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CONSORT-EHEALTH: Implementation of a Checklist for Authors and Editors to Improve Reporting of Web-Based and Mobile Randomized Controlled Trials

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Abstract

Background: Randomized trials of web-based and mobile interventions pose very specific issues and challenges, A set of best practices on how to conduct and report such trials was recently summarized in the CONSORT-EHEALTH statement (Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth), published in August 2011 as draft and in December 2011 as journal article (V1.6.1). The purpose of this presentation is to review the results of the pilot implementation at the Journal of Medical Internet Research (JMIR), a leading eHealth journal, where reporting of trials in accordance with CONSORT-EHEALTH became mandatory in late 2011. Methods: Authors of all randomized trials submitted to JMIR were asked to complete an electronic questionnaire, which involved copying pertinent manuscript sections into a CONSORT EHEALTH database form, were asked to score the importance of CONSORT EHEALTH items, and were asked to provide narrative feedback on the value of the process. Results: Between August 2011 and November 2012, 67 randomized trials were submitted, of which 61 were intended for publication in JMIR. Authors reported that it took between 1 and 16 hours to complete the checklist including making required changes to their manuscripts. 72% (48/67) of authors reported they made minor changes to the manuscript, 6% (4/67) made major changes. Most authors felt it was a useful process that improved their manuscripts: 63% (42/67) said it improved their manuscript, 13% (9/67) said it did not, 12% (8/67) indicated that it had improved a little. Conclusions: The CONSORT EHEALTH statement and checklist appeared successful in improving the quality of reporting. The checklist should be endorsed and used by authors and editors of other journals.

Keywords:

Medical Informatics, Publications, Knowledge Translation, Medical Informatics Education, Knowledge Management.

Introduction

Web-based health interventions (also called "Internet interventions" or "eHealth interventions") are, for the purpose of this paper, "treatments, typically behaviorally based, that are operationalized and transformed for delivery via the Internet" [1]. With mobile devices being an increasingly important access point for Internet-based or otherwise networked electronic interventions, this definition includes interventions that are delivered through mobile devices or the new generation of tablet computers (e.g., the iPad). Examples are behavior change interventions that help people quit smoking or lose weight, or mental health applications to address depression, anxieties, or other important health problems.

Web-based and mobile interventions are increasingly important instruments in the toolkit of public health professionals and researchers [1-3]. The web-based delivery mode makes it relatively easy to enroll and track a large number of participants in longitudinal studies, including RCTs, to test the effectiveness of specific program components, or to evaluate the effectiveness of the program as a whole. The ease of enrollment comes, however, at a cost: Compared to face-to-face trials, researchers in eHealth trials have less control over the participants, and Internet-based trials pose some other specific problems, related to execution and reporting of the trial [4].

While this is a young field, with less than a dozen web-based RCTs published before 2002 [4,5], the number of reports evaluating web-based interventions in the medical literature is increasing rapidly. In October 2010, a scan of literature indexed in PubMed with the publication type "randomized trial" and major medical subject headings (MeSH) term "Internet", elicited 582 published randomized trials [6]. This does not take into account evaluations of mobile networked applications (which may not be indexed with the "Internet" keyword but have terms like "mobile", "mhealth" or "smartphone" in the title/abstract), or studies with nonrandomized longitudinal designs. A repeat of the search in December 2012 elicited 899 randomized trials.

The *Journal of Medical Internet Research* (JMIR) is a leading eHealth journal (2010 Impact Factor: 4.7), committed to rapid and high-quality publishing of research studies with a focus on Internet- and mobile-based interventions, as well as innovations and policy issues in consumer health informatics [7] and health 2.0/medicine 2.0 [8]. While the journal also publishes qualitative studies and observational studies, the number of randomized controlled trials submitted and published is increasing rapidly. JMIR is actually the journal which (compared to other journals) publishes the most RCTs. For example, of the 101 RCTs published in 2012, 21 were published in JMIR, with *Behav Res Ther* as second ranked journal, having published 7 (for 2010 data see [6]). As the leading journal in this area (both in terms of impact and in terms of number of articles published), the JMIR editorial board sees it as their responsibility to create and enforce reporting standards.

To meet this responsibility, the journal initiated in 2011 a literature review and a Delphi process to extend the CONSORT statement, with the goal to develop a new instrument designed to improve the quality of reporting of eHealth and mHealth trials, dubbed CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth) [6].

A checklist containing reporting items is the core component of CONSORT-EHEALTH. Completing the checklist was made mandatory for authors of randomized controlled trials

(RCTs) submitting their reports to JMIR [6]. However, the checklist was designed to be also useful for researchers employing other evaluation methods (other than RCTs) or evaluating other types of health informatics interventions, beyond web-based and mobile applications.

In this paper, we report the results of the pilot implementation at JMIR in 2012, when the checklist was made mandatory for authors, focusing on the subjective feedback of authors themselves. A survey among editors was beyond the scope of this paper.

Materials and Methods

CONSORT-EHEALTH

The development of the initial CONSORT-EHEALTH statement and instrument through a literature review, Delphi-process and consensus workshop broadly followed the standard methodology developed by the CONSORT group [9] and is described in detail elsewhere [6]. The original 25 CONSORT items [10] (numbered 1-25 and occasionally broken into two subparagraphs numbered with a and b) were expanded by adding eHealth-specific subitems, which were indicated with Roman numerals (eg, CONSORT item 2a had two additional subitems numbered 2a-i and 2a-ii). We added 2 top-level items to the original 25-item CONSORT (item X26 on ethics, and item X27 on conflict of interest disclosure), which were not part of the original CONSORT checklist, but were deemed essential for any trial to report.

The resulting current iteration of CONSORT-EHEALTH V1.6.1 (which was pilot-tested at JMIR in 2012) has 17 subitems that are deemed "essential", and 35 subitems that are deemed "highly recommended" [6]. The checklist (V1.6.1) was published on the JMIR website on August 25, 2011 and was pilot-tested with the help of JMIR authors, who were asked to submit an electronic version of the checklist via an online questionnaire when they submit manuscripts reporting an RCT. In this questionnaire, authors of RCTs were required to quote (copy & paste) passages of their manuscript corresponding to each item, or to briefly explain why they are not applicable. They were also asked to (on a voluntary basis) rate the importance of the items for their trial on a scale of 1-5, where 5 means "essential" and 1 "unimportant", and (optionally) comment on changes made and degree of improvement.

Table 1 shows some subitems of the CONSORT-EHEALTH item 5 (Description of the intervention). The full CONSORT-EHEALTH checklist is available as Multimedia Appendix at http://www.jmir.org/2011/4/e126/ [6].

Table 1 –EHealth-specific subitems for CONSORT item 5 (Description of the intervention)

5-#	Item Description (short form)
i)	Mention names, credential, affiliations of the developers, sponsors, and owners
ii)	Describe the history/development process of the application and previous formative evaluations
iii)	Revisions and updating: Date and/or version number of the application/intervention under investigation (and comparator, if applicable)
iv)	Quality assurance
v)	Ensure replicability by publishing the source code (preferably as open source), and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used.
vi)	Digital preservation
vii)	Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group etc.
viii)	Describe mode of delivery, features/ functionalities/components of the intervention and comparator, and the theoretical framework
ix)	Describe use parameters
x)	Clarify the level of human involvement
xi)	Report any prompts/reminders used
xii)	Describe any co-interventions (including training/support)

Results

Quantitative Results

Between August 2011 and November 2012, 67 randomized trials were submitted, of which 61 were intended for publication in JMIR. Authors reported that it took between 1 and 16 hours to complete the checklist and make required changes to their manuscripts. 72% (48/67) of authors reported they made minor changes to the manuscript, 6% (4/67) made major changes. Asked whether they think the CONSORT-EHEALTH statement has improved their manuscript, 63% (42/67) said yes, 13% (9/67) said no, 12% indicated that it had improved a little (8/67). One author exclaimed "What a stupid exercise!" Another author remarked "The manuscript has improved. However, we felt that the amount of effort was considerably greater than the degree of improvement."

Authors' mean importance ratings for each item ranged from 2.5 (item 4b-ii "institutional affiliations display") to 4.4 (item 1b-iv: "results section in abstract must contain use data").

Changes Made to Manuscripts

Table 2 summarizes the free-text comments of authors when asked what the most important changes were they made to their manuscripts.

Qualitative Feedback on the Form and Process as a Whole

Most authors felt that going through the checklist was a useful process that improved their manuscripts. However, some commented that the questionnaire was too long, and that the usability of the online questionnaire should be improved, so that it is possible for authors to save progress and to return to the questionnaire. One author commented that some of the items/subitems seemed to overlap. One author expressed a strong sentiment commenting that "this exercise might be good for college students but is insulting for professionals". One authors commented that "The checklist is very complete, but to follow every single point is overwhelming. We believe it is a useful instrument but it is unrealistic to assume that every single suggestion can be detailed in a 6000-words manuscript."

In the following, we summarize some specific feedback on selected subitems, in particular those that will require some consolidation or revision.

Table 2 –Changes made by authors (as reported by authors)

Changes in Title and Abstract and Methods.
Adding information which was already previously published in the main RCT article.
Adding more "behind the scenes" details about the intervention.
A change to the title of the project, relabeling the 'online' intervention as 'web-based' intervention.
Adding power calculation information and discussing issues of protecting online privacy of participants.
Included extra information that we had not considered including prior
We included some sections that were already included in the clinical papers (currently under review elsewhere), but not in the cost-effectiveness one (e.g. the power analyses).
Adding information on specific intervention details.
The manuscript was enhanced to elaborate on the recruitment process and support resources. The abstract was expanded to describe the sampling frame.
No important changes - various small clarifications of procedures.
External validity better explained
Now we give more detailed information about the web-based intervention: for example, we added the target group to the title of the manuscript and specified all inclusion criteria in the text.
Description of bugs fixed during the trial and downtime
More detailed abstract terms used: "web-based vs. virtual" "face-to-face vs. in person"
More details about the application itself were added.
Information was added to the manuscript.
I have added some details about the intervention & procedure.
Title
I added some information: 1) the target group in the title, 2) the fact that we checked email and IP addresses for uncovering multiple identities, 3) participants had free access to the intervention, 4) technical assistance is provided, 5) randomization was done online using a computer program
Added the sentence "fully automated" and the word "adult" in title.
Specifying the title and adding to the abstract.
Providing more attrition details, described by group
Many updates and additions on all sections
Mentioning some of the asked information more explicitly in the manuscript, e.g. that all data was gathered via the web and that there was no face to face contact with the study team.
Tables and reporting of statistics.
Abstract information.
Title: added “web-based”
Added 'online' to abstract; In response to 5-ix I added this comment on how the participants were informed
Attrition diagram
I have made clearer where the results are based on analysis of a subgroup (completers).
Added some extra detail to methods section.
Inclusion of participant’s feedback in the manuscript.
Inserting flow diagram
Added details re randomization
Changes in the Method section.
Adding information to make the study more replicable and that provides further assurance of the credibility of the research.
Generalizability and sources of potential bias
Adding a Multimedia appendix (screenshot of the intervention), adding the URL, more details about intervention itself.
Some information was added to the abstract.

Specific Feedback on Subitems

Replicability/Digital Preservation (5-v and 5-vi)

Two of the subitems (5-v and 5-vi) speak to the problem of digital preservation of the intervention, which is a unique aspect of eHealth or mHealth trials. For scientific hypotheses and findings to be confirmed or disproved by other researchers, key elements should be available to other researchers, ideally as open source code, or at least be theoretically “reproducible” by disclosing algorithms, pathways of participants through the application, etc., or at a minimum by providing screenshots or archiving the interfaces in a web archive (such as the Internet Archive or WebCitation.org).

These two subitems were surprisingly controversial among respondents, with subitem 5-v receiving an average importance rating of 2.9 (out of 5) and, 5-vi being rated 3.0. While many respondents included screenshots as figures or multimedia appendix to document the intervention, some of the comments included

- “I’m not exactly sure how this is appropriate here as this is a huge and complex intervention, also the university has rules about the sharing of some of this information”
- “The intervention and control materials contain proprietary intellectual property from commercial vendors. Publishing source code, screen shots, etc. is not feasible.”
- “this would require another paper”
- “Not included in the manuscript, as it is a commercial program.”

The issue of complete transparency of the intervention remains a tricky issue, as some eHealth applications may have commercial use and some respondents were concerned about publicizing proprietary algorithms. On the other hand, the main concern from a readers and journal editor perspective is that the report must contain sufficient details and preferably screenshots to allow others to replicate or disprove the key findings – otherwise it cannot be considered scientific research and should be published in a trade journal rather than a peer-reviewed scholarly journal.

As a result of the feedback to these items, we will collapse these two items and clarify the requirements for CONSORT-EHEALTH 2.0. We continue to believe that at a minimum screenshots of the application should be provided, either as figures or as online appendix.

Usage, Adherence, Attrition

A number of guideline subitems (6a-ii, 12a-i, 13b-i, 17-i) are related to the important issue of attrition (non-use) and use (engagement, “dose”, adherence) of the intervention [11]. As participants in web-based evaluations usually have full control over whether or not they use the intervention, and how often and how long they engage with the application, real-world evaluations of web-based interventions and interpretations of reports on their effectiveness (or lack thereof) are often complicated by the fact that a substantial proportion of participants may have dropped out of the trial (non-use or loss-to-follow-up attrition) [11]. While non-adherence may be a problem in drug trials too, the attrition rates in Internet-based trials are by far higher than in trials with a face-to-face component. As effectiveness as measured in these trials is a function of (and dependent on) participants actually *using* the intervention, researchers should measure and report metrics of use (adherence) and/or non-use (attrition), which can be measured using a variety of metrics such as number of logins and average ses-

sion time. However, even these seemingly straightforward metrics require additional explanations, for example, if researchers report an average session time, this may be skewed by some participants never logging out; therefore, additional information such as the timeout policy should be provided (e.g., automatic logout after 15 minutes of inactivity) in order to enable accurate interpretation and across-trial comparisons.

In subitem 6a-ii (an expansion of CONSORT item 6 "outcomes"), we suggest that researchers explain how use and engagement was measured and defined, in addition to describing how the primary health outcomes were measured.

Subitem 6a-ii received an average importance rating of 3.4, indicating that many authors originally did not think of reporting use.

In subitem 17-i (an expansion of CONSORT item 17 "outcomes and estimation"), we ask that use and usage outcomes should be reported. The average importance rating from authors was 3.1, with some authors commenting that "Use and intensity of use were not part of the study objectives."

In subitem 12a-i (an expansion of CONSORT item 12 "statistical methods"), we specifically ask how missing values due to attrition were treated statistically (imputation). Most authors recognized that this was an important item (mean importance rating 3.8).

In addition to the traditional CONSORT flow diagram, we also highly encourage the provision of an attrition diagram (CONSORT-EHEALTH item 13b-i) in the results sections, illustrating the login behavior of participants in all groups over time as a survival curve [11]. This item received an importance rating of 3.3 and many authors provided an "attrition diagram" [11] although some confused it with the CONSORT-flow diagram.

Including Qualitative Analysis

There is a regrettable trend to split reports of randomized trials into "least publishable units", for example, to publish one paper with the results of the primary RCT outcomes, another paper with usage results, and another paper with a qualitative analysis of participant feedback. Many journals have a strict policy against "salami publication", a practice that limits the ability of the reader to interpret the overall findings, and will consider such multipart papers only in exceptional circumstances, and preferably when the reports are submitted together and published in the same journal issue. An in-depth qualitative evaluation may justify a separate paper, but a few CONSORT-EHEALTH items (6a-iii "Describe whether, how, and when qualitative feedback from participants was obtained", mean importance rating 3.2, and 19-ii "Include qualitative feedback from participants or observations from staff/researchers", mean importance rating 3.2) remind authors that some qualitative analysis should be part of any eHealth evaluation report, in particular if nonuse of the application or potential harmful effects were observed, which should shift the focus of the report to the question *why* these results occurred.

Some of the comments from authors received here included

- "This [obtaining feedback from participants] is a good idea, but we did not do this."
- "we have been doing appropriate qualitative analyses on these data that we wish to present more fully in a separate publication"
- "These will be reported elsewhere."

In fact, 8 out of the 67 submissions indicated that qualitative data will be or have been reported elsewhere.

As a result of the feedback to these items, we will collapse these two items and clarify the requirements for CONSORT-EHEALTH 2.0. We continue to believe that – if possible – qualitative data should be reported and discussed in conjunction with quantitative data.

Trial Registration in Ehealth

CONSORT item 23 requires the provision of the trial registration number and name of trial registry [10]. While there are not eHealth-specific additions here, we noted that a frequent problem in eHealth trials (which is not fixable at the reporting stage) is that authors frequently misinterpret trial registration requirements and failed to register trials before patients are recruited.

This is a violation of the International Committee of Medical Journal Editors (ICMJE) prospective trial registration requirements (which is in effect since 2005) and may render the trial unpublishable in any peer-reviewed medical journal.

The ICMJE does require public, prospective registration of clinical trials of all interventions, including devices (thus it includes Internet and mobile applications). As stated on the FAQ of the ICMJE [12], *"the ICMJE adopted the WHO's definition of clinical trial: ‚any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.' Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events."*

We noted that authors of Internet- or mobile-based trials frequently misunderstand "clinical trial" as a trial that is conducted in a clinical setting. In fact, only 68% (46 of the 67) CONSORT-EHEALTH submissions contained a trial registration identifier. Some of the explanations of authors included the following:

- "The RCT was initiated before trial registration became customary in Norway, and therefore does not have a Trial ID number."
- "No, initially this study was set up as a pilot study, as a precursor to a larger more intensive intervention study. This study was only to create 'preliminary data' to support grant proposals. As such, the trial was not registered."
- "This trial was not registered as it was originally set up as a pilot study, in order to obtain preliminary data prior to executing large intensive clinical trials. "
- "As this trial was a non-clinical trial, it was not registered in a trials registry."

Internet interventions often look at behavioral (i.e. health!) outcomes, and therefore require registration, regardless of whether the randomized participants are in a home setting or in a clinic. "Clinical" outcomes include outcomes like weight or behavioral outcomes. In most cases, authors evaluating Internet-based and mobile applications should therefore register their trial before recruitment starts.

As for pilot studies, these can be reframed as protocol or formative study, but will usually not be publishable in a high-impact journal (JMIR publishes such formative RCTs as research protocols in a sister journal, JMIR Research Protocols, see http://www.researchprotocols.org).

Discussion

Publication of the guideline in August 2011 and making the checklist a mandatory step for submission to JMIR had a significant impact on the quality of reports of web-based intervention evaluations, which will in turn enable better systematic reviews and facilitate knowledge translation. The guideline also serves as a useful starting point and framework for discussions around the quality of eHealth trials, how such trials should actually be conducted, which items should be reported in protocols, grant proposals and trial registries, and how trials should be classified and synthesized in systematic reviews.

Elements of the guideline may be useful for researchers of other disciplines who use web-based recruitment or data collection methods, even if it is not an Internet- or mobile intervention which is being evaluated.

Many elements of the guideline (particularly the section describing subitems of the intervention) are applicable not only to randomized trials, but any kind of evaluation report.

While the *Journal of Medical Internet Research* is the first journal to support CONSORT EHEALTH, we hope that other journals and organizations endorse and adopt the guideline. Authors are encouraged to report their research (and research protocols) in accordance with CONSORT-EHEALTH, regardless of the ultimate publication venue.

The current checklist is only the first step and the guideline will be very much a living document in an iterative and ongoing development process. As technology is changing constantly and rapidly, and reporting of eHealth and mHealth interventions is influenced by what is technologically possible, the checklist will need to be updated much more frequently than other guidelines dealing with more "static" interventions.

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