PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of the e-Tabac Info Service application for smoking cessation: A pragmatic randomised controlled trial
AUTHORS	Affret, Aurelie; Luc, Amandine; Baumann, Cédric; Bergman, Pierre; Lefaou, Anne Laurence; Pasquereau, Anne; Arwidson, Pierre; Alla, François; Cambon, Linda

VERSION 1 – REVIEW

REVIEWER	Akihiro Nomura CureApp Institute, Karuizawa, Japan Innovative Clinical Research Center, Kanazawa University, Kanazawa, Japan. I received consulting fees from CureApp, Inc.
REVIEW RETURNED	08-Jul-2020

GENERAL COMMENTS	In this manuscript entitled “Effectiveness of the e-Tabac Info Service application for smoking cessation: A pragmatic randomised controlled trial”, the authors evaluated the efficacy of new smartphone app (e-TIS app) for smokers recruited via the website of the French National Mandatory Health Insurance fund. They concluded that there was no difference between the e-TIS users and conventional website viewers in terms of 7-day PPA. This study was well-conducted except the significant loss of follow-ups at each outcome evaluation point (especially at 6 month of the primary outcome measurement). Also, this manuscript was well-written until Results section, but the Discussion section may need to be reconsidered. Major comments: 1. Results and Discussion: More than 70% of participants in both arms were lost-to follow-up at 6 months after randomisation. Even they considered the lost as failure of smoking cessation, this significantly influence evaluation of the e-TIS app efficacy. Also, there were significant cross-over rates in both arms. Unfortunately, I think you could say little about the efficacy of the app from this data. However, as the authors mentioned, this was a pragmatic trial. For readers who try to conduct clinical trials using such a mobile app, please describe why this trial was failed first at the Discussion section. It’s not because of the control group demographic issue. Isn’t it (largely and/or partly) because of the significant lost-to follow-up rates and cross-over rates in both arms, app engagement rates, study design (primary outcome should be measured at 1 month?), etc.? This is a crucial point and please describe the reason in Discussion.

	2. Discussion Moreover, based on the 1's answer, please demonstrate what should have changed or improved regarding study design, ways of running clinical trial, or the components of the e-TIS app. The authors partly mentioned the answer at the last part of Conclusion (move to the Discussion here). 3. Conclusion Do not include your speculation in the Conclusion. Please focus on the objective results first. "If smoking cessation rate was high or low" was not the primary scope of this study. Minor comment: 1. Conclusion in Abstract: Please remove the last sentence "The latest result must be confirmed" (not necessary). 2. Results: How was the engagement rate of the e-TIS app for intervention group? Please provide the app usage rate at each point (3-month, 6-month…etc.) Also, if you have engagement or accomplishment rates of each item (16 different activity?) in the app, please provide the information. These data might provide insight into the failure of proving the app's effectiveness. 3. Results, subgroup analyses: Please provide the data of "data not shown" in this paragraph on Supplemental data if possible. There is plenty of space to show your data.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. Results and Discussion:
More than 70% of participants in both arms were lost-to follow-up at 6 months after randomisation. Even they considered the lost as failure of smoking cessation, this significantly influence evaluation of the e-TIS app efficacy. Also, there were significant cross-over rates in both arms. Unfortunately, I think you could say little about the efficacy of the app from this data.
However, as the authors mentioned, this was a pragmatic trial. For readers who try to conduct clinical trials using such a mobile app, please describe why this trial was failed first at the Discussion section. It's not because of the control group demographic issue. Isn't it (largely and/or partly) because of the significant lost-to follow-up rates and cross-over rates in both arms, app engagement rates, study design (primary outcome should be measured at 1 month?), etc.? This is a crucial point and please describe the reason in Discussion.

Our answer: Done. We added a large paragraph at the beginning of the discussion that addresses these issues.

2. Discussion

Moreover, based on the 1's answer,
please demonstrate what should have changed or improved regarding study design, ways of running clinical trial, or the components of the e-TIS app. The authors partly mentioned the answer at the last part of Conclusion (move to the Discussion here).

Our answer: Done (see answer above)

3. Conclusion
Do not include your speculation in the Conclusion. Please focus on the objective results first. "If smoking cessation rate was high or low" was not the primary scope of this study.

Our answer: Done, conclusion has been refocused.

1. Conclusion in Abstract:
Please remove the last sentence "The latest result must be confirmed" (not necessary).

Our answer: Done, deleted

2. Results:
How was the engagement rate of the e-TIS app for intervention group?
Please provide the app usage rate at each point (3-month, 6-month…etc.)
Also, if you have engagement or accomplishment rates of each item (16 different activity?) in the app, please provide the information. These data might provide insight into the failure of proving the app's effectiveness.

Our answer: we added usage rates in results section. Unfortunately, we currently do not have these data for each item.

3. Results, subgroup analyses:
Please provide the data of "data not shown" in this paragraph on Supplemental data if possible. There is plenty of space to show your data.

Our answer: Done (supplementary tables 4 a to r)