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Corresponding author:
M. R. Cummins, PhD, RN, FAAN, FACMI;
Email: mollie.cummins@utah.edu

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Narrative review of telemedicine applications in decentralized research

Mollie R. Cummins^{1,2} , Hiral Soni², Julia Ivanova², Triton Ong², Janelle Barrera^{2,3}, Hattie Wilczewski², Brandon Welch^{2,4} and Brian E. Bunnell^{2,3}

¹University of Utah, College of Nursing, Salt Lake City, UT, USA; ²Doxy.me Research, Doxy.me Inc., Rochester, NY, USA; ³Department of Psychiatry and Behavioral Neurosciences, University of South Florida, Tampa, FL, USA and ⁴Department of Public Health Sciences, Medical University of South Carolina, Charleston, SC, USA

Abstract

Telemedicine enables critical human communication and interaction between researchers and participants in decentralized research studies. There is a need to better understand the overall scope of telemedicine applications in clinical research as the basis for further research. This narrative, nonsystematic review of the literature sought to review and discuss applications of telemedicine, in the form of synchronous videoconferencing, in clinical research. We searched PubMed to identify relevant literature published between January 1, 2013, and June 30, 2023. Two independent screeners assessed titles and abstracts for inclusion, followed by single-reviewer full-text screening, and we organized the literature into core themes through consensus discussion. We screened 1044 publications for inclusion. Forty-eight publications met our inclusion and exclusion criteria. We identified six core themes to serve as the structure for the narrative review: infrastructure and training, recruitment, informed consent, assessment, monitoring, and engagement. Telemedicine applications span all stages of clinical research from initial planning and recruitment to informed consent and data collection. While the evidence base for using telemedicine in clinical research is not well-developed, existing evidence suggests that telemedicine is a potentially powerful tool in clinical research.

Introduction

Clinical trials and other types of health sciences research traditionally centered around interactions with study participants at a central research site. Now, researchers increasingly leverage digital health technologies, including telemedicine, to enable remote participation [1]. Research that implements fully remote participation or a hybrid of remote and in-person participation is known as decentralized research. Some decentralized studies have demonstrated improved recruitment and retention [2,3]. Further, there is preliminary evidence and potential for decentralized studies to improve gender, racial, and ethnic diversity among participants [4–6]. Telemedicine, widely adopted for clinical use in recent years, enables critical human communication and interaction between researchers and participants during decentralized studies.

The adoption of clinical telemedicine accelerated during the COVID-19 pandemic due to public health restrictions [7–9]. Now, a large proportion of the US population has experience with telemedicine [8]. Though far from conclusive, current evidence suggests that clinical outcomes may not differ and that there are numerous benefits [10–15]. In decentralized research, researchers can use telemedicine to screen and recruit, educate, coordinate care, and conduct assessments or interventions with participants. In the case of hybrid studies, research staff can employ telemedicine and other digital health technologies to supplement in-person interactions with staff at a research site. Additionally, telemedicine may be used to educate and support participants using sensors, wearables, or other technology in the home. However, formal guidance for implementing telemedicine in decentralized clinical research has been scarce, despite the need to standardize interactions and processes in compliance with a research protocol.

Clinical research involving data collection from trial participants can entail multiple, varied activities (see Table 1), and clinical research interactions differ from traditional healthcare interactions in ways that require special consideration. Researchers implement a formal protocol that must be strictly followed. They collect complete and accurate data, obtain and ensure ongoing informed consent, and in some studies, deliver a standard educational or behavioral intervention. In drug and device trials, researchers have a particular need to assess and monitor symptoms over time [16]. The quality of these assessments is critical to ensure safety, an appropriate clinical response, and accurate scientific measurement. These assessments are also powerful in facilitating the overall research process and its ability to meet the needs of

Table 1. Common activities of prospective clinical research studies

Activity	Description
Study design/ protocol development	Develop and plan study protocol and activities at various stages of the study
Recruitment	Advertise and invite patients to participate
Screening	Determine participant eligibility according to study inclusion criteria
Informed consent	Educate participants on study risks and benefits, protocol, reporting, and withdrawal, and answer questions and obtain consent for participation; this occurs before participation and throughout the study.
Randomization	Assignment of a participant to intervention or control groups, if applicable
Intervention	Exposure to an intervention (e.g., behavioral, surgical, pharmaceutical) or placebo
Monitoring and assessment	Ongoing monitoring and identification of adverse events via periodic or continuous assessments and participant reporting
Data collection	Any data collected from or about participants at one or multiple time points during the study; varied in nature
Communication	Coordination of resources and services, among research teams, with funding and regulatory entities, and between researchers and participants
Education and training	Training study staff to successfully carry out research protocol; Participant preparation to engage in study processes and relevant procedures, devices, or interventions
Reporting	Documentation and reporting of study progress and outcomes for regulatory compliance, ethical oversight, and funding purposes
Compliance	Meet ethical, legal, and regulatory requirements and guidelines

society. As pointed out by Hastings *et al.*, “Observations made by nurses who are the agents of implementation in a clinical trial may . . . have a direct bearing on the speed with which translation to the next level of testing and use can occur [17].” There is a need to better understand how telemedicine, and specifically synchronous videoconferencing, is being used in clinical research as the basis for generating evidence to support good practices. Therefore, the purpose of this narrative, nonsystematic review of the literature is to review and discuss the literature describing the application of telemedicine, in the form of synchronous videoconferencing, in clinical research.

Methods

We conducted a narrative, nonsystematic review of the literature to review and discuss the literature describing the application of telemedicine, in the form of synchronous videoconferencing, in clinical research. Narrative, nonsystematic reviews are educational and broad in nature [18]. In conducting and reporting the narrative review, we followed available guidance related to quality of narrative, nonsystematic review articles [19–21].

Here, we define telemedicine as the use of synchronous videoconferencing to facilitate the conduct of clinical research, acknowledging that the secure technologies used for telemedicine can be flexibly used for various study-related activities and processes. This definition is narrow, as telemedicine is more typically defined as also encompassing asynchronous communication and related telecommunications technologies such as telephone, wearable sensors, and chatbots. However, we chose this definition to be consistent with an Association of Clinical Research Professionals (ACRP) typology of decentralization technologies published in a 2022 report [22]. We excluded telephone-only telemedicine given widespread existing use of telephone for communications with research study participants, regardless of whether a study is fully or partially decentralized.

Literature search

Two research team members (MC and HS) searched PubMed to identify English language literature published between January 1, 2013, and June 30, 2023. Initially, we searched titles and abstracts for the keywords “([Decentralized OR Virtual OR Remote] Clinical Trial) AND (Telemedicine).”

Article selection

After completing the biomedical literature search, we imported items to Covidence, and two independent screeners (HS, MC and/or HW) screened titles and abstracts to identify relevant research for the review. After initial title/abstract screening, a single reviewer (MC or HS) reviewed full-text publications, and we included the publications in the review if they met the inclusion and exclusion criteria. Our inclusion and exclusion criteria were as follows.

Inclusion criteria

Publications describing the use of telemedicine, or telemedicine in conjunction with other digital health technologies, as a means of conducting clinical research; English language; published January 1, 2013–June 27, 2023.

Exclusion criteria

Use of digital health technologies (e.g., chatbots, patient portals) without any use of synchronous videoconferencing; telemedicine limited to telephone calls; and use of telemedicine as an intervention rather than a means of conducting the study.

Assessment and analysis

Consistent with a narrative, nonsystematic review, we did not conduct quality assessment or formally extract variables. Two researchers with expertise in telemedicine (HS and MC)

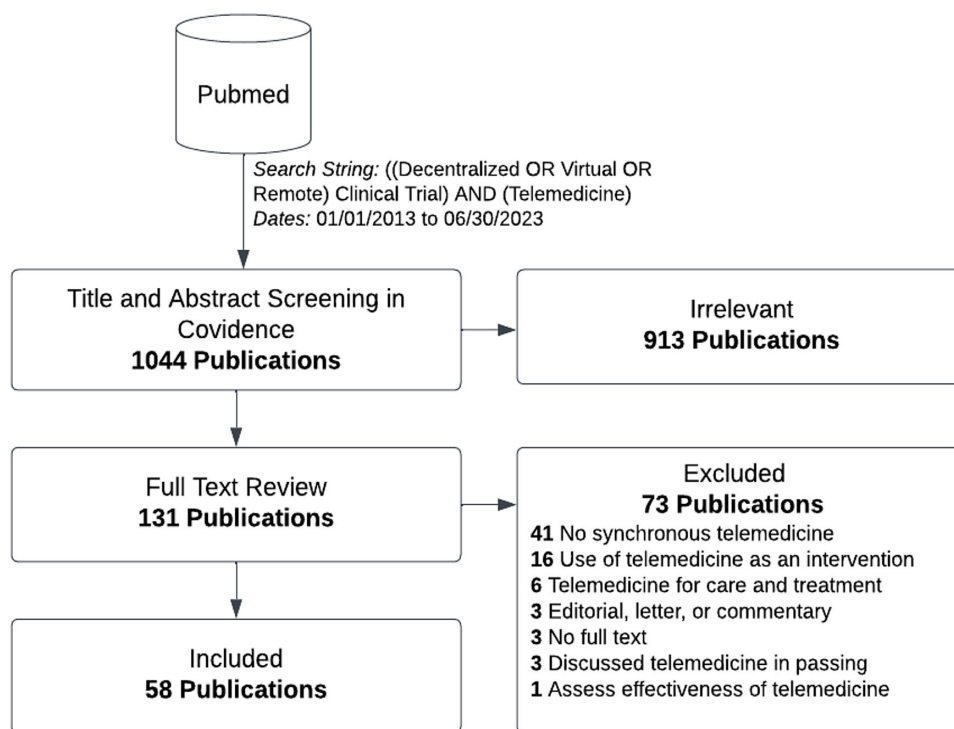


Figure 1. PRISMA diagram describing results of literature search.

synthesized the material in relation to prospective research activities (Table 1), identified related themes through consensus discussion, and presented a written summary to the larger, multidisciplinary team (nursing, clinical psychology, medical anthropology, and clinical research informatics) of coauthors for review and validation.

Results

The search, screening, and selection process are summarized in Figure 1. Through initial searches, we identified 1,044 publications. After deduplication and abstract screening, we conducted a single-reviewer full-text review of the remaining 91 publications. Of these, 48 met our inclusion and exclusion criteria. A list of all included publications is provided as supplemental file 1. Through written summarization and consensus discussion of the retrieved literature, we identified six themes classifying telemedicine applications in clinical research (see Fig. 2). The themes were infrastructure and training, recruitment, informed consent, assessment, monitoring, and engagement.

Discussion

Methods of decentralization

Researchers implement varied processes and technologies that we call decentralization technologies to enable remote study participation. For example, researchers may use patient portals (e.g., MyChart) and recruitment-focused portals (e.g., ResearchMatch) to connect directly with prospective participants or advertise on social media platforms such as Facebook or Twitter. Screening for eligibility can be accomplished using secure and compliant interactive technologies (e.g., chatbots), electronic surveys, or simply

videoconferencing. Researchers can use specialized electronic consent (e-consent) or teleconsent tools and technologies to support a remotely conducted informed consent process. Participants might report symptoms using mobile or web applications (e.g., ePROs). Physiological data may be collected and transmitted using sensors or other devices (e.g., Fitbit, apple watch, continuous blood glucose monitor, air quality sensor). Using these and other digital health technologies, researchers can collect data and biospecimens and monitor symptoms continuously without study participants traveling to a central research site. Across all these activities, telemedicine can be used to implement or enhance specific aspects of the study protocol.

Infrastructure and training

Infrastructure and training are essential in decentralized research [23]. Researchers must closely consider privacy and confidentiality when selecting and configuring telemedicine technologies. They must also design protocols and processes that incorporate telemedicine to minimize risk [24]. A telemedicine process and workflow must be designed to support participant interactions with the research team, including essential logistics such as scheduling and staffing, communication with participants, arrangement of physical space, and hardware management. The telemedicine process must also include in-call processes that support protocol integrity and participant engagement, configuration and implementation of adjunct telemedicine technologies such as teleconsent and messaging, and mechanisms for technical support [23,24]. Additionally, telemedicine technologies are secure communication modalities for investigative teams, stakeholders, and collaborators to discuss and manage study protocols, recruitment successes and challenges, and support efficient conduct of the study [25,26].



Figure 2. Applications of telemedicine in decentralized clinical research.

Telemedicine education and training are essential for study personnel. However, telemedicine curricula and resources could be better developed for either clinical or research purposes [27–30]. Examples of specialized *clinical* telemedicine training initiatives are found in the biomedical literature but are not widely implemented. These initiatives include specialized medical education curricula [29], simulation-based training experiences [31], and specialized initiatives such as digital health or e-health training centers [32]. Some training programs and courses prepare investigators to use telemedicine in research from a general standpoint [33]. However, study personnel must also be prepared to implement a specific protocol using specific technologies in the actual implementation environment while effectively engaging the participant and considering safety [34].

Researchers must understand and minimize security risks in using telemedicine. Kim, Choi, & Han (2020) describe the security vulnerabilities related to users, devices, home networks, public networks, the computer systems used for telemedicine, and the telemedicine service [35]. Federal regulation addresses privacy and security to some extent, and compliance with the US Food and Drug Administration (FDA), Health Information Portability and Accountability Act (HIPAA), and Federal Trade Commission (FTC) regulations mitigates some risks. Still, these regulations lag current technology, and compliance does not guarantee that the security risks are entirely addressed [36]. When researchers lack the security expertise to design robust telemedicine processes, they must collaborate to obtain appropriate expertise and guidance and to ensure regulatory compliance. Additionally, risks to privacy and confidentiality in telemedicine should be disclosed as part of the informed consent process.

To select a telemedicine platform compliant with HIPAA regulations, study personnel often collaborate with organizational information security officers or follow standard operating procedures that designate appropriate telemedicine platforms for clinical operations and human subjects research. In evaluating telemedicine platforms for use in clinical research, researchers must consider the extent and nature of data logged about participants in telemedicine interactions, including identifying information such as names, video or audio recordings, IP addresses, and specific dates and times of interactions. Researchers should also consider where the data are stored and who can access it. Study personnel must actively manage access and remain aware of which system users have access to sensitive information, updating permissions as needed. They are obligated to manage user rights and system access consistent with institutional review board (IRB) approval.

Recruitment

Traditionally, recruitment is centered around in-person contact with prospective participants. Typically, health professionals would provide information and refer potential participants to study sites. The onset of COVID-19 led to the widespread adoption of distance recruitment strategies in clinical trials. Now, using decentralized recruitment strategies, including online and/or direct-to-consumer recruitment, researchers can reach a larger pool of potential study participants using varied communication channels, including social media, online communities and crowdsourcing platforms, electronic health records, and community events (such as health fairs) [3,37]. Direct-to-consumer

recruitment can lead to increased participation and diversity in clinical trials, despite the loss of face-to-face interaction [38,39]. For example, in the VERKKO trial, online recruitment was completed 56% faster than in a traditionally conducted trial [40,41]. Other studies have similarly noted improved enrollment/accrual [42,43]. However, the results of online recruitment strategies can vary considerably according to how they are designed and implemented [44].

Telemedicine can facilitate interaction between potential participants and researchers during the recruitment process, ask-and-answer questions, and screen for fraudulent participation. Fully remote studies with online recruitment that require only interviews or surveys, and that compensate participants, can be plagued by imposter participants. These individuals misrepresent themselves in order to participate in a study, presumably to benefit from financial remuneration or some other incentive [45,46]. Synchronous videoconferencing between researchers and potential participants allows researchers to identify indicators of potential fraudulent participation, such as egregious misrepresentation, reading from a script, the physical presence of the participant in a call center, and difficulty engaging on topics relevant to the inclusion criteria.

As telemedicine enables remote participation, it can indirectly and positively affect recruitment. Patients have indicated they would like to participate in clinical trials if technology such as telemedicine and remote monitoring is used [47,48]. Patients have also indicated they would be more inclined to participate if the travel burden was lower [49]. In a decentralized study by Roberts *et al.*, the shift to virtual recruitment and telemedicine increased the flexibility of communication and study hours, leading to increased participation in a pediatric clinical trial for treating childhood obesity [50].

Informed consent

Researchers must ensure that study participants are engaging of their own volition, under no coercion or undue influence, and with a reasonable understanding of their participation's risks, benefits, and responsibilities [51]. These principles are most commonly managed as informed consent [52]. Video-based informed consent processes mirror the in-person face-to-face consent experience by maintaining participant engagement and understanding [53,54]. A 2016 randomized controlled trial in the emergency department setting found no differences in objective or subjective patient comprehension between telemedicine and face-to-face informed consent groups [55]. In the literature, we found multiple examples of specific studies or institutional practices that included telemedicine-facilitated informed consent [56–60].

With the adoption of decentralized research technologies and health information technology in general, there has been a rise in the development of HIPAA-compliant e-consent management tools (such as DocuSign) [61]. Multimedia tools with interactive audio and video-based consent explanations have been developed. These tools enhance communication about risks and allow researchers to respond to questions and concerns [62–64]. Teleconsent combines e-consent with synchronous videoconferencing [54,65]. Health information technology (HIT) embeddable solutions also support informed consent (e.g., REDCap, DrugDev, ClinConsent, 5thport) [66,67].

Fully asynchronous consent processes, where appropriate, can require third-party integrations, identity verification, and login accounts; and require consideration of privacy concerns [68].

These solutions augment the ability to obtain consent remotely and, in some cases, can be used to enhance and strengthen the informed consent process through multimedia and novel participant input processes [69–71]. However, fully asynchronous informed consent processes always lack face-to-face interaction with study personnel. There is no capability to synchronously explain aspects of the consent material nor the opportunity to ask and answer questions in real-time. Additionally, face-to-face interaction and witnessed consent would be likely required by IRBs for higher risk studies, such as greater than minimal risk clinical trials. For example, at the Mayo Clinic during the COVID-19 pandemic, participants in minimal risk clinical trials could consent by email, whereas video or telemedicine consent was usually required for higher risk studies [57].

Conversely, synchronous, telemedicine-based informed consent processes have demonstrated improved enrollment rates, trial efficiency, and decreased dropout rates [72]. Telemedicine sessions that offer participants the opportunity to ask questions and interact with study personnel, and provide for witnessed consent, can be augmented with remote processes for managing documents and signatures. Telemedicine-based synchronous consents are a viable solution to overcome barriers of asynchronous digital consent mechanisms and paper-based forms [59,65,69,73]. Many telemedicine platforms allow users to screen share or have in-built capacity to collect consent [26,65]. In the wake of COVID-19, Mayo Clinic and several other institutions have established synchronous, telemedicine-based consent processes [57,74].

Monitoring and assessment

Ongoing monitoring of participants in research studies, particularly clinical trials, is essential for safety and requires thoughtful planning. Adverse events must be detected, evaluated, and appropriately reported. In decentralized clinical research, information about adverse events could come from various sources, including patient-reported symptoms and outcomes, biosensors, laboratory and physiologic testing, direct observation by the research team, electronic health records, and healthcare providers. There are multiple examples of telemedicine use for assessment and monitoring in the literature [75–79]. A study by Alonzo *et al.*, reported of study staff monitoring participants remotely administering transcranial direct current stimulation for the treatment of depression at home [76]. A study protocol by Achey and colleagues described cognitive and Parkinson's disease rating assessments conducted using telemedicine [77]. Research has also reported telemedicine-based observation of medication-taking by study staff which could increase adherence during the trial period [65]. Telemedicine plays an essential role in also monitoring adverse events because it allows study personnel to directly interview and assess patients, to the extent assessments can be conducted via the telemedicine platform, and to rapidly follow-up on potential adverse events detected through other means of data collection [3]. It also may alleviate the travel burden on participants when virtual visits replace in-person visits to a central study site [80,81].

Telemedicine can be used to collect data and conduct limited direct assessments [3,26,74]. For example, researchers conduct qualitative interviews or administer surveys using telemedicine [82,83]. Multiple, varied studies have established feasibility of conducting diverse assessments via telemedicine, including cognitive and physical assessments [75–77,84–87]. Multiple published studies entailed researchers or healthcare providers meeting with participants via telemedicine to explain treatment

and conduct virtual exams [24,88]. Researchers have expressed that integrating devices such as blood pressure monitors, weighing scales, blood glucose meters, digital stethoscopes, pulse oximeters, otoscopes, and spirometers within telemedicine solutions is advantageous for clinical research [83]. Through telemedicine, researchers can guide participants in using the devices in real time or follow-up on participant-captured measurements, device data, or images taken in a store-and-forward telemedicine process [26,89]. Devices designed for clinical telemedicine applications are rapidly emerging in the healthcare marketplace.

Researchers may use other remote technologies to facilitate data collection during a telemedicine session with a participant [90]. Various electronic data capture tools are available to collect and manage clinical research data, with varied integration with telemedicine-based interactions [67,91–93]. Research Electronic Data Capture (REDCap) is a widely used global, secure web application for building and managing electronic data capture for clinical research [67]. REDCap is advantageous as a customizable, robust research data platform with research-specific features such as fine-grained data and user rights management, logging, longitudinal study management, and project dashboards. It facilitates data entry by researchers or survey completion by participants during a telemedicine session. In a study conducted by Dmochowski *et al.*, participants could complete follow-up visits via telemedicine where study coordinators verbally asked questions and entered them into the electronic data capture system [75]. A 2020 article by Persky surveys potential benefits of virtual reality (VR) for conducting decentralized research, including the ability to precisely control the virtual environment, the capability of digitally capturing and measuring behavioral data, and enhanced interaction between participants and researchers [94]. VR, though distinct from videoconferencing-based telemedicine, shares its key characteristics of synchronous audio and video interaction.

Telemedicine is also an important modality for validating remote, patient-collected measurements. In the study by Roberts *et al.*, patients were given tools such as digital weighing scales and measuring tapes, and trained staff members directly observed caregiver measurement of the height and weight of pediatric patients using telemedicine [50]. Supervision via telemedicine ensured that the data, collected remotely by patient caregivers, was accurate and collected in a manner consistent with the study protocol. Researchers have monitored heart rate and oxygen saturation levels using smartwatches as well as checked up on how participants were responding to the intervention via telemedicine or audio calls [5]. Telemedicine-based assessment can be supplemented by diagnostic testing at local laboratories or physical assessments at local health centers to validate routine measurements and self-reported outcomes [95]. The advent of digital imaging and pathology allows healthcare providers to interpret results virtually, increasing flexibility and access.

Scheduled or acute telemedicine consultations can help participants to report adverse events during the trial period and receive immediate medical care [24,95]. Furthermore, digital cloud-based platforms could empower researchers and clinicians by sending real-time alerts and notifications about potential concerns based on participants' self-reported symptoms or medical device data [23].

Engagement

There is emerging evidence that using digital health technologies can enhance engagement and retention in clinical trials. For

example, the SMART study, which implemented an engagement toolkit (MARKIT) based partly upon technology, reported 86% retention at 24 months [96]. In a 2018 noninterventional trial related to back pain, with both decentralized and traditional arms, decentralized study visits were conducted using telemedicine, and patients were provided with ongoing, supplementary, phone-based support [6]. The retention rate for the decentralized arm was 89% versus 60% in the traditional arm. These levels of retention are remarkable given engagement and retention are persistent challenges in traditional clinical trials [97–99]. Many studies fail to enroll any participants whatsoever, and a large proportion of studies are underenrolled [100]. Trust, communication, and attitude are critical for engagement in clinical trials, but challenging to convey without in-person visits, and it is a reasonable assumption that there is a higher need for virtual support and interaction in the absence of in-person visits [101]. Here, telemedicine could be a valuable modality allowing synchronous interaction between researchers and participants.

There is a growing recognition of the need to address digital health literacy to ameliorate health disparities and enable equitable access to digital health, especially in vulnerable populations [102–104]. To avoid the potential exclusion of vulnerable populations from research by requiring digital health literacy as an inclusion criterion, researchers should consider approaches to educate and support participants who might otherwise be excluded, to enable their participation. If telemedicine itself is feasible, but participants require support with other aspects of a decentralized study such as applications, sensors, or devices, telemedicine can function as a means of providing support [105].

Disadvantages of telemedicine

The use of telemedicine in decentralized clinical research also presents a set of limitations or trade-offs. Telemedicine platforms are generally designed for clinical care rather than research and usually lack integration with research-specific tools. Future enhancements of telemedicine platforms to support decentralized research include integrations with electronic data capture systems and clinical trial management systems, and enhanced integration of teleconsent and other e-consent tools to meet regulatory requirements and to improve researcher and participant experience [106]. Additionally, there is a need for decentralized technologies to accommodate single sign-on (SSO) processes typically required by academic research organizations [22].

While telemedicine is becoming increasingly routine, some participants may struggle using telemedicine because of physical or cognitive limitations, poor connectivity, lack of access to devices, or other barriers [107,108]. Sessa and colleagues expressed concern for geographical and cultural differences in telemedicine adoption that could cause disparities in decentralized trials [109]. Preliminary feasibility assessments that assess and address participant barriers are critically important. Additionally, researchers should provide participants with adequate guidance and support in using telemedicine and other remote technologies.

Limitations

This review was not a systematic review. Instead, we present a narrative overview based on a review of published literature. Formal, structured reviews such as systematic reviews, scoping reviews, or meta-analyses could be conducted to answer specific research questions related to telemedicine applications in clinical research as more evidence emerges. However, our objective here

was to inform the reader through a narrative overview rather than to address a more specific research question through literature-based analysis. We found that the nature and extent of telemedicine use in clinical trials were not well-characterized in published reports of clinical research, and a more detailed analysis of implementations may require prospective research.

Conclusion

In this narrative review, we reviewed and discussed literature describing the application of telemedicine, in the form of synchronous videoconferencing, in clinical research. In summary, we found that while a lack of face-to-face contact with study staff may discourage participants from enrolling or continuing with a decentralized research study, regular video-based conversations and asynchronous communication could alleviate participant concerns [3,110]. Telemedicine may also be useful in addressing research community concerns related to oversight and poor data quality [111], enabling periodic validation of measurements obtained using remote sensing devices or ePROs. Telemedicine could also overcome challenges in shared understanding, reducing protocol errors and issues of missing or incomplete data [2]. Routine follow-ups, on-site validations of self-reported participant data, or partnerships with local patient clinics may help increase adoption and ensure high data quality [50,106,112].

In this review, we also note that the use of telemedicine presumes that participants have access to appropriate devices and connectivity and a minimal level of digital literacy. These requirements may preclude participation on the part of some [54,112,113]. Furthermore, device and application usability issues, participant support, and data analytic support are potential issues among participants [114]. Telemedicine and remote technologies bring the challenges of remotely supporting participants with technology and connection issues. Staff members may need to help participants set up and troubleshoot telemedicine calls and remote technologies, creating additional staff burden for participant support [115].

The adoption of telemedicine in health care and health sciences research has rapidly expanded in recent years, primarily due to the public health restrictions during the COVID-19 pandemic. Clinical researchers have turned to telemedicine and other remote technologies to recruit and monitor research participants in ways that turned out to be safe, valid, naturalistic, and with more representative recruitment [83,116–118]. Here, we provided an overview of telemedicine applications in decentralized clinical research. Telemedicine applications span all stages of clinical research, from initial planning and recruitment to data collection and safety monitoring. Current evidence indicates that multiple research studies have experienced an improvement in recruitment and retention related to decentralized technologies, including telemedicine. While the evidence base for using telemedicine in clinical research is not well-developed, a growing evidence base suggests that telemedicine is a potentially powerful tool in decentralized research, with value across multiple aspects of the research process.

Supplementary material. The supplementary material for this article can be found at <https://doi.org/10.1017/cts.2024.3>.

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