Experiences of clinical trials in homes and local settings outside of clinics - a research project using interviews

Acknowledgement & Disclaimer

This article is not an original, it has been translated by the Trials@Home Layman Translation Team for purpose of a better understanding by a general audience. The team consists of a diverse group of Trials@Home consortium members and the members of the Trials@Home Patient Expert Panel.

*Original paper - **Learning from remote decentralised clinical trial experiences: A qualitative analysis of interviews with trial personnel, patient representatives and other stakeholders.***

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What is this article about?

This article is about clinical trials, which are studies for new medical treatments, drugs, or procedures to see if they work and are safe. Usually, these tests involve people going to hospitals or other healthcare centres to meet face-to-face. This way of doing things is usually expensive, slow, inconvenient, and inefficient. Sometimes, the people running these trials can't find enough people to join, which leads to delays or even having to stop the trial early. It's also tough for volunteers because they must travel to visit these places.

People who work full-time, have disabilities, take care of others, or live in rural areas might not be able to participate in these trials. So, the results might not be as meaningful because they don't include certain groups or types of people.

Now, there's a newer way to do these trials using digital technology and other approaches so that people can do most of the trial activities at home or in their local area. They don't have to go to a clinic or hospital as often. This way of doing clinical trials is called "decentralised clinical trials" or DCTs.

This change should make it easier for more people to join trials and should give the researchers results that are meaningful for more people. During the COVID-19 pandemic, when we couldn't visit places as often as usual, this approach became even more important.

Recent technological advancements have opened new possibilities, such as virtual visits (via phone call, video call or mobile app) and online data collection. Despite challenges, there's a growing interest in developing decentralized trials.

The Trials@Home project aims to learn from various organizations about their experiences in applying them, with the goal of improving the design and the way we manage future trials. This article describes research done through the Trials@Home project to identify useful lessons to improve future DCTs.

What did the researchers do?

The researchers interviewed people who had previous experience with DCTs. In these meetings, the researchers asked questions, encouraging people to talk about their experiences with these trials. They used interviews because they are flexible and can cover a lot of different areas.

These interviews took place in 2020. Some were in person, but most were done through video calls or on the phone. Each interview lasted around an hour and was recorded and written down word by word. Two researchers later independently looked closely at what was said to find common themes and shared their findings with the rest of the team.

Who was interviewed?

The researchers interviewed 48 people who were involved in DCTs. The interviewees included staff who worked at trial sites, service providers, and patient representatives. These people were selected from 20 different case studies identified by the Trials@Home consortium that represent a wide range of DCT approaches.

What questions were asked?

When creating a tool to understand people's experiences, it's important to base it on what individuals themselves find meaningful. In this case, the team developed a set of interview questions that allowed for flexibility. They tested these questions in five interviews to see how well they worked. As the researchers conducted interviews, they adjusted and added new questions based on the issues participants brought up that the team hadn't initially anticipated. This process helped ensure the tool was thorough and captured the most relevant information.

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What were the results?

They identified several important things that affected how remote clinical trials were managed. The general themes from their responses included what helps or makes it difficult to find people to participate, how technology is used, and issues caused by COVID-19. When asked about recruitment, participants shared that it was easier to take part from home, especially for trials where the medicine was sent to them directly; this made the trial more convenient, as they didn't have to meet with a doctor to receive the treatment.

One interviewee who had participated in a DCT mentioned how taking blood pressure at home was easy and fit well into their routine: *"There was something very real world about it … Every quarter I would take my blood pressure measurements … at 8 o'clock in the morning and 8 pm - every day for three days. It was very good … I could do it at home."*

Trial staff felt that DCTs could encourage better diversity in patients. One interviewee said, *"It also allows for diversifying patients that participate … we've had patients share back with us they've never been asked to do a research study, and this was really exciting for them."*

The researchers also learned that patients are more likely to join a trial when they can relate it to their own lives. One interviewee said: *" … blindness is the number one fear of people with diabetes, and these are people that have been told they've got changes to their eyes and there's nothing we can do about it."*

They found that involving patients in planning and designing the study encouraged people to sign up and participate fully.

Some studies tried to include a diverse group of participants and found that using social media or other traditional channels for advertising didn't work well. Instead, they succeeded in using health data to find potential participants, even though it took more time.

How to keep participants engaged?

Some people talked about the difficulty of keeping participants engaged in their study activities. They found that it was easier for participants to stay involved when they were in familiar environments.

Having a quiet place to focus and having their own devices, like blood pressure monitors, made it more convenient for participants. Some participants liked feeling involved and responsible when they could take their own measurements and report them.

Participants welcomed regular feedback on how the study was progressing. Simple and user-friendly websites with clear directions made it easier for participants to stay engaged and complete online questionnaires. Involving participants in creating the content of the study materials helped make them more user-friendly.

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However, some participants had challenges with the technology. Participants sometimes missed completing questionnaires or measurements, or their devices didn't connect properly. Participants felt overwhelmed, did not fully understand the study requirements, and sometimes were burdened with too much digital technology.

In one example, a participant in an asthma trial had to use multiple devices and answer daily questionnaires, which felt like a big demand. Even though the total time for these tasks was short, participants still found it overwhelming. Some felt that the study team tried to test too many new technologies and devices at once, leading to confusion.

Misunderstandings also came up. For example, one screening question excluded three-quarters of participants because they didn't quite understand what the question was asking. This problem led to frustration for participants and study staff. Additionally, because of limited in-person interactions, there were fewer chances to explain and check participants' understanding of the study.

Were there any issues with technology?

Some people faced challenges with technologies that they felt weren't tried and tested enough for use in a clinical trial setting, leading to frequent errors and frustrations for doctors and participants and causing them to lose confidence in the trials.
Technology and digital tools that were not fit for purpose overwhelmed participants and even led to the cancellation of two trials.

One interviewee said: *"It would encounter an error at every juncture … little failures where either the data wouldn't transfer, a menu wasn't accessible … When you're dealing with the patient's and investigator's tolerance for having these types of errors … it was death by a thousand papercuts."*

People emphasized that clinical trials are already complex, and introducing remote technology made them even more complicated. They stressed the importance of keeping things simple and using well-established and tested technology or testing the new technology in small studies.

Some interviewees assumed that technology providers understood the clinical trial environment, but misunderstandings led to delays and setbacks.

To avoid such issues, the researchers recommend working with technology partners with experience in clinical trials and ensuring they are dedicated to making things work while the trial is running. It might be necessary to make changes to the apps and devices after hearing the feedback from trial participants and study sites using them.

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Was it easy being involved in a study?

Making it easier for participants in a study may unintentionally make things more challenging for the research staff. Nurses, for example, mentioned facing new and stressful challenges when they had to perform activities in unfamiliar locations closer to the participants. This included dealing with issues like finding rooms in healthcare facilities, accessing patient data and managing equipment.

Nurses also found receiving emails, messages or calls challenging in busy and unfamiliar environments. Some reported feeling disoriented when trying to keep track of information in such situations. The use of digital technology also became a burden for research staff, sometimes needing them to enter the same data twice in different apps and devices.

In addition, some nurses felt isolated, especially when dealing with technical problems or professional dilemmas. Remote communication methods didn't always provide the necessary professional support, especially when handling serious medical events during follow-ups. This made it harder for them to determine if certain situations should be reported.

Was it easy to use data?

Some studies that used data from routine healthcare records faced challenges because of delays in getting the data, and sometimes the information was incomplete. This led to some studies needing more funding and time to complete, even though they had agreements to share data.

Changes in European laws, like the General Data Protection Regulations (GDPR), created confusion and made it harder for researchers to access patient data. Some healthcare organizations were cautious about using data collected for regular patient care in clinical research.

To overcome these challenges, researchers suggested using multiple ways to collect information, for example, directly from participants or their healthcare practitioners. Having clear guidelines in the study plan for handling this kind of data was important.

However, with the arrival of COVID-19, there was a shift in culture, and more people understood that knowledge from clinical trials was crucial for treating patients during the pandemic.

Did COVID-19 have an impact?

The COVID-19 pandemic caused some challenges for research studies. Lockdown measures led to problems like staff shortages, the need for social distancing, and delays in getting approvals. Some studies faced difficulties because clinical staff were moved to work on COVID-related tasks, leading to delays in their regular research activities.

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Trials that involved both in-person and remote activities were especially affected by restrictions on face-to-face research. Some studies had to temporarily stop because they couldn't carry out important visits that required nurses. Even regular healthcare activities were impacted, as seen in a case where community health workers couldn't visit new mothers due to COVID-19 restrictions. This delay meant trials needed more time and money to reach their goals. Additionally, review boards were focusing more on research related to COVID-19, causing delays for studies that weren't directly related to the pandemic and impacting timelines, costs, and recruitment.

What have we learned?

Involving patients and patient organisations in planning the trial and making it less complicated for them is very important. It's also important to work closely with their families and caregivers and use technology that people are familiar with or can learn quickly. For those running the trial, it's essential to communicate clearly and understand the technology being used. The COVID-19 pandemic has also shown the need to plan for unexpected situations.

- **Participant-Focused Lessons:**

Get More Patients to Participate:
Actively involving participants in the research process is important, including asking them to help identify research questions and designing materials that make the trials more relatable.

Make It Easier:
Participation should be as uncomplicated as possible by creating user-friendly websites, providing clear instructions, and giving regular feedback on the progress of the trial.

Keep It Simple:
Use familiar technologies and avoid complexity, especially for patients who may not be comfortable with digital tools.

- **Trial-Focused Lessons:**

Collaborate from the Start:
Involve experts early, such as decision-makers and technology providers, to avoid later misunderstandings.

Use Different Ways of Collecting Information:
This can help overcome challenges such as missing information and unexpected issues. Support Research Staff: While these trials aim to make participation easier for those involved, considering the impact on research staff is equally important. The logistical and

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psychological challenges staff face, such as technological problems and not being around colleagues, must be addressed and supported.

Think About Backup Plans:
The COVID-19 pandemic highlighted the importance of backup plans for unexpected events, such as staffing changes, delays in healthcare activities, and clinical trial approvals.

There are also considerations for special groups, like older populations, who may not be as comfortable using digital technology. Strategies such as providing devices with a mobile internet connection, larger keypads, and simpler interfaces can make participation easier. In short, the most important lessons learned from this project were to try to make trials more participant-friendly, include everyone who needs to be involved as early as possible and be prepared for unexpected challenges.

What didn't go as planned?

The researchers interviewed more people directly involved in running trials and fewer providers and patient representatives than planned. This could affect how well the findings can be applied to different situations. The authors are confident that the findings in this article are relevant because they spoke to people involved in various activities and processes of the day-to-day running or overseeing of a DCT or those who worked with the trial data.

In Summary

Using digital technology or nurses who visit people at home for trials without face-to-face interactions is still relatively new. There still are challenges in using new technology to engage participants and collect patient data. However, by focusing on participant and staff needs and simplifying the process, trials with less face-to-face interaction can be more successful in finding and keeping participants engaged and ensuring they stay in the study.

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