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Objective

High participant burden in clinical trials has been an issue among standard site based clinical trials, especially among older adults. Additionally, due to their age, older populations are seen as resistant to modern technologies and devices that make decentralized clinical trials (DCTs) possible and may help reduce patient burden. This study sought to elucidate an older population's preference toward participation in DCTs that utilize modern devices and technologies.

Introduction

Older adults are underrepresented in clinical trials¹ for a range of indications^{2,3} despite being a significant proportion of the treatment population. It is widely recognized that increasing older adults' participation in clinical trial is critical to determining the safety and efficacy of new treatment.

DCTs and technology may increase enrollment, reduce participant burden, and improve access to clinical trials as 98% of older adults, in one study, reported that barriers to participation included cost and transportation^{2,4}. In addition, the gap in use of social media and smartphone between those ages 18 to 29 and those 65 and older have decreased in the past 10 years⁵. However, there are still concerns that older adults are less accepting of technology and devices, particularly in clinical trials. This study examined older adults' attitudes towards the use of technology and DCT elements.

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 169 participants aged 45 years or older 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.

- Participants were asked about their preference in conducting study activities at their home vs. at the study site with the following question: If you were participating in a clinical trial, which of the following would you prefer to do? *Participants selected one of the two choices:*
 - Go to see a doctor for study visits in person as much as possible
 - Do everything that I can from home as much as possible
- Participants' preference on how to be instructed on the use of devices at home was assessed with the following question: Imagine you are asked to use a device to measure parameters such as blood pressure, heart rate, oxygen saturation or weight. How would you prefer to be instructed on how to use the device? *Participants selected one of the three choices:*
 - Review a "how to do" digital training video on my smartphone
 - Telehealth video call with a nurse
 - At a doctor's office and be trained at an in-person visit
- Participants were presented a hypothetical dermatology clinical trial and asked how they prefer to communicate their skin condition to a study staff member with the following question: If you were participating in a clinical trial for a skin condition, such as a rash, how would you prefer to show a clinician your rash? *Participants selected one of the three choices:*
 - By taking a photo with my smartphone and sending the photo to my doctor to review
 - Showing my doctor my rash during a telehealth visit
 - Going to my doctor's office for an in person clinical visit

Results

Demographics

- Age ranged from 45 years to 75+ years. The majority of the participants were in the 55 to 64 year group (Figure 1).
- 72.2% of the participants were female and 27.8% of the participants were male.
- The majority of participants (36.1%) reported that the highest level of education they attained was a (2 or 4 year) college or university degree (Figure 2). 0.6% of participants attained some high school, 13.0% a high school degree or GED, 5.9% a vocational school or certificate program, 23.1% some college, and 20.7% a graduate degree. 0.6% indicated Other.
- 38.5% of participants reported that they had participated in the past or are currently still participating in a clinical trial (Figure 3). 47.9% reported that they had never been invited to participate, 3.6% declined to participate, 8.9% were willing to participate but were not eligible, and 1.2% enrolled but withdrew before the end of the trial.
- The majority of participants (88.2%) indicated that they use their smartphones every day, throughout the day (Figure 4). 5.3% a couple times a day, 4.7% a couple times a week, and 1.8% a couple times a month.

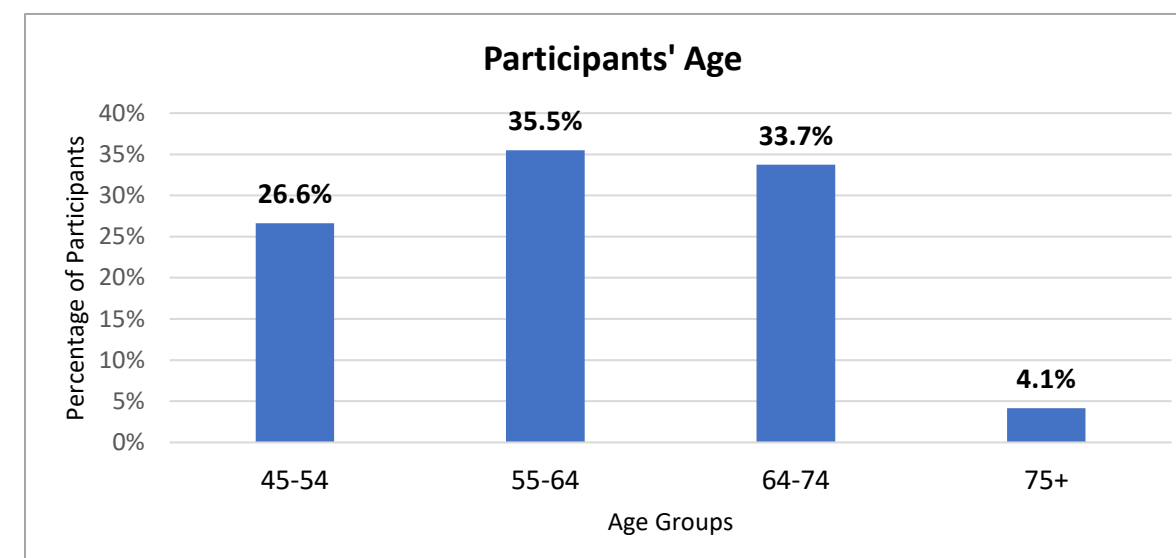


Figure 1. Participants' age

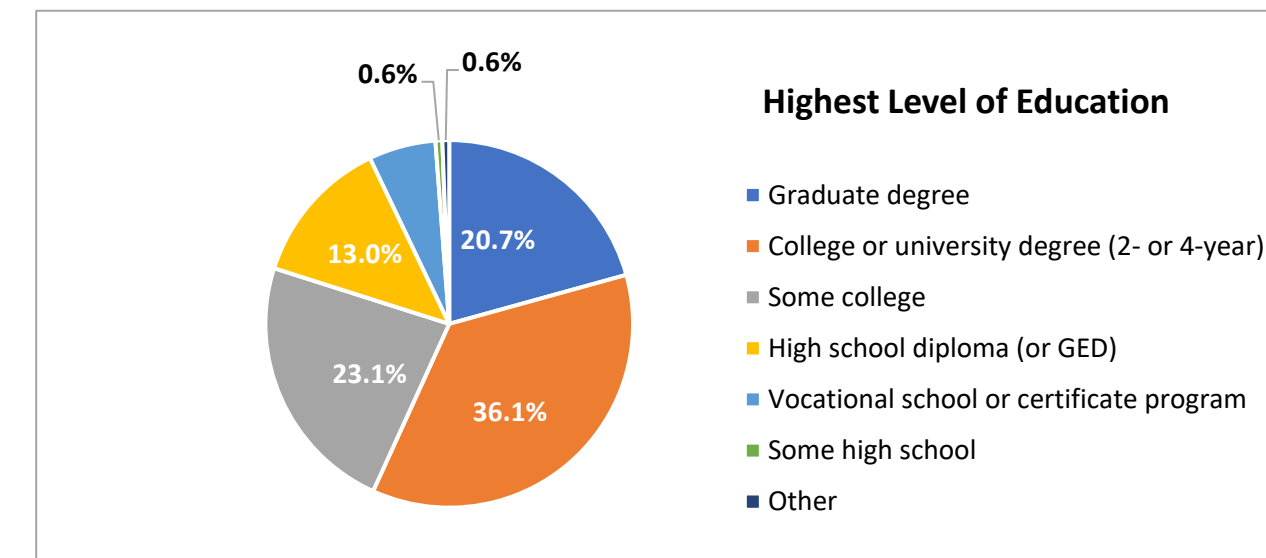


Figure 2. Highest level of education participants attained

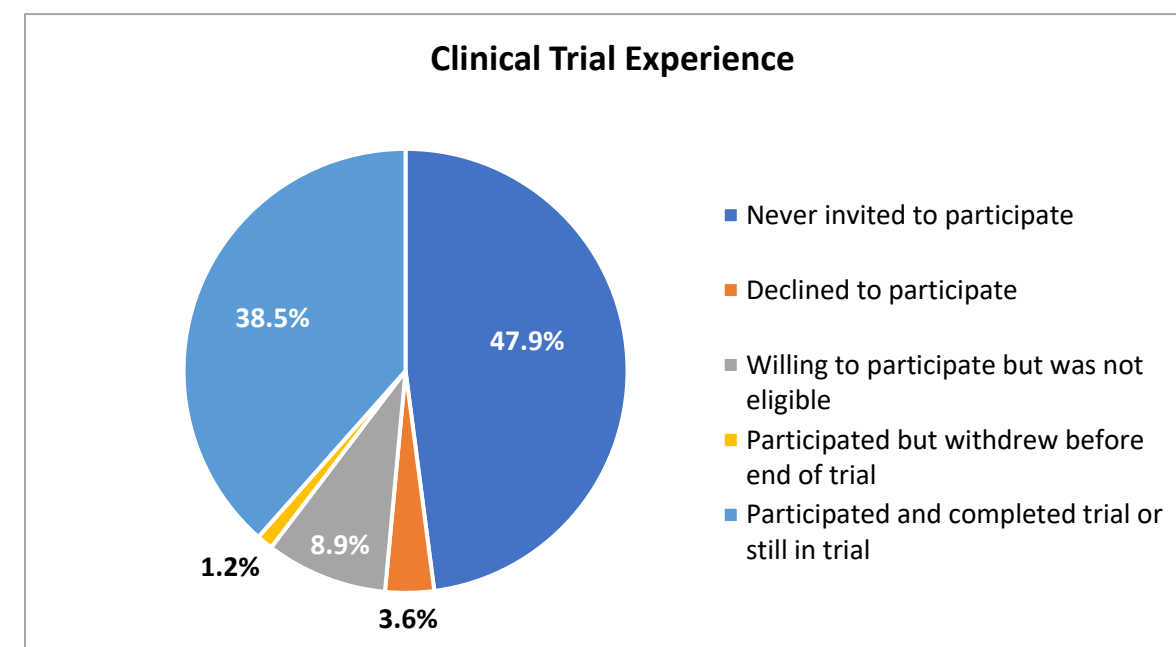


Figure 3. Participants' clinical trial experience

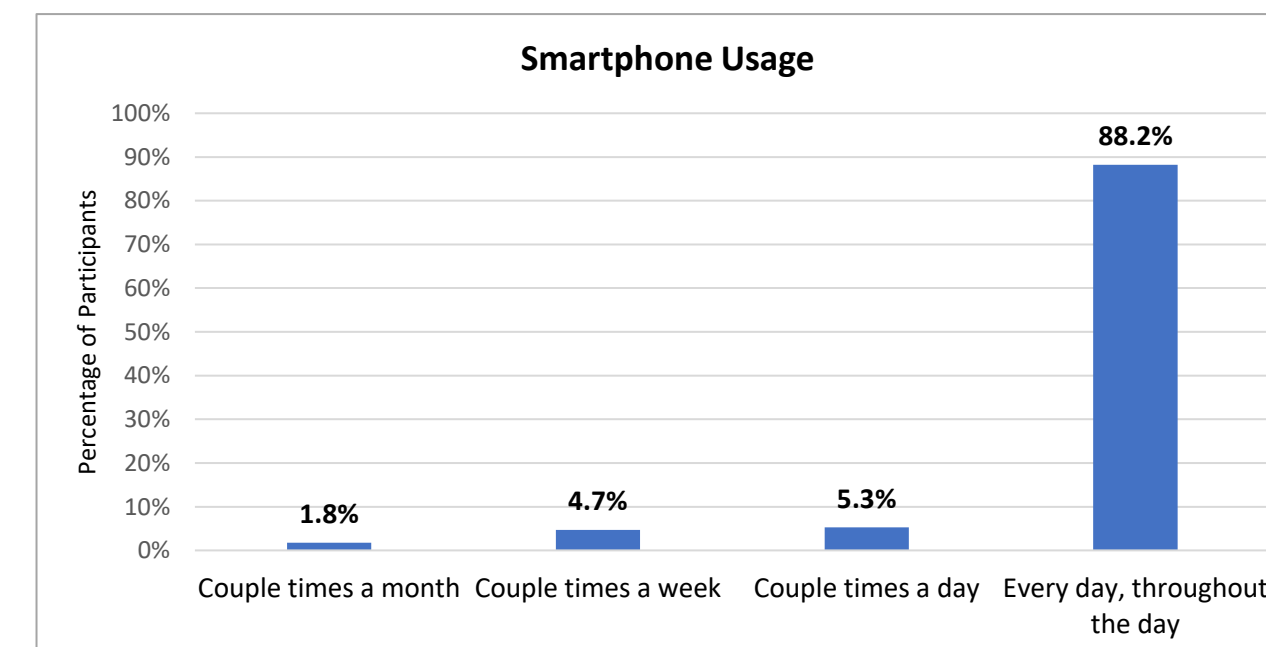


Figure 4. Participants' smartphone usage

Participants' preferences

1) Setting for completing study activities

84.6% of participants indicated that they preferred to do as much study activities from home as possible (Figure 5). Only 15.4% of participants preferred to go to the doctor for in-person study visits to complete study activities. Responses did not differ with age, $\chi^2=2.34$, $p=0.50$.

2) Instructions or training for device use

80.9% of participants reported they preferred to be trained with a digital training video on their smartphone (57.1%) or through a telehealth video call with a nurse (23.8%; Figure 6). 19.0% of participants wanted to be trained in person at the doctor's office. Preferences did not differ with age, $\chi^2=8.69$, $p=0.19$.

3) Communication with study staff

80.9% of participants stated they would prefer to show their skin condition by taking a photo and sending it to the doctor to review (45.6%) or during a telehealth visit with the doctor (24.3%; Figure 7). 30.2% wanted to go to the doctor's office for an in-person visit. Preferences did not differ with age, $\chi^2=10.06$, $p=0.12$.

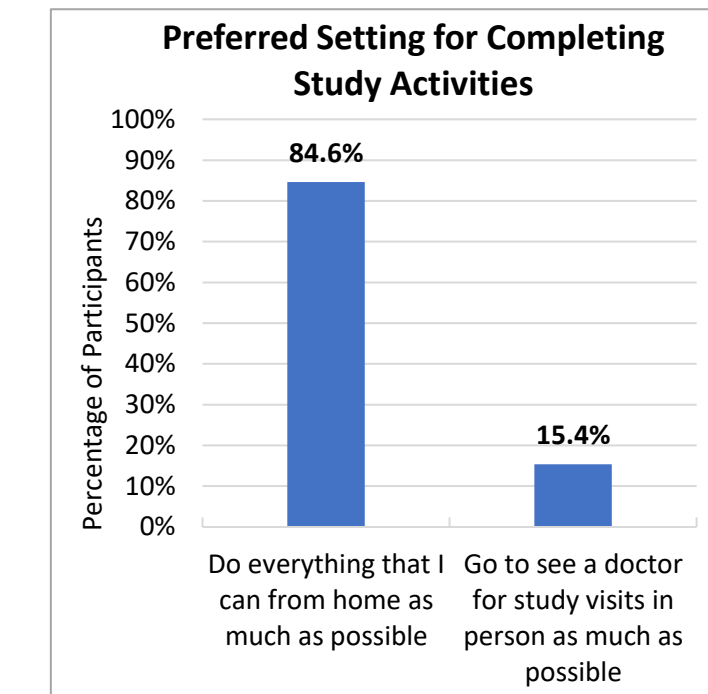


Figure 5. Preferred setting for completing study activities

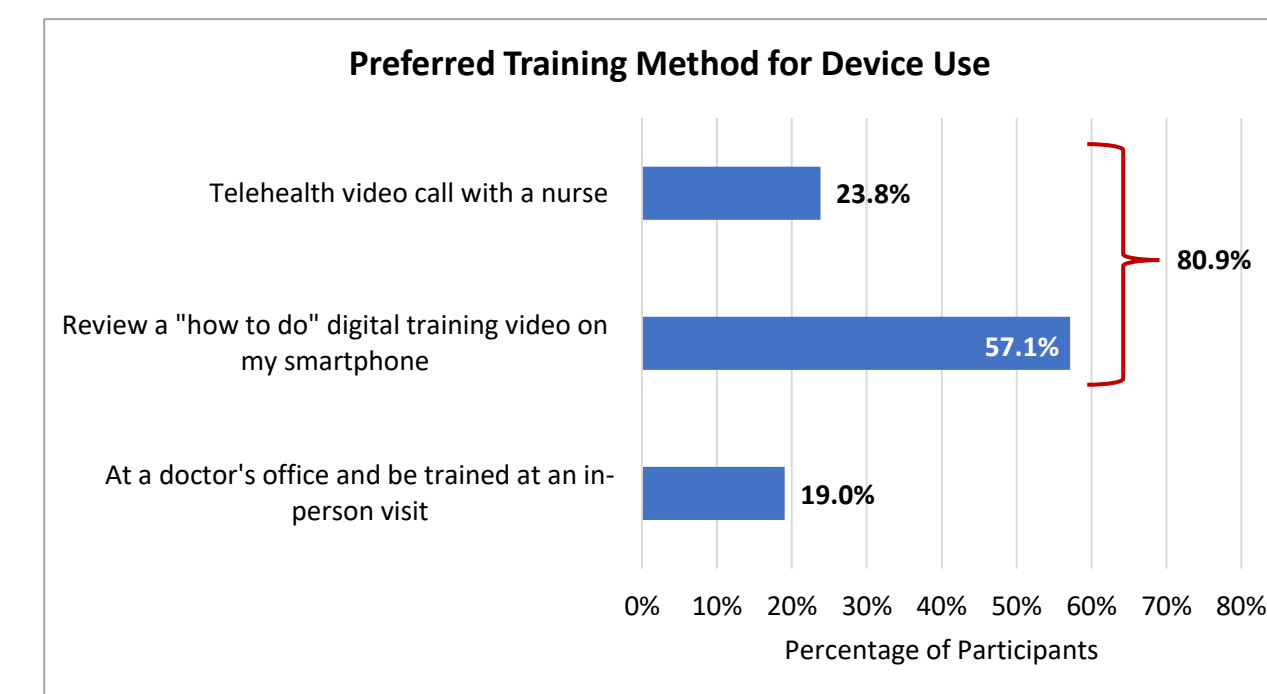


Figure 6. Preferred method for training on device use

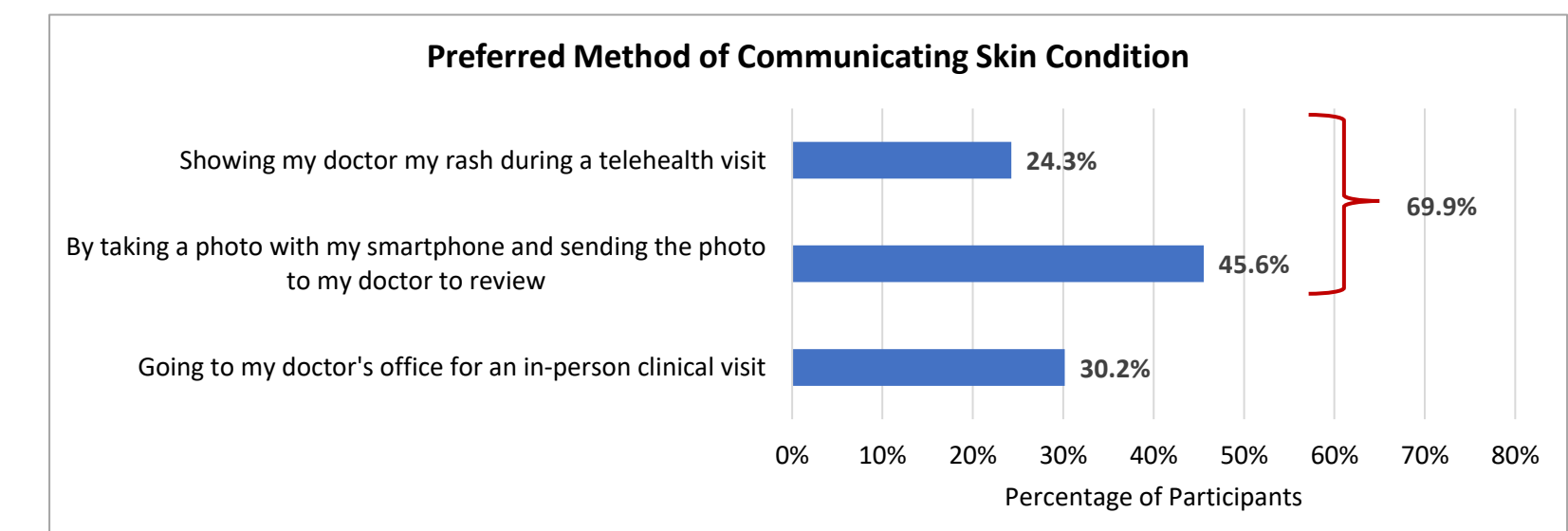


Figure 7. Preferred method of communicating skin condition to their doctors

Conclusions

- Results showed that the majority of participants preferred to complete as much study related activities from home as possible.
- Our findings also show that most participants preferred to be trained via digital training video on their smartphone or telehealth video call with a nurse.
- Participants preferred to take a photo of their skin condition and send it to the doctor in a hypothetical dermatology study.
- Overall, participants in this study, regardless of their age, demonstrated that they were comfortable with technology and elements of DCT. This indicates that among older adults in the United States, there is an interest and inclination toward participating in DCTs, being trained through digital methods or remotely, and completing study procedures from the home using devices over traditional clinical trial procedures. This is in line with studies that found patients were willing to adopt DCT elements such as home delivery of study drugs, electronic consent, use of health app, and wearables⁶. Though participants in this study may be more familiar with technology because of our online recruitment and survey modality, DCTs have a strong potential to reduce study participant burden, especially among older adults, through clinical visit reduction and reducing patient burden as use of technology continues to grow.

References

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