CONSORT-EHEALTH

Consolidated standards for reporting ehealth/mhealth trials

G. Eysenbach MD MPH FACMI
Editor-in-Chief, J Med Internet Res
Publisher, JMIR Publications
Centre for Global eHealth Innovation
University of Toronto, Dept of Health Policy, Management and Evaluation
CONSORT-EHEALTH checklist (V.1.6.1): Information to include when reporting ehealth/mhealth trials (web-based/Internet-based intervention and decision aids, but also social media, serious games, DVDs, mobile applications, certain telehealth applications)

Do you feel items are missing/unclear/unnecessary? Please comment at [http://tinyurl.com/consort-ehealth-v1-5](http://tinyurl.com/consort-ehealth-v1-5)

If you are working on a manuscript submission, please fill in this checklist electronically at [http://tinyurl.com/consort-ehealth-v1-6](http://tinyurl.com/consort-ehealth-v1-6)

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<th>Section/Topic</th>
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<td>i) Identify the mode of delivery in the title. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if intervention includes non-web-based Internet components (e.g., email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.</td>
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Electronic checklist (questionnaire) for ms submissions
[http://tinyurl.com/consort-ehealth-v1-6](http://tinyurl.com/consort-ehealth-v1-6)
• Top ranked journal in health services research and health informatics (2010 Impact Factor 4.7)
• Open Access => broad readership & dissemination beyond specialized audience
Recently launched: JMIR Serious Games, JMIR Medical Informatics
JMIR publishes (by far) the most Internet/Web-based RCTs

Over 100 Trials with Internet[MAJR] AND Randomized Controlled Trial[PT] in 2012

Number of RCTs published in 2012

- J Med Internet Res. 2012
- Behav Res Ther. 2012
- Trials. 2012
- Addict Behav. 2012
- Psychol Serv. 2012
- Contemp Clin Trials. 2012
CONSORT-EHEALTH: Goals

• Improve **reporting**: guideline for authors
• Facilitate **evaluation**: for editors, reviewers, decision-makers/readers
• Facilitate **planning/protocol/grant writing**
• **Educational** tool (PhD students, journal clubs...)
• Improve visibility, profile, **credibility** of the field
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<td>ratio</td>
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Criteria for EHEALTH subitems

- if not conducted properly it may lead to (empirical evidence of) bias or threaten internal validity
- if not reported properly this is associated with (empirical evidence of) bias
- it may be associated with the success of the trial
- it may be associated with external validity/implementation success (applicability or success of the application/intervention in other settings)
- it reflects crucial trial results
- it aids in the interpretation of results
CONSORT-EHEALTH

• original 25 CONSORT items (numbered 1-25 and occasionally broken into two subparagraphs numbered with a and b)
• 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)
• Added 2 new top-level items to the original 25-item CONSORT (item X26 on ethics, and item X27 on conflict of interest disclosure)
• CONSORT EHEALTH has 17 sub-items that are deemed “essential”, and 35 subitems that are deemed “highly recommended” (based on initial Delphi survey)
### CONSORT 2010 checklist of information to include when reporting a randomised trial

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http://tinyurl.com/consort1-6

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Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial | Essential |
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# Importance of guidance on terminology:

>125 ways to say ESG

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<th>Term 2</th>
<th>Term 3</th>
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<td>Group(s)</td>
</tr>
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<td>Discussion</td>
<td>Forum/Fora/Forums</td>
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<tr>
<td>Internet(-based)</td>
<td>Peer-to-peer</td>
<td>Board(s)</td>
</tr>
<tr>
<td>Virtual</td>
<td>Self-Help</td>
<td>Community/Communities</td>
</tr>
<tr>
<td>Web(-based)</td>
<td>Social Networking</td>
<td>Platform(s)</td>
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5 x 5 x 5 = 125 (not counting plural forms)
1a-i) Identify the mode of delivery in the title

- use “web-based” and/or “mobile” and/or “electronic game” in the title
- avoid ambiguous terms like “online”, “virtual”, “interactive”
- use “Internet-based” only if Intervention includes non-web-based Internet components (e.g., email), use “computer-based” or “electronic” only if offline products are used
- use “virtual” only in the context of “virtual reality” (3-D worlds)
- use “online” only in the context of “online support groups”
- complement or substitute product names with broader terms for the class of products (such as “mobile” or “smartphone” instead of “iphone”), especially if the application runs on different platforms
Methods

Development Process 2010-2013

• Literature review & item collection (2010-2011)
• eDelphi process – rate subitems & comment (until April 15th, 2011)
• Presentation @ ISRII (Int. Society for Internet Interventions) 2011 Sydney
• Editorial + Checklist published Dec 2011
• Pilot Implementation at JMIR 2011-2013: mandatory electronic checklist + author feedback
Methods

• checklist (V1.6.1) published on the JMIR website on August 25, 2011
• JMIR authors were asked to submit an electronic version of the checklist via an online questionnaire when they submit manuscripts reporting an RCT
• 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
• authors 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 to the manuscript as result of using CONSORT-EHEALTH and degree of improvement.
1a) Identification as a randomized trial in the title

1a-i) Identify the mode of delivery in the title
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1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Comment on subitem 1a-i)


1a-ii) Non-web-based components or important co-interventions in title
Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential
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).
• 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.
• I have added some details about the intervention and 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
• 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 participants 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 URL, more details about intervention itself
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<td>i)</td>
<td>Mention names, credential, affiliations of the developers, sponsors, and owners</td>
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<td>ii)</td>
<td>Describe the history/development process of the application and previous formative evaluations</td>
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<td>iii)</td>
<td>Revisions and updating: Date and/or version number of the application/intervention under investigation (and comparator, if applicable)</td>
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<td>iv)</td>
<td>Quality assurance</td>
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<td>v)</td>
<td>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.</td>
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<td>vi)</td>
<td>Digital preservation</td>
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<td>vii)</td>
<td>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.</td>
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<td>viii)</td>
<td>Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework</td>
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<td>ix)</td>
<td>Describe use parameters</td>
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<tr>
<td>x)</td>
<td>Clarify the level of human involvement</td>
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<tr>
<td>xi)</td>
<td>Report any prompts/reminders used</td>
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<td>Describe any co-interventions (including training/support)</td>
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5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used.

• Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

METHODS: 5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.
5-vii) Digital preservation

- Provide the URL of the application
- Also make sure the intervention is archived
  - Internet Archive
  - webcitation.org
  - publishing the source code or screenshots/videos
- As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login

METHODS: 5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Digital Preservation / Replicability
Screenshots or Open Source

• 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.”
  – “Not included in the manuscript, as it is a commercial program.”
  – “this would require another paper”

• The issue of complete transparency of the intervention remains a tricky issue
Attrition/Use/Adherence
1b-iv) Results in abstract should contain usage data

- the *use/uptake/adooption* of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes
- especially important for “negative” trials
- *Most highly rated CONSORT EHEALTH item by authors* (mean 4.4 on 5-point scale)
13b-i) Attrition diagram

- e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve [“Law of Attrition”]
- or other figures or tables demonstrating usage/dose/engagement

RESULTS: 13b) For each group, losses and exclusions after randomisation, together with reasons
6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

- Includes logins, logfile analysis, etc.
- Use/adoptions metrics are important process outcomes that should be reported in any ehealth trial

METHODS: 6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
23) Registration number and name of trial registry

- Original CONSORT item, no EHEALTH-specific additions here
- ICMJE requires mandatory prospective trial registration since 2005
- BUT 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.”
Conclusions

• CONSORT-EHEALTH, while adding some burden to authors, improves the quality of reporting, as observed by authors themselves
• Some revision and consolidation of items is needed (CONSORT-EHEALTH 2.0)
• Forthcoming workshop will revise CONSORT-EHEALTH and develop Elaboration Paper
• Adoption by organizations (ISRII, IMIA?) and other journals
• More research needed (before-after study?)
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<td>i) Identify the mode of delivery in the title. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if Intervention includes non-web-based Internet components (e.g., email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.</td>
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<td>i) Mention non-web-based components or important co-interventions in the title, if any (e.g., “with telephone support”).</td>
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<td>i) Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”)</td>
<td></td>
</tr>
<tr>
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<td></td>
<td>Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions</td>
<td>Methods (in Abstract):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>i) Mention key features/functionality/components of the intervention and comparator in the abstract. If possible, also mention theories and</td>
<td></td>
</tr>
</tbody>
</table>

Electronic checklist (questionnaire) for ms submissions
http://tinyurl.com/consort-ehealth-v1-6
Appendix
CONSORT-EHEALTH Checklist

Information to include when reporting an ehealth (web-based/Internet-based intervention and decision aids, but also social media, serious games, DVDs etc) or mhealth trials (mobile applications)
1a-ii) Mention non-web-based components or important co-interventions in the title

- Mention non-web-based components or important co-interventions in the title, if any
- e.g., “with telephone support”
1a-iii) Primary condition or target group in the title

• Mention primary condition or target group in the title, if any
• e.g., “for children with Type I Diabetes”
• Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial
1b-i) Describe Key features/functionalities/components of the intervention and comparator in the abstract

• If possible, also mention theories and principles used for designing the site
• Keep in mind the needs of systematic reviewers and indexers by including important synonyms
1b-ii) Level of human involvement in the abstract

• e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted”

• mention number and expertise of providers involved, if any
1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in abstract

• Mention how participants were recruited, e.g.,
  – online vs. offline
  – from an open access website (open trial) vs. from a clinic or other closed user group (closed trial)

• purely web-based trial or there were face-to-face components (as part of the intervention or for assessment)

• clearly state if outcomes were *self-assessed* through questionnaires
1b-v) Conclusions/Discussions in abstract for negative trials

• Discuss the primary outcome

• if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons
2a-i) Problem and the type of system/solution

- Intended as stand-alone intervention vs. incorporated in broader health care program? [1]
- Intended for a particular patient population? [1]
- Goals of the intervention, e.g., being more cost-effective to other interventions [1], replace or complement other solutions?
- (Note: Details about the intervention are provided in “Methods” under 5)
2a-ii) Scientific background, rationale

- what is known about the (type of) system that is the object of the study (discuss the use of similar systems for other conditions/diagnoses, if appropriate)
- motivation for the study, i.e., what are the reasons for and what is the context for this specific study
- from which stakeholder viewpoint is the study performed
- potential impact of findings [2]
- briefly justify the choice of the comparator
2b) Specific objectives or hypotheses

• *No EHEALTH-specific additions here*

• (note: Contrary to STARE-HI we do not recommend to mention IRB approval in this section - JMIR and other journals typically recommend this as a subheading under “methods”. CONSORT-EHEALTH has a separate item for ethical considerations)
3a) Description of trial design (such as parallel, factorial) including allocation ratio

- No EHEALTH-specific additions here
3b-i) Bug fixes, downtimes, content changes

- description of important changes made:
  - on the intervention or comparator during the trial
    - e.g., major bug fixes or changes in the functionality or content) (5-iii)
  - other “unexpected events” that may have influenced study design such as staff changes
    - e.g., system failures/downtimes, etc. [2]
4a-i) Computer/Internet literacy

• Is often an implicit “de facto” eligibility criterion

• should be explicitly clarified [1]
4a-ii) Open vs. closed, web-based vs. face-to-face assessments

• How participants were recruited (online vs. offline), e.g., from an open access website or from a clinic
• purely web-based trial, or were there face-to-face components (as part of the intervention or for assessment), i.e., to what degree the study team got to know the participants
• in online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these
4a-iii) Information given during recruitment

- Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26)
- This information may have an effect on user self-selection, user expectation and may also bias results
4b-i) Report if outcomes were (self-) assessed through online questionnaires

• Clearly report if outcomes were (self-) assessed through online questionnaires or otherwise
4b-ii) Report how institutional affiliations are displayed

- Report how institutional affiliations are displayed to potential participants [on ehealth media]
- Affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention [1]

METHODS: 4b) Settings and locations where the data were collected
5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

- Mention names, credential, affiliations of the developers, sponsors, and owners [6]
- If authors/evaluators are owners or developer of the software, this needs to be declared in a “Conflict of interest” section

METHODS: 5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
5-ii) Describe the history/development process

• Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing)

• these will have an impact on adoption/use rates and help with interpreting results
5-iii) Revisions and updating

• Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated
• describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial
• describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b)

METHODS: 5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
5-iv) Quality assurance methods

• Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.
5-vii) Access

• 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.
  – how they obtained “access to the platform and Internet” [1]

• To ensure access for *editors/reviewers/readers*, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi)

METHODS: 5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

- Describe **mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework** [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc.)[7],[8]
- description of the content (including where it is coming from and who developed it) [1]
- “whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback” [6]
- description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]
- information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources etc [1]

METHODS: 5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
5-ix) Describe use parameters

• e.g., intended “doses” and optimal timing for use [1]

• Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use [1], if any, or was the intervention used *ad libitum*
5-x) Clarify the level of human involvement

• Describing care providers, health professionals, technical assistance involved in the e-intervention or as co-intervention:
  – number and expertise of professionals involved
  – type of assistance offered [6]
  – the timing and frequency of the support [6]
  – how it is initiated [6]
  – the medium by which the assistance is delivered [6]

• It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21)
5-xii) Report any prompts/reminders used

• Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency, etc. [1]

• It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability)
5-xii) Describe any co-interventions (incl. training/support)

- Clearly state any “interventions that are provided in addition to the targeted eHealth intervention” [1], as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]
- It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability

METHODS: 5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
6a-i) *Online questionnaires*, describe if they were validated for online use

- describe if surveys used to obtain outcomes were validated for online use
- apply CHERRIES items to describe how the questionnaires were designed/deployed [9]

**METHODS:** 6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
6b) Any changes to trial outcomes after the trial commenced, with reasons

- No EHEALTH-specific additions here
7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size
7b) When applicable, explanation of any interim analyses and stopping guidelines

• *No EHEALTH-specific additions here*
8a) Method used to generate the random allocation sequence

• No EHEALTH-specific additions here
8b) Type of randomisation; details of any restriction (such as blocking and block size)

- No EHEALTH-specific additions here
9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

• *No EHEALTH-specific additions here*
10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

• No EHEALTH-specific additions here
11a-i) Specify who was blinded, and who wasn’t

• Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind:
  – outcome assessors
  – those doing data analysis
  – those administering co-interventions (if any)
11a-ii) Whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

- Informed consent procedures (4a-ii) can create biases and certain expectations
11b) If relevant, description of the similarity of interventions

• (this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)
12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

• No EHEALTH-specific additions here
X26-i) Comment on ethics committee approval

METHODS: X26) Ethics & Informed Consent (Not a CONSORT item)
X26-ii) Outline informed consent procedures

• e.g., was consent obtained offline or online
• how? Checkbox, etc.
• what information was provided (see 4a-ii)
• See [6] for some items to be included in informed consent documents
X26-iii) Safety and security procedures

• Privacy considerations
• “any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)” [1]
13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

• *No EHEALTH-specific additions here*
CONSORT 2010 Flow Diagram

Enrollment

Assessed for eligibility (n=)

Excluded (n=)
- Not meeting inclusion criteria (n=)
- Declined to participate (n=)
- Other reasons (n=)

Randomized (n=)

Allocation

Allocated to intervention (n=)
- Received allocated intervention (n=)
- Did not receive allocated intervention (give reasons) (n=)

Allocated to intervention (n=)
- Received allocated intervention (n=)
- Did not receive allocated intervention (give reasons) (n=)

Follow-Up

Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)

Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)

Analysis

Analysed (n=)
- Excluded from analysis (give reasons) (n=)

Analysed (n=)
- Excluded from analysis (give reasons) (n=)
14a-i) Indicate if critical “secular events” fell into the study period

- e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources” [1]

RESULTS: 14a) Dates defining the periods of recruitment and follow-up
14b) Why the trial ended or was stopped [early]

- No EHEALTH-specific additions here
15-i) Report demographics associated with digital divide issues

• such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known
16-i) Report multiple “denominators” and provide definitions

• Report N’s (and effect sizes) “across a range of study participation [and use] thresholds” [1]

• Examples:
  – N exposed
  – N consented
  – N used more than x times
  – N used more than y weeks
  – N participants “used” the intervention/ comparator at specific pre-defined time points of interest (in absolute and relative numbers per group).

• Always clearly define “use” of the intervention

RESULTS: 16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
16-ii) Primary analysis should be intent-to-treat

- secondary analyses could include comparing only “users”, with the appropriate caveats that this is no longer a randomized sample (see 18-i)
17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

- No EHEALTH-specific additions here
18-i) Subgroup analysis of comparing only users

• if done it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii)
19-i) Include privacy breaches, technical problems

- does not only include physical “harm” to participants, but also incidents such as:
  - perceived or real privacy breaches [1]
  - technical problems
  - unexpected/unintended incidents. “Unintended effects” also includes unintended positive effects [2]

RESULTS: 19) All important harms or unintended effects in each group
19-ii) Include qualitative feedback from participants or observations from staff/researchers

• if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses

• includes (if available) reasons for why people did or did not use the application as intended by the developers

RESULTS: 19) All important harms or unintended effects in each group
22-i) Restate study questions and summarize the answers suggested by the data [2], starting with primary outcomes and process outcomes (use).

DISCUSSION: 22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
22-ii) Highlight unanswered new questions, suggest future research [2].

- No EHEALTH-specific additions here
20-i) Typical limitations in ehealth trials

• Participants in ehealth trials are rarely blinded
• ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error
• discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events

DISCUSSION: 20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
21-i) Generalizability to other populations

• discuss generalizability:
  – to a general *Internet* population
  – outside of a RCT setting
  – to a general patient population
  – including applicability of the study results for other organizations [2]
21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

- e.g., prompts/reminders, more human involvement, training sessions or other co-interventions
- what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

DISCUSSION: 21) Generalisability (external validity, applicability) of the trial findings
24) Where the full trial protocol can be accessed, if available

• No EHEALTH-specific additions here
25) Sources of funding and other support (such as supply of drugs), role of funders

- No EHEALTH-specific additions here
X27-i) State the “relation of the study team towards the system being evaluated” [2]

• In addition to the usual declaration of interests (financial or otherwise)
• i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention