

Does app-based consent enhance participant comprehension and satisfaction by parents in pediatric clinical research? - A randomized controlled equivalence trial

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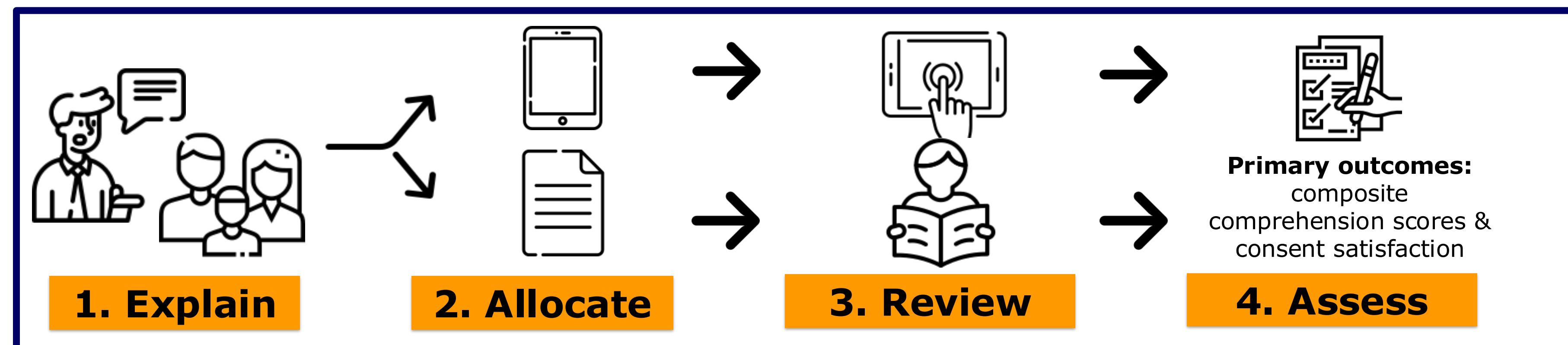
Background

- Fewer in-person hospital visits and increased implementation of virtual care = fewer opportunities for research recruitment¹
- Presents the opportunity to implement electronic consenting processes^{2,3}
- App-based consent:** limited comprehensive evaluation in pediatric settings = more information required to improve feasibility and acceptability⁴

Objectives

- Investigate the effectiveness of app-based versus paper consent
- Determine if app-based consenting methods increase trust in research

Methods



REB-approved non-inferiority randomized controlled trial of app-based versus paper consent

Sample size: ~ 120 parents of children being enrolled in a separate study that runs in tandem under the same ethical approval

Analysis: Wilcoxon rank sum tests for the differences between

- Composite correctness scores of multiple-choice questions, using a non-inferiority target of 2.5/4 points with a margin of 0.5 points for comparison
- Groups compared elementwise for Likert scale questions

Results

Demographics (n = 120)

- 85 (71%) female; 16 (13%) <30, 80 (67%) 30-39, 22 (18%) 40-49 years, and 2 (2%) >50 years old
- 62 paper (control) consent and 58 app-based (intervention) consent

Primary outcome and secondary outcomes:

- Comprehension:** Median composite comprehension scores were 3.0/4.0 [IQR (interquartile range) 2.5, 3.5] for paper and 3.5/4.0 [2.5, 4.0] app-based consent; median difference: 0.0 (95% CI -0.5 to 0.0), p=0.481. Participants responded to each question similarly (Figure 1)
- Satisfaction & trust ratings:** Participants rated satisfaction and trust statements similarly (Figure 2)
- 16/33 (49%) participants who experienced paper-based and 17/30 (57%) app-based consent felt their consenting process was better than others.

Limitations:

- Use of a simulated, not fully-functioning app
- Parental consent only
- Simple evaluation

Future Research:

- Creation of a functional app
- Usage of accessibility tools (auto-translation, speech-to-text, etc.) to accommodate a wider variety of patients

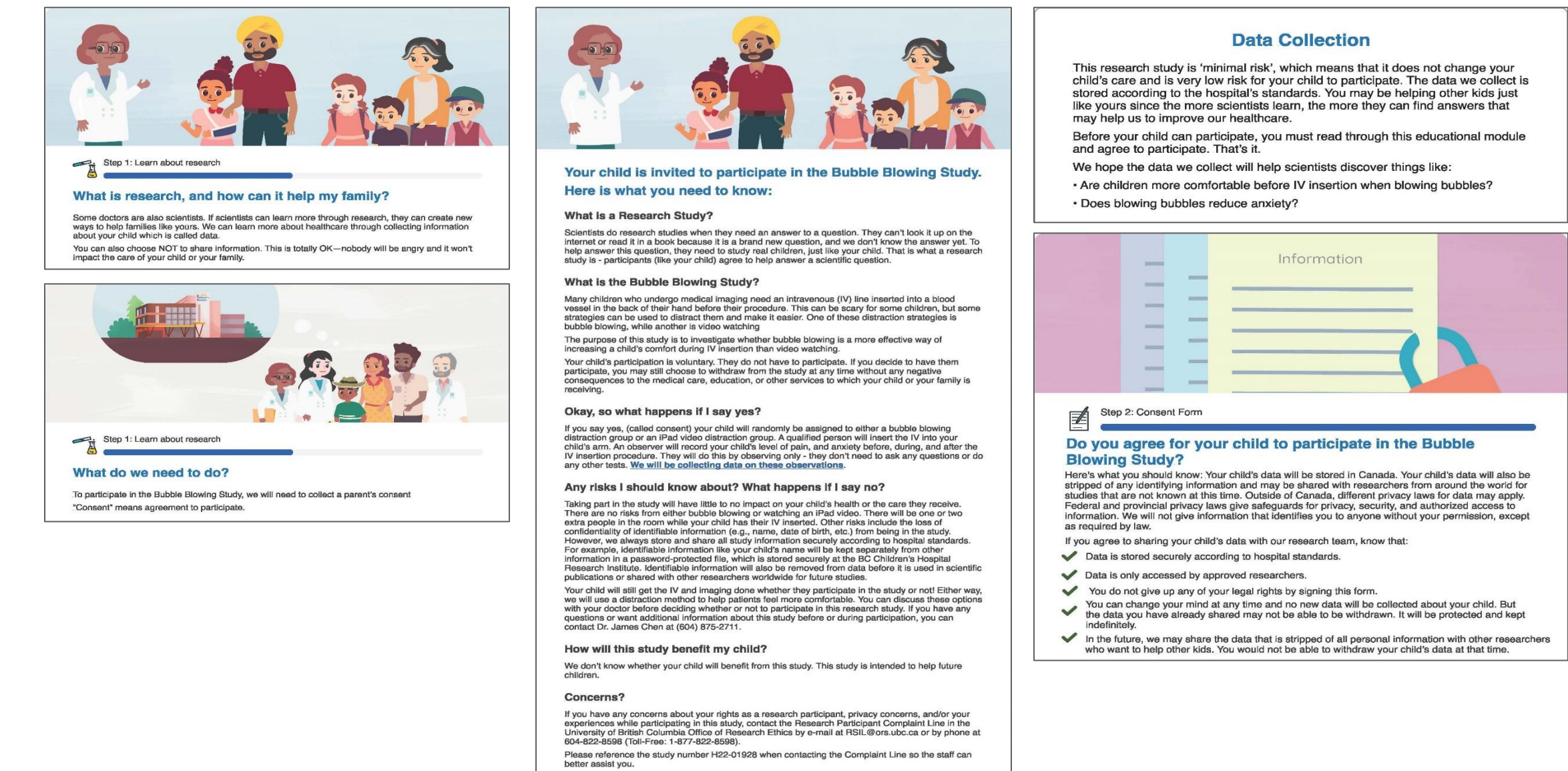
App-based consent did not diminish comprehension, satisfaction, or trust in the pediatric clinical research setting



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App-based consent design

Figure 1: Screenshots of app-based consent forms implemented as a REDCap project using their eConsent framework. The forms were personalized using Consent App Figma designs, images, subsections to click through, and colors.



Comprehension

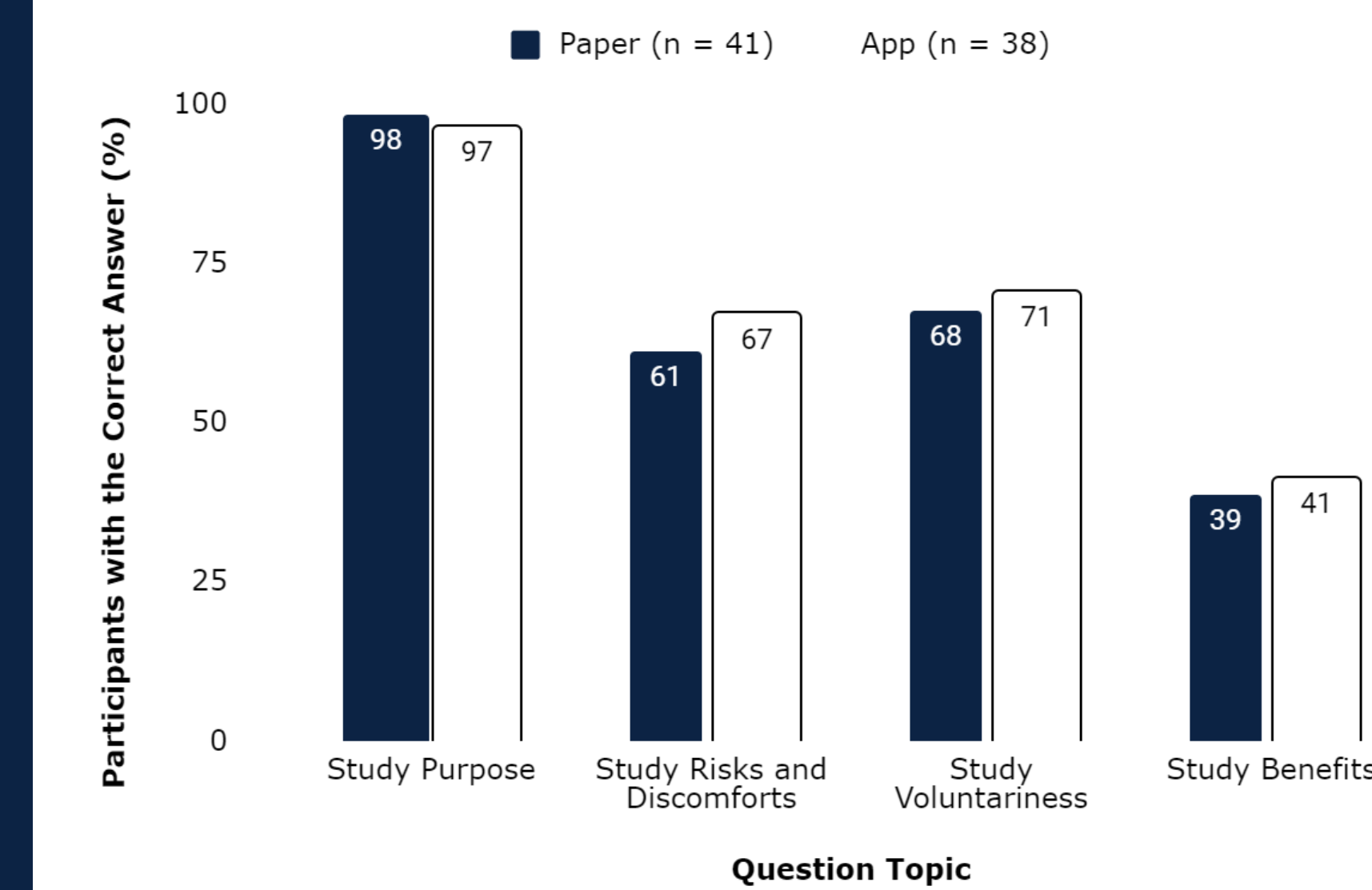


Figure 1: Percentage of participants with the correct answer for each question.

Participants in each group answered four multiple-choice questions regarding information found in the study consent form. No difference between paper and app-based groups was found in the study comprehension scores.

Satisfaction & Trust

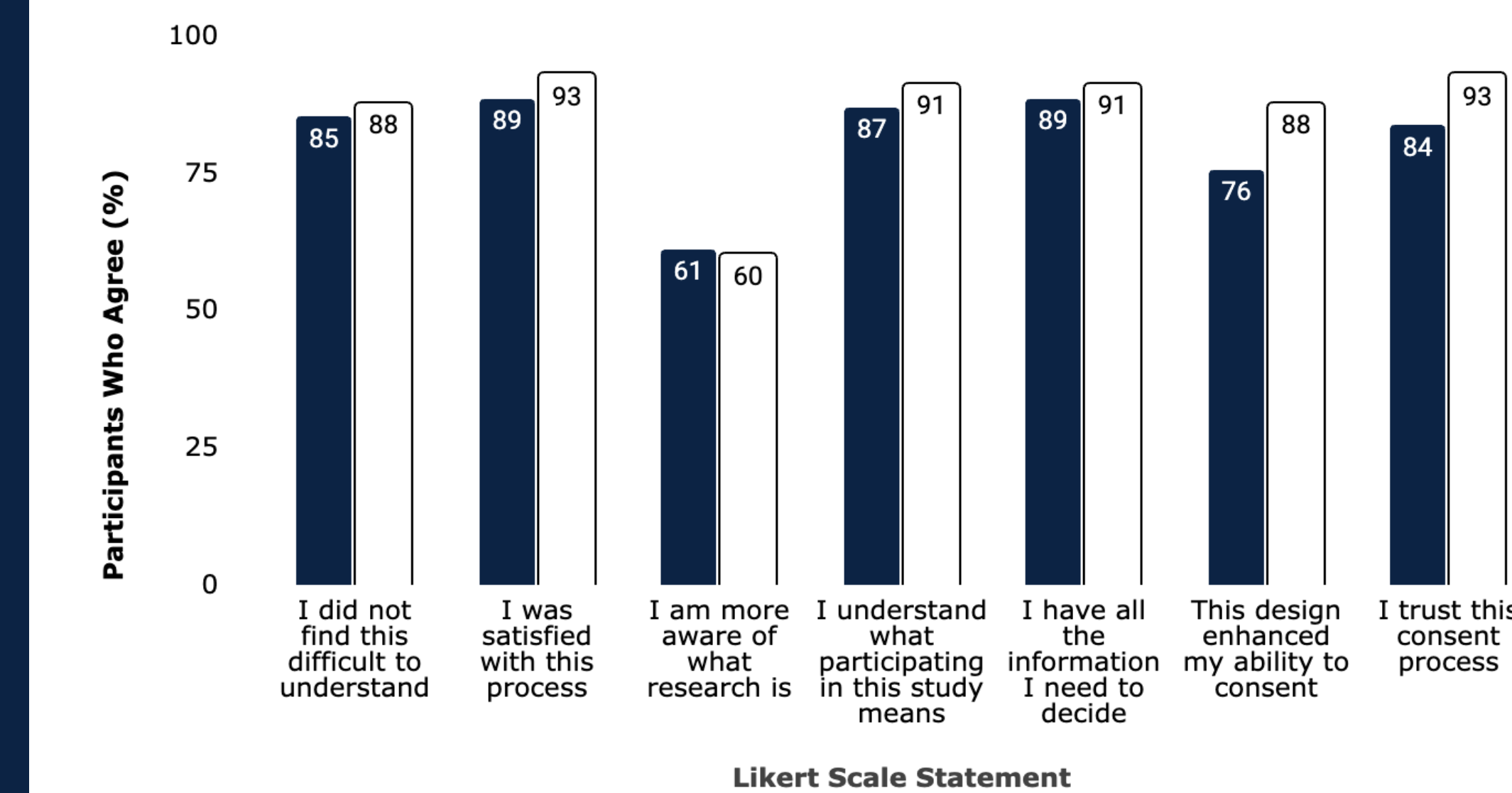


Figure 2: Percentage of participants who agreed with Likert scale statements regarding consent satisfaction and trust.

Participants in each group assessed each statement regarding the consenting process on a Likert scale. There was no difference between paper and app-based groups in satisfaction or trust ratings.

Acknowledgements



References

- PLoS One. 2013;8(3):e58603 [2] J Empir Res Hum Res Ethics. 2020;15(4):252-260
- Contemp Clin Trials Commun. 2016;17(3):32-38
- JMIR Mhealth Uhealth. 2017;5(2):e14.