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Establishing the Feasibility of a Tablet-Based Consent Process with Older Adults: A Mixed-Methods Study

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Abstract

Purpose of the Study: This mixed-methods study explored the feasibility and acceptability of using a tablet-based research consent process with adults aged ≥65 years.

Design and Methods: In the first phase, focus group participants reported on their perceptions of a tablet-based consent process. In the second phase, older adults were randomized to view either a tablet-based or paper-based consent for a mock clinical trial. Measurements included: time to complete, adverse/unexpected events, user-friendliness, immediate comprehension, and retention at a 1-week delay.

Results: Focus group participants (N = 15) expressed interest in the novel format, cautioning that peers would need comprehensive orientation to use the technology. In the randomized pilot (N = 20), retention was 100% and all participants completed the protocol without the occurrence of adverse/unexpected events. Although the participants took longer to complete the tablet-based consent than the paper-based version, user-friendliness, immediate comprehension, and retention of the tablet-based consent were similar to the paper-based consent.

Discussion and Implications: The findings suggest that a tablet-based consent process is feasible to implement with older adults and acceptable to this population, but we would underscore that efforts to optimize design of tablet-based consent forms for older adults are warranted.

Keywords: Informed consent, Mixed methods, Technology

The written informed consent process is crucial to human subjects research that is necessary for advancing health care and health care outcomes (Belmont Report, 1979; World Medical Association, 2013). It aspires to convey the purpose, procedures, and potential harms and benefits of the research study. To conduct research ethically, it must be ensured that participants must understand the procedures to which they are consenting. Critical elements include information on the voluntary nature of participation, the difference between research and treatment, and—for randomized studies—how randomization works and what constitutes an active treatment. Despite guidance from and extensive review with research staff, traditional paper-based informed consent forms can be confusing for individuals, thus alienating them from the research process (Agoritsas & Perneger, 2011; Henry et al., 2009). Studies indicate that significant numbers of participants do not fully understand the research in which they are taking part (Montalvo &

Larson, 2014). Recognition of the importance of tailoring the way information is presented to best meet the needs of participants is growing (Brink, 2012).

Over the past two decades, there has been a proliferation of efforts to supplement the written or verbal informed consent process with audio-visual material provided via videocassette, DVD, computer, or the Internet (Ryan, Prictor, McLaughlin, & Hill, 2008; Synnot, Ryan, Prictor, Fetherstonhaugh, & Parker, 2014). A tablet-based process is particularly appealing for several reasons. First, the touch-screen and the ability to customize font for readability may be more user-friendly than paper. Second, the interactive potential of a tablet-based process makes it possible to provide additional information, in the form of definitions, images, and multiple-choice questions, which may make it possible to overcome barriers related to lack of familiarity with the research process (Ridda, MacIntyre, Lindley, & Tan, 2010; Sugarman, McCrory, & Hubal, 1998). Third, but by no means last, the Internet/web capabilities of tablets may also ease sharing and consulting with trusted members of the participant's social circle. There may also be potential administrative advantages to an electronic system, including tracking and storage. In the hope of achieving these benefits, several initiatives have begun to generate tablet-based consent processes (Neuer, 2013; Rowbotham, Astin, Greene, & Cummings, 2013).

Much remains to be learned about the feasibility and acceptability of using electronic consents. Official guidance on the use of electronic consents has also been published (U.S. Department of Health and Human Services, 2016). As long ago as 2004, the Veteran's Affairs Healthcare system introduced an electronic consent process for medical procedures, but only a few studies have examined its efficacy (e.g., Hall, Hanusa, Switzer, Fine, & Arnold, 2012). A recent systematic review of studies that attempted to improve the consent process indicates the variability of findings, and highlights the need for high-quality evidence on whether electronic processes improve outcomes such as comprehension of research and willingness to participate in research studies when compared with a customary in-person process (Synnot et al., 2014; Zuniga, 2016). A few studies have documented the acceptability and efficacy of tablet-delivered informed consents, but these investigations have not been conducted in an older adult patient population (Doerr et al., 2017; Lewis, Hsieh, Gaydos, Peterson, & Rothman, 2017; Smith, 2014). There is also a lack of conceptual models of theory-driven rationale guiding the development of multimedia consent aids (Palmer, Lanouette, & Jeste, 2012).

The development of enhanced informed consent options may be particularly relevant for older adults. Studies show that participants in the 65 and older age group (vs younger-aged adults) are more likely to not understand the clinical trials in which they are enrolled (Herrera et al., 2010; Hoover-Regan, Becker, Williams, & Shenker, 2013). Compared with younger cohorts, older adults are more likely to experience problems that can negatively impact their ability to fully participate in a paper-based consent. Physical aspects of aging—reductions in vision (Dagnelie, 2013), hearing (Tun, Williams, Small, & Hafter, 2012), and manual dexterity (Desrosiers, Hebert, Bravo, & Rochette, 1999)—can impact their ability to interact with paper-based formats. Moreover, cognitive aging can lead to reductions in attention or information processing speed (Deary et al., 2009; Glisky, 2007; Hannon & Daneman, 2009), which can in turn compromise an older adult's ability to comprehend the presented information. Furthermore, older adults may have greater concerns about the risks involved in participation in a clinical trial (Bloch & Charasz, 2014), which could reflect an age-related aversion toward taking risks (Rutledge et al., 2016). Older patients may, therefore, be more interested than younger patients in sharing details of a clinical trial with others in their social circle before making a decision about whether or not to participate (Ford et al., 2008). This highlights the need for age-friendly research materials (Herrera et al., 2010).

Cognitive theory of multimedia learning (CTML) proposes that learning involves the development of a coherent mental representation of information (Sorden, 2016). The "cognitive aging" principle within this theory asserts that measures that expand the capacity of working memory are particularly helpful for older learners (Sorden, 2016). This may be accomplished through efforts to promote richer processing, such as the integration of pictures and written material rather than written words alone (Bol, van Weert, de Haes, Loos, & Smets, 2015; Sorden, 2016). Additionally, learning is aided by measures that orient the learner to the task at hand and reduce the interference of extraneous material (Sorden, 2016). Together, these principles, along with the aforementioned multimedia features (e.g., customizable touch screen and font, interactive nature) offered by tablet-based consent processes, encourage the development of the hypothesis that older adults would have a better experience with tablet-based research consents than paper-based consents. This could be the case particularly if color and graphics were used (e.g., Dzulkifli & Mustafar, 2013). Additionally, there are reasons to think that providing research information on a tablet would be less threatening than paper, because it would reduce the likeness to legal documents. The congruence between tablet-based format and CTML is summarized in a table in Supplementary Appendix. Aside from CTML, the ease of sharing tablet-based information with one's social circle could be viewed as a plus among older adults. Admittedly, concerns have been raised about the willingness of older adults to use tablets. In one Norwegian study, researchers had difficulty training older adults to use this technology for a practical purpose (Stangeland, 2013). Along similar lines, a recent survey indicates that older Americans perceive the need for orientation to use tablets (Chan, Haber, Drew, & Park, 2016). However, these concerns are offset by the fact that older adults are the fastest growing demographic of tablet

users (Bonnington, 2011), and that technology is increasingly being used to relay information.

Design and Methods

In this mixed-methods study, we examined the feasibility and acceptability of using a tablet-based informed consent process to enroll older individuals in a mock clinical trial. The study had two phases. In the first phase, we gathered feedback from older adults about their perceptions of a multimedia, interactive tablet-based consent process. In this phase, the key question was: What would participants perceive as advantages and concerns about a tablet-based (vs paper-based) consent form. In the second phase, we gathered additional data on the feasibility and acceptability of using this format with older adults, as well as preliminary evidence of efficacy. In this phase, key questions were: Would participants be able to complete procedures involving a tablet-based consent without problems and in a reasonable amount of time? Would they feel sufficiently informed to make a choice about participation? What level of comprehension would there be in the tablet-based versus the paper-based format? Because participation in a clinical trial often extends over time, we were also interested to learn if participants could retain information presented to them in the consent form during the consent process.

Participants

Participants in both phases of the study were community-dwelling women and men who provided paper-based written informed consent to participate in the study. Study inclusion criteria were: (a) age 65 years or older, (b) cognitively intact (MMSE ≥ 25; Folstein, Folstein, White, & Messer, 2010), and (c) ability to speak and read English. Exclusion criteria (assessed by self-report) were: (a) legal blindness, (b) severe hearing loss not correctable by assistive device, (c) inability to use finger to swipe a touchscreen, and (d) no working telephone at home to permit follow up.

Procedure

This study was approved by the Institutional Review Board of Weill Cornell Medical College. Participants were recruited via the posting of flyers and distribution in the local community of tri-fold pamphlets describing the study. In addition, brief announcements were made about the study at local senior centers. Each participant received $30 compensation for his/her participation.

Phase 1 involved three dual-moderator focus groups. Each focus group included 4–6 participants, who were unacquainted with each other before the study, and all of whom participated in discussion. Groups were segmented by age into young-old (65–74 years), middle-old (75–84), and old-old (85 and over) because there might be differences in familiarity with technology and physical ability to use the tablet. The groups, which were not segmented by gender, included both men and women. Participants completed brief baseline measures (more details are provided in the "Measures" section) and paper-based written informed consent to participate in the study before participating in a focus group. Two researchers then co-led discussions that lasted up to 60 min. There were two tablets available at each focus group. Focus groups began with orientation to the tablet-based consent, after which each participant interacted individually with the tablet-based consent for 5 min. Each participant also briefly viewed the paper consent. This was followed by a guided group discussion. The focus group moderators posed a series of open-ended questions that probed perspectives on the tablet-based and paper-based consents, comparisons between the two formats, perceptions of how age-peers would react, and responses to novel features of the tablet-based consent. (The full set of questions is available in Supplementary Appendix). The discussions were audio recorded and transcribed by a third researcher.

The second phase was conducted with each participant individually. Participants were assigned to a study condition after scheduling a study appointment in blocks of two. One was assigned to the tablet condition and the other to the paper condition. Block randomization was performed by computer to achieve similar group sizes while minimizing bias and confounding. One researcher completed a paper-based written informed consent to participate in the study with each participant and then administered a series of study measures (described below), which constituted the baseline assessment. Immediately after this baseline assessment, a second researcher (who had received the study group assignment in a sealed envelope) oriented the participant to a hypothetical clinical trial involving psychosocial treatment for falls-related anxiety and instructed him/her: "Take the perspective of someone considering participation in this trial." With participants in the paper-based informed consent condition, the second researcher read out the paper consent and answered questions the participant may have had. With participants in the tablet-based informed consent condition, the second researcher was present, and the participant reviewed text on the tablet and simultaneously listened to a verbatim audio version of the text. The participant was oriented both by a video and by the researcher on how to do the following: swiping from page to page, activating audio recording, and viewing definitions of terms and pictorial illustrations of concepts. The participant then proceeded independently unless help was needed, in which case the researcher assisted by answering the participant's question and/or demonstrating on the tablet. Upon completion of the consent form, the second researcher assessed participants' comprehension of the consent information using a standardized interview (Jeste et al., 2007). The consent was not made available to the participant to refer to while responding. One week later, retention of the consent

information was assessed by a phone interview conducted by the second researcher using the same standardized interview. The decision was made to have the second researcher conduct the comprehension and retention even though she was not blind to the participant's condition (tablet vs paper) to reduce the possibility that participants would confuse information from the study consent (administered by the first researcher) and the mock clinical trial consent.

The sample size for this mixed methods study was guided by the goal of adequately assessing older adults' perceptions of table-based informed consent (focus group $N = 15$; Carlsen & Glenton, 2011) and pilot-test the feasibility and acceptability of tablet-based (vs paper-based) consent form, (pilot randomized study $N = 20$, tablet-based consent $N = 10$, paper-based consent $N = 10$; Julious 2005; the pilot procedures were initially trialed on five subjects before being finalized, and data from these subjects are not included in the analyses).

Consent Forms

Consent forms presented information about a mock clinical trial comparing two interventions for older adults with anxiety that develops after falls. Since this study aimed to evaluate the tablet format rather than to evaluate the impact of different literacy levels of wording, the core wording of the tablet-based consent was the same as that of the paper-based consent. The wording was drawn from a paper-based consent already written and approved by an IRB for a clinical trial approved at the study's home institution. The core elements of the consents are summarized in Table 1. The paper-based consent was nine pages long and consisted of 141 paragraphs (3,536 words) in Times New Roman 12-point font. The tablet-based consent was created using a software application available at no cost. It consisted of a 44 MB file presented on a tablet computer (an iPad Air™). The tablet-based consent was comprised of 39 "pages" (separate screen views). The information presented included the same core text as the paper consent form. The tablet consent did differ from the paper consent in the following ways: (a) larger font size, (b) use of colored text for headings, (c) audio narration of the text in a human voice, (d) pop-up definitions of key terms, (e) pop-up illustration of concepts, (f) multiple choice self-test, and (g) signature using a stylus or finger. (Screenshots are provided in the Supplementary Appendix). The tablet consent form also began with an introductory video (75 s duration) in which a member of the study team welcomed participants, described the features of the tablet-consent, and demonstrated how to interact with/utilize them.

Table 1. Core Content of the Tablet-Based and Paper-Based Consent Forms

	Sections	Subsections (if any)
1.	Heading	Project title Project number Name of principle investigator
2.	Introduction	Voluntary nature of participation Possibility of benefiting or not Choice to not enroll/discontinue
3.	Why is the study being done?	
4.	How many people will take part in the study?	
5.	What is involved in the study?	
6.	How long will I be in the study?	Withdrawal by investigator, physician, or sponsor
7.	What are the risks of the study?	
8.	Are there any benefits?	
9.	What other options are there?	
10.	What about confidentiality?	
11.	What are the costs?	
12.	Policy/procedures for research related injury	
13.	Compensation for participation	
14.	What are my rights as a participant?	
15.	Who do I call if I have questions or problems?	

Measures

Background Measures

Participants in both phases of the study completed measures of mental status (Mini-mental State Exam; Folstein et al., 2010), attitudes toward technology (Computer Anxiety Rating Scale; Heinssen, Glass, & Knight, 1987), and attitudes toward clinical trials (adapted version of the Attitudes Towards Cancer Trials Scale; Schuber, 2008). Sociodemographic information collected included age, gender, race, ethnicity, education, number of medical conditions, number of prescription medications, use of eyeglasses, and prior experience with research participation.

Participants in the randomized study completed additional measures that were included to evaluate the comparability of study groups with respect to factors that might affect use of the tablet-based (vs paper-based) consent. Measures were made of cognitive functioning (Trail-Making Test; Reitan, 1979), health literacy (Test of Functional Health Literacy; Nurss, Parker, Williams, & Baker, 2001), anxiety (State-Trait Anxiety Scale, Trait subscale; Spielberger & Sydeman, 1994), depression (Patient Health Questionnaire-9; Kroenke, Spitzer, & Williams, 2001), and upper extremity disability (Quick-DASH; Kennedy, Beaton, Solway, McConnell, & Bombardier, 2011). Upper extremity disability was measured even though participants were initially screened for ability to swipe the tablet, because there is a range of shoulder, elbow, or hand issues that could reasonably affect response to the

tablet format. Additional variables were collected to evaluate the relevance for participants of the mock study (which involved clinical intervention for anxiety after falls). For this purpose, measures were made of fear of falling (Falls Efficacy Scale-International; Yardley et al., 2005) and falls in the past 12 months (self-report).

Randomized Pilot Outcomes

Time spent by the participant in reviewing the consent form was recorded (in minutes) by the researcher. User-friendliness was measured by a 10-item scale created for the study, on which each participant rated his/her perceptions of the consent form on a 5-point Likert scale ranging from "1" to "5." Immediate comprehension of the study and retention of information at one-week was assessed using the University of California, San Diego, Brief Assessment of Capacity to Consent (UBACC; Jeste et al., 2007). The UBACC involves 10 open-ended questions that are designed to evaluate whether participants make an informed and voluntary decision to enroll in research. Questions probe for comprehension of elements of research such as the purpose of a study, the option to not enroll or withdraw, procedures involved, potential for benefit, and the difference between research and treatment. Responses can be coded for accuracy on a nominal scale from 0 to 2. The coding scheme was developed *a priori* and scored by study team members who were blind to the participant condition. A copy of the coding is available upon request.

Data Analysis

Phase 1: Focus Groups

A summative content analysis approach (Hsieh & Shannon, 2005) was applied to the focus group data. One of the researchers (a postdoctoral-level clinical psychologist) read through the transcripts several times, identified idea units, and generated a coding scheme of themes. Next, the transcripts were coded independently by another team member (a clinical psychologist) using the coding scheme. The coders then discussed their coding of each and every idea unit. The themes were then categorized into superordinate themes: advantages of the tablet-based consent, concerns about the tablet-based consent, and lack of preference. The level of agreement was computed to be 70%. Differences in coding were reconciled through discussion between the two coders. Several strategies were used to ensure rigor in this phase of the study. Credibility was maintained through systematic content analysis by the research team. To establish auditability, documentation of the analytic decisions was maintained by keeping electronic copies of coding at every stage. In addition, to ensure reflexivity, two coders were employed to preempt the development of bias, and their qualifications and potential for bias toward tablet or paper formats were considered. Descriptive statistics were generated for the overall sample.

Phase 2: Randomized Pilot Study

For the randomized pilot study, participants in the tablet-consent and paper-consent conditions were compared on sociodemographic and clinical measures to evaluate group equivalence with independent samples *t*-tests for continuous variables and chi-square tests for categorical variables. Key feasibility and acceptability outcomes of the duration of time taken to view the consent forms, adverse/unexpected events, user friendliness, and informed consent comprehension were assessed using descriptive statistics. Effect sizes (Hedges' *g* and partial η^2) were computed and statistical significance of observed group differences was explored using independent samples *t*-tests (Mann–Whitney *U* for non-normally distributed data) and 2 × 2 repeated measures ANOVA. To explore the possibility of item-level differences between the study conditions on the UBACC, independent *t*-tests were also conducted for each of the UBACC's 10-items both at baseline and follow-up. Significance level was set at 0.05 and no adjustment was made for multiple tests. All analyses were conducted using SPSS v.20-v.22®.

Results

The age, gender, and race/ethnicity composition of the study samples was as follows. Focus groups: 77.47 years (SD = 7.54), 80% female, 93% White, 8% Hispanic. Randomized Pilot: 74.65 years (SD = 7.36), 85% female, 90% White, 5% Hispanic. To save space, a table summarizing this and additional demographics is included in the Supplementary Appendix.

Focus Groups

The focus group transcripts yielded 245 statements, 19 of which received multiple codes, yielding a total of 264 codes. The coded statements were disproportionately derived from the first two groups: 116 (43.9%) from focus group 1, 96 (36.4%) from focus group 2, and 52 (19.7%) from focus group 3. The types of statement were as follows: advantages of tablet-based consent = 120 (45.45%), concerns about tablet-based consent = 125 (47.35%), and lack of preference = 19 (7.20%). Table 2 summarizes the coding of these statements. The three most frequently cited advantages of the tablet consent process articulated by focus group participants were: convenience of using a tablet format; usefulness of extra features such as definitions, graphics, and audio; and the higher level of engagement afforded by the interactive tablet format. The top three concerns expressed by focus group participants were: older users would require careful orientation to using the tablet consent, older users would be unfamiliar with a tablet, and dissatisfaction with aspects of the design of the tablet. Lack of preference centered on equivalence of the formats or on factors affecting appropriateness.

Table 2. Summary of Themes Extracted From Focus Group Feedback (Grouped by Theme)

Example statement	Derived units	*N*	%	Derived theme
Advantages of tablet-based consent				
This is easier than I thought.	Convenience/ease	27	22.50	Easier to understand
The writing was bolder.	Readability/font	10	8.33	
The tablet was less overwhelming and it broke down the sections.	Organization of information	9	7.50	
Just thought that I was reading it faster.	Speed	1	0.83	
The tablet is helpful for looking at definitions.	Extra features (video, audio, …)	24	20.00	Involvement/enjoyment
When you hear it rather than look at it, it makes more sense.	Engagement	12	10.00	
This is a lovely tablet. You sold me on the tablet.	Like design	4	3.33	
I'd like to use one.	Curiosity	4	3.33	
They'll be amused by the unexpected factor.	Novel	1	0.83	
I'm still working…I need it for work.	Daily uses	10	8.33	Growing uses
I think that they would like it because a lot of them have smart phones so they would be very familiar with the iPad.	Familiar device	8	6.67	
By learning these programs, I am stimulating and keeping my brain working.	Cognitive health	3	2.50	
I think the tablet's good for people who have a handicap in some way.	Assist with limitations	2	1.67	
It's better on the tablet.	General	5	4.17	General
Concerns about tablet consent				
If you have someone to teach them, I'm sure they could get it.	Need Training	33	26.40	Personal anxiety
I don't have a tablet. I haven't used it yet.	Unfamiliar	21	16.80	
I feel rushed on the tablet.	Feel rushed	4	3.20	
I also feel like you feel a loss of sense of control when you have a computer.	Not in control	3	2.40	
I found both of them hard. The finger and the stylus.	Difficult to use	6	4.8	Difficulty of use
Does it have a directory where you can find all the subjects?	Organization of Information	1	0.80	
I still have this fear of my words going into the air.	Confidentiality concerns	9	7.20	Risks
It feels like there's more that can go wrong with a tablet.	Undependable	6	4.80	
I found it heavy to hold.	Dislike design	13	10.40	
The audio is too soft and a lot of older people would have difficulty hearing it.	Volume	7	5.60	Dislike
I don't like the computers.	Dislike computers	2	1.60	
They're very expensive.	Financial cost	7	5.60	Financial costs
I need to have paper.	Habit/familiarity/	4	3.20	Comfort with paper
I still like the paper because I can really read it on my own pace.	Perception of control with paper	2	1.60	
I enjoy taking paper in my hand and reading it.	Paper is more tangible	2	1.60	
Yikes!	General	5	4.00	General
Lack of preference				
I think no difference for me. I think they're equal.	Tablet and paper are equivalent	11	57.89	Equivalent
I think it depends on the person.	Depends on person	5	26.32	Personal fit
There's a difference between people who are not working versus who are working.	Depends on daily use	1	5.26	Broader considerations
I didn't use it…so I don't know.	General	2	10.53	General

Note: N = number of times a derived unit or derived theme was coded as present in the transcripts.

Randomized Pilot Study

There were no significant between-group differences in sociodemographic or clinical characteristics with one exception: Participants in the tablet consent condition had significantly greater upper extremity disability (mean rank = 13.80) than subjects in the paper consent condition (mean rank = 7.20), Mann–Whitney $U = 17.00$, $p = .012$. There were no drop outs, nor were there adverse or unexpected events in either consent condition. Participants in the tablet-based consent condition took significantly longer to review the consent ($M = 32.30$ min, $SD = 3.74$) than participants in the paper consent condition ($M = 21.00$ min, $SD = 2.16$), $t(18) = 8.27$, $p < .001$. Table 3 presents data on user-friendliness. Overall, ratings of the user-friendliness of the consent process were similar between participants in the tablet-based consent condition ($M = 41.30$, $SD = 5.83$) and paper-based consent conditions ($M = 41.00$, $SD = 5.46$), $t(18) = .119$, $p > .907$. Participants in the tablet-based consent condition expressed significantly less uncertainty about how to go back to a previous section of the consent form ($M = 1.20$, $SD = 0.42$) than participants in the paper-based consent condition ($M = 2.10$, $SD = 1.10$), $t(18) = -2.42$, $p = .033$. There were no other item-based differences.

Finally, the mean comprehension score in the overall sample was 15.00 ($SD = 3.84$) and was above the 14-point threshold cut-off for adequate comprehension (Jeste et al., 2007). It is notable that a substantial proportion of participants ($N = 6$, 30%) scored below the threshold, although there was no significant difference between-consent conditions. Mean immediate comprehension scores were 15.60 ($SD = 3.56$) and 14.40 ($SD = 4.20$) for the tablet and paper conditions, respectively. Mean follow-up scores were 13.10 ($SD = 3.70$) and 12.10 ($SD = 3.84$), respectively. The observed between group effect sizes were small (immediate and follow-up comprehension Hedges' $g = .30$ and .25 and interaction effect size $\eta^2 = .10$). Repeated measures ANOVA suggested neither a main effect for condition, $F(1, 18) = .472$, $p = .501$, nor evidence of interaction, $F(1, 18) = .027$, $p = .872$. It did, however, reveal a significant decrease in consent comprehension scores from immediate comprehension to retention at 1-week follow-up in both groups, $F(1, 18) = 15.406$, $p = .001$. Exploratory analysis of the item scores on the UBACC were nonsignificant in all but 1 of the 20 t-tests performed: Mean immediate comprehension scores were 1.90 ($SD = .32$) and 1.20 ($SD = .92$) for the tablet and paper conditions, respectively on an item that probed reasons why one might wish to participate in the mock study.

Discussion

This mixed-methods study provides encouragement for continued efforts to develop tablet-based consent processes for older adults. The focus groups voiced some positive perceptions of tablet-based consents centering on the usefulness of the multimedia format, convenience, and added level of engagement in comparison to paper formats. Participants appreciated the delivery of information through multiple channels (visual, auditory) and the capacity for enriched information. Concerns about using a tablet-based consent process centered on the need among older individuals for orientation to using the tablet itself. Older adults' perceptions of the advantages of a tablet consent process closely parallel the arguments made in the scientific community for the adoption of multimedia consent formats. Their concern that peers would not be familiar with using tablets in general and would need specific orientation to the consent process suggests that care needs to be taken in this regard, but it may also reflect stereotypes held about their peers. This barrier will lessen as middle-aged and young-adult technology users

Table 3. Mean Ratings of User-Friendliness of Tablet-Based ($N = 10$) and Paper-Based ($N = 10$) Consent Forms

	Tablet[a]		Paper[a]	
Item	Mean	*SD*	Mean	*SD*
It was easy to move through the different sections of the consent form.	4.30	0.82	4.20	0.79
The information was not clearly presented.[b]	1.90	1.00	1.50	0.71
I could understand the content of the consent without additional explanation.	4.60	0.52	4.30	1.25
I had difficulty finding the information I needed.[b]	1.30	0.48	1.80	1.23
I wasn't sure how to go back to a previously read section.[b,c]	1.20	0.42	2.10	1.10
The appearance of the consent made me want to keep reading.	3.40	1.58	3.00	1.05
It was cumbersome to hold the consent while reading.[b]	2.70	1.64	1.80	0.92
The consent was longer than it needed to be.[b]	3.00	1.70	2.20	1.03
The organization of the consent made it easy to follow.	4.30	0.82	4.50	0.53
After reading the consent, I feel I understand it well enough to make a decision about whether or not to participate.	4.80	0.42	4.40	0.70
Total score	41.30	5.83	41.00	5.46

[a]Group comparisons (tablet vs paper) based on independent samples t-tests, all $p > .05$, except for item "I wasn't sure how to go back to a previously read section."
[b]Item was reverse scored in the computation of the total score.
[c]$t(18) = -2.42$, $p = .033$.

age. Although confidentiality ranked only fourth in terms of stated concerns, it should also receive ongoing attention. Recent studies have suggested that a segment of older adults prefer tablet-delivered research materials over paper-based versions (Fanning & McAuley, 2014; Tait & Voepel-Lewis, 2015). However, contrary to these studies, the randomized pilot study did not indicate that participants judged more favorably the user-friendliness of the tablet-based consent than its paper-based counterpart.

The randomized pilot study provides additional support for the feasibility and acceptability of using a tablet-based consent processes for older adults. There was 100% retention of participants and there were no adverse or unexpected events. These two points suggest that tablet-based consents forms may be acceptable and practical for older adults. In terms of the ease of use, it is notable that participants in the tablet-based condition took longer to view the consent than participants in the paper-based condition (on average 11 min, which amounts to a 53% increase). This could be explained by factors such as the use of opportunities to view additional information or take the self-test, or the fact that the participants in the former group demonstrated significantly higher levels of upper extremity disability. Because, in the present study, a researcher sat with the participant throughout, and was available to provide assistance (although it was rarely solicited), it remains to be determined to what extent older participants could view a tablet-consent form independently (e.g., if a subject is interested in reading the contents ahead of time).

The pilot study data lean toward slightly more understanding of the consent information in the tablet condition, but there was no difference between the formats in terms of participants' expressed confidence in understanding consent information well enough to make a decision to participate or not (as indicated on an item in the user-friendliness questionnaire). It is noteworthy that a significant number of participants demonstrated suboptimal comprehension of the consent material regardless of group assignment. This points to the general issue of consent comprehension in clinical research studies, which may be particularly germane to psychological treatment studies where there may be complexity of the interventions and study procedures. The fact that the participants did not have a copy of the consent form to refer to may have reduced the accuracy of responses. Alternatively, the mock nature of the study may have decreased participants' effort and motivation to process the information, and completing an initial paper-based consent to enroll in the study may have influenced the reception of the mock consent. It is our observation that participants do not try to learn all the details of a study from a consent process. Rather, in many cases, participants may be willing to embrace a process and expect to be guided through the research process in an ongoing way. This is consistent with the observation that older patients are more willing than younger ones to take their cues from trusted authority figures such as physicians (Puts et al., 2015). The results thus highlight the broader phenomenon of informed consent as a communication process and the potentially different agendas of researchers and participants. In the real-world setting, participants can receive a printed copy of the informed consent to which they can refer, so problems with retention of material are of less importance than problems with comprehension. The lack of significantly improved understanding of tablet-based consent over paper-based consent also raises the question of whether options other than multimedia consent are needed to engage under-represented populations such as older adults in clinical trials. Flory and Emanuel (2004) have argued that much of the understanding of clinical trials can occur through in-person conversations with the research team that take place outside of the formal informed consent process. The present study has several limitations. More data could have been collected on participants' interactions with the tablet-consent form (e.g., number using definitions, viewing pop-up images, taking the self-test) to provide information on the extent to which participants use its capabilities. In addition, measures that examined variables such as decisional conflict might have better captured the effect of the tablet-consent than the UBACC, which focuses on capacity to consent. Another limitation is the small size of the pilot trial. Future, and larger, studies should conduct focus groups separately for men and women because gender can affect involvement in focus group interviews and what participants say. The use of a larger sample might have yielded greater power to detect differences in the impact of paper-based and tablet-based consent forms on comprehension. The study cannot rule out the possibility that with larger numbers of participants the tablet-based consent form would have outperformed the paper-based consent, although it is unlikely given the obtained effect size. In addition, participants were drawn from a similar demographic pool (primarily Caucasian, college educated, accessing services at an academic medical center, with prior experience of participating in research). These participants are not representative of the diversity of participants that must be enrolled to gain quality evidence from clinical trials. There was also no younger participant pool available to capture age-specific factors in perceptions of tablet-based consent processes. Finally, the study did not evaluate thematic saturation. It is possible that older adults have additional concerns that were not captured here. Future studies should examine whether additional themes emerge in focus groups with older adults from diverse sociocultural backgrounds.

Among the strengths of this study is the fact that it is one of the few studies to explore the feasibility of using a tablet-based research consent process with older adults. Its mixed-method approach provides a starting point for understanding the feasibility of enrolling older participants in clinical trials using tablet-based consent forms. The study also gathered information on a range of cohorts (young-old, mid-old, and old-old) rather than treating older adults as a homogenous group. Finally, the study utilized technology

that is widely available at relatively low cost and is thereby accessible to many researchers.

Overall, the study suggests that if a tablet-based consent process is to be used with older adults care must be taken to optimize design to prevent undue burden of time to complete the consent process and to ensure good understanding of the consent information.

Supplementary Material

Supplementary data are available at *The Gerontologist* online.

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Conflicts of Interest

None declared.

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