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REVIEW

SMOOTH: Self-Management of Open Online Trials in Health analysis found improvements were needed for reporting methods of internet-based trials

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Abstract

Background and Objectives: The growth of trials conducted over the internet has increased, but with little practical guidance for their conduct, and it is sometimes challenging for researchers to adapt the conventions used in face-to-face trials and maintain the validity of the work. The aim of the study is to systematically explore existing self-recruited online randomized trials of self-management interventions and analyze the trials to assess their strengths and weaknesses, the quality of reporting, and the involvement of lay persons as collaborators in the research process.

Study Design and Settings: The Online Randomized Controlled Trials of Health Information Database was used as the sampling frame to identify a subset of self-recruited online trials of self-management interventions. The authors cataloged what these online trials were assessing, appraised study quality, extracted information on how trials were run, and assessed the potential for bias. We searched out how public and patient participation was integrated into online trial design and how this was reported. We recorded patterns of use for registration, reporting, settings, informed consent, public involvement, supplementary materials, and dissemination planning.

Results: The sample included 41 online trials published from 2002 to 2015. The barriers to replicability and risk of bias in online trials included inadequate reporting of blinding in 28/41 (68%) studies; high attrition rates with incomplete or unreported data in 30/41 (73%) of trials; and 26/41 (63%) of studies were at high risk for selection bias as trial registrations were unreported. The methods for (23/41, 56%) trials contained insufficient information to replicate the trial, 19/41 did not report piloting the intervention. Only 2/41 studies were cross-platform compatible. Public involvement was most common for advisory roles (n = 9, 22%), and in the design, usability testing, and piloting of user materials (n = 9, 22%).

Conclusion: This study catalogs the state of online trials of self-management in the early 21st century and provides insights for online trials development as early as the protocol planning stage. Reporting of trials was generally poor and, in addition to recommending that authors report their trials in accordance with CONSORT guidelines, we make recommendations for researchers writing protocols, reporting on and evaluating online trials. The research highlights considerable room for improvement in trial registration, reporting of methods, data management plans, and public and patient involvement in self-recruited online trials of self-management interventions.

Keywords: Internet trials; Reporting methods; Self-management; Online trials; Public involvement; Reporting guidelines; Self-recruited

Conflict of interest: No authors have any personal, professional, or financial conflict of interest to declare.

Differences between protocol and review: The preliminary protocol was amended following public feedback and input was incorporated into the data extraction process. We had hoped to include an investigation of online research impact, but this was not reported or easily measured for all 41 included trials.

Dissemination: The results will be distributed to clinicians, researchers, industry, and members of the public using blogs, open access online classes, and as a keynote address in one conference, with results shared in two other conferences as part of a workshop.

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What is new?

Key findings

- Barriers to replicability and progress in online trials were identified by unclear reporting of the trial and methods used.

What this adds to what was known?

- Little is reported about the reporting methods used in online trials and this research reviews what is reported. The technology across devices may be too recent, costly to develop, or not sufficiently stable for widespread use; early adoption of good reporting methods may provide a way for research quality and innovation to keep pace with emergent technologies.

What is the implication and what should change now?

- Challenges might be overcome by reporting on the dashboard design, software used in the intervention, and the online materials used to train, test, and assess participants. Following the sporadic use of reporting guidelines in online trials, we propose the development and implementation of an online reusable protocol where reporting requirements would be embedded in the protocol to assist authors in writing up the online trials research.

1. Introduction

Modern digital technologies can provide health interventions through the use of mobile health apps, text messaging and telehealth video consulting, and provide an opportunity to conduct research solely over the internet in the format of online randomized trials. These trials can be conducted remotely over the internet using a computer, tablet, or smartphone without the need for face to face human interactions. Online trials continue to grow in scope and accessibility, and patients are becoming empowered to use these technologies to explore their health questions. However, the methods used for these trials raise specific benefits and challenges. (Table 3).

The aim of this research is to systematically explore existing self-recruited online randomized controlled trials (RCTs) of self-management interventions and analyze the trials to assess their strengths and weaknesses and to report how participants were involved in the research process with the objective of developing guidance for the design, conduct, and reporting of online RCTs of self-management interventions.

The benefits of using digital technologies for online trials include cost-reduction through the use of online rather than physical trial sites, ease of reaching multiple sociodemographic groups, the ability to use multiple languages with minimal cost, and the inclusion of trial participants who have limited mobility but who can participate with access to an internet connection, through a computer, tablet, or smartphone [1]. These trials can also provide insights into the use of interventions outside of the lab or clinic, and online access has become affordable and accessible in low resource settings providing more equitable global access to research. Public health and epidemiology researchers in low-resource areas struggle with the challenge of accessing valid data on disease and population, where collection methods are inconsistent, culturally diverse, and subject to administrative delay [2]. Mobile device platforms might be designed for collecting valid health research data from the potential 5 billion unique mobile subscribers who account for 67−80% of the world's population as of May 2018 according to the GSMA intelligence calculator [3].

Online trials have unique methodological challenges including limited face-to-face interaction, limited to participants who are willing to respond online, reliance on self-reported outcomes, and the need for applications to work across different operating systems, be user accessible and compatible with aging technology and bandwidth variations [4]. Data protection breaches may be brought on by participants themselves through social media, or through health research data, purchased or stolen by third parties [5]. Inconsistent reporting of methods and public and patient involvement in online trials can limit opportunities for research replication, end-user experience transfer, and the development of strategies to build on previous work [6]. Therefore, research analyzing current practice for these trials might help in developing strategies to improve recruitment, intervention adherence, participant retention, research methods, and reporting practices [7].

Writing protocols to conduct online trials and to report them requires robust methods, informed by best practice. To learn from previously published research, the Online Randomized Controlled of Health Information Database (ORCHID) was constructed to collect reports of online trials and methodology research about them [8], using a search strategy available in Appendix 1. ORCHID was used to investigate reporting methods, and the extent of public involvement in online trials and preliminary analysis showed that the number of online clinical trials was growing exponentially but with limited methodology research on validity and best practice of these trials [8].

In this research study, we analyzed randomized, self-recruited, self-management trials conducted over the internet. Self-recruitment is defined as the participants themselves enrolling in a trial online, via smartphone, tablet or computer without assistance by face-to-face contact with trial personnel. For this study, self-management or self-monitoring of health is the use of a medical device, intervention, or process that, while it may be recommended by a physician or other clinician, can be used or undertaken without the assistance of a