

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A self-directed multimedia process for delivering participant informed consent
AUTHORS	Chapman, Niamh; McWhirter, Rebekah; Armstrong, Matthew; Fonseca, Ricardo; Campbell, Julie; Nelson, Mark; Schultz, Martin; Sharman, James

VERSION 1 – REVIEW

REVIEWER	Peter Knapp University of York, UK
REVIEW RETURNED	30-Jan-2020

GENERAL COMMENTS	<p>This is an interesting and potentially useful article. The RCT methods have been designed and reported well.</p> <p>I have two concerns: first, that the statistics are not reported in full – the methods section reports the statistics intended to be used for the analysis. The results section reports the p values but not the statistics – this should be amended. Also in Table 3 it's unclear which analyses have been used. The question on information sufficiency is (I think) a categorical variable and so there will only be one statistical calculation (possibly Chi-squared) and a single p value. Currently Table 3 reports four p values. Similarly the question in table 3 on delivery preferences is categorical (if people could only choose one option) and so a single p value is required.</p> <p>I thought the conclusions were a little over-stated. The study may show that multi-media provision is possible but it is only one study & one setting and not very large – and the implications should be more measured.</p> <p>Finally it was unclear whether patients could have recourse to contacting anyone if they had questions about the research or their participation in it. This would be essential and I am surprised it was not requested by the research ethics committee – could this be clarified?</p>
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REVIEWER	Stephanie Kraft Seattle Children's Research Institute, USA
REVIEW RETURNED	03-Feb-2020

GENERAL COMMENTS	This manuscript addresses the important ethical question of how to engage prospective participants in an informed consent process that uses standalone multimedia. I have a few concerns regarding how it is framed and the conclusions that it draws.
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	<p>First, the introduction frames this study as being about multimedia consent, but it seems to be more specifically about the use of self-directed consent or e-consent; there is not much discussion of the features of the multimedia itself or how those influence people's decisions. It would be helpful to the reader to rework the introduction, and probably the title as well, to focus more on the "standalone" aspect of it.</p> <p>Second, how was it decided what information would go in the required versus optional multimedia? There is mention of community involvement - what was the process? Who decided what was important enough to be mandatory? Also, how long was the optional portion? Did participants know how long it would be before clicking on it? Relatedly, how did you determine which questions would be used to assess understanding? It is hard to draw conclusions about the value of the "optional" information in relation to the results on understanding, because it appears that there were no questions asked about the information in this section.</p> <p>Third, a small point, I do not know what the finding about "engaging with the study" means. Please clarify what this means.</p> <p>Fourth, the discussion describes this study as increasing generalizability of research on multimedia beyond "special populations," but there have been other studies of multimedia interventions across a variety of populations. Also, this section should more explicitly acknowledge the limitation of this participant population and avoid implying that findings in this group of older, mostly white patients are more generalizable than other groups.</p> <p>Fifth, it is not clear what to make of the finding that very few participants wanted research staff present during consent. How was this question worded and what were the answer options? Was it that only 4% thought someone MUST be present, or that only 4% wanted the option of asking someone for help?</p> <p>Sixth, the discussion of engagement with the optional audio is hard to interpret without more information. Did they know what information was in these parts and decided they didn't need it? Was it framed as "extra"? Did you have a way to measure whether participants in the control group read any/all of the second page? And, to repeat my earlier question, did you compare understanding of any of the topics in these sections between groups?</p> <p>Seventh, the section on health economics savings seemed unrelated to much of the prior results and discussion. First, in this study only 4 people in the control group asked for staff assistance, which seems like a low staff burden in both groups and not significant enough to create major cost savings. Second, is there any evidence to suggest that improved understanding of participation is linked to cost savings? If this argument is to be made, it needs to be better fleshed out and supported. Also, this part discusses understanding of risks and benefits, but as I understand it, these were in the optional audio and participants' understanding of risks and benefits were not assessed.</p> <p>Eighth, while I agree that a benefit of multimedia consent is that it can support standardized delivery, the discussion previously</p>
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	argued that it was good for participants to be able to choose which parts of the consent they wanted to review. I don't believe these two findings are necessarily incompatible, but the authors should clarify their views on this.
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VERSION 1 – AUTHOR RESPONSE

Response to reviewers

We thank reviewers for their time and prompt feedback on our manuscript.

Additions to the manuscript are highlighted in yellow.

Reviewer 1

Comment 1: first, that the statistics are not reported in full – the methods section reports the statistics intended to be used for the analysis. The results section reports the p values but not the statistics – this should be amended.

Response: As suggested, the statistical test performed has been added to the results as a footnote to the tables to clearly state that the p values in the table relate to the chi-squared test for comparison of categorical variables and t test for continuous variables, as shown below.

Page 18, Table 2:

P values relate to the chi-squared test used for comparison of categorical variables and t test for continuous variables.

Page 19, Table 3:

The chi-squared test was used for comparison of categorical variables.

Comment 2: Also in Table 3 it's unclear which analyses have been used. The question on information sufficiency is (I think) a categorical variable and so there will only be one statistical calculation (possible Chi-squared) and a single p value. Currently Table 3 reports four p values. Similarly the question in table 3 on delivery preferences is categorical (if people could only choose one option) and so a single p value is required.

Response: As suggested, the categorical variable on delivery preferences has been amended to report a single p value. As mentioned in our response to the previous comment above, the statistical test used is now reported in the footer of the table.

Comment 3: I thought the conclusions were a little over-stated. The study may show that multi-media provision is possible but it is only one study & one setting and not very large – and the implications should be more measured.

Response: As suggested, the conclusions have been toned down and also modified so that it is clear we have only studied a specific population. The section now reads as follows:

Page 12, lines 313-316:

A self-directed, multimedia consent process free from research staff was effective and acceptable to deliver participant information and receive informed consent in a middle-to-older age population. Our findings suggest that multimedia consent processes may be suitable for reducing the burden on research staff and improving the delivery of consent for research.

Comment 4: Finally it was unclear whether patients could have recourse to contacting anyone if they had questions about the research or their participation in it. This would be essential and I am surprised it was not requested by the research ethics committee – could this be clarified?

Response: Contact details in which patients could have recourse for more study information were provided on the study postcard for each person. A statement to this effect has been added to the methods section as copied below. The consent process for both the traditional and multimedia approach, including all materials, were reviewed and approved by community advisors and the local human research ethics committee. This information is already contained in the manuscript.

Page 5, lines 120-122:

Referred patients that met the criteria for participation received a postcard that contained basic information about the study and contact details for more information (Supp 1, Study Postcard).

Reviewer 2

Comment 1: First, the introduction frames this study as being about multimedia consent, but it seems to be more specifically about the use of self-directed consent or e-consent; there is not much discussion of the features of the multimedia itself or how those influence people's decisions. It would be helpful to the reader to rework the introduction, and probably the title as well, to focus more on the "standalone" aspect of it.

Response: As requested, the title, abstract and introduction have been amended to explicitly reference "self-directed" when discussing multimedia in the context of this research study and consent in the absence of research staff.

Comment 2: Second, how was it decided what information would go in the required versus optional multimedia? There is mention of community involvement - what was the process? Who decided what was important enough to be mandatory? Also, how long was the optional portion? Did participants know how long it would be before clicking on it? Relatedly, how did you determine which questions would be used to assess understanding? It is hard to draw conclusions about the value of the "optional" information in relation to the results on understanding, because it appears that there were no questions asked about the information in this section.

Response: Firstly, all information from the information sheet was provided and neither the video or audio were described as mandatory or optional to participants. Designation of video or audio was detailed in the methods section as follows:

Page 6, lines 138-145:

"Intervention participants received study participation information via multimedia approach using a three-minute animated video and separate audio content using the same terminology and content as the paper-based study participant information sheet. The study video was congruent with the first page of the information sheet and focused on the aims and requirements of the study (Supp 2. Study Video). The separate audio content was congruent with the second page of the information sheet and provided information on study funding, ethical approval, risks and benefits associated with participation and privacy protection, which was clearly labelled."

Secondly, additional information has been added to the methods section to provide further detail on the process for community involvement as detailed below:

Pages 6-7, lines 153-156:

"An iterative process was undertaken with community advisors to develop consent materials, with initial drafts completed by researchers. Community advisors provided several rounds of feedback (and final approval) on all consent materials, including the information sheet, postcard, video and audio recordings."

Thirdly, information on the duration of the audio component has been added to the methods section of the manuscript as shown below. Information on duration of video and audio content was not visible to participants, a statement has been added to the discussion of the manuscript as shown below.

Page 6, lines 142-146:

"The separate audio content was congruent with the second page of the information sheet and provided information on study funding, ethical approval, risks and benefits associated with participation and privacy protection, which was clearly labelled. Each audio segment was approximately 30 seconds in duration. Participants were shown how to play the audio content as part of the app demonstration."

Page 11, lines 309-311:

"Additionally, the duration of video and audio content was not visible to participants before selection, which may have deterred some participants from engaging with this information and should be rectified in the future."

Lastly, true or false questions were used to determine understanding, developed by a researcher with expertise in evaluating consent and reviewed by community advisors as detailed in the manuscript methods and shown below. Efficacy, usability and acceptability were assessed of the consent process as a whole and not specifically of the information provided on the second page of the information

sheet or the separate audio. This is a limitation of the study, a statement to this effect has been added to the strengths and limitations section of the manuscript as shown below.

Page 7, lines 169-172

“The effectiveness of the allocated consent processes to inform participants about the study was assessed via two measures: 1) the extent to which participants understood participation was voluntary and 2) participant understanding of specific aspects of study participation by true or false questions.”

Page 11, lines 305-309:

“Efficacy, usability and acceptability were assessed of the consent process as a whole and not specifically of the information provided on the second page of the information sheet or the separate audio in the multimedia consent process. Consequently, we cannot draw definitive conclusions on these different aspects of the consent process.”

Comment 3: Third, a small point, I do not know what the finding about "engaging with the study" means. Please clarify what this means.

Response: The methods and discussion of manuscript has been amended to clarify this point as follows:

Page 7, lines 172-179:

“Four measures denoting user-friendliness of the allocated consent processes were used to indicate usability: 1) participant engagement with the study information by reading, watching or listening, 2) participant perceived understanding of the study, 3) successful completion of the consent process and 4) the time taken to complete the consent process. The app automatically recorded the time for both groups as the app set-up and demonstration took place before the consent process. The time included the set-up, the consent process and the cardiovascular assessment questionnaire. All other parameters were measured by self-report questionnaire.”

Page 10, lines 255-257:

“This indicates that engaging with all study information, by reading, watching or listening, is not necessarily a priority for making an autonomous choice for most participants and is highly individual.”

Comment 4: Fourth, the discussion describes this study as increasing generalizability of research on multimedia beyond "special populations," but there have been other studies of multimedia interventions across a variety of populations. Also, this section should more explicitly acknowledge the limitation of this participant population and avoid implying that findings in this group of older, mostly white patients are more generalizable than other groups.

Response: As suggested, the discussion and strengths and limitations section of the manuscript have been modified to reiterate the study population and acknowledge the potentially limited generalisability of the findings as follows:

Pages 9, lines 240-244:

“Our findings, in a middle-to-older population without specific support needs, further develop this knowledge beyond a special population and in a larger sample to confirm that a self-directed multimedia platform may be useful among populations without special needs, such as community dwelling, older adults (i.e. average age 63 years).”

Page 11, lines 297-299:

“We cannot be sure whether the findings will be generalisable beyond our study population of middle-to-older age, mostly white adults with high levels of education attainment, and this will need to be tested in future.”

Comment 5: Fifth, it is not clear what to make of the finding that very few participants wanted research staff present during consent. How was this question worded and what were the answer options? Was it that only 4% thought someone MUST be present, or that only 4% wanted the option of asking someone for help?

Response: This question asked participants their preferred mode of information delivery for the consent process. Participants were asked to choose one option from the following categorical options:

1. Paper or written document
2. Video
3. Audio

4. Video and audio
5. Any of those/no preference
6. A researcher must be present.

Video and/or audio preferences were grouped into “multimedia” in the presentation of results. Only 4% of participants reported that a researcher must be present for the consent process. To clarify this point the following amendment has been made to the manuscript:

Page 9 lines 219-221:

“Only 4% of participants reported that a researcher must be present for the consent process and there was no difference between groups.”

Comment 6: Sixth, the discussion of engagement with the optional audio is hard to interpret without more information. Did they know what information was in these parts and decided they didn't need it? Was it framed as "extra"? Did you have a way to measure whether participants in the control group read any/all of the second page? And, to repeat my earlier question, did you compare understanding of any of the topics in these sections between groups?

Response: Firstly, participants were shown how to play the audio, with clear content headings, as part of the app demonstration. Second, the manuscript has been modified to reflect that this was separate audio to the video rather than “additional” or “extra”. A statement to clarify both points has been added to the manuscript as detailed below:

Page 6, lines 142-146:

“The separate audio content was congruent with the second page of the information sheet and provided information on study funding, ethical approval, risks and benefits associated with participation and privacy protection, which was clearly labelled. Each audio segment was approximately 30 seconds in duration. Participants were shown how to play the audio content as part of the app demonstration.”

Third, a self-report question on engaging with study information was used to measure whether participants read any/all of the information sheet or watched the studio video and listened to the separate audio component. These data have been added to the results section as shown below.

Page 8, lines 201-208:

“Intervention participants demonstrated better understanding of the follow-up requirements and data sharing practices of the study compared with control participants (Table 2, $P < 0.001$ and $P = 0.025$, respectively). Intervention participants were more likely to spend more time on the consent process and study questionnaire ($P = 0.006$). Altogether, more intervention participants engaged with any form of study information compared to control participants. However, when the section of the information sheet that was congruent with the audio component were compared, only 9% of intervention participants listened to the separate audio and 35% of control participants read the second page of the information sheet.”

Finally, a statement has been added to the strengths and limitations section of the manuscript to highlight the efficacy, usability and acceptability of the second page of the information sheet and the separate audio component were not specifically assessed as stated below.

Page 11, lines 305-309:

“Efficacy, usability and acceptability was assessed of the consent process as a whole and not specifically of the information provided on the second page of the information sheet or the separate audio component of the multimedia consent process. Consequently, we cannot draw definitive conclusions on these different aspects of the consent process.”

Comment 7: Seventh, the section on health economics savings seemed unrelated to much of the prior results and discussion. First, in this study only 4 people in the control group asked for staff assistance, which seems like a low staff burden in both groups and not significant enough to create major cost savings. Second, is there any evidence to suggest that improved understanding of participation is linked to cost savings? If this argument is to be made, it needs to be better fleshed out and supported. Also, this part discusses understanding of risks and benefits, but as I understand it, these were in the optional audio and participants' understanding of risks and benefits were not assessed.

Response: As suggested, the discussion has been amended to draw on specific data from the results as detailed below. We agree that further evidence would be needed to discuss cost savings linked to participant understanding and, therefore, reference to this has been removed. Other aspects of potential cost savings are retained.

Page 10, lines 262-273:

“A key benefit of the self-directed consent process evaluated in this research, is its potential to improve participant understanding of study information while reducing the burden of consent for research staff. Another key advantage is the possible economic benefit. Current healthcare consumers and research participants are highly ‘information-savvy’ and may seek the delivery of information from different platforms or prefer diverse options for information delivery such as multimedia.[27] We suggest that the benefits of better delivery of consent information will drive cost savings both in the short and longer terms. Short term savings include the cost of time and the uptake of information that is more beneficial (and better understood) by the participant including understanding participation requirements. Longer term savings could include cost savings through widespread uptake of self-directed multimedia consent processes to reduce staff burden (noting that only 4 participants asked for staff assistance in our study).”

Comment 8: Eighth, while I agree that a benefit of multimedia consent is that it can support standardized delivery, the discussion previously argued that it was good for participants to be able to choose which parts of the consent they wanted to review. I don't believe these two findings are necessarily incompatible, but the authors should clarify their views on this.

Response: We agree that this point needed to be more clearly linked between the paragraphs in the discussion and have amended accordingly.

Pages 10-11, lines 276-281:

“Multimedia tools offer an inherently standardised method of information delivery, as the delivery is predetermined, that would otherwise be difficult to achieve in standard consent processes undertaken in multi-site research projects with large staff teams. As demonstrated in this study, a self-directed multimedia consent process allows flexibility to engage with study information relevant to support participant decision making while also ensuring the delivery of that information is standardised for each participant.”

VERSION 2 – REVIEW

REVIEWER	Peter Knapp University of York, UK.
REVIEW RETURNED	16-Apr-2020

GENERAL COMMENTS	The authors have responded thoroughly to the review comments and, in my view, the paper has been improved.
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REVIEWER	Stephanie Kraft Seattle Children's Hospital and Research Institute and University of Washington School of Medicine, Seattle, WA, USA
REVIEW RETURNED	24-Apr-2020

GENERAL COMMENTS	Thank you for the opportunity to review this revised manuscript, which I believe will be a valuable contribution to the literature on informed consent. All of my prior comments have been adequately addressed.
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