Decentralized Clinical Trials and Time Burden: Important Considerations for Potential Clinical Trial Participants

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Objective

High participant burden in clinical trials has been a long-standing issue among standard site based clinical trials. This burden weighs heavily on the decision of potential study participants to enroll in and complete clinical trials. This study sought to elucidate preferences of potential clinical trial participants in for partaking in clinical trials.

Introduction

Low recruitment rate and retention of participants in clinical trials can impact the trials' statistical power to detect possible treatment effect or external validity if the samples are not representative of the treatment population. Participant burden has consistently been cited as a barrier to clinical trial enrollment in a wide range of indications, including oncology, cardiac diseases, diabetes, lung disease, psychiatric, and neurologic disorders[1]. Potential participants often report time and financial burden as significant factors that deter their participation, such as time commitment and absence from work due to frequent site visits and travel to sites, time to arrange and cost associated with transportation and childcare, and cost of meals and lodging[2, 3].

Decentralized trials (DCTs) or elements of DCTs such as collecting trial data remotely through mobile apps and wearables and conducting some or all study visits via telehealth visits may reduce some of the time and financial burdens faced by participants. This study examined factors that were important to participants in considering and factors that affect their likelihood of participating in clinical trials.

Methods

Participants were recruited from an online patient recruitment resource. A digital survey was issued for 90 days in the United States and a total of 217 participants completed the survey. Demographic information, including gender, age, and education level were collected. Respondents also reported on their usage of smartphone and prior experience participating in clinical trials. Respondents were asked two questions and given a series of statements in which they were asked to respond on a 5-point Likert scale.

1) "If you were considering participating in a clinical trial, how important would the following be to you?"
   - That the clinical trial is fully virtual, such as through an app on my smartphone and being shipped needed items to my home
   - Some clinical trial visits are virtual, from home, while some visits take place in a clinic/hospital
   - All clinical trial visits take place in a clinic or hospital
   - The distance I would have to travel for my trial visits
   - The number of visits and total time per month to participate in that trial
   - Have a nurse come to my house for some or all the required checks ins for that clinical trial
   - The clinical trial provided monetary compensation
   - I am reimbursed for time and travel expenses
2) "If you were considering participating in a clinical trial, how would each of these required activities affect your likelihood of participating in that clinical trial?"
   - Tavel 30 to 60 minutes distance for study visits
   - Having to attend multiple in person study visits with multiple examinations and tests
   - Have a nurse come to my home to conduct examinations or tests
   - Being able to collect trial data at home and provide health information remotely, via a website or a smartphone app
   - Trials doesn't take too much of my time
   - If my doctor recommends that I participate in that trial

Results

Demographics

- Age ranged from 18 years to 75+ years. The majority of the participants were age 55 years or older (Figure 1).
- 70.0% of the participants were female and 30.0% of the participants were male.
- The majority of participants (31.8%) reported that the highest level of education they attained was a (2 or 4 year) college or university degree (Figure 2). 1.4% of participants attained some high school, 12.9% a high school degree or GED, 7.4% a vocational school or certificate program, 27.2% some college, and 18.9% a graduate degree. 0.5% indicated "Other".
- 33.2% of participants reported that they had participated in the past or were currently participating in a clinical trial (Figure 3). 53.9% reported that they had never been invited to participate, 2.8% declined to participate, 8.8% were willing to participate but was not eligible, and 1.4% enrolled but withdrew before the end of the trial.
- The majority of participants (84.3%) indicated that they use their smartphones everyday, throughout the day (Figure 4). 10.6% a couple times a day, 3.7% a couple times a week, and 1.4% a couple times a month.

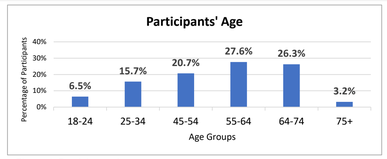

Figure 1. Participants' age

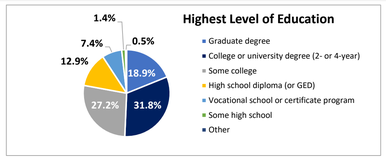

Figure 2. Highest level of education participants attained

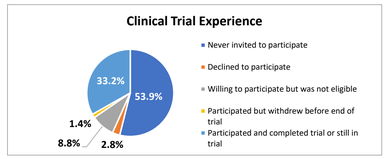

Figure 3. Participants' clinical trial experience

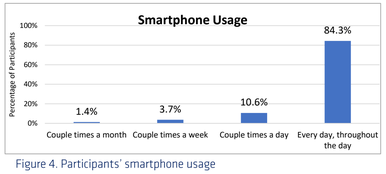

Figure 4. Participants' smartphone usage

Factors in participating in clinical trials

1) Important factors when considering participation in a clinical trial
   - The top factor participants reported was being reimbursed for their time and travel expenses, with 86.2% stating that it was "very important" or "important" (54.4% and 31.8% respectively; Figure 5).
   - 82.9% stated that the distance to travel for trial visits was "very important" (49.3%) or "important" (33.6%).
   - The third factor was monetary compensation with 80.2% endorsing "very important" (53.0%) or "important" (27.2%).
   - 70.1% indicated that the number of visits and the total time per month required to participate was "very important" or "important" (33.2% and 36.9%, respectively).
   - 57.6% thought that a fully virtual clinical trial utilizing an app on their smartphones and being shipped needed items to their homes was "very important" (23.5%) or "important" (34.1%).
   - 53.9% stated that having some virtual visits and some visits at the clinic or hospital was "very important" or "important" (14.3% and 39.6%, respectively).
   - Factors including having a nurse visit their home for some or all required check-ins and having all the visits take place in a clinic or hospital were the least important, with 31.3% and 25.3% reporting that they were "very important" or "important".
2) Factors affecting the likelihood of participating in clinical trials
   - The top factor participants (80.2%) reported was being able to collect trial data at home and provide health information remotely (Figure 6). 43.3% and 36.9% stated that it was "much more likely" or "more likely" for them to participate.
   - 65.0% stated that their doctor's recommendation would make it "much more likely" (30.0%) or "more likely" (35.0%) for them to participate.
   - 58.1% indicated that time commitment was a factor, with 22.6% reporting that they were "much more likely" and 35.5% were "more likely" to participate if the trial didn't take too much time.
   - 47.0% thought that having a nurse come to their homes to conduct examinations or tests would make it "much more likely" or "more likely" for them to participate (16.1% and 30.9%, respectively).
   - Factors including traveling 30 to 60 minutes for trial visits and having to attend multiple in person visits with exams and tests would not have increased the likelihood of participation, with 35.5% and 24.5% reporting "much more likely" or "more likely".

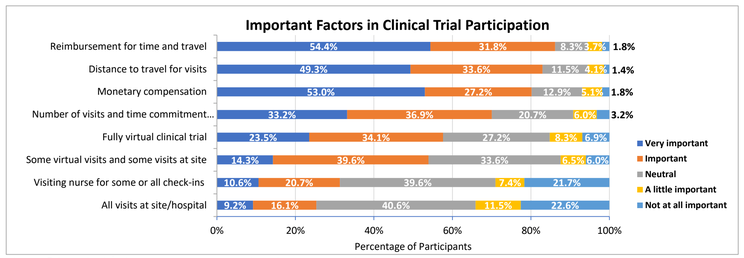

Figure 5. Important factors when considering participation in a clinical trial

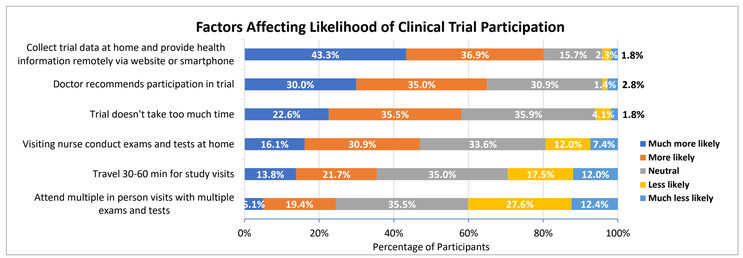

Figure 6. Factors affecting the likelihood of participating in a clinical trial

Conclusions

- This study found that the factors that were important to participants when considering enrolling in a clinical trial were being reimbursed for their time and travel expenses, the distance they would have to travel for trial visits, monetary compensation, the number of visits and time commitment per month, full DCT, and having some DCT elements in the trial.
- Our results also showed that participants were much more likely or more likely to participate in a clinical trial if the trial data and health information were collected at home remotely via website or smartphone app, if recommended by their doctors, if the trial didn't take too much time, and if a nurse came to their homes to conduct examinations or tests.
- Our findings, similar to other studies, indicated that time and financial burdens were significant barriers to participants enrollment. For instance, travel time and distance, cost associated with travel, and number of in person visits were major considerations for potential clinical trial participants. DCTs have strong potential to decrease time burden through reduction, or even elimination, of required in person site visits, thus reducing travel time, making clinical trials more attractive to prospective study participants. Participants in this study, as well as other studies, had expressed comfort with replacing traditional site visits with remote telehealth or at home visits, and the use of technology to collect trial data remotely[4].

References

1. Walsh, E., & Sheridan, A. (2016). Factors affecting patient participation in clinical trials in Ireland: A narrative review. Contemp Clin Trials Commun, 3, 23–31. https://doi.org/10.1016/j.conctc.2016.01.002
2. Kinder, B. W., Sherman, A. C., Young, L. R., Hagaman, J. T., Oprescu, N., Byrnes, S., & McCormack, F. X. (2010). Predictors for clinical trial participation in the rare lung disease lymphangioleiomyomatosis. Respir Med, 104(4), 578-583. https://doi.org/10.1016/j.rmed.2009.09.023
3. Nipp, R. D., Hong, K., & Paskett, E. D. (2019). Overcoming Barriers to Clinical Trial Enrollment. American Society of Clinical Oncology educational book. American Society of Clinical Oncology. Annual Meeting, 39, 105–114. https://doi.org/10.1200/EDBK_243729
4. de Las Heras, B., Daehnke, A., Saini, K. S., Harris, M., Morrison, K., Aguilo, A., Chico, I., Vidal, L., & Marcus, R. (2022). Role of decentralized clinical trials in cancer drug development: Results from a survey of oncologists and patients. Digital health, 8. https://doi.org/10.1177/20552076221099997

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