"Who Says Older Folks Aren't Tech-Savvy? Experience with a Fully Electronic Consent Procedure in a Trial with Older Adults"

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ABSTRACT

It is widely perceived that older adults have challenges using digital technology to participate in research. We used our experience in the BackInAction study (NIH-funded RCT of acupuncture for adults aged ≥65 with chronic back pain, #NCT04982315) to examine this belief. **Methods:** At two of the four clinical sites, patients were offered two options for consenting: mailed written paper consent or electronic consent using Adobe Sign (Kaiser Permanente Northern California (KPNC)) or REDCap (Sutter Health (SH)). Consent completion rates for each type and associations with age, sex, and race/ethnicity were examined**. Results:** Of the 509 patients completing consent, 295 (58.0%) were KPNC members and 214 (42.0%) were SH patients; 53% of patients were 65-74 years old, 41% were 75-84 years old, and 6.5% were at least 85 years old. Overall, 423 respondents (83.1%, 95%CI: 79.6% to 86.3%) successfully completed an electronic consent. The use of electronic consent at KP was similar to that of SH (85.4% vs 79.9%, respectively). Use of electronic consent was associated with younger age at both sites, White race at SH, and no association with sex at either site. **Conclusions:** In this trial of older individuals, the great majority of patients chose and fully executed an electronic consent form, greatly facilitating trial recruitment. Electronic consenting should not be viewed as a barrier to enrollment of older adults in clinical research.

OBJECTIVES

1. To identify proportion of older adults who complete an electronic consent (e-consent) versus traditional paper consent (mailed) in the remote recruitment of clinical trial participants.

2. To compare e-consent completion proportions among sociodemographic groups including age, sex-assigned-at-birth, race, ethnicity, education, income, and marital status.

MATERIALS & METHODS

An NIH-funded multi-arm randomized trial entitled "BackInAction" (clinialtrials.gov # NCT04982315) was conducted with participants of at least 65 years of age, with chronic low-back pain. Participants were randomized to either 1) Standard acupuncture 2) Enhanced acupuncture or 3) usual care and followed for 12 months.

Two of the four clinical sites (Kaiser Permanente and Sutter Health, both in Northern California) offered two options for consenting: (1) a standard paper consent (mailed) or (2) an electronic consent ("e-consent"), using either Adobe Sign or REDCap. Those participants who consented and were randomized to the study completed a baseline interview, from which the sociodemographic variables were derived. Tests of proportions were conducted with Fisher's exact test

RESULTS

At KPNC and SH, 509 patients were consented but only 498 were randomized into the study (the 7 not randomized did not complete the baseline questionnaire). Of those consented and randomized, 288 (58.0%) were from KPNC and 210 (42%) were from SH.

Socio-demographics of the sample:

Attribute	KPNC (n = 288)	Sutter (n = 210)	Combined (n = 498)
Age (years)			
65 – 74	176 (61.1%)	88 (41.9%)	264 (53.0%)
75 – 84	103 (35.8%)	102 (48.6%)	205 (41.2%)
≥ 85	9 (3.1%)	20 (9.5%)	29 (5.8%)
Sex			
Female	173 (60.1%)	128 (61.5%)	301 (60.7%)
Male	115 (39.9%)	80 (38.5%)	195 (39.3%)
Race			
Asian	20 (7.0%)	15 (7.1%)	35 (7.1%)
Black	54 (19.0%)	27 (12.9%)	81 (16.4%)
White	183 (64.2%)	161 (76.7%)	344 (69.5%)
Other	28 (9.8%)	7 (3.3%)	35 (7.1%)
Ethnicity			
Hispanic/Latinx	23 (8.0%)	2 (1.0%)	25 (5.1%)
Not Hispanic/Latinx	259 (89.9%)	205 (97.6%)	464 (94.9%)

RESULTS

Of the 498 consented patients, 404 completed their consent electronically (81.1%; 95% Confidence Interval: 77.4% to 84.5%).

Those in the lowest age category had the highest e-completion rates (87%) compared to those in the middle (77%) and highest categories (59%). Significant differences were also observed among self-reported race categories, educational background, annual household income, and marital status, but in all subgroups, the majority of consents were completed electronically.

Characteristic	e-consent users	p-value
Overall (n=498)	404 (81.1%)	
Age (years)		<0.001
65 – 74 (n=264)	230 (87.1%)	
75 – 84 (n=205)	157 (76.6%)	
≥ 85 (n=29)	17 (58.6%)	
Sex		0.41
Female (n=303)	242 (79.9%)	
Male (n=195)	162 (83.1%)	
Race		0.003
Asian (n=35)	30 (85.7%)	
Black (n=81)	55 (67.9%)	
White (n=344)	291 (84.6%)	
Other (n=35)	25 (71.4%)	
Ethnicity		0.44
Hispanic/Latinx (n=25)	19 (76.0%)	
Not Hispanic/Latinx (n=464)	378 (81.5%)	
Education		<0.001
< College graduate (n=165)	125 (75.8%)	
≥ College graduate (n=331)	277 (83.7%)	
Annual household income		0.03
< $75,000 (n=173)	131 (75.7%)	
≥ $75,000 (n=214)	182 (85.0%)	
Marital status		0.02
Married/living with partner (n=300)	253 (84.3%)	
Never married / divorced / separated / widowed (n=190)	144 (75.8%)	

CONCLUSIONS

In two sites of this four-center trial of older adults aged ≥65 years, the vast majority (81%) of patients chose and fully executed an electronic consent procedure, greatly facilitating trial recruitment.

However, in certain subgroups e-consenting may be a greater barrier to participation. Electronic consenting should not be viewed as a barrier to enrollment of older adults in clinical research, but a paper option should be considered for certain subgroups.

Further analyses should be conducted to understand disparities between groups based on age, race, ethnicity, or SES.

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