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Original Article

Transitioning to Remote Recruitment and Intervention: A Tale of Two Palliative Care Research Studies Enrolling Underserved Populations During COVID-19

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Abstract

Context. During the COVID-19 pandemic, community-based research studies experienced prolonged shutdowns unless able to pivot to remote study procedures.

Objectives. To describe the revision of two National Institutes of Health funded community-based palliative-focused clinical trials serving underserved populations to accommodate remote subject enrollment and examine its impact.

Methods. Transitioning to remote processes required multiple protocol and procedural changes including: altering informed consent processes; reducing the number of surveys administered; adding internet access as an inclusion criterion. To understand technological challenges, a screening tool was developed for one study to identify potentially eligible subjects' technology abilities and accessibility.

Results. Subjects' limited access to the internet and internet-enabled devices and discomfort with technology led to changes in recruitment patterns. Lack of familiarity with technology increased the amount of time it took research team members and subjects to connect remotely. Patients with significant cognitive and/or sensory deficits were at higher risk of experiencing fatigue during remote study visits leading to streamlining of data collection. A researcher-developed technology screening tool found that potential subjects were not comfortable with videoconferencing through Zoom expressing a preference for phone visits. Reduced travel time made scheduling remote study visits more efficient.

Conclusion. Future community- and home-based palliative care trials must consider the best way to utilize remote recruitment, enrollment, and data collection processes to increase efficiency and reduce costs. Researchers should consider technology accessibility and train staff to ensure the greatest possible opportunity to recruit underserved populations who have traditionally been underrepresented in research studies. J Pain Symptom Manage 2022;63:151−159.

Key Words

Palliative care, recruitment, virtual enrollment, underserved population, dementia, lay navigator

Key Message

We describe protocol modifications to accommodate remote enrollment during the COVID-19 pandemic for two community-based palliative care RCTs. Internet access and comfort with technology was limited in our underserved populations leading to

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screening failures. Remote processes can reduce barriers related to travel time for research coordinators or participants, increasing efficiency.

Introduction

The World Health Organization first reported the SARS-CoV2 outbreak causing COVID-19 infection in January 2020. The pandemic's global spread had significant impact on research programs housed at academic centers across a broad continuum. Determining schedules to support social distancing in lab environments and prioritizing therapeutic trials with judicious use of Personal Protective Equipment (PPE) enabled cautious resumption of some research. Community-based research, including interventional palliative care trials, often without access to limited PPE supplies, faced prolonged shutdowns unless able to pivot to virtual study procedures.

This manuscript's purpose describes the revision of two National Institutes of Health (NIH) funded community-based palliative-focused clinical trials to accommodate remote subject enrollment. Both experienced an initial pause at pandemic's start and initiated protocol modifications to facilitate study resumption. We outline eligibility alterations, technology transitions, and staff training processes each study adapted to this changing environment, ensuring safety for both study team and participants while maintaining protocol integrity. We also examine the impact of these adaptions to research recruitment, enrollment, and discuss lessons learned. With arrival of effective vaccines, this is an ideal moment to reflect upon innovations both research teams developed throughout the pandemic and sustain those highly effective procedures to run more equitable, accessible, and efficient community-based palliative clinical trials in the future.

Methods

A brief overview of purpose, aims, recruitment, and enrollment procedures of each clinical trial is presented followed by challenges faced and protocol modifications made due to the pandemic.

Case Study 1 - The Dementia Symptom Management at Home Program (DSM-H)

Overview

The DSM-H trial (NCT03255967) is a National Institute on Aging hybrid stage 3-4 embedded pragmatic cluster randomized control trial (RCT).[1] The multicomponent dyadic quality improvement intervention (Aliviado Dementia Care) provides home health clinicians with training, mentoring, and a toolbox of evidence-based resources to embed within the electronic health record (EHR) and use in daily practice to ensure person and caregiver-centered care, and includes specific components on addressing needs of specific underserved groups. Aims focus on whether the intervention, provided to persons living with dementia (PLWD) and their informal caregivers, improves dyadic quality of life, reduces symptoms, and decreases hospitalization and emergency room visits. Subject dyads are recruited within three days of admission across urban, suburban, and rural settings to one of three home health agencies specifically selected for their diverse populations. Overall enrollment target is 345 dyads, each completing four home research visits (days 1, 15, 30, and 60).

Inclusion and Exclusion Criteria

Eligible participants are: 1) ≥65 years; 2) admitted to one of three participating home health agencies; 3) English and/or Spanish speaking; 4) scored at least 6+ on the Quick Dementia Rating Scale (at least mild dementia); and 5) with a caregiver ≥18 years who provides in person care to the PLWD for at least 8 hours/week.[2]

Participants are excluded if they: 1) have a separate serious mental illness (bipolar disorder, schizophrenia) other than forms of dementia, depression, or anxiety; 2) are solely receiving infusion or home health aide services; 3) reside in assisted living facilities or board and care homes.

Recruitment Practice Prior to Pandemic

A point of contact, at each agency, either reviewed patient information at intake and admission or developed an automated report. Eligible subjects were submitted into a REDCap database.[3] Research staff contacted patients and caregivers to introduce them to the study and complete eligibility screening. Once eligible, an in-person home visit was scheduled within three days of the patient's start-of-care date to complete subject informed consent and enrollment.

Study Pausing Period Due to COVID-19

On March 10, 2020 all in-person recruitment and enrollment activities were suspended. The five-year (54 month) multisite study was in its 31st month with 109 subjects enrolled. Following discussion with the Data Safety Monitoring Board (DSMB) and IRB, follow-up visits with previously enrolled subjects were conducted by phone, and when possible, data were collected via Zoom® teleconferencing. As the pandemic's severity became clearer, study protocol modification from in-person to fully remote data collection was presented to the DSMB in June 2020. The revised protocol was approved by the DSMB in June and IRB in July for the New Jersey site and October for the Utah site. The third site in Florida was about to implement at the start of the pandemic, and as of May

2021, had not restarted due to a large proportion of staff still unable to be vaccinated and staff burnout due to the pandemic.

Case Study 2 - Apoyo con Cariño (Support with Caring): Improving Palliative Care Outcomes for Latinos with Advanced Medical Illness

Overview

Apoyo is a National Institute of Nursing Research-funded RCT of a culturally tailored, lay patient navigator intervention versus enhanced usual care (NCT03181750) aimed at improving palliative care outcomes for Latinos with serious non-cancer illness.[6] Conducted across Colorado in urban, rural, mountain, and frontier communities, all enrolled patients, recruited from five academic-affiliated sites and five community sites, receive culturally tailored, linguistically appropriate materials discussing advance care planning (ACP), pain/symptoms, and hospice care written at a 5th grade reading level. Intervention patients receive five home visits from bicultural, bilingual lay community navigators who address palliative care barriers. Visits follow a prescribed visit manual and aim to improve quality of life, ACP, pain/symptom experience, and hospice utilization. The enrollment target is 240 patients with up to 210 family caregivers.

Inclusion and Exclusion Criteria

Eligible participants are: 1) ≥18 years, 2) self-identified Latinx; 2) English and/or Spanish speaking; 3) capable of providing informed consent; 4) diagnosed with advanced medical illness having limited life expectancy as identified by either a) meeting one of the non-cancer CARING[7] (Cancer, Admissions ≥ 2, Residence in a nursing home, Intensive care unit admission with multi-organ failure, ≥ 2 Non-cancer hospice Guidelines) criteria, a prognostic index to identify patients who may benefit from a palliative approach; or b) patient's primary or specialty care provider answers "no" to the following question: "Would you be surprised if this patient died within the next year?"[8,9] Patients may invite a patient-defined family caregiver (≥18 years and have decisional capacity to provide informed consent), although their presence and participation are not required for enrollment. Participants are excluded if they: 1) lack decisional capacity; or 2) are already enrolled in hospice care.

Recruitment Practice Prior to Pandemic

The research team identified a healthcare provider (e.g., nurse, physician, clinical trials coordinator, medical assistant) as the onsite coordinator. Patients were invited to participate by their primary or specialty provider either in person at an appointment or via letter generated by the research team who screened Latinx patients for serious illness eligibility criteria through EHRs, then messaged or emailed the provider to confirm participants' eligibility and to electronically sign a letter inviting patient participation. Ten days post letter mailing to the patient's home, the navigator telephoned the patient to schedule an in-person consenting visit and baseline data collection in the home or place of their choosing. Navigators contacted patients within the week to inform them of intervention or control arm assignment.

Study Pausing Period Due to COVID-19

On March 16, 2020 the academic center's campus closed and halted all research activities. Two days prior, the study team had paused all in-person interactions with patients due to the vulnerable nature of their underlying serious illnesses and the lack of PPE for home use. The four-year (48 months) study was in its 41st month with 195 participants enrolled, 178 had completed participation, 17 were in active study period, and 10 were active in the intervention. Enrollment was in the final quarter and due to funding constraints, further extension for subject enrollments was impossible.

Protocol Modifications

Case Study 1. In transitioning to an all-remote data collection process, several changes were made to both protocol and standard operation procedures. First, because of social distance restrictions in senior housing, and concerns among caregivers of reducing risk even in those not in senior housing, some family caregivers had shifted much of the direct care they were providing to management of care. Because of this, caregiver inclusion criteria which initially required 8+ hours of "in-person" care were changed to "managing care". Second, the number of surveys administered was decreased because we found that Zoom or telephone interviews took longer than in-person surveying, causing greater burden. PLWD, suffering from moderate to severe impairment (QDRS[2] score of >12), were no longer questioned on pain, quality of life, and confusion. Caregivers or direct observation became the sole source of this information. Additionally, we learned there were frequent webcam problems during visits with already enrolled subjects at the beginning of the pandemic. Therefore, the 3D-CAM,[4] a delirium assessment that required observing the PLWD, was replaced by the FAM-CAM,[5] another instrument by the same researchers that uses a family informant. Third, informed consent was moved to an electronic format utilizing REDCap.[3] Fourth, internet access was added as an additional inclusion criterion due to consenting and data collection process changes. Finally, an additional algorithm-based dementia identification report was added at the New Jersey-based site in an attempt to increase subject referrals. Research coordinators were trained through mock remote visits prior to restarting.

Case Study 2. The patient navigator team served as key informants in shifting to a remote enrollment process and intervention delivery. In response to navigators' concerns about barriers to technology, screening questions (SDC1) were developed for potentially eligible participants. The team also queried researchers with experience in remote enrollment for additional ideas related to training for consenting and delivering a palliative-focused intervention remotely. The Colorado Multiple IRB approved the revised protocol April 23, 2020. The research team conducted remote role-playing with the navigators until the investigators determined navigators' comfort and ease in following virtual scripts.

The research team continued to use pre-COVID-19 screening and patient identification methodologies. Potentially eligible patients were still contacted by their primary or specialty care provider via letter or at virtual visits. Unless patients opted out, one of the navigators attempted to contact the patient, conducted technology screening, and invited them to participate. Consenting visits and collection of baseline measures were completed remotely via the participant's preferred mode of communication. For participants randomized to the intervention arm, visits were conducted over the participant's preferred mode of communication. Follow-up data collection measures continued by telephone, unchanged from pre-pandemic study procedures.

Analysis

Simple descriptive statistical tests including frequencies, means, and medians were used to analyze the enrollment data in both trials.

Results

Changes made to both study protocols regarding participant eligibility, enrollment, technology access, and data collection are summarized in Table 1. Results of these changes and impact on each study are described.

Eligibility

Case Study 1. One of the key issues that arose was that the additional algorithm-based referral approach to recruit more individuals served as a barrier as it was not specific enough. This led to higher ineligibility rates due to a lack of dementia, sapping staff resource time (Table 2). Additionally, we found it harder to make contact with caregivers to perform screenings (Table 3), which we hypothesize relates to increased but unmeasurable caregiver burden during the pandemic.

Case Study 2. The first challenge during this time was a decrease in potentially eligible patients based on screening procedures. This phenomenon was well documented during the first surge; the number of persons admitted for acute and chronic health conditions such as heart failure and chronic obstructive pulmonary disease decreased while the number of admissions related to COVID soared.[10] This led to a smaller eligible patient pool to approach for study participation.

Enrollment

Case Study 1. Overall, between July and December 2020, 928 automated referrals were generated, of whom 221 dyads were contactable by telephone and agreed to be screened, 62 were found eligible, and 30 consented to participate in the study.

Case Study 2. Overall, 14 participants consented during the remote enrollment and intervention delivery phase of the study from May 1 through July 31, 2020. At three-month follow-up survey completion, outcomes assessors unblind themselves to collect direct feedback on patient navigator visits. Seven patients were randomized to the intervention group with follow-up data collected.

Technology Access

Case Study 1. Prior to receiving the Zoom link, subjects were screened for internet access; usage of videoconferencing software on their device(s) was confirmed. Some subjects failed enrollment due to poor internet connectivity or computer issues (Fig. 1 and Table 3), e.g., signal was not strong enough to view documents online and/or receive control of the mouse to sign consent digitally. In other cases, subjects connected to Zoom using smartphones but were not enrolled as electronic signatures could not be completed due to platform limitations. Overall, eligibility, and in particular lack of internet (n=32, 26.8% of failed enrollments among eligible subjects), became a significant enrollment barrier to otherwise willing individuals. Among this group, 21 adult children, eight spousal caregivers, one sibling caregiver, and two PLWD who did not live with their caregiver did not have access. Another issue affecting enrollment was subject's familiarity with or access to technology. Some older adult caregivers did not have a computer and/or were not comfortable with downloading the Zoom app. If one part of the dyad was without access to internet and computer screen, the dyad would fail enrollment.

Case Study 2. Access and comfort level with technology proved to be a significant barrier to virtual study conduct. All eligible persons were screened using the technology screening survey (SDC1) and the majority reported having either limited internet access or Zoom capabilities (Table 3). All screened patients (100%, N = 19) recruited during COVID-19 were not comfortable with videoconferencing through Zoom expressing a preference for phone visits.

Table 1
Summary of Study Activities and Adaptations During COVID-19

Case Study 1 — DSM-H Study Activity	Adaptations due to COVID-19	Rationale
Recruitment	No changes	Recruitment and Screening were already performed remotely
Eligibility Screening	No changes	
Enrollment with informed consent	Now performed remotely using REDCap for eSignature of consents	Had previously been performed in-home on initial study visit. Allows for documentation of consent without mailing of forms in this time-bound enrollment period (three days from admission) Team was trained in how to perform electronically. However, eSignature could not be performed on phones causing missed enrollments as some potential subjects only had a smartphone and not a computer.
Study intervention	No changes	Intervention is pragmatic, performed by practicing home health team members, not an interventionist.
Data Collection	All study data was transitioned to collection by zoom. Number of instruments was modestly paired and the delirium instrument (3D-CAM[4]) had to be changed (FAM-CAM[5]).	All visits transitioned to remote due to the pandemic. Zoom visits take longer than in-person, and thus we paired down instruments to what was absolutely necessary to reduce study burden. Delirium instrument changed as 3D-CAM requires observation that was challenging to perform over Zoom vs FAM-CAM which is answered by the caregiver.
Research Staff Training	New training via Zoom on the following: Remote consenting Collection of data via Zoom Changed data collection flow and instrument.	Research staff needed to become aware of the differences of performing remote data collection and new processes/instrument. Simulations were performed and signed off on by the project director to ensure rigor in data collection.
Case Study 2 - Apoyo		
Study activity	Adaptations due to COVID-19	Rationale
Recruitment	No in-person recruitment site visits, depended solely on recruitment letter process	No change to referral process Relied on communication with PCPs via EHR
Eligibility screening	Added remote screening questions	Necessary to screen for participant access to internet and/or phone
Enrollment with informed consent	Enrollment visits were completed remotely by phone Consent forms mailed to eligible participants prior to consent visit, then mailed back to the study team after signatures provided (team provided return envelope) Consent forms was checked once mailed to study team and returned if a signature was missed Mailed all study materials Mailed baseline gift cards	Prepared and trained our team for electronic consent; however, 100% of our participants during COVID-19 preferred to communicate by phone (whether or not they had access to the Internet). Mailing consent forms, study materials, and gift cards were the best options.
Study Intervention	Visits were completed remotely by phone (no longer in patient's home)	Population was very high risk and meeting in-person was not safe
Patient Navigator Training	New training via Zoom[a] on the following: Remote consenting Mailing process for consenting Providing remote intervention	Patient navigators were trained to improve comfort with research process

[a]Zoom was offered but not used for any of the participants.

Data Collection

Case Study 1. For those who were contacted, research coordinators were trained to administer assessments by telephone and Zoom teleconference. To reconceptualize for Zoom administration, survey questions were shared with subjects as PowerPoint slides (PDF) prior to the visit to enable greater ease of administration. To complete informed consent electronically, research coordinators invited caregivers to attend a Zoom meeting. Prior to receiving the Zoom link, subjects were screened for internet access; usage of videoconferencing software on their device(s) was confirmed. When collecting data virtually, caregivers were heavily relied upon to provide reassurance, focus, and clarity to PLWD as research coordinators conducted assessments. If the PLWD did not have

Table 2
Eligibility Exclusions - Case Study 1 - DSM-H

	Pre COVID-19 Aug 2018 – Mar 2020	During COVID-19 July 2020 – Dec 2020
Total referrals	559	928[a]
Total screenings	187 (33.5% of referrals)	221 (23.8% of referrals)
Total failed screenings	78 (41.7% of screenings)	181 (81.9% of screenings)
Inclusion criteria failures	36 (46.2% of failures)	119 (65.7% of failures)
Negative for dementia	8 (22.2%)	60 (50.4%)
English/Spanish	7 (19.4%)	18 (15.1%)
Aged 65+	3 (8.3%)	1 (0.8%)
Internet/Technical Difficulties	0	32 (26.9%)
CG spends <8hrs	16 (44.4%)	5 (4.2%)
CG is a Home Health Aide	2 (5.6%)	3 (2.5%)
Exclusion Criteria Failures	3 (3.8% of failures)	3 (1.7% of failures)
Serious Mental Illness other than ADRD, anxiety, depression	2 (66.7%)	2 (66.7%)
Reside in assisted living, board, or care home	1 (33.3%)	1 (33.3%)
Other Screening Failures	39 (50.0% of failures)	59 (32.6% of failures)
Rehospitalization	12 (30.8%)	15 (25.4%)
Start of care data too old to complete initial study visit	19 (48.7%)	0
Repeat referrals / enrolled previously	8 (20.5%)	40 (67.8%)
Unavailable (other)	0	3
Unavailable (Death)	0	1

[a]substantially greater volume due to addition of second algorithm for referring subjects.

assistance from the primary or a secondary caregiver, we could not facilitate data collection. Additionally, primary caregivers often experienced challenges when trying to download Zoom software, run the application, and/or found they had insufficient internet or non-compatible device(s). In several cases, connectivity issues impacted study sessions by extending call duration, affecting assessment data completeness.

Case Study 2. Patient navigators, pre and during the pandemic, administered survey assessments by telephone. The structured interview, previously performed in patient's homes, used paper and pen to administer surveys where the questions were both visible to the subjects and read aloud. To reconceptualize for telephone administration, informed consent documents were mailed to participants prior to the consenting visit enabling them to read along with the navigators and sign consent documents. Consent forms must be completed correctly and mailed back to the navigator prior to administering baseline surveys. If signatures were missing, the IRB required that the form was returned to patients for revision prior to any data collection.

Pandemic Silver Linings

Case Study 1. The flexibility provided by Zoom visits allowed the dyad to be in different locations at the same time, which led to fewer scheduling conflicts causing failed enrollment (7.7% vs. 2.4%). Remote visits enabled more interviews in a day due to lack of travel time, and increased hours to perform enrollments facilitating access for caregivers working during daytime hours.

Case Study 2. Patients reported high levels of satisfaction with remote navigator visits (100% rated visits very satisfying) and perceived them to be very helpful (86%). Overall, remote processes proved to be more time efficient without time required for travel. This was especially important if a patient missed a visit, as the navigator could shift to other study tasks.

Discussion and Lessons Learned

This manuscript provides information around technology use in elderly, their caregivers, and underserved populations. There are opportunities across all home-based and outpatient care to move to telephonic or virtual care – not only in research but from a clinical perspective.

Case Study 1. The most important lessons learned in the remote study processes include: 1) caregivers who did not live with the PLWD were now providing more care remotely due to COVID-19 social distancing; 2) PLWD with significant cognitive and/or sensory deficits were at higher risk of experiencing subject fatigue during televisual study visits leading to a streamlining of data collection; 3) lack of access to internet or internet-enabled devices led to increased screening failures; 4) lack of familiarity with technology increased the amount of time it took for research team members and caregivers to connect remotely for data collection; 5) remote data collection required a reconsideration of what assessment instruments were required and/or feasible; 6) remote processes could increase efficiency and access for working family caregivers.

Case Study 2. This study garnered similar and unique lessons from remote recruitment and enrollment processes: 1) both providers and patients were less likely to respond to outreach efforts compared with the time prior to the pandemic; 2) internet access was limited in the population, the majority of whom are socioeconomically underserved; 3) even for those with internet access, comfort and familiarity with technology was limited; 4) a simple technology screening tool helped the study team accommodate participants' preferences on how to interact with patient

Table 3
Participant Enrollment

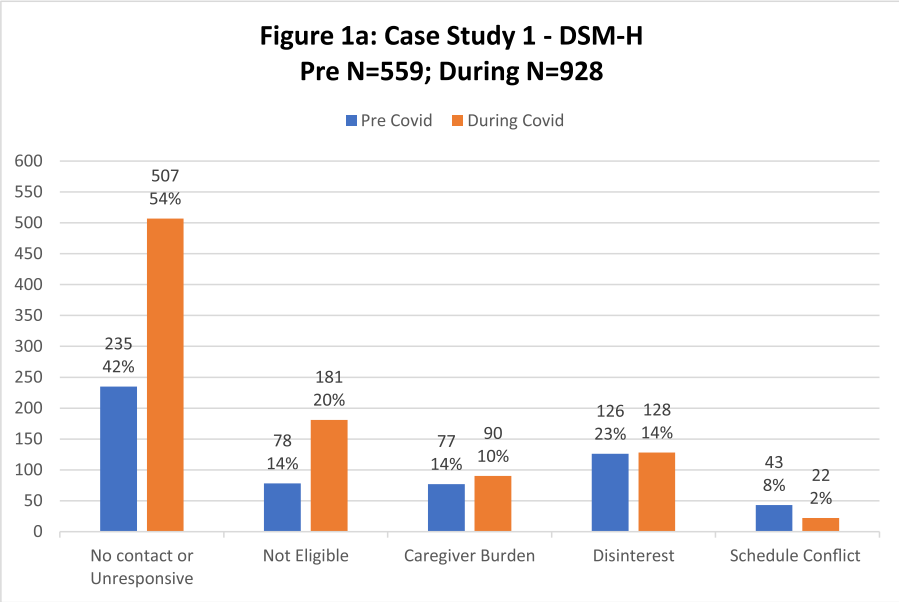
	Case Study 1 - DSM-H		Case Study 2 - Apoyo	
	Pre-COVID-19[a] *n* (%)	During COVID-19[b] *n* (%)	Pre-COVID-19[c] *n* (%)	During COVID-19[d] *n* (%)
Male gender	52/126 (41.3%)	10/30 (33.3%)	100/195 (51.3%)	8/14 (57.1%)
Spanish speaking	12/126 (9.5%)	4/30 (13.3%)	73/195 (37.4%)	4/14 (28.6%)
Less than high school education	18/126 (14.3%)	6/30 (20.0%)	109/195 (55.9%)	5/14 (35.7%)
Underrepresented racial/ethnic group	58/126 (46.0%)	13/30 (43.3%)		
Annual Income < $15,000			151/195 (77.4%)	11/14 (78.6%)
Number of patients potentially eligible	559	928	51	37
Eligible n (%) for approach	559	928	37 (73%)	29 (78%)
Unable to contact	235 (42%)	507 (54%)	2 (5%)	8 (28%)
Refused	203 (14%)	208 (20%)	11 (30%)	5 (17%)
Not Eligible	78 (14%)	181 (20%)	5 (14%)	3 (10%)
Deceased	0	1 (0.1%)	1 (2%)	0 (0%)
Enrolled	126 (23%)	30 (3%)	18 (49%)	13 (45%)
Technology screening		221		N = 19
Internet Access		164 (74.2%)		12 (63.2%)
Smartphone		n/a		14 (73.7%)
Familiar with Zoom		n/a		1 (5.3%)
Prior Use of Zoom		n/a		0 (0%)
Comfortable meeting over Zoom		n/a		0 (0%)
Landline or cellular plan with unlimited Minutes		n/a		18 (94.7%)
Preferred platform for visits		n/a		N = 19
Phone		n/a		19 (100%)
Zoom		n/a		0 (0%)
FaceTime		n/a		0 (0%)

n/a: not applicable.
[a]Pre COVID-19: November 15, 2019 to March 15, 2020.
[b]During COVID-19: March 15, 2020 to July 15, 2020.
[c]Pre COVID-19.
[d]During COVID-19.

navigators; 5) satisfaction with the intervention remained high despite visits by phone rather than in person.

This manuscript describes two methodologically different clinical trials, in separate areas of the country, recruiting and enrolling distinct yet similarly underserved populations. Both trials adapted to pandemic conditions by shifting in-person research activities to remote environments. Not surprisingly, both trials experienced a decrease in recruitment due to lower eligibility rates, whether due to inability to identify and contact potential participants or an increase in screening failures (Fig. 1). Technology challenges proved to be important barriers across both trials. Even those with smartphone access but no computer had difficulty accessing systems such as REDCap as small screens were not optimized for consents. While data support the pervasiveness of household smartphones[11] and computers, this is not evenly distributed across populations. Older adults and households with lower median income are far less likely to own these devices compared to younger populations or those in higher socioeconomic brackets. We found that access was an important barrier although lack of comfort and proficiency with the technology proved to be significant barriers as well. This led to a preference for telephone over video technology in some circumstances. In other cases, using video technology demanded considerable additional time to conduct research tasks or visits, leading to increased burden and fatigue for participants and staff. These issues may raise substantial issues of equity and ability to recruit and enroll underrepresented groups into studies, particularly those of low socioeconomic status or living in rural areas. Given the already significant inequities in recruitment of underrepresented groups in palliative studies and generally worse outcomes, this issue merits particularly careful consideration.[12] On the positive side however, the Federal Communications Commission has just approved a substantial new broadband subsidy program, which includes a device purchase subsidy that may address some access issues.[13]

Our findings highlight the need for clinical trials utilizing technology-based interventions to ensure they have adequate resources (time, training, or technology itself) to support all participants. Additional resources may help avoid increasing inequities through barriers to participation in research using innovative technology-based interventions. Another approach that could increase representation given technology barriers is to apply for waiver of written authorization and documentation of consent so that telephone consent can be obtained. Especially for remote or telephonic studies that are minimal risk this may be a feasible option to



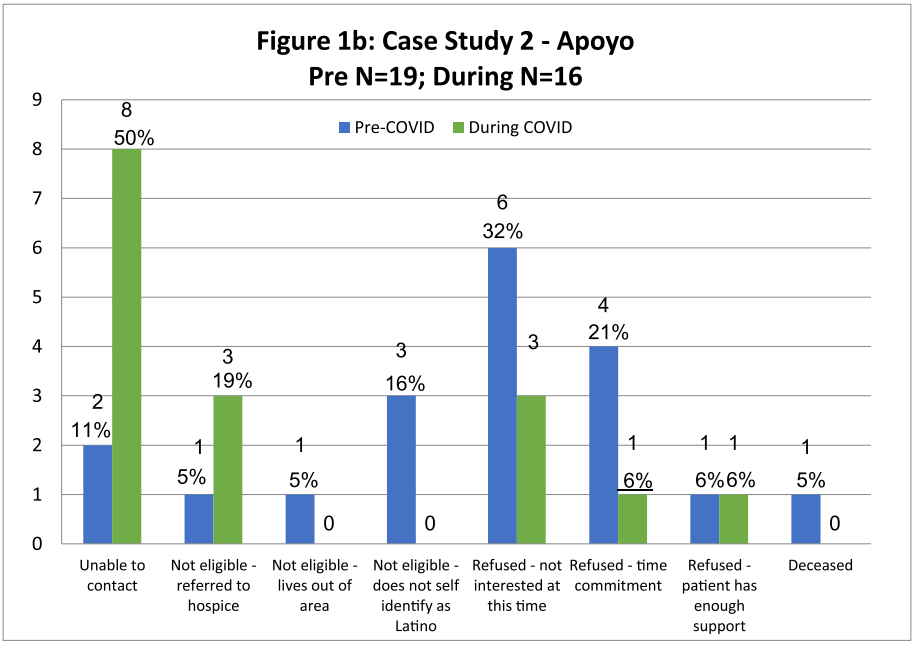


Fig. 1. Participants' reasons for not enrolling in the trials. (b): Case Study 2 - Apoyo Pre N=19; During N=16. For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.

increase access to participation without affecting the rights and welfare of participants. Funders, including NIH, may want to consider supplemental funding for clinical trials that include a substantial proportion of persons who are less likely to have access or proficiency with technology.

Both studies focus on underserved and underrepresented populations and were designed for an in-person intervention delivered in a home-based setting. Other projects, e.g., ENABLE trials,[14,15] have effectively utilized telephone-based interventions. Our findings raise concerns that the necessary shift to remote study recruitment and intervention delivery may have impacted both study teams' ability to reach the most vulnerable patients. The impact of study adaptations on respective trial outcomes will need to be addressed in the analyses.

Limitations

We detail the experiences of only two clinical trials and cannot generalize the impact COVID-19 pandemic had on research, in general. The intent was to provide an in-depth description of adaptation to the pandemic

from two geographically, methodologically diverse studies that include vulnerable or underserved populations, exploring differing and similar lessons and themes from the research experience.

Conclusion

With several highly effective vaccines now available, it is possible to consider a landscape beyond the COVID-19 pandemic. Converting future community-based, in particular home-based, palliative trials to remote recruitment, enrollment, and data collection processes may increase efficiency and reduce costs. Yet, depending on the population and technologies used, using remote technologies may increase inequities in palliative research participation. Researchers should very intentionally consider, both the necessity and accessibility of various technologies and how research staff are trained to ensure the greatest possible opportunity to recruit groups who have traditionally been underrepresented from research studies.

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Supplementary materials

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