CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

This document contains the CONSORT-EHEALTH checklist and guideline to be completed and submitted together with your manuscript. It contains 5 parts: 1) the CONSORT-EHEALTH checklist, 2) the CONSORT-EHEALTH flow diagram, 3) the CONSORT-EHEALTH Glossary, 4) the CONSORT-EHEALTH Glossary of Terms and 5) the CONSORT-EHEALTH Glossary of Acronyms. Please use the CONSORT-EHEALTH Glossary of Terms and Glossary of Acronyms only if needed. Please do not change the structure of the checklist.

Cite the CONSORT-EHEALTH checklist and guideline as follow:
"Consort-ehealth: Checklist and guideline for reporting randomized controlled trials in ehealth and mhealth research, interventions, and services (V 1.6.1 and later)".

CONSORT-EHEALTH Checklist is still under development. It is recommended that you also REPORT the CLICKLE (V 1.0 beta) Implementation guide that will feature in TOR (Transparency of Online Research) Network (http://www.tor-network.org).

Mandatory reporting items are marked with "M".

In the textbox either copy & paste the relevant sections from your manuscript into the textbox or type in your comments. Please do not forget to indicate the page and paragraph where the corresponding information about the reporting information can be found (e.g. "p. 3 par. 2 lines 3-5").

YOUR MANUSCRIPT WILL BE RETURNED OR A REJECTION/REVISE TO COMMUNICATE REQUESTED WILL BE SENT TO YOU IF YOU DO NOT PROVIDE THE REQUESTED INFORMATION.

Please fill these questions diligently. Incomplete information will not be considered, as others are waiting for your work. Please do not write questionnaire, and not abbreviations.

DO NOT FORGET TO SEND YOUR WORK, JUST THE SUBMITTED TOR FORM TOGETHER WITH YOUR MANUSCRIPT.

Citation Suggestion for your manuscript: Consort-ehealth: Checklist and guideline for reporting randomized controlled trials in ehealth and mhealth research, interventions, and services (V 1.6.1 and later).

Version: CONSORT-EHEALTH Checklist V 1.6.1 (including Evaluation Reports of Web-based and Mobile Health Interventions)
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Contact: http://www.consort-ehealth.com

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URL of your manuscript *
https://dspace.lib.fsu.edu/...
Accessibility *
Can an ordinary access the intervention presently?
access to free and open
access only for special campus, not open
access to open to everyone, but requires payment/subscription to use/purchase
Accessibility *
Can an ordinary access the intervention presently?
access to free and open
access only for special campus, not open
access to open to everyone, but requires payment/subscription to use/purchase
Recommended Version *
Which is the version/date for users to use/see when they are allowed to use?
Recommended Version *
Which is the version/date for users to use/see when they are allowed to use?
Experiment Status *
Is the intervention/service/app/tool/... still running?
Experiment Status *
Is the intervention/service/app/tool/... still running?
Primary Outcome Measured in Years *
Is the intervention/service/app/tool/... still running?
Primary Outcome Measured in Years *
Is the intervention/service/app/tool/... still running?
Secondary Other outcomes
Are other key outcomes (the intervention is expected to affect)
Secondary Other outcomes
Are other key outcomes (the intervention is expected to affect)
Accessibility is measured by the post-server survey and accessory as measured by the device (TOR) and measured by self-report. Thus, *
Accessibility is measured by the post-server survey and accessory as measured by the device (TOR) and measured by self-report. Thus, *
Recommended "Version"
What is the instructions for users to use/see when they are allowed to use?
Recommended "Version"
What is the instructions for users to use/see when they are allowed to use?
Experiment Status
Is the intervention/service/app/tool/... still running?
Experiment Status
Is the intervention/service/app/tool/... still running?
Agonist, Pharmacologic of Covers (Variation) (still using the app as recommended after 2-3 months
Agonist, Pharmacologic of Covers (Variation) (still using the app as recommended after 2-3 months
Secondary Other outcomes
Are other key outcomes (the intervention is expected to affect)
Secondary Other outcomes
Are other key outcomes (the intervention is expected to affect)
Accessibility
Can an ordinary access the intervention presently?
Accessibility
Can an ordinary access the intervention presently?
Recommended "Version"
What is the instructions for users to use/see when they are allowed to use?
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Agonist, Pharmacologic of Covers (Variation) (still using the app as recommended after 2-3 months
Agonist, Pharmacologic of Covers (Variation) (still using the app as recommended after 2-3 months

Does your paper addresses subtask 3a?

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". To indicate direct quotes from your manuscript, or elaborate on the text by providing additional information and / or the e.g. to briefly explain why the item is not applicable/relevant for your study.

No changes to the protocol expected and no changes were made.

5c) Eligibility criteria for participants

Does your paper addresses CONSORT subtask 5c?

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". To indicate direct quotes from your manuscript, or elaborate on the text by providing additional information and / or the e.g. to briefly explain why the item is not applicable/relevant for your study.

Participants will be all participants that are attending one of the participating services and meet the following criteria: Inclusion criteria: Participants will be included in the study if they fulfill the criteria for one of the participating Youth outreach alcohol services: (1) aged 16 years or older, (2) consumed alcohol in the last 30 days, (3) have a score of 2 or more on the AUDIT-C, (4) participate in a group session, (5) have the ability to understand the Dutch language, (6) have the ability to give informed consent. Exclusion criteria: Participants will be excluded if they fulfilling exclusion criteria: (1) current use of weekly (or more) drugs or alcohol, (2) participation in a treatment for alcohol or drug addiction, (3) participation in a study with a control group, (4) aged 15 or younger.

Are 5c) Controlled / Internal Validity

Computer / Internet Survey is often an subject "be-bias" eligibility criteria - this should be carefully verified.

Does your paper addresses CONSORT subtask 5c?

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". To indicate direct quotes from your manuscript, or elaborate on the text by providing additional information and / or the e.g. to briefly explain why the item is not applicable/relevant for your study.

Participants will be invited to participate in the study by the youth outreach alcohol services and meet the following criteria: Inclusion criteria: Participants will be included in the study if they fulfill the criteria for one of the participating Youth outreach alcohol services: (1) aged 16 years or older, (2) consumed alcohol in the last 30 days, (3) have a score of 2 or more on the AUDIT-C, (4) participate in a group session, (5) have the ability to understand the Dutch language, (6) have the ability to give informed consent. Exclusion criteria: Participants will be excluded if they fulfilling exclusion criteria: (1) current use of weekly (or more) drugs or alcohol, (2) participation in a treatment for alcohol or drug addiction, (3) participation in a study with a control group, (4) aged 15 or younger.

essential and not at all essential 1 2 3 4 5 6 7 8 9 10

Clear selection

Does your paper addresses subtask 5c?

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". To indicate direct quotes from your manuscript, or elaborate on the text by providing additional information and / or the e.g. to briefly explain why the item is not applicable/relevant for your study.

Not relevant for this study

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

This is a controlled study. Participants will be individually randomized into either the control group or the SM group (+ / -). The randomization will be done and answers to questionnaires will be collected by a third party (Medical Research Institute of New Zealand). Participants will be blinded to the intervention (SM or control) and will be asked to complete a questionnaire at baseline, immediately post-intervention and at 12 weeks post-intervention (assumed +/-). When a participant is enrolled, the assessor will then open the envelope containing the allocation for the participant. Therefore, a participant's allocation is concealed from the assessor until after the baseline questionnaire has been completed. The assessor will then open the envelope containing the allocation for the participant. Therefore, a participant's allocation is concealed from the assessor until after the baseline questionnaire has been completed.

Q6. Type of randomisation, details of any restriction (such as blocking and block size)

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

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Q7.Randomized under-or-stratified sample size

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Q8.Blinding (masking) of participants, caregivers, and assessors

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

This is a controlled study. Participants will be individually randomized into either the control group or the SM group (+ / -). The randomization will be done and answers to questionnaires will be collected by a third party (Medical Research Institute of New Zealand). Participants will be blinded to the intervention (SM or control) and will be asked to complete a questionnaire at baseline, immediately post-intervention and at 12 weeks post-intervention (assumed +/-). When a participant is enrolled, the assessor will then open the envelope containing the allocation for the participant. Therefore, a participant's allocation is concealed from the assessor until after the baseline questionnaire has been completed. The assessor will then open the envelope containing the allocation for the participant. Therefore, a participant's allocation is concealed from the assessor until after the baseline questionnaire has been completed.

Q9.Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Q10.Blinding (masking) of participants, caregivers, and assessors

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

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Q11.Who, when, and how blinded other arrangements to interventions (for example, placebo, sham, or other) and assessments were made

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Q12.Specify who (eg, clinician, patient, carer, nurse) and how (eg, double-blind, triple-blind, open-label) blinding was achieved, and if it was successful. Provide the reasons for and against success, if they are given. Provide the reasons for and against success, if they are given.

1 2 3 4 5 6 7 8 9 10

Comments

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Q13.Blinding of participants and caregivers

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Participants and researchers were aware

Q14.Blinding of assessors

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Participants and researchers were aware

Q15.Blinding of the analysis of the similarity of interventions

Were it is possible not relevant the sheetfit mean it refers to similarity of a placebo or sham intervention to the intervention, or if it is not applicable, leave blank.

1 2 3 4 5 6 7 8 9 10

Comments

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Described under the Intervention and Procedures headings in the Method

Q16.Statistical methods used to compare groups for primary and secondary outcomes

MTT, Mann-Whitney U test, chi-squared and the two-tailed sig.(sig.) are provided in the results section.

Copy and paste relevant sentences from the manuscript (include quotes in question marks "like this". It indicates direct quotes from your transcripts), or elaborate on this item by providing additional information (not in the q.) or briefly explain why the item is not applicable/relevant to your study

Reports and demographic variables were descriptive statistics (special. Scorecard Research, Inc.). Differences between the groups were tested using the Mann-Whitney U test (Mann and Whitney, 1947) and the chi-square test (Pearson, 1900). Because the distribution of the dependent variable was not normal, and statistical assumptions of the parametric equivalent were violated, the Mann-Whitney U test was used to compare the groups. The Mann-Whitney U test is a non-parametric equivalent of the independent-samples t-test and is used to compare two groups when the assumptions of the parametric equivalent are not met. Because the distribution of the dependent variable was not normal

providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

19) All important harms or unintended effects in each group
(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

19-i) Include primary harms, technical problems
Include primary breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 19-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

19-ii) Include qualitative feedback from participants or observations from staff/researchers
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. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

	1	2	3	4	5	
subitem not at all important	○	○	◉	○	○	essential

Clear selection

Does your paper address subitem 19-ii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
MT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)
Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

	1	2	3	4	5	
subitem not at all important	○	◉	○	○	○	essential

Clear selection

Does your paper address subitem 22-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

22-ii) Highlight unanswered new questions, suggest future research
Highlight unanswered new questions, suggest future research.

	1	2	3	4	5	
subitem not at all important	○	◉	○	○	○	essential

Clear selection

Does your paper address subitem 22-ii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials
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.

	1	2	3	4	5	
subitem not at all important	○	◉	○	○	○	essential

Clear selection

Does your paper address subitem 20-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

21) Generalizability (external validity, applicability) of the trial findings
MT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations
Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient populations, including applicability of the study results for other organizations

	1	2	3	4	5	
subitem not at all important	○	◉	○	○	○	essential

Clear selection

Does your paper address subitem 21-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting
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) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting

	1	2	3	4	5	
subitem not at all important	○	◉	○	○	○	essential

Clear selection

Does your paper address subitem 21-ii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - protocol manuscript

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Trial registration: ISRCTN ISRCTN48455361"

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *
Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is the protocol so not applicable

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

yes in the Acknowledgment section

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated
In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

	1	2	3	4	5	
subitem not at all important	○	◉	○	○	○	essential

Clear selection

Does your paper address subitem X27-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks 'like this' to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes under Conflicts of Interest heading

About the CONSORT EHEALTH checklist

As a result of using this checklist, did you make changes in your manuscript? *

- ○ yes, major changes
- ○ yes, minor changes
- ◉ no

What were the most important changes you made as a result of using this checklist?

Your answer

How much time did you spend on going through the checklist INCLUDING making changes in your manuscript

45 minutes roughly to go through this survey

As a result of using this checklist, do you think your manuscript has improved? *

- ○ yes
- ◉ no
- ○ Other:

Clear selection

Would you like to become involved in the CONSORT EHEALTH group?
This would involve for example becoming involved in participating in a workshop and writing an 'Explanation and Elaboration' document

- ○ yes
- ◉ no
- ○ Other:

Clear selection

Any other comments or questions on CONSORT EHEALTH

Your answer

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To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select 'print' and then select 'print as PDF') before you submit it.

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