Reviewer’s report

Title: Digital Pills: a scoping review of the empirical literature and analysis of the ethical aspects

Version: 1 Date: 05 Dec 2019

Reviewer: Craig Klugman

Reviewer's report:

Thank you for taking my comments and suggestions so seriously. I believe the changes you made address my main concerns and make your project much clearer. My only remaining note is a statement you made in the response to reviewers where you talked about these devices being reviewed by the FDA. The FDA actually has not figured out how to review these products yet. Plus, if the DP is considered a "device" then it is not reviewed as long as it is substantially similar to something that has previously been approved. Over 90% of medical devices are not reviewed.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
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Yes

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Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable
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If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

Yes, I was a paid bioethics consultant for Otsuka Pharmaceuticals which is the manufacturer of the Abilify My Cite system (i.e. digital pill). This consulting relationship ended in July 2019.

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