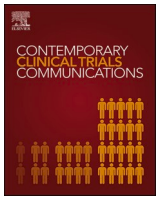
Contemporary Clinical Trials Communications 28 (2022) 100927

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



Participant comprehension and perspectives regarding the convenience, security, and satisfaction with teleconsent compared to in-person consent: A parallel-group pilot study among Danish citizens

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ARTICLE INFO

Keywords:
Informed consent
e-consent
Decentralized trials
Remote consent

ABSTRACT

Background: Teleconsent via video conferencing enables decentralized trials with remote consent and has the additional benefit of allowing a real-time reaction to potential misunderstandings. However, participant acceptance of and satisfaction with teleconsent versus in-person consent processes are unknown.
Methods: We conducted a parallel-group pilot study to evaluate participant comprehension and perspectives regarding the convenience, security, and satisfaction with teleconsent compared to in-person consent among Danish citizens for a hypothetical research study.
Results: There were no statistically significant differences in perceptions of security or satisfaction between teleconsent and in-person consent arms. However, participants viewed teleconsent as more convenient than in-person consent, as no transportation was needed and the process was less time-consuming. Recruitment was also faster in the teleconsent arm, and more people dropped out of the in-person arm, citing difficulties with transportation and time.
Conclusion: Decentralized clinical trials have been demonstrated to increase recruitment and enrollment rates, improve trial efficiency, and decrease dropout rates and trial delays. We add to this literature by suggesting that patients perceive teleconsent as similar to in-person consent, suggesting this is a feasible and acceptable substitution for in-person consent in multisite, decentralized trials. Future work should include patient perspectives from a larger, more diverse group of participants.

1. Introduction

Remote consent may help clinical trials be more patient-centered, as it allows participants to be recruited and enrolled without physically being present. Teleconsent, which includes videoconferencing, enables researchers and participants to review the consent document together, sign the document electronically in real-time, and download the signed consent document. While both electronic consent (e-consent) and teleconsent allow remote consent and thereby reduce travel, planning, and time costs [1], teleconsent, with a videoconferencing component, has the additional benefit of enabling the observation of potential misunderstanding cues and addressing them directly [1,2]. However, participant acceptance of and satisfaction with the teleconsent process versus consenting in person needs to be investigated. In addition, there may be privacy concerns [3] or difficulties using technology, particularly in the elderly. Previous studies indicate that comprehension is similar for e-consent versus traditional written consent even in the elderly [4,5]; however, this has not yet been examined for teleconsent [1], nor have patient perspectives been gathered regarding using telemedicine technology (i.e., video conferencing) versus in-person consent.

The U.S. Food and Drug Administration (FDA) established regulatory guidance for the use of e-consent, but the European Medical Agency (EMA) has not, and therefore researchers may be reluctant to use teleconsent or e-consent approaches, particularly for the conduct of decentralized multisite trials, which may have multiple country-specific ethic committees [6,7]. Although EMA has published formal contemporaneous guidelines to manage e-consent in clinical trials during the pandemic, including guidance on how to handle consent during clinical trials [8], general guidance and consensus regarding e-consent and teleconsent are still needed to decrease the burden of researcher and ethics

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https://doi.org/10.1016/j.conctc.2022.100927
Received 19 November 2021; Received in revised form 9 March 2022; Accepted 24 May 2022
Available online 27 May 2022

committees and protect patients' safety and rights [6].

Thus, we conducted a parallel-group pilot study to evaluate participant comprehension and perspectives regarding the convenience, security, and satisfaction with teleconsent compared to in-person consent among Danish citizens for a hypothetical research study.

2. Methods

The study included an enrollment process, a pre-consent consultation process, and one consent session for a hypothetical research study involving itch in Parkinson's disease. The consent process lasted approximately 60 min.

2.1. Participants

Study participants were recruited through public notices, online advertising in social media, e-mail, and direct communication. Interested participants received information and were provided with the opportunity to ask questions. Those consenting to participate provided contact information (e-mail and phone number) and were sent an e-mail containing a link to a questionnaire (SurveyXact) for the collection of demographic, exclusion and inclusion criteria, and the Danish version of the Short Assessment of Health Literacy (SAHL-E) questionnaire, which was used to ensure the participants' ability to understand and make appropriate decisions. Inclusion criteria were people 18–85 years of age, with access to internet and a smartphone, tablet or computer with a microphone or camera, the ability to understand and speak Danish, normal cognitive function, and a SAHL score $\geq$14. Exclusion criteria were people younger than age 18 and older than age 85, severe visual limitations or physical disabilities, lack of e-mail, and a SAHL score $<$14, indicating low health literacy [9]. Participants indicating headaches/migraine during the teleconsent session were excluded.

2.2. Study design

Eligible participants were enrolled on the teleconsent (video conferencing) arm, and then a second group was matched according to age ($\pm$10 years) and enrolled in the traditional consent arm.

Participants were contacted by phone to schedule an appointment for the consent consultation. Subsequently, each group received an information sheet via e-mail or within the teleconsent application explaining a hypothetical study. The participant was encouraged to read and understand the information provided about the hypothetical study the day before the consent consultation. In addition, both groups were encouraged, however not obligated, to involve friends and family members to discuss the study. The consent session was performed either at Aalborg University or remotely via the teleconsent app between March and June 2021 (Fig. 1). On the day of consent consultation, the information sheet was reviewed in-depth with the principal investigator (PI), who used the teach-back method. Afterwards, the participants were directed to SurveyXact (Aarhus, Denmark) to answer questions regarding comprehension, convenience of outcome measure, security, and satisfaction about the consenting process. The survey took approximately 20 min to complete.

2.3. Traditional group setting (n = 16)

Eligible participants were invited to schedule an appointment to meet the PI at a specific location via e-mail. The study was conducted in a quiet room with no distractions. The traditional in-person sessions for the 16 participants were completed within 4 weeks based on participant availability. After the participant verified their understanding of the study orally, they were provided with an informed consent document and asked to mark it with an X, indicating their comprehension of the hypothetical study and their (hypothetical) willingness to participate.

2.4. Intervention group setting (n = 21)

The participants in the intervention group received an invitation e-mail with instructions on how to access the web-based application for the teleconsent application (designed by Medable), specifics of the remote consent procedure, and contact information of the PI. The next day, participants received an e-mail containing a link that directed them to the web-based application where participants created a profile, personal username, and password. The PI followed up via phone or e-mail to support participants who did not accomplish these tasks. Each participant received a confirmation e-mail when the date for the consent session was scheduled. When Participants were signed into the app (via their phone, tablet, or computer), they had access to the information sheet. They were encouraged to read and understand the study information in a non-distracting setting, and participants had at least one day to review the document. On the day of the consent consultation session, the participant and PI signed into the teleconsent application using their individual username and password. After the call connection was

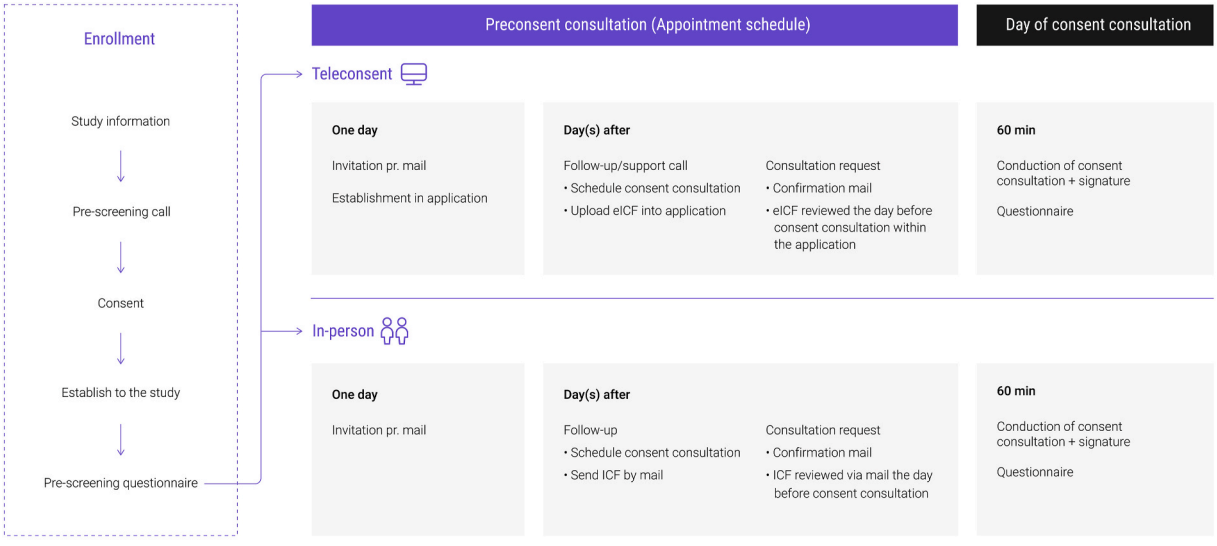

Fig. 1. Overview of enrollment procedure
EICF: electronic informed consent form; ICF: informed consent form.

established securely, the informed consent process was conducted as described above (Figs. 2 and 3). At the end of the session, participants were asked to verify their comprehension of the study orally and by using their personal password and username; this was timestamped for use in auditing. The participants and PI were able to print the signed and countersigned document for storage. Each party received a confirmation of the signed consent document by e-mail. The teleconsent sessions for the 21 participants were completed within 3 weeks based on participants' availability.

2.5. Teleconsent application

The application was developed by Medable and has been translated into multiple languages, including Danish. It allows researchers to upload documents and control access. The software was designed to be simple and straightforward for use on personal digital devices. The application was developed and adapted for European standards for data storage, processing, and handling, and this information was presented to all participants. The PI primarily controlled access to participant data. The teleconsent application facilitates capturing and storage of signatures to ensure that the signatures cannot be changed, copied, or reused within the application. In addition, the signature was uniquely linked to the specific version of the consent document.

2.6. Outcome measures

2.6.1. Comprehension

Comprehension was measured using the validated Quality of Informed Consent (QuIC) item. The wording of the questions was modified from the original to reflect the context of consenting to the information sheet of the hypothetical study and translated into Danish. The response options remained the same as in the original item.

2.6.2. Geographical distance

Distance was estimated from the postcode to the consenting site (measured in kilometers), where the participants either obtained or could have obtained informed consent. Time spent travelling was estimated as the travelling time from the postcode to the consenting site (minutes). The travelling costs were estimated by dividing the distance by the average number of kilometers travelled using 1-L gasoline. This number was multiplied by the gasoline price per liter.

2.6.3. Experience: convenience, security, and satisfaction

2.6.3.1. Definition security. The term secure was assessed as participants' perception of feeling secure when considering the consenting process in terms of data storage, the consenting forum and the signature format. The term secure was assessed using a 5-point Likert Scale, rating 1: Feeling secure in no degree, 2: Feeling secure in a less degree, 3: Neutral, 4: Feeling secure in some degree and 5: feeling secure in a highly degree.

2.6.3.2. Definition convenience. Convenience was assessed as difficulty considering the consenting process in general and in terms of transport, time and planning. Difficulty was rated using a 5-point Likert Scale, rating 1: really difficult, 2: difficult, 3: neutral, 4: easy (few difficulties) and 5: really easy (without difficulties). Stating 5 with total convenience.

2.6.3.3. Definition satisfaction. Satisfaction was assessed as participants' perception of being satisfied with the consenting process in general and in terms of information needed to make a decision and the likeliness to consent likewise in the future. Satisfaction was rated using a 5-point Likert Scale, rating 1: no degree of satisfaction, 2: less degree of satisfaction, 3: neutral, 4: some degree of satisfaction and 5: highly degree of satisfaction.

Two preference questions related to the pandemic situation were added to the questionnaire.

2.7. General feedback

Participants were asked open-ended questions about the advantages, disadvantages, and suggestions for improving the two consenting approaches. Open-ended questions were evaluated by content analysis, and answers were divided into categories based on the content of the answers.

2.8. Statistical analysis

The data was collected from SurveyXact, transferred to, and assembled in Microsoft Excel (Version: 16.54, Microsoft 2021). All statistics were conducted in IBM SPPS Statistical software version 26. All data was tested for normality using the Shapiro Wilks test. To investigate the differences in health literacy between the two groups, non-parametric tests were conducted based on SAHL scores. Comprehension was

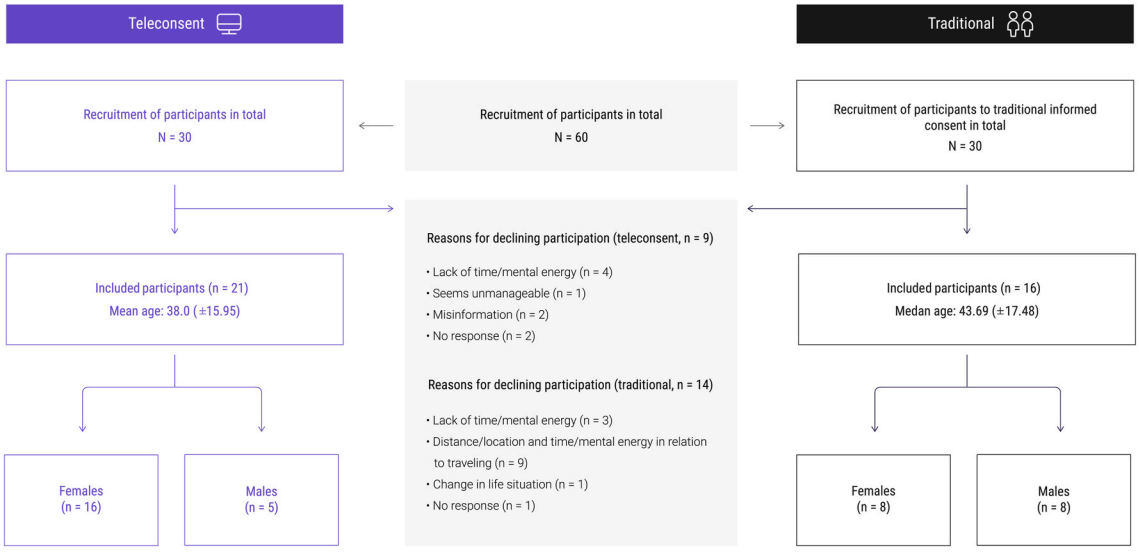

Fig. 2. Recruitment flowchart.

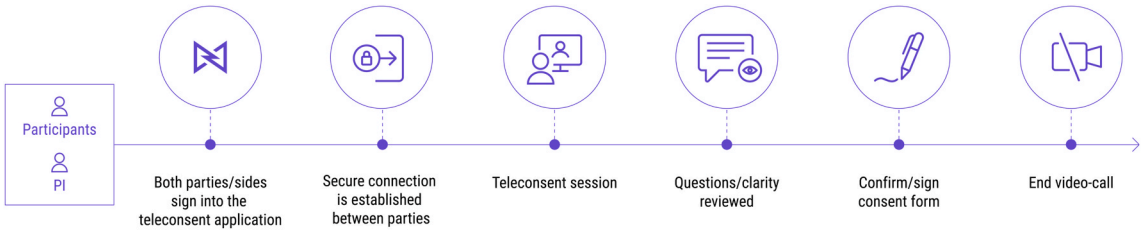

Fig. 3. Workflow of the teleconsent video call procedure.

measured based on the summary scores calculated from the comprehension assessment (QuIC test); the difference between the groups was measured with independent t-tests or non-parametric tests for age, distance, time of travelling, costs of travelling, convenience, security, comprehension, and satisfaction. A chi-square test was used to identify differences in categoric data. Each group was divided into lower and higher age ranges to investigate responses based on age. A non-parametric test was used to compare the younger and elder group's perspectives within each category (convenience, security/trust and satisfaction). All statistics were considered significant at a p-value of <0.05.

3. Results

3.1. Participants

Sixty participants were recruited (n = 30 per group). No participants indicated headache or migraine during the informed consent using the teleconsent tool. One participant declared compromised hearing; a hearing aid allowed the participant to participate in the study. Nine participants within the intervention group and 14 within the control group declined to participate based on different reasons listed in the recruitment flowchart (Fig. 2). The main reason for declining participation within the control group was transportation and travelling time to the location for the informed consent consultation (n = 9). The dropout rate for the participants consenting by teleconsent was 30%, whereas the dropout rate for consenting in-person was 47%. No significant difference in the proportion of dropouts between the consent conditions or by age or gender was observed.

Demographic characteristics are shown in Table 1. No significant differences were found between the two groups, except for the median age for the group never or rarely using tablets (median age 30, range 22–63) and for the group using tablets daily or weekly (median age 57 range 22–71; p = 0.015). All included participants declared to have access to internet and digital tools such as computer, smartphone, or tablet. Most participants within the teleconsent group consented within the first 2 weeks (3 weeks maximum). In contrast, the participants consenting in-person consented with higher variability during the 4 weeks of enrollment, indicating faster enrollment in the teleconsent group.

3.2. Geographical location

According to postcode information, the number of participants residing near the consent clinic (North of Denmark) was equally distributed among the recruited participants across the original two arms of the study (n = 60). However, after some of the participants declined, this number became skewed: participants in the in-person arm had significantly less travel distance, time, and costs than those in the teleconsent arm would have had if they travelled to the clinic (Table 2).

Eleven of 16 participants (68%) in the in-person arm resided close to the consent clinic, while only 8 of 21 in the teleconsent arm (38%) resided close to the clinic.

Table 1
Demographic characteristics.

	Teleconsent (n = 21)	In-person (n = 16)
Age: Overall	38 (±15.95)	44 (±17.48)
Age: young cohort	26 (22–35; ±3.58)	28 (22–37; ±5.37)
Age: older cohort	58 (47–63; ±5.46)	59 (48–71; ±7.96)
Gender		
Male	5	8
Female	16	8
Educational level (%)		
Candidate	57.14%	31.25%
Bachelors'	23.81%	50.00%
Vocational	9.52%	12.50%
Primary school	4.76%	0%
Other education	4.76%	6.25%
SAHL-score	17 (16–18)	18 (14–18)
Use of smartphone (%)		
Daily	100%	100%
Weekly	0%	0%
Rarely	0%	0%
Never	0%	0%
Use of computer (%)		
Daily	85.71%	81.25%
Weekly	14.29%	18.75%
Rarely	0%	0%
Never	0%	0%
Use of tablet (%)		
Daily	23.81%	25.00%
Weekly	0%	25.00%
Rarely	57.14%	12.5%
Never	19.05%	37.5%
Access to digital tool	100%	100%
Access to internet	100%	100%

Table 2
Differences in the distance, travel time, and associated travelling costs for enrolled participants if they travelled to the consent clinic.

	Teleconsent (n = 21)	In-person (n = 16)	P value
	Mean (±SD)	Mean (±SD)	
Distance to informed consent location (km)	104.21 (±96.5)	42.35 (±52.85)	0.027
Travel time (min)	66.10 (±57.15)	31.88 (29.61)	0.036
Costs	57.95 (±53.66)	23.55 (±29.39)	0.027

3.3. Comprehension

Comprehension scores were not statistically different across the two arms for the overall, younger, and older age groups.

3.4. Convenience

There was no difference in overall perceptions of convenience or planning; however, there was a statistically significant difference in difficulties in transportation and time used with regard to the informed consent consultation (both p-values <0.05).

3.5. Security

There was no significant difference between the two arms regarding perception of security of private data storage or about the consent forum and signature form, nor was there a difference by age groups.

3.6. Satisfaction

There was no significant difference between the two arms in overall satisfaction, decision-making, or likeliness to consent. Participants were asked whether they preferred consenting from home over consenting at clinics during and not during a pandemic such as COVID-19. In general, the participants preferred to consent from home to some degree during non-pandemic conditions (median 4, IQR: 2.5–5), whereas participants preferred to consent from home to a high degree during pandemic conditions (median 5, IQR: 4–5).

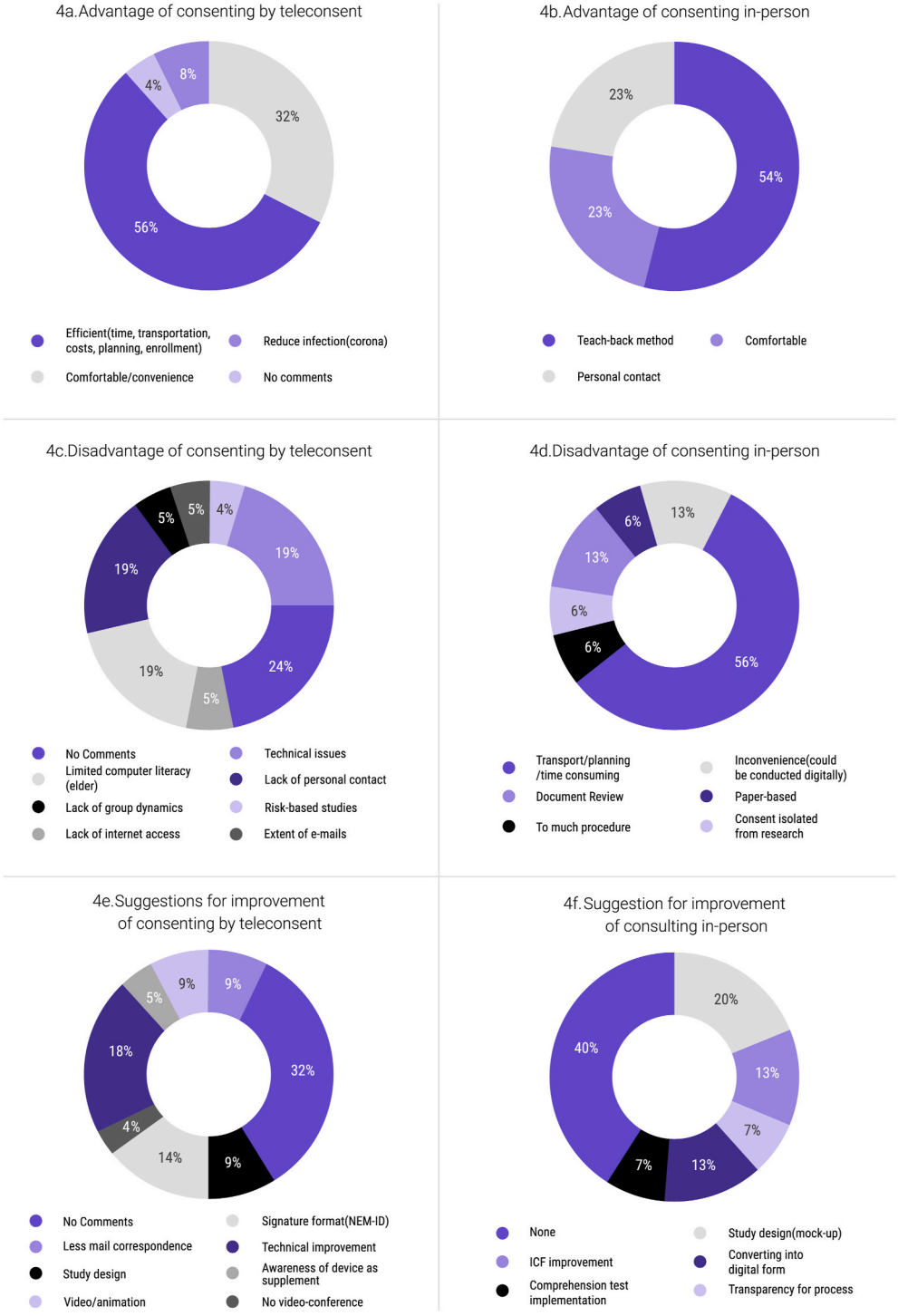

Fig. 4. Advantages, disadvantages, and suggestions for improvement
4a: Advantages of consenting by teleconsent 4b: Advantages of consenting in-person 4c: Disadvantages of consenting by teleconsent 4d: Disadvantages of consenting in-person 4e: Suggestions for improvement of consenting by teleconsent 4f: Suggestions for improvement of consenting in-person.

3.7. General feedback

The categories for each section are presented in Fig. 4 (panels 4a-4f).

3.8. Advantages

Participants within each consenting group were asked to mention the greatest advantage of the consenting procedure they had just experienced (Fig. 4a/4b). Advantages of using the teleconsent approach included efficiency in terms of time, transportation, planning, allowing more participants to enter the study (enrollment), and the convenience/comfort in consenting from home. The teleconsent users also recognized the advantage of using teleconsent during the pandemic to avoid infection. In contrast, participants consenting in person highlighted the teach-back method of conducting informed consent as the main advantage. Additionally, they considered comfortability and personal contact equally beneficial for consenting in-person (Fig. 4b).

3.9. Disadvantages

The disadvantages for the teleconsent approach were variated and included technical issues (19%), computer literacy (19%) and lack of personal contact (19%) (Fig. 4c). Conversely, personal contact was considered a major advantage for participants consenting in-person (Fig. 4d). The participants consenting in-person mentioned transportation, planning, and time as the greatest disadvantages, which were the greatest advantages of the teleconsent approach. Additionally, a few participants consenting in-person mentioned disadvantages of the teach-back method and the time taken to review the document.

3.10. Suggestions for improvements

Participants were asked to suggest improvements for the consenting approach they had just experienced. For the teleconsent approach, suggestions were mainly technologically based (18%) (Fig. 4e). Several participants suggested converting the signature format into NEM-ID to avoid the username and password (14%). A few participants suggested less mail correspondence (9%) and implementation of short explanatory videos or animations (9%) to improve the teleconsent experience visually. Some participants suggested study design improvements for in-person consent, especially focusing on the premise that the informed consent was isolated from actual research (20%) (Fig. 4f). Those participants suggested the informed consent document be sent beforehand, conducting the informed consent discussion digitally or by phone, and signing the document at the site when the clinical trial was conducted.

4. Discussion

This study aimed to compare in-person consent with teleconsent in terms of comprehension, demographics, convenience, security, and satisfaction in overall, young (aged 22–37), and older cohorts (aged 47–71).

4.1. Enrollment, dropout rate, geographical location, convenience

Similar to other findings [10], enrollment was fast in the teleconsent group. Although we recruited 30 people for each arm, 14 people dropped out of the in-person consent group, and 9 dropped out of the teleconsent group. While this difference was not significant, it is worth noting that more people dropped out in the traditional consenting group, mainly citing transportation and time, indicating that retainment might also be improved by teleconsent. Those who stayed enrolled in the in-person arm tended to reside closer to the clinic, and those in the teleconsent group represented a dispersed geographical area, indicating that teleconsent may be a valuable mechanism to enroll participants from more diverse geographical locations, as would be the case in a decentralized trial with remote consent. Similarly, when questioned about convenience, participants in the in-person arms ranked transportation and time used on transport as more of a difficulty than those in the teleconsent arm. Thus, offering teleconsent may provide flexibility and convenience for patients, especially those farther away from the clinic. These findings are in agreement with previous work, where a preference for remote consent is demonstrated for sensitive issues [11,12].

4.2. Comprehension and satisfaction

Similar to another study [13], we found no significant difference in comprehension or satisfaction between the two arms. Due to the small sample size in this pilot study, the older cohort ranged in age from 47 to 71, and in the teleconsent arm, the most senior person was 63. Additionally, our study population had a relatively high education level, which has formerly been demonstrated to impact preferences for consent approaches [14]. Therefore, future studies should be powered to discern differences for older age ranges and differing education levels. Recent studies demonstrated a non-significant difference in comprehension scores for an older cohort when using an e-consenting system with multimedia compared to a paper-based consent [4,5].

Although the application facilitated online videoconference interaction, this feature might not allow the full range of expressions of empathy needed for severe or high-risk conditions. The pandemic may have raised awareness of remote capabilities for medical care: in both arms of the study, participants preferred consenting from home during pandemic situations, and responses for non-pandemic situations were more varied.

4.3. Security

Security and privacy aspects of data access and data collection have been described as major concerns for participants who use remote consent, [1,15]. We found no difference in participants' perceptions of security between the two arms. Prioritizing transparency and limiting the amount of personal data collected for studies using e-consent has been recommended previously [16]. Therefore, we provided information on how and which type of data would be handled. Those over age 65 have noted privacy concerns compared to a younger control group [17], and future work should investigate teleconsent preferences with an adequate sample size for those over 65 and 75. The signature format (username and password) used in the teleconsent application was perceived as highly secure for Danish participants. Those in other countries might feel differently for a variety of reasons. For example, in a study involving German participants, many felt less comfortable signing an informed consent form (ICF) electronically, citing privacy and security concerns [3]. A primary reason for not implementing teleconsent or e-consent in general throughout Europe is the variable national legislation for accepting consent electronically. Country-specific differences in signature formats and the risk of faking or misinterpretation of patient identity provide problems for unified European acceptance of e-consent in general [7]. Country-specific differences in signature formats across Europe may threaten the acceptance of teleconsent. Teleconsent provides an interactive videoconference solution allowing identity verification (but not identity documentation). Other teleconsent applications offer the ability for researchers to attach a photo snapshot or a fingerprint to the patient's electronic signature to document patient identity [18]. However, this approach requires a database containing matchable photos/fingerprints and well-established algorithms to minimize false positives. Connecting identification to a signature has been established in Scandinavia due to a national registry, such as NEM-ID in Denmark. A few participants suggested the signature format could be based on NEM-ID (converted into MIT-ID) (Fig. 4). However, the purpose of this pilot study was to demonstrate the feasibility of teleconsent, with an ultimate goal of testing this more broadly in future decentralized clinical

trials that span many countries.

4.4. Limitations

The consent form we used was for a hypothetical study. This limits our ability to truly assess comprehension because someone enrolling in a trial for a disease may be in a different mental place than someone participating in the study regarding the consent process. In our study, all 37 participants were Danish, had a device of their own, were between the ages of 22 and 71, and many had high levels of education with high health literacy. Thus, while our enrolled population for this pilot study limits generalizability, it demonstrates feasibility. We also did not gather information on computer literacy, which may be necessary if other populations are included.

4.5. Future work

Future clinical research comparing teleconsent to in-person consent may need to broaden this population to include more individuals over the ages of 65 and 75, those from other countries, those with lower education and health literacy, and those with and without devices. If an older population were to be included, it might be beneficial focus on using the teleconsent application for tablets because tablets contain technological features suitable for older participants [4]. Future studies may also investigate the effect of multimedia (i.e., videos explaining the study, images, video animations) on comprehension when implemented within a teleconsent application. A screening tool may help ensure patients' consent capacity, and follow-up may be necessary to assess information retention levels.

5. Conclusion

Decentralized clinical trials have been demonstrated to increase recruitment and enrollment rates, improve trial efficiency, and decrease dropout rates and trial delays [19]. Delays due to inadequate patient recruitment and engagement and retention can result in high costs for pharmaceutical companies [19]. Teleconsent and e-consent are critical tools for decentralized trials, and we found the use of teleconsent to be comparable to in-person consent. Although we suggest that teleconsent is a feasible and acceptable substitution for in-person consent, patient perspectives from a larger, more diverse group of participants are needed.

Images are from Medable's teleconsent application.

Funding

No financial support beyond the author's employment is reported for this publication.

Authors' contributions

AG came up with the concept of the work as part of her Master's thesis in Industrial Medicine, MD and RH were the supervisors for the thesis work. All authors contributed to the data interpretation, writing and revising the manuscript critically for important intellectual content and approved the final version.

Conflicts of interest/Competing interests

MD and AG report no conflicts of interest. RH is an employee of Medable, the company that developed the teleconsent app.

Data availability

Data will be made available on request.

Acknowledgements

No specific funding was utilized for this article. The views represented are those of the authors and do not specifically reflect the views of their employers. Anne would like to thank Morten Lund for the time and help in questionnaire revisions and all the participants who supported the study through their participation.

References

[1] B.E. Bunnell, G. Sprague, S. Qanungo, et al., An exploration of useful telemedicine-based resources for clinical research, Telemed J E Health 26 (1) (2020) 51–65, https://doi.org/10.1089/tmj.2018.0221.
[2] S. Khairat, P. Ottmar, B. Sleath, et al., Facilitating the informed consent process using teleconsent: protocol for a feasibility and efficacy study, JMIR Res Protoc 7 (10) (Oct 17 2018), e11239, https://doi.org/10.2196/11239.
[3] H. Vanaken, S.N. Masand, Awareness and collaboration across stakeholder groups important for eConsent achieving value-driven adoption, Therapeut. Innovat. Regul. Sci. 53 (6) (2019) 724–735, https://doi.org/10.1177/2168479019861924.
[4] N. Jayasinghe, B.I. Moallem, M. Kakoullis, et al., Establishing the feasibility of a tablet-based consent process with older adults: a mixed-methods study, Gerontol. 59 (1) (2019) 124–134, https://doi.org/10.1093/geront/gny045.
[5] A.H. Warriner, P.J. Foster, A. Mudano, et al., A pragmatic randomized trial comparing tablet computer informed consent to traditional paper-based methods for an osteoporosis study, Contemp Clin Trials Commun 3 (Aug 15 2016) 32–38, https://doi.org/10.1016/j.conctc.2016.02.003.
[6] E. De Sutter, D. Zace, S. Boccia, et al., Implementation of electronic informed consent in biomedical research and stakeholders' perspectives: systematic review, J. Med. Internet Res. 22 (10) (Oct 8 2020), e19129, https://doi.org/10.2196/19129.
[7] (Medidata. Electronic Informed Consent in Clinical Research. White paper).
[8] European Medicines Agency, Guidance on the management of clinical trials during the covid-19 (coronavirus) pandemic. Version 4: april 2, 2021, Available at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/guidance clinicaltrials_covid19_en.pdf. (Accessed 28 October 2021).
[9] H. Pander Maat, M.L. Essink-Bot, K.E. Leenaars, M.P. Fransen, A short assessment of health literacy (SAHL) in The Netherlands, BMC Publ. Health 14 (Sep 23 2014) 990, https://doi.org/10.1186/1471-2458-14-990.
[10] T. Newlin, T. McCall, P. Ottmar, B. Welch, S. Khairat, Assessing the Satisfaction of Citizens Using Teleconsent in Clinical Research, 2021, pp. 685–689.
[11] C. Sommer, D. Zuccolin, V. Arnera, et al., Building clinical trials around patients: evaluation and comparison of decentralized and conventional site models in patients with low back pain, Contemp Clin Trials Commun 11 (Sep 2018) 120–126, https://doi.org/10.1016/j.conctc.2018.06.008.
[12] S. Daniel, S. Raifman, S. Kaller, D. Grossman, Characteristics of patients having telemedicine versus in-person informed consent visits before abortion in Utah, Contracept. 101 (1) (2020) 56–61, https://doi.org/10.1016/j.contraception.2019.08.010.
[13] M.R. Bobb, P.G. Van Heukelom, B.A. Faine, et al., Telemedicine provides noninferior research informed consent for remote study enrollment: a randomized controlled trial, Acad Emerg Med 23 (7) (2016) 759–765, https://doi.org/10.1111/acem.12966.
[14] D.C. Haussen, L. Craft, S. Doppelheuer, et al., Legal authorized representative experience with smartphone-based electronic informed consent in an acute stroke trial, J Neurointerv Surg 12 (5) (2020) 483–485, https://doi.org/10.1136/neurintsurg-2019-015283.
[15] S. Khairat, K. Tirtanadi, P. Ottmar, B. Sleath, J. Obeid, Evaluating the perceptions of teleconsent in urban and rural communities, Eur J Biomed Inform (Praha) 15 (2) (2019) 1–10. https://www.ejbi.org/abstract/evaluating-the-perceptions-of-teleconsent-in-urban-and-rural-communities-5201.html.
[16] C.M. Simon, H.A. Schartz, G.E. Rosenthal, E.L. Eisenstein, D.W. Klein, Perspectives on electronic informed consent from patients underrepresented in research in the United States: a focus group study, J Empir Res Hum Res Ethics 13 (4) (Oct 2018) 338–348, https://doi.org/10.1177/1556264618773883.
[17] M. Doerr, A. Maguire Truong, B.M. Bot, J. Wilbanks, C. Suver, L.M. Mangravite, Formative evaluation of participant experience with mobile eConsent in the app-mediated Parkinson mPower study: a mixed methods study, JMIR Mhealth Uhealth 5 (2) (Feb 16 2017) e14, https://doi.org/10.2196/mhealth.6521.
[18] B.M. Welch, E. Marshall, S. Qanungo, et al., Teleconsent: a novel approach to obtain informed consent for research, Contemp Clin Trials Commun 3 (Aug 15 2016) 74–79, https://doi.org/10.1016/j.conctc.2016.03.002.
[19] H. Moseson, S. Kumar, J.L. Juusola, Comparison of study samples recruited with virtual versus traditional recruitment methods, Contemp Clin Trials Commun 19 (2020), 100590, https://doi.org/10.1016/j.conctc.2020.100590.