



## The impact of internet connectivity when conducting a virtual clinical trial with participants living in rural areas

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### ABSTRACT

**Aim:** The purpose of this secondary analysis was to describe issues related to internet connections during a virtual randomized clinical trial (v-RCT) that included family caregiver participants living in rural areas.

**Background:** Success of v-RCTs depends on reliable, high-quality internet access, which can be problematic in rural areas.

**Methods:** Interventionists documented connectivity issues and corrections made to address connectivity in a narrative note after each virtual visit with family caregivers enrolled in a v-RCT. Notes were reviewed for descriptions of the internet connection during the visit and then coded into those with and without connectivity problems. Two investigators reviewed notes and codes to assure reliability. Discrepancies in codes were discussed or arbitrated by a third investigator until consensus was reached. Analysis was completed using descriptive statistics.

**Results:** Of the 1003 visits reviewed, only 11 % of visits (115/1003) contained a documented problem with internet connectivity. Visits with documented connectivity problems were experienced by 27 % of participants (58/215). However, 60 % (35/58) of participants with a documented issue had a problem with only one visit. None of the participants withdrew from the v-RCT due to problems with their internet connections.

**Conclusions:** The findings support the effective use of virtual visits in research involving participants living in rural locations. V-RCTs provide a strategy that enables participation for individuals who may not otherwise have access to clinical trials conducted in-person in urban settings. Utilizing internet access to connect with and support people who live in rural areas is critically needed to advance clinical research.

### 1. Introduction

The wide availability of virtual modalities for health care interventions offers previously unavailable opportunities for participation in clinical trials that can diversify, extend, and enhance the reach and impact of study results. Virtual randomized clinical trials (v-RCTs) – also known as remote or decentralized trials – are changing *how* clinical

studies are conducted. V-RCTs are types of trial designs and approaches to utilizing internet connections to enable access to and participation in clinical trials from locations distant from urban medical centers [1]. Participants describe v-RCTs as an acceptable and valuable modality that reduces participation burden [2]. The advantages of v-RCTs include reduced cost (e.g., time or travel), capacity to recruit a wider range of participants, and ability to communicate with participants remotely.

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V-RCTs may be especially beneficial for participants who are homebound and/or have limited access to traditional clinical trials, like those in rural areas. Limited internet access is increasingly recognized as a substantial threat to the well-being of rural residents [3,4]. Internet access is recognized as vital for rural prosperity by ensuring modern communications between rural households and healthcare centers, schools, and employment opportunities [5,6]. However, little is known about how challenges with internet connectivity impact participation in v-RCTs in rural areas.

Studies on telehealth for providing care to older adults have shown that using virtual modalities is both feasible and acceptable [7]. Although telehealth for clinical care is becoming more widely accepted by patients and providers, the use of virtual visits in clinical trials is less ubiquitous. Sabesan et al. suggest it is feasible to enroll, consent, and follow patients in clinical trials using lessons learned from telehealth models [8]. However, individuals in rural areas face challenges for participation in virtual visits in v-RCTs because many have less internet access than those in urban areas [9]. The use of technology is influenced by numerous factors, including but not limited to having devices that consistently connect to the internet and that provide high-quality digital access.

Access, use, and quality of internet services are interdependent and have been identified as a social determinant of health [10]. A recent study reported that access to reliable broadband internet varied significantly across geography with rural individuals experiencing more challenges in accessing and connecting to needed technology [11]. Unreliable internet connection and delays with the technology affect flow of conversation and overall experience [2]. V-RCTs depend on reliable, high-quality internet access, and poor-quality internet connectivity is considered a structural barrier to v-RCT utilization [12], an issue magnified in rural populations.

Underrepresented in v-RCTs are rural family caregivers of seriously ill patients. Recognizing that caregiving is associated with physical, psychological, and social problems for caregivers, there is growing interest in utilizing v-RCTs to support rural family caregivers who have difficulty participating in trials in urban medical centers [13]. Caregivers living in rural areas face challenges with clinical trial participation due to travel, time, cost, work disruptions, and distance from the care recipient and existing family support. V-RCTs can facilitate rural caregivers' involvement, reducing burdensome trial-related participation that can increase trial accrual rates [14] and minimizing participation barriers [8]. Research shows v-RCTs are well-accepted by patients and caregivers, noting no adverse financial, social, or emotional impacts, and enhanced connections to and support from study teams located in urban sites [2].

Incorporating virtual modalities into trial protocols enables access to clinical trials for geographically remote participants [8]. This secondary analysis aims to describe internet connectivity issues in a v-RCT involving caregivers from rural areas.

## 2. Materials and methods

A v-RCT was conducted with family caregivers living in rural areas of three states (Minnesota, Iowa, and Wisconsin) in the Upper Midwest. Rural residence was defined as living in areas with a population of <50,000 [15]. Although we recognize that there are numerous definitions of rurality [16], we utilized a pragmatic approach in which family caregivers were recruited in real time at the point of care [17]. A study coordinator reviewed a list of palliative care patients from one health system and the home location of their primary caregiver. If the address was in a location with a population of less than 50,000, the caregiver was contacted to ascertain their interest in study participation. Prior to the Covid-19 pandemic, participants were recruited in person at the patient's bedside. During the pandemic, participants were recruited by phone. All participants had internet availability, either through cellular or broadband coverage. Trial details are registered at [ClinicalTrials.gov](https://ClinicalTrials.gov)

(NCT03339271 Protocol version: 11), were approved by the Institutional Review Board (IRB# 17-005188), and are described elsewhere [18].

Experienced palliative care nurses provided teaching, guidance, and counseling initially using the Vidyo platform on study-provided tablets (2018–2020). During the Covid-19 pandemic (March 2020–2022), we transitioned to using a secure Zoom platform or FaceTime on participants' own devices (desktops, tablets, smartphones, etc.) [19].

Data were collected between 2018 and 2022. Data for this secondary analysis pertain solely to the intervention group. Interventionists used a cloud-based electronic health record (EHR) to record virtual visit details [20], including connectivity issues and how troubleshooting and adaptations to other modalities were used to continue with the visit. The outcomes of interest were the presence and impact of internet connection issues that affected the delivery of the v-RCT intervention using virtual visits. Documentation in the narrative notes was initially reviewed for descriptions of the internet connection during the visit and then coded into those with and without connectivity problems. Two investigators reviewed notes and codes to assure reliability. Discrepancies in codes were discussed or arbitrated by a third investigator. An iterative process was used until consensus was reached. Comparisons between those with and without internet connection issues were analyzed. Analysis was completed using descriptive statistics.

## 3. Results

The majority of the 184 participants were white (97.6 %), women (68.6 %), under 65 years of age (60.3 %), and spousal caregivers of the care recipient (61 %). Participants lived in Minnesota (78 %), Iowa (14 %), and Wisconsin (8 %). The interventionists spent, on average, 45 min conducting the virtual visits to counsel, educate, and support the caregivers [19].

Interventionists conducted 1120 virtual visits during the v-RCT. Documentation on the internet connection was missing for 117 visits (10 %), therefore, documentation from 1003 visits was reviewed. Only 11 % of visits (115/1003) contained a documented problem with connectivity. Those visits with documented connectivity problems were experienced by 27 % of participants (58/215). However, 60 % (35/58) of participants with a documented connectivity issue had a problem with only one of their virtual visits.

The virtual modality used during a visit could be modified or changed to a phone call at the discretion of the interventionist. Of the visits with documented technological issues, 17 (17/115, 15 %) required changing from a virtual to a phone visit. Only eight visits (8/115, 7 %) were completed utilizing only the audio portion of the virtual technology. Five visits (5/115, 4 %) were completed using virtual technology for the visual component of the visit and phone service for the audio component.

The most common types of connection problems were described as: frame freezing, dropped connections and, in some cases, difficulty using the virtual technology by the participant (Table 1). None of the participants withdrew from the v-RCT due to an issue with their video visit connections.

## 4. Discussion

The lessons learned from this secondary analysis support the effective use of virtual visits in clinical trials involving participants living in rural locations. Most of the participants were able to connect and communicate with the intervention nurses for nearly all the virtual encounters.

The few connectivity problems experienced by participants included both inconsistent internet service availability and poor connection issues, as well as some problems resulting from participants' limited experiences in utilizing technology. None of the technological issues posed reason enough for participants to withdraw from the study.

**Table 1**

Narrative comments on connectivity issues.

- Intermittent screen freezing noted.
- Participant had difficulty with the software program and was unable to get connected. A phone visit was completed instead.
- Video connection with visual freeze-up; participant needed to repeat statements.
- Connectivity good. A few screen freezes but not enough to hamper communication.
- Fair reception with occasional freezing, continued using video.
- Good connectivity. Participant having trouble hearing but will ask family member for help to figure out volume control.
- Video connectivity poor at times with multiple freezing screen/dropped connection on participant end. Participant moved to other locations to improve video, able to complete virtual visit.
- Participant used her smart phone for the virtual visit. Initial difficulty starting the virtual visit audio. Was able to troubleshoot and good connection for the remainder of the visit.
- Much freeze-framing. Mostly used audio function; participant would drop off screen and have to re-establish link. We stayed with the virtual visit.
- Connectivity fair, with video lagging behind audio.
- Challenges with sign-on to virtual visit; needed her to sign off/sign on. Coached by phone. Mild freezing/loss of video during visit but manageable.
- Some video problems and unable to get visual for virtual visit. Completed visit with voice only.
- Started with virtual visit and had technical problems halfway through. Completed visit by phone.

These results are consistent with previous literature describing the effectiveness of virtual visits in clinical care. There is less literature describing data of v-RCTs as an effective and efficient model for delivering research interventions. Lee [2] described tele-trials as an acceptable and valuable initiative that reduced the overall burden of trial participation. Cox [21] found that if it is difficult to engage with the design of a v-RCT intervention, it can become a disruption or a burden.

Internet access is recognized as a social determinant of health as it broadly affects the public's health [10]. According to the Pew Research Center, approximately one-quarter of American adults do not have internet access [22]. This estimate does not account for the millions of people with unstable internet connections [23]. The ability to conduct v-RCTs may benefit from recent federal and state policy initiatives, including the Bipartisan Infrastructure Law, which aims to ensure every American has access to high-speed, affordable, and reliable internet [24]. Our findings suggest the possibility of mitigating research participation disparities among people living in rural areas.

**Limitations.** The study intervention consisted solely of providing teaching, guidance, and counseling. Although the intervention was designed to utilize virtual visits because of the importance of observing visual cues [25], it was possible to utilize phone visits if a participant's internet was not working properly. This may not be the case for v-RCTs measuring physiological variables, such as blood pressure or glucose monitoring, which require additional demands on internet connectivity.

The v-RCT included participants from three states in the Upper Midwest Region, all having high concentrations of rural populations. Internet accessibility and broadband access varies by state [12]; therefore, results may not apply to other states with differing internet availability. Individuals may have decided not to participate in the v-RCT, knowing their connectivity was inconsistent or because of limited knowledge or use of the internet. It is also possible that a different definition of rurality, such as RUCC or RUCA codes, which use measures of population density, urbanization, and daily commuting, may classify participants into micropolitan areas instead of rural [26], however, a different definition would not change how few had connectivity issues. Likewise, it is possible to use census data to estimate, retrospectively, broadband access and connectivity quality; but because we did not ascertain whether participants were connecting for the intervention visits from home, work, or a public space, these estimates would have limited value. Future studies may consider budgeting funds to provide hotspots, conducting environmental assessments of broadband speeds, and assessing location of where the visits were conducted. While reporting broadband speeds may enhance the understanding issues related to designing studies with similar methods, we believe that the perceived experience of connectivity challenges by participants (and nurses) is equally if not more important than broadband strength measures for study engagement. Finally, connectivity data were missing for 117 visits. It is unknown if those visits had connectivity problems; therefore, it is possible we underestimated the number of problems encountered. Nevertheless, there were very few issues with connectivity

reported. The results of this study add to the body of knowledge regarding internet connectivity in rural areas while conducting v-RCTs.

## 5. Conclusions

Participation of family caregivers of seriously ill patients in clinical trials remains a challenge, especially for individuals living in rural areas. V-RCTs may enable participation for rural individuals who may not, otherwise, have access to clinical trials. Further study of internet access to connect with and support rural family caregivers in research endeavors is critically needed.

## Data availability

The corresponding author will respond to requests for data, either by providing the requester with results and output or with specific de-identified components of the dataset that address the request. Requests can be made to [griffin.joan@mayo.edu](mailto:griffin.joan@mayo.edu).

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## CRediT authorship contribution statement

**Diane E. Holland:** Writing – review & editing, Writing – original draft, Supervision, Funding acquisition, Conceptualization. **Catherine E. Vanderboom:** Writing – review & editing, Writing – original draft, Supervision, Funding acquisition, Conceptualization. **Jay Mandrekar:** Writing – review & editing, Visualization, Formal analysis. **William S. Harmsen:** Writing – review & editing, Visualization, Formal analysis. **Allison M. Gustavson:** Writing – review & editing, Writing – original draft. **Brystana G. Kaufman:** Writing – review & editing, Writing – original draft. **Ann Marie Dose:** Writing – review & editing, Writing – original draft, Data curation. **Ellen M. Wild:** Writing – review & editing, Writing – original draft, Data curation. **Cory Ingram:** Writing – review & editing, Writing – original draft. **Joan M. Griffin:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Conceptualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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