on-site priorities, potentially leaving patients feeling neglected. Clinicians also expressed concern about the absence of individualised attention for patients and the challenge of providing personalised care in remote trials.

"Sometimes I've even caught myself doing it where I'm like, who even is this person that I have to contact today? Like, I don't even recognise their name because I could tell you about that person when they came into the site four months ago. But now they kind of just fade into a number in the system… …..I don't want to say dehumanises, but it definitely takes away from that relationship when they go remote." – RA1

Questions arise regarding patient concerns for their data, utility, and their overall contribution to the trial. The patient perception of data going into a void, with a limited understanding of where the data they provide goes and is used, raises questions about participation and meaningfulness, as does the limited positive feedback to patients through technology. Clinicians acknowledge the importance of on-site face-to-face interactions, enabling direct communication. Enabling them to assess patients' comfort levels, provide tailored support, build connections, and focus on their needs, fostering a humanised approach to care. Some technologies support clinicians, and for those with access, leveraging video platforms enhances attempts to replicate the in-person experience and deliver person-centred care remotely.

Theme 4 Discussion

The relationship connection between trial staff and participants is crucial for fostering positive trial experiences [57]. Similarly, the relationship between patients and their healthcare professionals is fundamental to the concept of patient-centred or person-centred care [28]. Relationships are not just a psychological concept but are integral to human motivation and self-determined behaviour [58] and a cornerstone for retaining participants and sustaining their motivation throughout a trial [59]. Mohr et al. [60] highlight the correlation between clinicians fostering personalised relationships with patients and increased treatment adherence. Personalisation can enhance relatedness [58]. Fogel [53] highlights the significance of personalising clinical trial interactions to support a successful trial's execution. Similarly, De Silva [61] underscores its importance as a critical component of the person-centred care concept. Our research findings highlight how DCT negatively impacts the formation of relationships and interpersonal connectivity between clinicians and patients and restricts opportunities for personalisation and connection. Decentralised trials face considerable hurdles in both motivating [59] and maintaining a patient-centred experience due to the indispensable role of human connection in care [62] and staff traditionally enabling the patient experience [40]. Challenges in relationships, interpersonal connections and personalisation stem from technology, remote constraints, and limited human connection. DCTs struggle to replicate the vital human element necessary to deliver patient-centred trial experiences. As a result, DCTs will face challenges in adherence and in effectively motivating, engaging, and retaining patients.

Theme 5 - Difficulty in delivering desired level of support and care

Theme five explores the challenges for clinicians in delivering the desired level of support and care to their patients. This theme underscores the difficulties clinicians face in achieving their intended level of support, highlighting intricate and multifaceted challenges in addressing diverse and individualized patient needs.

Affects holistic patient care and support

Clinicians voiced concerns about DCT's patient-centricity, noting a misalignment with patient-centred principles. Some believe these trials prioritise data and project management over patient needs, hindering a patient-centred experience. The limitations imposed by DCT reduce the site's ability to support a patient-centred experience compared to traditional on-site approaches.

> *"They don't get the patient centric experience. They don't. That's what I'm trying to tell you. They don't. they're just a collecting tool for the industry that we are facilitating, and we have to explain that this is all very Cool. Distant.…… ……. Again, as I started this conversation, these things are set up from a data management and a project management point of view, never from a site or a patient's point of view.…… ……. So we are calling it patient centric. But the device is literally shoved done my throat, and then they go. Is it patient centric?"* – PI2

Clinicians noted challenges in maintaining patient care in the DCT setting, which impacted clinical support and posed potential barriers to fulfilling care roles, with some not considering DCT and remote approaches synonymous with patient care. Delivering care through short remote calls using technology was considered challenging. Clinicians expressed uneasiness about perceived care levels, with concerns that patients might question the care provided in a DCT. On-site interactions were deemed more impactful for personalised, in-person engagements, contrasting with remote DCTs, which raised concerns about patient safety and appropriate usage of investigational products, requiring a delicate balance in maintaining patient interactions.

> *"With the traditional setup, it's obviously a higher level of patient care because you're physically bringing the patient in."* – CRC2

DCT and remote settings hinder clinicians from fully understanding and addressing patients' emotional and psychological well-being. Participants revealed perceived challenges in offering emotional support to patients, with clinicians perceiving that patients may interpret this as a lack of empathy, validation and acknowledgement from the site, potentially straining empathetic connections.

> *"It can come off as we don't care about the patient emotionally, the sponsor doesn't really care about the patient, doesn't care about them as an individual, they are just seeing them as our participant. And obviously that's not true. But when you don't put in those measures to effectively monitor someone's emotional state or even just ask them how they're doing. It can come off as extremely cold and just unfeeling."* – RA1

Barriers and obstacles impeding the support of patients' needs

Clinicians face various challenges in providing technical and troubleshooting support. Inadequate site support capabilities for executing remote technical assistance are among these limitations, making it difficult for clinicians to guide patients remotely and leading to delays in resolving support issues.

> *"So definitely trying to help someone remotely with technology is one of the most frustrating things, I think I've ever faced. because a lot of the times I can't see what that person is looking at. I log into my account on the sponsor's website, my view is completely different from a patient's view. So the patient might be looking at a home screen that looks completely different than mine and so I have to figure out, how do I get them to what I need them to get through when I can't even see what the heck they're seeing, whereas being physically on site I can see everything."* – RA1

Insufficient help desk support presents challenges for patients, who experience poor response times to their issues, leading to frustration for patients and clinicians. Due to these insufficiencies, clinicians are forced to take on help desk roles or refrain from using the help desk altogether. This results in a misalignment between the support provided and patient requirements. Some clinicians also expressed frustration about their lack of qualifications for tech support roles. These inherent challenges contribute to clinician frustration amidst the myriad of issues they encounter.

> *"Being an IT worker that I'm not qualified to be. trying to walk them through their technology, walk them through repairing things."* – RA1

Our study highlights the challenges of a reactive clinician support model in DCT, where patients initiate contact during challenging personal and technical situations. Some clinicians note that support is reactive, leading to crisis management instead of proactive interventions. Clinicians identify challenges in comprehending and addressing patient support needs, often experiencing delays in recognizing the intricacies of patients' needs. Participants discussed challenges with timely communication and follow-up support mechanisms, compounded by patient availability and unresponsiveness. These factors delay patient communication and hinder the site's ability to provide timely support.

> *"it's definitely harder to recognize when a patient needs support when we're doing remote interactions."* – CRC6

Furthermore, clinicians encounter challenges during onboarding and initially educating patients of trial requirements, particularly ensuring their competence with technology, processes, and tools. The onboarding process proved challenging and time-consuming, remote education complicates support further, and real-time assistance is lacking. Overall, clinicians emphasise the effectiveness of on-site support, highlighting its advantages in providing comprehensive and interactive assistance to patients compared to remote methods.

Theme 5 Discussion

At the core of the patient-centred trial concept is addressing patient's individual need [13]. Research by Moser et al. [47] highlights the importance of addressing patient's personal, emotional, and psychosocial aspects to enhance retention in clinical trials. Similarly, Ferrell et al. [63] emphasise the critical role of compassion and nonphysical support for trial patients. Furthermore, Keshtkar et al. [64] demonstrate that empathy enhances patient satisfaction with their care, and influences favourable patient outcomes. The importance of interconnected support components for successful troubleshooting in DCT is critical to ensure data integrity[65], Clinical support connected to good clinical practice [66] and patient competence necessary for retention [59] and crucial for continued motivation [58]. Johnson & Marsh [67] highlight the challenges faced in supporting the practical trial needs of patients and Polhemus et al. [68] support patient's technology needs. Our study supports these insights and outlines the challenges clinicians working in a DCT context face in

supporting patient's needs, emphasising the limitations of site abilities and technology in offering adequate support in their absence.

Theme 6 - Perceived affects to conduct of trial

Theme six uncovers the impacts on the conduct of trials, exploring the dual nature of benefits and challenges associated with DCT. It examines their influence on crucial aspects such as patient retention, engagement, responsiveness, and compliance. It highlights benefits such as ease of participation, convenience, flexibility, and patient empowerment.

Benefits DCT technology provides to patients

Some clinicians outlined how conducting a DCT has several patient benefits, supporting their overall experience, including ease of participation and increased eligibility due to reduced barriers. Logistical burdens, such as travel to clinic visits, are reduced, benefiting patients by alleviating stress and avoiding exposure to potential hospital infections. Clinicians perceive patients to appreciate being in the familiar environment of their homes, which is especially beneficial for vulnerable patients, with family members and caregivers experiencing reduced travel. Additionally, some clinicians view DCT as enabling greater participation and convenience, which younger patients particularly appreciate due to the reduced frequency of on-site visits, and younger patients also prefer digital diaries over paper diaries.

> *"It improves eligibility because it eliminates a lot of the logistical barriers."* – PI3

Moreover, some clinicians perceive DCT technologies as empowering patients, involving them directly in monitoring and fostering control and understanding of their health through measurements and insights, instilling a sense of ownership in patients. Remote health monitoring with some DCT technologies allows clinicians to collect factual and relevant patient data, which is then used to enhance clinicians' support of patients. Regular data reviews reassure patients and improve monitoring and support effectiveness. Some clinicians felt DCT was seen to enable flexible and efficient trials, saving time through quick assessments, remote communication, and information sharing, while telehealth effectively assesses patient concerns, reducing paper-based processes and benefiting trial efficiency.

> *"They have control, they have power and where maybe traditionally you feel you have no power, that you go to Doctor, he gives you tablets, but there might be no explanation. You don't know the mechanism of what's going on, where we go to pains to say why we're increasing tablets, why we're decreasing tablets and you're able to show them the next time they're in, or if they're in hospital the next day, how the drug reacted and how their pressures came down. So you, they can physically see how things are working."* – SRN2

Impacts on Patient Participation

Clinicians outlined the multifaceted impacts and challenges to patient trial participation. These include affecting patient comfort in opening up during conversations and reluctance to share important health updates or concerns. Compliance with the trial is impacted, and missed diary entries necessitate significant site efforts to re-engage patients. Clinicians also noted compliance being affected by technology issues and slow site responsiveness. Furthermore, delays in accessing patient data affect clinicians' ability to identify non-compliance. Conversely, on-site care and monitoring can aid patient adherence to protocols. Clinicians

perceive lower patient engagement, responsiveness, and commitment levels in DCT settings. The DCT approach may impact patients' understanding of study details and their willingness to participate in future trials, as some patients decline trial involvement due to technological reluctance and their unfamiliarity with site staff. DCT impacted accountability, responsibility, patients' understanding of their roles, and obstacles like forgetfulness and non-responsiveness. Additionally, ongoing consent and retention may be affected, and challenges faced during DCT could lead to higher dropout rates.

> *"I know that if I didn't put that effort in, which isn't expected of us, that we would have non-compliance or patients dropping out or lost to follow up because it's hard to work with."* – SC1

Theme 6 Discussion

Minimizing patient burden is crucial for retaining patients in trials [50], and DCT promises to reduce patient burdens [8]. Logistical hurdles such as travel time and distance to trial sites pose significant barriers to patient participation [69]. DCT addresses these challenges by offering convenience and flexibility [65], [70]. Our research suggests that clinicians perceive DCT as providing enhanced ease of participation, reduced logistical burdens, time savings, and, in some cases, increased patient control over their health, aligning with research findings. The benefits inherent in these measures give patients autonomy, allowing them flexibility, convenience, and empowerment, enabling patients to exercise volition concerning their health and ownership of their experience. The importance of supporting autonomy cannot be understated, as autonomy is an ethical mandate of patients in medical research [71] and a vital component of sustaining motivation [58]. However, our study also suggests that clinicians perceive DCTs as also contributing detrimentally to the conduct of trials, affecting retention [72], accountability [71], and understanding of patients [73], all crucial to a successful clinical trial.

Discussion

Through a qualitative approach we conducted 15 expert interviews and performed thematic analysis to explore clinician perspectives in executing DCTs. By focusing on clinicians' experiences and perceptions, we have developed rich insights about the types and nature of additional tasks needed to make this type of trial work, and how remote participation affects the clinician-patient dynamic and patient experiences. The findings highlight the heightened demands placed on clinicians within DCTs, necessitating increased adaptability, competency, and resource allocation. Challenges arise from a lack of contact with patients, leading to a perceived diminished understanding of individual patients and their experiences, hindering the delivery of optimal support and patient-centred and holistic care. Consequently, we identify difficulties forming clinician-patient relationships and the perceived negative implications for patient participation, retention, engagement, competence, and compliance throughout the trial process. Findings also acknowledge benefits of the DCT approach, such as reduced travel burden, flexible and efficient trials, and increased accessibility. We offer several insights into the implications of transitioning to DCTs and their impact on clinical trial practices.

Implications for trial clinicians

Firstly, our data underscores the evolving working dynamics and conditions, increased demands, and an expansion of the clinician's role to include technology support. Clinicians must adjust to new ways of supporting, monitoring, and interacting with patients remotely. These changes necessitate additional expectations, time and effort on behalf of clinicians, mirroring challenges observed in other contexts [74] when remote and technologically mediated approaches replace face-to-face interactions. The evolving

technical expectations of clinicians may require a reimagining of DCT clinicians' roles and necessitate formal adjustments in role expectations. Consequently, it is imperative to reassess and update training and professional development programs to ensure clinicians are equipped with the necessary skills for navigating DCTs to meet technical challenges [5]. This re-evaluation underscores the importance of enhanced training that covers remote communication and support, IT, and digital proficiency. These programs can support successful practice in DCTs and prepare clinicians for future DCT advancements. Based on our observations, despite retaining their responsibilities for patients and the delivery of the trial, clinicians face a loss of control and ability to exert the same influence on patient behaviour compared with traditional trials. This loss of control and influence hampers their ability to support patients and to fulfil their roles to their desired standards. Our data shows clinicians adapt to the implications of running a DCT and find ways to make it work. This adaptability is crucial for maintaining patient engagement, standards, operational efficiency and trial success. As observed in other contexts [75], with the integration of new technology-mediated approaches into established practises, these adaptations may come with hidden or even unintended costs to clinicians. These may include increased cognitive load, potential for errors, reduced job satisfaction, and burnout among clinicians.

Implications for DCT design

A concern with conducting clinical trials in a decentralised manner is the potential for negative impacts on critical factors necessary for the successful execution of clinical trials. Clinicians identified that patient engagement, responsiveness, commitment, retention [72], accountability [71], and compliance [76] may all be adversely affected in DCT contexts. If this is indeed the case, it necessitates strategic reconsiderations from a trial design and technology choice perspective. Our observations suggest that while DCTs offer the potential to overcome some challenges associated with traditional site clinical trials, such as improving accessibility and convenience [36], [77] for patients, they introduce new complexities that clinicians and patients must overcome, including challenges in support, communication, understanding patient experiences, engagement, technical complexities and the burdens and expectations placed on patients. Our research suggests that transitioning from traditional site trials to DCT requires rethinking the design of patient engagement practices. Approaches practical in traditional, in-person trials may not be suitable for DCTs. The clinician-patient relationship plays a pivotal role in patient/person-centred paradigms [28], [57] and is an important component in successful trials [59]. Furthermore, clinicians perceived additional aspects such as personalisation [31], trust[32], well-being [26], and satisfaction [27] are also impacted. These elements are integral to a positive patient experience and play a significant role in achieving favourable outcomes. DCTs have the potential to significantly improve the access, inclusivity, and diversity of trial participants [78]. Our observations reveal that DCT trials offer an Instrumentalised, mechanistic, and transactional experience for patients; we see evidence of this impacting personal interactions and a detachment from clinicians. Clinicians discussed various challenges patients face, particularly among older demographics. These challenges may hinder the participation of certain groups and, in turn, exacerbate disparities in trial representation. In envisioning the future of DCT and trial design, emphasis should be placed on prioritising greater patient choice and flexibility to accommodate the crucial need for patient autonomy [58], [71]. We speculate that a more flexible and adaptive trial could be instrumental in addressing patient challenges related to competence issues, technological capabilities, accessibility factors, the necessity for human connection and providing patients with choices to meet their individual needs.

Implications for technology design

Based on our observations, there should be a careful consideration of both site and patient technology in order to better understand how it can address the challenges outlined in this paper. Our data suggests that current

technologies in DCTs, which primarily focus on data collection, would benefit from focusing more on supporting the experience of patients. Technology that supports understanding patients' experience and creates conditions for personalisation [31], trust [32], well-being [26] and the relationships between clinician and patient [28], [57] would enhance the overall experience. Resolving patient issues, such as ease of use, accessibility, and reliability, can reduce barriers to acceptance and enhance adoption and usage [79]. We suggest applying a theoretical and behavioural science-grounded approach to inform strategic patient technology direction, interventions, guide design, and define solutions tailored to meet patient psychological needs and supporting behaviours [57], [80]. Our results highlight the critical need to involve diverse stakeholders in future design processes to create more comprehensive and inclusive technologies, with benefits in doing so [81]. Stakeholders must continue engaging with the challenge's complexity, including technology vendors, designers, behavioural scientists, regulatory bodies, patients, clinicians, and pharmaceutical companies. Leveraging our findings, designers can focus their efforts towards addressing the issues outlined, ensuring that technological solutions align with clinician and patient needs and support optimal experiences and effective technological solutions for both.

Limitations and future research

This research engages solely with the DCT clinician perspective. While analysis of clinicians' experiences and observations is valuable for providing insights into the conduct, impacts, and perceived patient experiences, future research should incorporate the perspectives of patients, pharmaceutical companies, and technology vendors to provide a comprehensive view of decentralised clinical trials. Future research holds promising opportunities for both academia and practice. We recommend expanding on stakeholder perspectives, suggesting further investigation of how DCTs are experienced and perceived by patients. Focusing on specific technological experiences to better understand the perspectives surrounding those technologies. Additionally, future studies should explore integrating behavioural science into the DCT design approach to better support participants' experiences and practitioners' efforts to deliver more patient-centred trial experiences.

Conclusion

Firstly, we must acknowledge that one of the primary goals of clinical trials is to collect patient data while navigating several complex challenges, such as regulatory compliance, patient burden, study objectives, safety, scalability, protocols, and ethical considerations. Despite the many benefits of a remote approach, such as improved accessibility and data collection, DCTs have changed the dynamics for patients and clinicians. Approaches that work in traditional face-to-face trials may be less effective in the context of DCTs. As workplaces evolve with increasing technological mediation, clinicians face challenges that inevitably impact their working dynamics and potentially impact overall performance. Clinicians are crucial in navigating DCTs, acting as essential intermediaries between patients, support systems, and trial protocols. To adapt effectively to DCTs and the evolving trial dynamics, clinicians need adequate support and resources. The emphasis on patient technologies in DCT that focus on data collection, understandably vital for clinical trials, and the remote, reduced frequency and types of clinician-patient interactions to minimise patient burden, introduce new expectations and repercussions that impact the overall patient trial experience. Relying on clinicians to support the patient experience without adequately understanding each patient's unique experiences undermines their abilities to fulfil this role. Despite DCTs being presented as a patient-centred approach to trials, our research suggests that significant progress is still needed to realise this vision fully. While DCTs and the technology solutions employed show promise, they often fall short of adequately supporting important components of a patient-centred trial experience, potentially even detracting from it. A patient-centred experience requires a perspective that extends beyond convenience and reduced travel; it

involves a complex interplay of personal, emotional, health, environmental, cultural, design, and contextual factors. Refocusing DCTs and how technology enhances these trials is necessary to support patients' diverse needs, recognising them as individuals with unique, personalised requirements backed with clear evidence of benefits. Prioritising conditions and technology that enhance the patient experience in DCTs while maintaining rigorous data collection standards can create a more balanced and effective approach to DCT, ultimately benefiting both patients and clinicians.

Acknowledgements

EG, CH and CL conceived the study. EG, CL and CH were involved in protocol development, gaining ethical approval. EG researched literature. EG recruited participants and conducted data analysis. EG wrote the first and subsequent drafts of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript. We would like to thank all the participants interviewed for their invaluable contributions to this study and extend our gratitude to all individuals who assisted in participant recruitment. Productivity tools were employed for polishing and refining the research article's language.

Conflicts of Interest

EG received funding from Novartis Pharmaceutical company to partially support the first author's PhD studies. I have disclosed the interests fully to JMIR Journals, and my academic institution has an approved plan for managing any potential conflicts arising from this arrangement.

Ethical approval

The ethics committee of University College Cork approved this study (SREC Log umber: 2022-215)

Consent to participate

All participants provided written informed consent prior to engaging in this research.

Abbreviations

DCT: Decentralised Clinical Trials
Vendors: DCT Technology providers
HCI: Human-computer interaction
Clinicians: Principal investigators, Study coordinators, Research staff and Site nurses

Multimedia Appendix of supplementary files

Supplementary Material 1 – Interview Guide

References

[1] V. Braun and V. Clarke, ‘Thematic analysis: a practical guide’, 2021.

[2] D. L. Sackett and R. J. Cook, ‘Understanding clinical trials: What measures of efficacy should journal articles provide busy clinicians?’, *Bmj*, vol. 309, pp. 755–756, 1994.

[3] K. Stanley, ‘Design of Randomized Controlled Trials’, *Circulation*, vol. 115, no. 9, pp. 1164–1169, Mar. 2007, doi: 10.1161/CIRCULATIONAHA.105.594945.

[4] A. Bhide, P. S. Shah, and G. Acharya, ‘A simplified guide to randomized controlled trials’, *Acta Obstet Gynecol Scand*, vol. 97, no. 4, pp. 380–387, Apr. 2018, doi: 10.1111/aogs.13309.

[5] O. T. Inan *et al.*, ‘Digitizing clinical trials’, *NPJ Digit Med*, vol. 3, no. 1, p. 101, Jul. 2020, doi: 10.1038/s41746-020-0302-y.

[6] U.S Food & Drug Administration, ‘21st Century Cures Act | FDA’. Accessed: May 29, 2024. [Online]. Available: https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act

[7] I. B. Hirsch *et al.*, ‘Incorporating Site-less Clinical Trials Into Drug Development: A Framework for Action’, *Clin Ther*, vol. 39, no. 5, pp. 1064–1076, May 2017, doi: 10.1016/j.clinthera.2017.03.018.

[8] B. de las Heras *et al.*, ‘Role of decentralized clinical trials in cancer drug development: Results from a survey of oncologists and patients’, *Digit Health*, vol. 8, p. 205520762210999, Jan. 2022, doi: 10.1177/20552076221099997.

[9] G. A. Van Norman, ‘Decentralized Clinical Trials’, *JACC Basic Transl Sci*, vol. 6, no. 4, pp. 384–387, Apr. 2021, doi: 10.1016/j.jacbts.2021.01.011.

[10] D. Alemayehu, R. Hemmings, K. Natarajan, and S. Roychoudhury, ‘Perspectives on Virtual (Remote) Clinical Trials as the “New Normal” to Accelerate Drug Development’, *Clin Pharmacol Ther*, vol. 111, no. 2, pp. 373–381, Feb. 2022, doi: 10.1002/cpt.2248.

[11] E. R. Dorsey, B. Kluger, and C. H. Lipset, ‘The New Normal in Clinical Trials: Decentralized Studies’, *Ann Neurol*, vol. 88, no. 5, pp. 863–866, Nov. 2020, doi: 10.1002/ana.25892.

[12] Amy Rogers, Rachel Copland, and Sonia Houston Pichardo, ‘Trials@Home Glossary - Trials@Home’. Accessed: May 29, 2024. [Online]. Available: https://trialsathome.com/trialshome-glossary/

[13] Y. Santa-Ana-Tellez *et al.*, ‘Decentralised, patient-centric, site-less, virtual, and digital clinical trials? From confusion to consensus’, *Drug Discov Today*, vol. 28, no. 4, p. 103520, Apr. 2023, doi: 10.1016/j.drudis.2023.103520.

[14] C. Petrini, C. Mannelli, L. Riva, S. Gainotti, and G. Gussoni, ‘Decentralized clinical trials (DCTs): A few ethical considerations’, *Front Public Health*, vol. 10, Dec. 2022, doi: 10.3389/fpubh.2022.1081150.

[15] J. Moore, N. Goodson, P. Wicks, and J. Reites, ‘What role can decentralized trial designs play to improve rare disease studies?’, *Orphanet J Rare Dis*, vol. 17, no. 1, p. 240, Dec. 2022, doi: 10.1186/s13023-022-02388-5.

[16] J. Coyle, A. Rogers, R. Copland, G. De Paoli, T. M. MacDonald, and I. S. Mackenzie, ‘A secondary qualitative analysis of stakeholder views about participant recruitment, retention, and adherence in decentralised clinical trials (DCTs)’, *Trials*, vol. 23, no. 1, p. 614, Dec. 2022, doi: 10.1186/s13063-022-06521-4.

[17] E. S. Izmailova, J. A. Wagner, and E. D. Perakslis, ‘Wearable Devices in Clinical Trials: Hype and Hypothesis’, *Clin Pharmacol Ther*, vol. 104, no. 1, pp. 42–52, Jul. 2018, doi: 10.1002/cpt.966.

[18] S. J. Coons, S. Eremenco, J. J. Lundy, P. O’Donohoe, H. O’Gorman, and W. Malizia, ‘Capturing Patient-Reported Outcome (PRO) Data Electronically: The Past, Present, and Promise of ePRO

Measurement in Clinical Trials', *The Patient - Patient-Centered Outcomes Research*, vol. 8, no. 4, pp. 301–309, Aug. 2015, doi: 10.1007/s40271-014-0090-z.

[19] A. De Jong, R. Grupstra, Y. Santa-Ana-Tellez, M. G. P. Zuidgeest, A. de Boer, and H. Gardarsdottir, 'Which decentralised trial activities are reported in clinical trial protocols of drug trials initiated in 2019–2020? A cross-sectional study in ClinicalTrials.gov', *BMJ Open*, vol. 12, no. 8, p. e063236, Aug. 2022, doi: 10.1136/bmjopen-2022-063236.

[20] S. Stergiopoulos, D. L. Michaels, B. L. Kunz, and K. A. Getz, 'Measuring the Impact of Patient Engagement and Patient Centricity in Clinical Research and Development', *Ther Innov Regul Sci*, vol. 54, no. 1, pp. 103–116, Jan. 2020, doi: 10.1007/s43441-019-00034-0.

[21] U.S Food & Drug Administration, 'CDER Patient-Focused Drug Development | FDA'. Accessed: May 29, 2024. [Online]. Available: https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development

[22] B. T. Li *et al.*, 'Reimagining patient-centric cancer clinical trials: a multi-stakeholder international coalition', *Nat Med*, vol. 28, no. 4, pp. 620–626, Apr. 2022, doi: 10.1038/s41591-022-01775-6.

[23] K. A. Getz, 'Establishing Return-on-Investment Expectations for Patient-Centric Initiatives', *Ther Innov Regul Sci*, vol. 49, no. 5, pp. 745–749, Sep. 2015, doi: 10.1177/2168479015579521.

[24] L. Slater, 'Person-centredness: A concept analysis', *Contemp Nurse*, vol. 23, no. 1, pp. 135–144, Oct. 2006, doi: 10.5172/conu.2006.23.1.135.

[25] N. Mead and P. Bower, 'Patient-centredness: a conceptual framework and review of the empirical literature', *Soc Sci Med*, vol. 51, no. 7, pp. 1087–1110, Oct. 2000, doi: 10.1016/S0277-9536(00)00098-8.

[26] S. J. Kuipers, J. M. Cramm, and A. P. Nieboer, 'The importance of patient-centered care and co-creation of care for satisfaction with care and physical and social well-being of patients with multi-morbidity in the primary care setting', *BMC Health Serv Res*, vol. 19, no. 1, p. 13, Dec. 2019, doi: 10.1186/s12913-018-3818-y.

[27] M. R. Cowie, 'Person-centred care: more than just improving patient satisfaction?', *Eur Heart J*, vol. 33, no. 9, pp. 1037–1039, May 2012, doi: 10.1093/eurheartj/ehr354.

[28] J. Zhao, S. Gao, J. Wang, X. Liu, and Y. Hao, 'Differentiation between two healthcare concepts: Person-centered and patient-centered care', *J Nurs*, vol. 2352, no. 0132, pp. 10–1016, 2016.

[29] J. M. Louw, T. S. Marcus, and J. F. M. Hugo, 'Patient- or person-centred practice in medicine? – A review of concepts', *Afr J Prim Health Care Fam Med*, vol. 9, no. 1, Oct. 2017, doi: 10.4102/phcfm.v9i1.1455.

[30] B. McCormack *et al.*, 'Person-centredness-the'state'of the art', 2015.

[31] J. Lewis and H. Sanderson, *A practical guide to delivering personalisation: person-centred practice in health and social care*. Jessica Kingsley Publishers, 2011.

[32] L. M. Ferguson, H. Ward, S. Card, S. Sheppard, and J. McMurtry, 'Putting the "patient" back into patient-centred care: An education perspective', *Nurse Educ Pract*, vol. 13, no. 4, pp. 283–287, Jul. 2013, doi: 10.1016/j.nepr.2013.03.016.

[33] E. M. Langberg, L. Dyhr, and A. S. Davidsen, 'Development of the concept of patient-centredness – A systematic review', *Patient Educ Couns*, vol. 102, no. 7, pp. 1228–1236, Jul. 2019, doi: 10.1016/j.pec.2019.02.023.

[34] M. F. Dockendorf, B. J. Hansen, K. P. Bateman, M. Moyer, J. K. Shah, and L. A. Shipley, 'Digitally Enabled, Patient-Centric Clinical Trials: Shifting the Drug Development Paradigm', *Clin Transl Sci*, vol. 14, no. 2, pp. 445–459, Mar. 2021, doi: 10.1111/cts.12910.

[35] P. Daniore, V. Nittas, and V. von Wyl, 'Enrollment and Retention of Participants in Remote Digital Health Studies: Scoping Review and Framework Proposal', *J Med Internet Res*, vol. 24, no. 9, p. e39910, Sep. 2022, doi: 10.2196/39910.

[36] A. Rogers *et al.*, 'A systematic review of methods used to conduct decentralised clinical trials', *Br J Clin Pharmacol*, vol. 88, no. 6, pp. 2843–2862, Jun. 2022, doi: 10.1111/bcp.15205.

[37] A. Suman *et al.*, 'A cross-sectional survey on the early impact of COVID-19 on the uptake of

decentralised trial methods in the conduct of clinical trials', *Trials*, vol. 23, no. 1, p. 856, Oct. 2022, doi: 10.1186/s13063-022-06706-x.
[38] J. C. Hermanowicz, 'The Great Interview: 25 Strategies for Studying People in Bed', *Qual Sociol*, vol. 25, no. 4, pp. 479–499, 2002, doi: 10.1023/A:1021062932081.
[39] C. K. Riessman, *Narrative methods for the human sciences*. Sage, 2008.
[40] Wolf and Jason, 'Defining patient experience', *Patient Exp J*, vol. 1, no. 1, pp. 7–19, 2014.
[41] B. DiCicco-Bloom and B. F. Crabtree, 'The qualitative research interview', *Med Educ*, vol. 40, no. 4, pp. 314–321, Apr. 2006, doi: 10.1111/j.1365-2929.2006.02418.x.
[42] S. Kvale and S. Brinkmann, *Interviews: Learning the craft of qualitative research interviewing*. sage, 2009.
[43] D. KNOKE, 'Networks of Elite Structure and Decision Making', *Sociol Methods Res*, vol. 22, no. 1, pp. 23–45, Aug. 1993, doi: 10.1177/0049124193022001002.
[44] D. F. Hanley *et al.*, 'Decentralized clinical trials in the trial innovation network: Value, strategies, and lessons learned', *J Clin Transl Sci*, vol. 7, no. 1, p. e170, Jul. 2023, doi: 10.1017/cts.2023.597.
[45] E. R. Dorsey, C. Venuto, V. Venkataraman, D. A. Harris, and K. Kieburtz, 'Novel Methods and Technologies for 21st-Century Clinical Trials', *JAMA Neurol*, vol. 72, no. 5, p. 582, May 2015, doi: 10.1001/jamaneurol.2014.4524.
[46] M. R. Cummins *et al.*, 'Decentralized research technology use in multicenter clinical research studies based at U.S. academic research centers', *J Clin Transl Sci*, vol. 7, no. 1, p. e250, Nov. 2023, doi: 10.1017/cts.2023.678.
[47] D. K. Moser, K. Dracup, and L. V. Doering, 'Factors Differentiating Dropouts from Completers in a Longitudinal, Multicenter Clinical Trial', *Nurs Res*, vol. 49, no. 2, pp. 109–116, Mar. 2000, doi: 10.1097/00006199-200003000-00008.
[48] A. Wolf, L. Moore, D. Lydahl, Ö. Naldemirci, M. Elam, and N. Britten, 'The realities of partnership in person-centred care: a qualitative interview study with patients and professionals', *BMJ Open*, vol. 7, no. 7, p. e016491, Jul. 2017, doi: 10.1136/bmjopen-2017-016491.
[49] A. G. Mainous, 'Development of a Measure to Assess Patient Trust in Medical Researchers', *The Annals of Family Medicine*, vol. 4, no. 3, pp. 247–252, May 2006, doi: 10.1370/afm.541.
[50] P. Natale *et al.*, 'Transparency, trust and minimizing burden to increase recruitment and retention in trials: a systematic review', *J Clin Epidemiol*, vol. 134, pp. 35–51, Jun. 2021, doi: 10.1016/j.jclinepi.2021.01.014.
[51] S. Chhatre *et al.*, 'Patient-centered recruitment and retention for a randomized controlled study', *Trials*, vol. 19, no. 1, p. 205, Dec. 2018, doi: 10.1186/s13063-018-2578-7.
[52] W. W. Weston, J. B. Brown, and M. A. Stewart, 'Patient-centred interviewing part I: understanding patients' experiences.', *Can Fam Physician*, vol. 35, pp. 147–51, Jan. 1989.
[53] D. B. Fogel, 'Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review', *Contemp Clin Trials Commun*, vol. 11, pp. 156–164, Sep. 2018, doi: 10.1016/j.conctc.2018.08.001.
[54] A. Coravos, S. Khozin, and K. D. Mandl, 'Developing and adopting safe and effective digital biomarkers to improve patient outcomes', *NPJ Digit Med*, vol. 2, no. 1, p. 14, Mar. 2019, doi: 10.1038/s41746-019-0090-4.
[55] C. Sommer *et al.*, 'Building clinical trials around patients: Evaluation and comparison of decentralized and conventional site models in patients with low back pain', *Contemp Clin Trials Commun*, vol. 11, pp. 120–126, Sep. 2018, doi: 10.1016/j.conctc.2018.06.008.
[56] O. L. Aiyegbusi *et al.*, 'Digitally enabled decentralised research: opportunities to improve the efficiency of clinical trials and observational studies', *BMJ Evid Based Med*, vol. 28, no. 5, pp. 328–331, Oct. 2023, doi: 10.1136/bmjebm-2023-112253.
[57] K. Gillies and V. A. Entwistle, 'Supporting positive experiences and sustained participation in clinical trials: looking beyond information provision', *J Med Ethics*, vol. 38, no. 12, pp. 751–756, Dec. 2012, doi: 10.1136/medethics-2011-100059.

[58] E. L. Deci and R. M. Ryan, ‘Motivation, Personality, and Development Within Embedded Social Contexts: An Overview of Self-Determination Theory’, in *The Oxford Handbook of Human Motivation*, Oxford University Press, 2012, pp. 85–108. doi: 10.1093/oxfordhb/9780195399820.013.0006.

[59] E. Gamble, C. Linehan, and C. Heavin, ‘Establishing Requirements for Technology to Support Clinical Trial Retention: Systematic Scoping Review and Analysis Using Self-determination Theory’, *J Med Internet Res*, vol. 25, p. e38159, Apr. 2023, doi: 10.2196/38159.

[60] D. C. Mohr *et al.*, ‘Treatment adherence and patient retention in the first year of a Phase-III clinical trial for the treatment of multiple sclerosis’, *Multiple Sclerosis Journal*, vol. 5, no. 3, pp. 192–197, Jun. 1999, doi: 10.1177/135245859900500309.

[61] D. De Silva, *Helping measure person-centred care: a review of evidence about commonly used approaches and tools used to help measure person-centred care*. Health Foundation London, 2014.

[62] S. Sharp, M. McAllister, and M. Broadbent, ‘The vital blend of clinical competence and compassion: How patients experience person-centred care’, *Contemp Nurse*, vol. 52, no. 2–3, pp. 300–312, May 2016, doi: 10.1080/10376178.2015.1020981.

[63] B. Ferrell, A. C. Williams, T. Borneman, V. Chung, and T. Smith, ‘Clinical Trials: Understanding Patient Perspectives and Beliefs About Treatment’, *Clin J Oncol Nurs*, vol. 23, no. 6, pp. 592–598, Dec. 2019, doi: 10.1188/19.CJON.592-598.

[64] L. Keshtkar *et al.*, ‘The Effect of Practitioner Empathy on Patient Satisfaction’, *Ann Intern Med*, vol. 177, no. 2, pp. 196–209, Feb. 2024, doi: 10.7326/M23-2168.

[65] M. Apostolaros *et al.*, ‘Legal, Regulatory, and Practical Issues to Consider When Adopting Decentralized Clinical Trials: Recommendations From the Clinical Trials Transformation Initiative’, *Ther Innov Regul Sci*, vol. 54, no. 4, pp. 779–787, Jul. 2020, doi: 10.1007/s43441-019-00006-4.

[66] A. Vijayananthan and O. Nawawi, ‘The importance of Good Clinical Practice guidelines and its role in clinical trials’, *Biomed Imaging Interv J*, vol. 4, no. 1, Jan. 2008, doi: 10.2349/biij.4.1.e5.

[67] E. Johnson and L. Marsh, ‘Clinical research nurse utilisation and role in the conduct of decentralised clinical trials: a literature review’, *Journal of Research in Nursing*, vol. 28, no. 3, pp. 214–226, May 2023, doi: 10.1177/17449871231162497.

[68] A. M. Polhemus *et al.*, ‘Accelerating Adoption of Patient-Facing Technologies in Clinical Trials: A Pharmaceutical Industry Perspective on Opportunities and Challenges’, *Ther Innov Regul Sci*, vol. 53, no. 1, pp. 8–24, Jan. 2019, doi: 10.1177/2168479018801566.

[69] D. V. Adams, S. Long, and M. E. Fleury, ‘Association of Remote Technology Use and Other Decentralization Tools With Patient Likelihood to Enroll in Cancer Clinical Trials’, *JAMA Netw Open*, vol. 5, no. 7, p. e2220053, Jul. 2022, doi: 10.1001/jamanetworkopen.2022.20053.

[70] R. Izem *et al.*, ‘Decentralized Clinical Trials: Scientific Considerations Through the Lens of the Estimand Framework’, *Ther Innov Regul Sci*, vol. 58, no. 3, pp. 495–504, May 2024, doi: 10.1007/s43441-024-00615-8.

[71] T. K. Owonikoko, ‘Upholding the Principles of Autonomy, Beneficence, and Justice in Phase I Clinical Trials’, *Oncologist*, vol. 18, no. 3, pp. 242–244, Mar. 2013, doi: 10.1634/theoncologist.2013-0014.

[72] M. Coday *et al.*, ‘Strategies for Retaining Study Participants in Behavioral Intervention Trials: Retention Experiences of the NIH Behavior Change Consortium.’, *Annals of Behavioral Medicine*, vol. 29, pp. 55–65, Mar. 2005, [Online]. Available: http://10.0.4.183/s15324796abm2902s_9

[73] A. Kearney *et al.*, ‘Reducing attrition within clinical trials: The communication of retention and withdrawal within patient information leaflets’, *PLoS One*, vol. 13, no. 10, p. e0204886, Oct. 2018, doi: 10.1371/journal.pone.0204886.

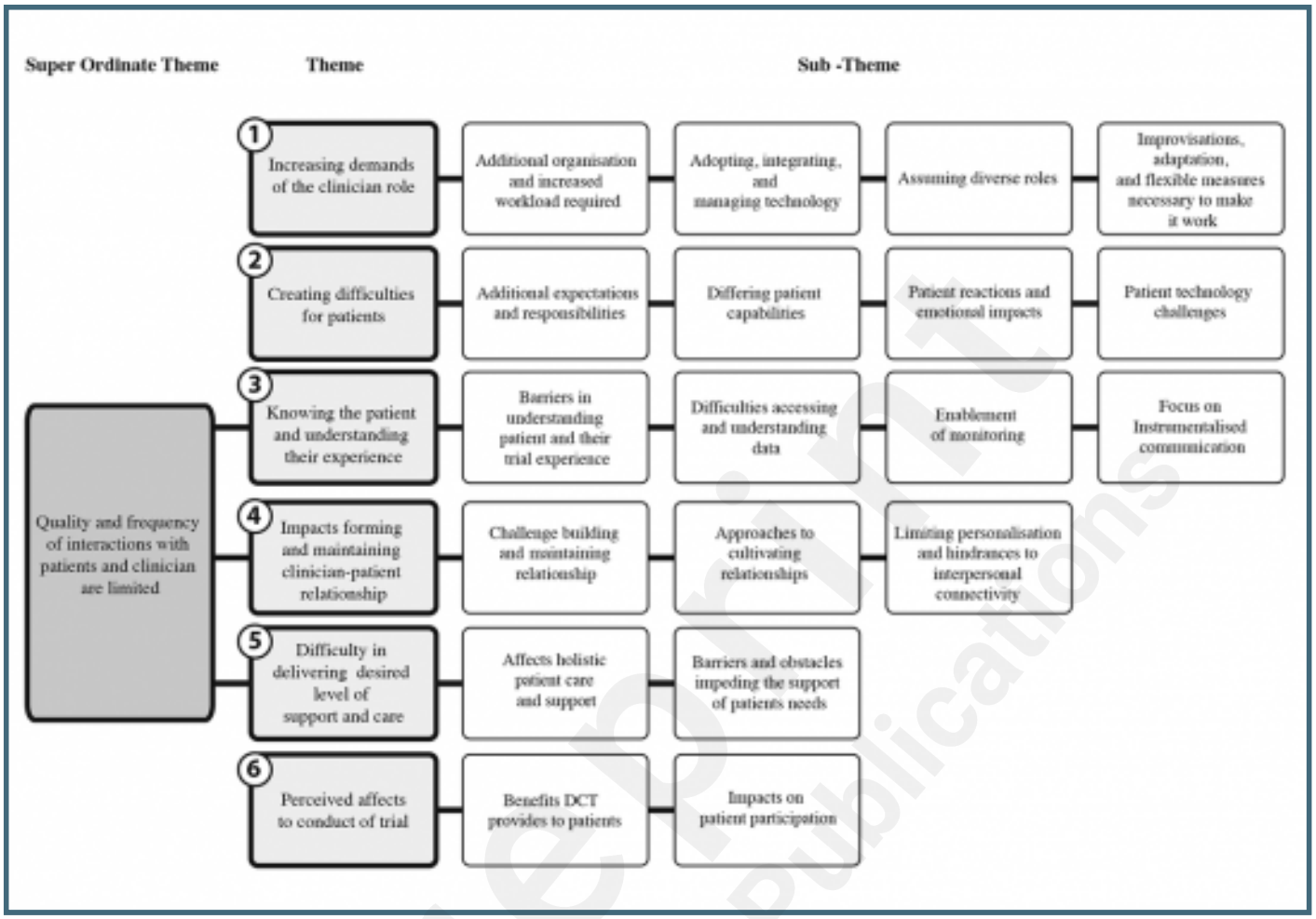
[74] J. Herbsleb, ‘Building a socio-technical theory of coordination: why and how (outstanding research award)’, in *Proceedings of the 2016 24th ACM SIGSOFT International Symposium on Foundations of Software Engineering*, New York, NY, USA: ACM, Nov. 2016, pp. 2–10. doi: 10.1145/2950290.2994160.

[75] E. G. Poon, S. Trent Rosenbloom, and K. Zheng, ‘Health information technology and clinician burnout: Current understanding, emerging solutions, and future directions’, *Journal of the American Medical Informatics Association*, vol. 28, no. 5, pp. 895–898, Apr. 2021, doi: 10.1093/jamia/ocab058.
[76] C. L. Besch, ‘Compliance in clinical trials’, *Aids*, vol. 9, no. 1, pp. 1–10, 1995.
[77] L. A. Simmons *et al.*, ‘From hybrid to fully remote clinical trial amidst the COVID-19 pandemic: Strategies to promote recruitment, retention, and engagement in a randomized mHealth trial’, *Digit Health*, vol. 8, p. 205520762211290, Jan. 2022, doi: 10.1177/20552076221129065.
[78] A. J. De Jong *et al.*, ‘Opportunities and Challenges for Decentralized Clinical Trials: European Regulators’ Perspective’, *Clin Pharmacol Ther*, vol. 112, no. 2, pp. 344–352, Aug. 2022, doi: 10.1002/cpt.2628.
[79] A. Chammas, M. Quaresma, and C. Mont’Alvão, ‘A Closer Look on the User Centred Design’, *Procedia Manuf*, vol. 3, pp. 5397–5404, 2015, doi: 10.1016/j.promfg.2015.07.656.
[80] S. Pagoto and G. G. Bennett, ‘How behavioral science can advance digital health’, *Transl Behav Med*, vol. 3, no. 3, pp. 271–276, Sep. 2013, doi: 10.1007/s13142-013-0234-z.
[81] E. R. Nilsen, K. Stendal, and M. K. Gullslett, ‘Implementation of eHealth Technology in Community Health Care: the complexity of stakeholder involvement’, *BMC Health Serv Res*, vol. 20, no. 1, p. 395, Dec. 2020, doi: 10.1186/s12913-020-05287-2.

Supplementary Files

Figures

Findings: Theme and Sub-themes.



Multimedia Appendixes

Supplementary Material 1 – Interview guide.
URL: http://asset.jmir.pub/assets/2a3c4346bdd64b64caac45cf5eb9e2c3.pdf