EVALUATION OF A GROUP-BASED ONLINE INFORMED CONSENT CONVERSATION (ECONSENT) IN PARTICIPANTS FROM A VACCINATION CLINICAL TRIAL: A MIXED METHOD STUDY

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INTRODUCTION

- Use of eConsent has expanded during the pandemic.
- Slow recruitment rate, limited reach to participants from different backgrounds are some challenges in clinical research.
- Given the benefits of eConsent and group counselling reported in literature, group eConsent was used in recruitment for SWITCH ON study.
- Aim: exploring the experience of participants with group eConsent and evaluate the potential of this tool for future use.

METHOD

- SWITCH ON study aims to analyse the immunogenicity of healthy population following bivalent COVID-19 booster vaccination.
- 434 healthcare workers aged between 18 to 65 were recruited and sent a questionnaire about their experience with group eConsent.
- Out of 399 completed questionnaire received, 360 responses were from participants who attended group eConsent
- Descriptive analyses were used for quantitative data and thematic analyses were used for qualitative data

CONCLUSION

- Group eConsent can be an effective tool for research recruitment with further optimisations to overcome the limitations raised by participants.
- Using webinars to provide general information about the study, followed by an individual session for each participant will retain the benefits of group eConsent and minimise the limitations it posed.

Group eConsent settings

- Consent sessions were organised as a group meeting.
- Participants were informed of this setting and advised to book 1:1 meeting with the study team if preferred.
- During the group session, information about the study was given and there was time for questions.
- After all questions have been addressed, participants would stay in the webinar to sign the consent form if they want participate in the study.

RESULT

Experience with group eConsent

"How do you feel about having other participants in your consent session?" 0 - 10 (negative to positive) Score: 8 [IQR: 6-9]

Advantages of group eConsent

Hearing questions from others

"It is indeed nice to hear others' questions. In this way, more questions can be asked and answered, which ultimately makes me better informed"

Disadvantages of group eConsent

Sense of togetherness

"It was quite nice to see other fellow participants and it was also nice that together we can make this study possible"

Efficient and flexible

Privacy

"For certain studies I would indeed not want others to see that I am participating. For this study, I don't find that a problem, but when it comes to studies in a certain patient population, for example, I wouldn't appreciate potentially running into someone I know"

Barriers to asking questions

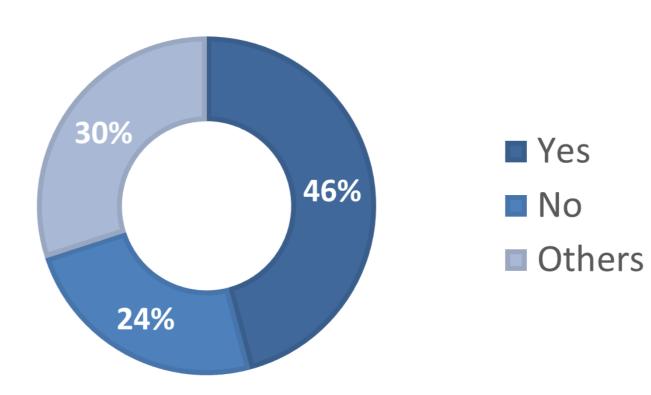
The session is longer than needed

Peer pressure

"Peer pressure to give consent, not necessarily experienced that way myself, but I did notice that it is harder not to give consent"

Considerations for group eConsent

"Healthy volunteers participate in the SWITCH ON study. Do you think this method of informed consent can also be used in studies involving people with a disease or condition?"

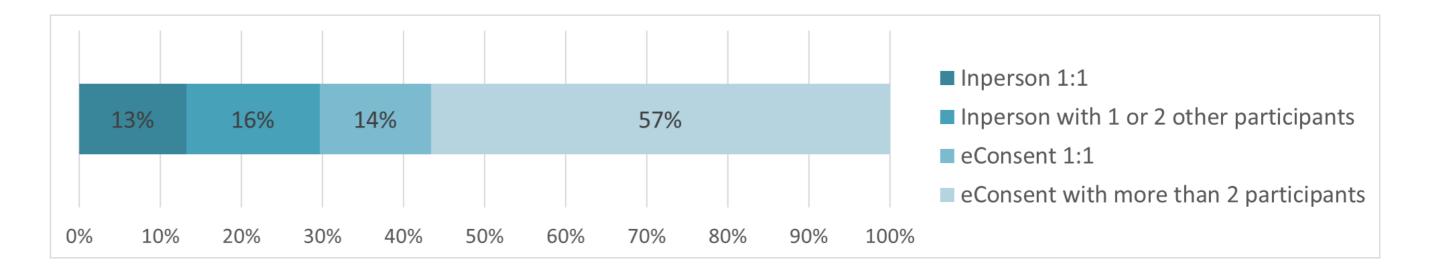


Group eConsent is possible as one of the options, not the only option

Depending on the study population

"I think that depends on what kind of disease is involved. For some diseases people can be ashamed, so maybe they don't like being recognised. [...] For diseases that people are generally not ashamed of, I think it is generally a good possibility. Finally, I think you should also consider the age: diseases that occur mainly in elderly people are less suitable for Teams sessions because they may not be used to it and will experience technical problems. [...]"

"If you have attended a face-to-face informed consent session before, which format of those sessions do you prefer in the future?"



182 (51%) out of 360 participants have attended face-to-face informed consent session before. The above results are based on those participants' response.

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