

12 tips for mobile health randomized controlled trials

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At the end of last year the Journal of Medical Internet Research (JMIR) recently published an editorial that argues standards are sorely needed to help edify the growing number of mobile health and eHealth efficacy studies. The [editorial is a must-read](#) for anyone looking to conduct randomized controlled trials (RCTs) of mobile health apps and services.

Here's our quick summary of 12 of the essential or highly recommended best practices for mHealth RCTs:

1. Be sure to include the names, credentials, and affiliations of the developers, sponsors, and owners of the software, and disclose whether those evaluating the service own or developed it, too.
2. Be sure to detail the development process of the mobile health app and any previous focus groups or usability tests that led to its development. Those will help others to interpret the results.
3. Be sure to mention and revisions or updates that the app underwent during the evaluation period or whether development was frozen during the RCT.
4. Be sure to include information on quality assurance (QA) methods to ensure accuracy of the information provided.
5. This is likely a difficult one: Be sure to include a source code (open source) or provide screen shots of the app that can help other researchers to replicate the study.
6. Be sure to archive the intervention and provide the URL of the app or demo pages that are not hidden behind login screens.
7. Be sure to describe how participants in your study accessed your application, whether they were paid or not, or had to be a member of a particular group.
8. Be sure to include an in-depth description of the app's content, including the its mode of delivery, components of its intervention and comparator, as well as the theoretical framework it is based on. For example, is it synchronous or asynchronous?
9. Be sure to clarify what instructions or recommendations were given to the user (if any) for how often they should use the app.



To date, WellDoc's DiabetesManager is one of the few mobile health apps to have gone through an RCT.

10. Be sure to clarify the level of human involvement, for example, were care providers or health professionals a part of the intervention? Did users receive technical assistance?

11. Be sure to note any reminders used, whether they were letters, emails, phone calls, text messages, or other. Include what triggered the prompts and how often they were given.

12. Finally, be sure to describe any co-interventions if the RCT did not include a standalone intervention. Also describe any training given to the participants.

These were just high-level summaries of some of the recommendations. For a much more robust discussion, [be sure to read this editorial in JMIR](#).