

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

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be

- a) a guide for reporting for authors of RCTs,
- b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.

Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red \*.

In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).

Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF \_AND\_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):

Eysenbach G, CONSORT-EHEALTH Group

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions

J Med Internet Res 2011;13(4):e126

URL: <http://www.jmir.org/2011/4/e126/>

doi: 10.2196/jmir.1923

PMID: 22209829

 [Switch account](#)

 Not shared

 Draft saved

\* Indicates required question

Your name \*

First Last

Daniel Vigo

Primary Affiliation (short), City, Country \*

University of Toronto, Toronto, Canada

University of British Columbia, Vancouver, Can

Your e-mail address \*

[abc@gmail.com](mailto:abc@gmail.com)

daniel.vigo@ubc.ca

Title of your manuscript \*

Provide the (draft) title of your manuscript.

Effectiveness of the Minder Mobile Mental Health and Substance Use Intervention for University Students: A Randomized Controlled Trial

Name of your App/Software/Intervention \*

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

Minder

Evaluated Version (if any)

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Your answer

Language(s) \*

What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

English

URL of your Intervention Website or App

e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

<https://www.myminder.ca/>

URL of an image/screenshot (optional)

Your answer



**Accessibility \***

Can an enduser access the intervention presently?

- ☐ access is free and open
- ☒ access only for special usergroups, not open
- ☐ access is open to everyone, but requires payment/subscription/in-app purchases
- ☐ app/intervention no longer accessible
- ☐ Other:

**Primary Medical Indication/Disease/Condition \***

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Mental Health and Substance Use (University :

**Primary Outcomes measured in trial \***

comma-separated list of primary outcomes reported in the trial

anxiety symptomology, depressive symptomol

**Secondary/other outcomes**

Are there any other outcomes the intervention is expected to affect?

frequency of substance use (cannabis, alcohol, opioids, and non-medical stimulants) and mental well-being

**Recommended "Dose" \***

What do the instructions for users say on how often the app should be used?

- ☐ Approximately Daily
- ☐ Approximately Weekly
- ☐ Approximately Monthly
- ☐ Approximately Yearly
- ☒ "as needed"
- ☐ Other:



Approx. Percentage of Users (starters) still using the app as recommended after 3 months \*

- ☒ unknown / not evaluated
- ☐ 0-10%
- ☐ 11-20%
- ☐ 21-30%
- ☐ 31-40%
- ☐ 41-50%
- ☐ 51-60%
- ☐ 61-70%
- ☐ 71-80%
- ☐ 81-90%
- ☐ 91-100%
- ☐ Other:

Overall, was the app/intervention effective? \*

- ☐ yes: all primary outcomes were significantly better in intervention group vs control
- ☒ partly: SOME primary outcomes were significantly better in intervention group vs control
- ☐ no statistically significant difference between control and intervention
- ☐ potentially harmful: control was significantly better than intervention in one or more outcomes
- ☐ inconclusive: more research is needed
- ☐ Other:

Article Preparation Status/Stage \*

At which stage in your article preparation are you currently (at the time you fill in this form)

- ☐ not submitted yet - in early draft status
- ☒ not submitted yet - in late draft status, just before submission
- ☐ submitted to a journal but not reviewed yet
- ☐ submitted to a journal and after receiving initial reviewer comments
- ☐ submitted to a journal and accepted, but not published yet
- ☐ published
- ☐ Other:



## Journal \*

If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- ☐ not submitted yet / unclear where I will submit this
- ☒ Journal of Medical Internet Research (JMIR)
- ☐ JMIR mHealth and UHealth
- ☐ JMIR Serious Games
- ☐ JMIR Mental Health
- ☐ JMIR Public Health
- ☐ JMIR Formative Research
- ☐ Other JMIR sister journal
- ☐ Other:

## Is this a full powered effectiveness trial or a pilot/feasibility trial? \*

- ☐ Pilot/feasibility
- ☒ Fully powered

## Manuscript tracking number \*

If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- ☒ no ms number (yet) / not (yet) submitted to / published in JMIR
- ☐ Other:

## TITLE AND ABSTRACT

## 1a) TITLE: Identification as a randomized trial in the title

## 1a) Does your paper address CONSORT item 1a? \*

I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- ☒ yes
- ☐ Other:



## 1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. 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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

## Does your paper address subitem 1a-i? \*

Copy and paste relevant sections from manuscript title (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

"Mobile Mental Health and Substance Use Intervention"

## 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

## Does your paper address subitem 1a-ii?

Copy and paste relevant sections from manuscript title (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

Your answer

## 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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
Clear selection						



Does your paper address subitem 1a-iii? \*

Copy and paste relevant sections from manuscript title (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

"Mental Health and Substance Use Intervention for University Students"

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention 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. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 1b-i? \*

Copy and paste relevant sections from the manuscript abstract (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

"The Minder app delivers evidence-based content through an automated chatbot and connects participants with services and social groups at the university."

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the 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). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						



Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (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

"Participants are also provided a trained peer coach to support them throughout the trial."

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or "unblinded" to indicated the level of blinding instead of "open", as "open" in web-based trials usually refers to "open access" (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 1b-iii?

Copy and paste relevant sections from the manuscript abstract (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

"participants were recruited from the university", "The primary outcomes were measured through in-app self-assessments"

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						





Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (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

"80% of participants in the intervention group (n=589) and 83% of participants in the control group (n=619) completed the follow-up survey.", "496 participants from the intervention group (67%) accessed at least one app component during the study period."

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

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. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (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

Your answer

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						



Does your paper address subitem 2a-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

University students have high rates of mental health and substance use problems, yet many do not receive treatment. The Minder app uses a transdiagnostic approach to provide interventions to a general population of students to support their mental health and risk related to substance use. It was co-developed with students to align with the perceived needs and preferences of this population.

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to 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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 2a-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

"E-interventions can be accessed by users at any time and have been demonstrated to be effective in improving various mental health and substance use outcomes in university students", "These interventions have also been identified as key components in proposed models of care for universities". This intervention has been designed for a general population of students to provide tools that are accessible and can be integrated with existing university health services.

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? \*

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

"The objective of this study was to test the effectiveness of the Minder mobile app in improving mental health and substance use outcomes in a general population of university students."

METHODS



## 3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? \*

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 study is based on a 2-arm parallel assignment single blinded (the statistician was blinded) 30-day randomized controlled trial with 1 intervention group and 1 waitlist control group."

## 3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? \*

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

"No significant changes to the trial protocol or intervention content were made during the trial period; however, several minor adjustments along with a description of minor technical issues can be found in Appendix A."

## 3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes 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) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 3b-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

A list of bug fixes, downtimes, and content changes can be found in Appendix A.

## 4a) Eligibility criteria for participants



Does your paper address CONSORT subitem 4a? \*

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

"The inclusion criteria were as follows: student currently enrolled at the UBC Vancouver campus, aged  $\geq 17$  years, have access to and be able to use a smartphone with Wi-Fi or cellular data, and speak English. The only exclusion criterion was based on a single screening question assessing suicidality risk ("We want to make sure that this app is appropriate for you at this time. Do you have a current suicidal plan [i.e., a plan to end your life]?")."

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 4a-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

Participants needed to "have access to and be able to use a smartphone with Wi-Fi or cellular data"

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. 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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						



Does your paper address subitem 4a-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

Participants were recruited using both online and in- person methods; however, registration was done through an online form which did not require contact with the research team. All assessments were done through the Minder app. "The eligibility criteria of being a current UBC student was confirmed using a unique student login checkpoint as part of the registration process. This process also ensured that each student could only enroll once."

4a-iii) Information giving during recruitment

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), as this information may have an effect on user self-selection, user expectation and may also bias results.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 4a-iii?

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

"The consent form indicated that participants would either gain access to the full app immediately or in 30-days following completion of the final survey."

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? \*

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

"The study was conducted at the University of British Columbia (UBC) Point Grey (Vancouver) Campus."



**4b-i) Report if outcomes were (self-)assessed through online questionnaires**

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

**Does your paper address subitem 4b-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

"Main assessments of the primary and secondary outcomes were collected through self-assessment within the Minder app at baseline and 30-day follow-up"

**4b-ii) Report how institutional affiliations are displayed**

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item – describe only if this may bias results)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

**Does your paper address subitem 4b-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

Your answer

**5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered**

**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 or mentioned elsewhere in the manuscript).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection



Does your paper address subitem 5-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

The app was developed as an academic research project at the University of British Columbia. The software developers were contracted by the research team to develop the app based on the direction of the research team. Health Canada funded the research grant. The Intellectual Property for this research is owned by the University of British Columbia.

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), as these will have an impact on adoption/use rates and help with interpreting results.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-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

"The co-development process consisted of ongoing student input through student-staff members and volunteers, along with several phases of purposeful student engagement and feedback." The full development process is described in a manuscript published by the research team (Vereschagin et al., 2023)

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or 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).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						



Does your paper address subitem 5-iii?

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

Only minor changes to the intervention were made to correct technical aspects. These are summarized in Appendix B.

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-iv?

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

All content in the Minder app was thoroughly reviewed and tested by both clinicians and student team members.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Does your paper address subitem 5-v?

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

Screenshots of the Minder app can be found in Figure 1 and Figure 2.





## 5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, [webcitation.org](https://webcitation.org), and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

## Does your paper address subitem 5-vi?

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

The intervention is not currently available to the public or listed in the smartphone app stores for download.

## 5-vii) Access

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. If known, describe how participants 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).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

## Does your paper address subitem 5-vii? \*

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

"Individual accounts were created for each participant and sent to them with a link to download the app. Upon downloading the app and completing the baseline survey, participants were randomly assigned through the app to the intervention group which received full access to the Minder app or to the control group which only had access to a restricted version of the app which included a short introduction video and the baseline and follow-up surveys. Participants received a \$10 gift card for completion of the baseline survey and an additional \$10 gift card for completion of the 30-day follow up survey; however, the use of the app itself was not remunerated."



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., see e.g., [7, 8] for terminology). This includes an in-depth 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]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-viii? \*

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

"Participants who were randomized to the intervention group were given full access to the Minder app and instructed to use the app as they wanted.", "The Minder intervention contains 4 main components—Chatbot, Services, Community, Peer Coaches.", "The content is based primarily on Cognitive Behavioural Therapy (CBT) and psychoeducation; however, there is also content adapted from Dialectical Behavioural Therapy, Mindfulness, Metacognitive Training, and Motivational Interviewing." Non-clinical support was provided to users through trained Peer Coaches who could communicate synchronously or asynchronously with participants and provide recommendations, answer questions or chat about anything the participants needed support with.

5-ix) Describe use parameters

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-ix?

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

Participants were told that they have free control over which components they choose to use and that it is not required they spend any specific amount of time using the app outside of completing the baseline and follow-up surveys.



## 5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". 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 – generalizability).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
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## Does your paper address subitem 5-x?

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

"The Peer Coaching component consists of trained volunteers assigned to each participant. These Peer Coaches reach out to participants at the beginning of the trial and midway through. They can provide support navigating the app or provide non-clinical peer support based on active listening and problem-solving. Peer Coaches can communicate with participants through an in-app chat asynchronously or synchronously through scheduled appointments delivered over text, audio, or video call."

## 5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. 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).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
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## Does your paper address subitem 5-xi? \*

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

For participants in the intervention group, "[g]eneral notifications were sent on days 4, 18, and 24. Reminders to complete the 2-week and 30-day follow up survey were sent as push notifications and by automated email reminders on those dates, respectively. Additional email reminders were sent on day 35 and day 41 to remind participants to complete the follow-up survey if they had not done so already." For participants in the control group, "[t]he app also provides push-notifications and automated email reminders to complete the follow up survey on day 30, as well as additional email reminders on day 35 and day 41 if the survey is not yet complete." In both groups, participants who consented to the study but did not complete the baseline survey received 3 additional emails to remind them to begin the study.

## 5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, 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).

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subitem not at all important   ☐   ☒   ☐   ☐   ☐   essential

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## Does your paper address subitem 5-xii? \*

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, there were no co-interventions offered

## 6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

## Does your paper address CONSORT subitem 6a? \*

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

All primary and secondary outcomes were measures at baseline and 30-day follow up survey. The primary outcomes were anxiety symptoms (General Anxiety Disorder Assessment – GAD-7), depressive symptoms (Patient Health Questionnaire 9 – PHQ-9), and alcohol consumption risk (United States Alcohol Use Disorders Identification Test-Consumption - USAUDIT-C). The secondary outcomes were frequency of substance use (cannabis consumption, drinking sessions, drinks consumed in a typical session, binge drinking, opioid use, and non-medical stimulant use) and mental well-being (Short Warwick-Edinburgh Mental Wellbeing Scale - SWEMWS).

## 6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

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subitem not at all important   ☐   ☒   ☐   ☐   ☐   essential

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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

The primary and secondary outcomes utilized previously validated measures/scales that are widely used in both paper and online surveys.

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
<a href="#">Clear selection</a>						

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

"The participants utilization of the app components were recorded through the app backend system. This includes starting each of the chatbot activities, completing the Services survey and receiving recommendations, viewing Community groups and communicating with a peer coach."

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Your answer

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? \*

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

No changes to the trial outcomes were made after the trial commenced

**7a) How sample size was determined**

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

**7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size**

Describe whether and how expected attrition was taken into account when calculating the sample size.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

**Does your paper address subitem 7a-i?**

Copy and paste relevant sections from manuscript title (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

"The a priori sample size calculation for a small effect assessed by the PHQ-9, GAD-7, and USAUDIT-C was calculated using an effect size defined by Cohen's  $d = \Delta / \sigma$ , where  $\Delta$  is the group mean difference at the completion of the study and  $\sigma$  is the (pooled) within-group SD. For a small effect size (Cohen's  $d = 0.2$ ), the sample size required to have 80% power at the level of significance  $P = .02$  (i.e., 0.05/3 primary outcomes) is 524 in each group."

**7b) When applicable, explanation of any interim analyses and stopping guidelines****Does your paper address CONSORT subitem 7b? \***

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, no interim analyses were conducted

**8a) Method used to generate the random allocation sequence**

NPT: When applicable, how care providers were allocated to each trial group

**Does your paper address CONSORT subitem 8a? \***

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

"The randomization lists (one for each stratification group) were generated using the web-based stratified block randomization list creator in the clinical trial software Sealed Envelope (Clerkenwell Workshop, n.d.)."



8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? \*

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

"The system assigned participants to either the intervention group or control using a predetermined block randomization list (1:1 randomization in blocks of 10), stratified for past drug use (any lifetime use of opioids or non-medical stimulants)."

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

Does your paper address CONSORT subitem 9? \*

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

"Participants were randomized using a custom-developed automated process incorporated directly into the mobile app following completion of the baseline survey."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? \*

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

The random allocation list was generated by a data analyst outside of the research team.  
"The system assigned participants to either the intervention group or control using a predetermined block randomization list"

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how  
NPT: Whether or not administering co-interventions were blinded to group assignment



## 11a-i) Specify who was blinded, and who wasn't

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 or those administering co-interventions (if any).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

## Does your paper address subitem 11a-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

"The study used a single-blinded approach where only the statistician who is external to the team was blinded to the treatment group assignment when examining the primary hypotheses."

## 11a-ii) Discuss e.g., 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 - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

## Does your paper address subitem 11a-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

"Participants who were randomized to the control group had access to a locked version of the app which only allowed them to complete the 30-day follow up survey and view a short introduction video that appears before the login screen."

## 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)





Does your paper address CONSORT subitem 11b? \*

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 relevant, trial consisted of an intervention and waitlist control group

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? \*

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

"The primary analysis was intention-to-treat including all participants who completed the baseline assessment and were randomized into either the control or intervention group, following the analysis plan prespecified in our protocol paper (Wang et al., 2023)... For the 3 primary end points (GAD-7, PHQ-9, and USAUDIT-C), a global test for the null hypothesis of no treatment difference in all primary end points between the control and treatment groups was conducted first using a multivariate analysis of covariance (MANCOVA) for correlated data on GAD-7, PHQ-9, and USAUDIT-C at 30 days post baseline, adjusting for their values at baseline and randomization blocks. When the global test rejects the null hypothesis and we conclude that there is an intervention effect on at least 1 of the 3 end points, we would then analyze each end point separately to identify which of the 3 study end points are affected by the intervention. We then used the sequential Hochberg correction method (Hochberg, 1988) to control the overall family-wise error rate at  $\alpha=.05$  when testing the hypothesis for each individual primary end point... For secondary outcomes, we used linear mixed-effect models to analyze mental well-being measures, a mixed-effects quasi-Poisson regression models with the log link (a special case of GLMMs) for substance use frequency measures, and the Zero Inflated Poisson was used for the number of drinks to deal with the excess zeros counts."

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						



Does your paper address subitem 12a-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

"GLMMs have been widely used for conducting ITT analysis in randomized controlled trials with missing outcome data and can account for data missing at random without the need to model why data are missing or to perform explicit imputations of the missing values (Diggle, 2013)."

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? \*

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, subgroup analyses will be conducted in future papers

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem X26-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

"Ethics approval was obtained by the UBC Behavioral Research Ethics Board on January 6, 2022 (Ethics ID: H21-03248)."



## x26-ii) Outline informed consent procedures

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

## Does your paper address subitem X26-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

"Participants' consent was obtained using Qualtrics, a web-based form, after completing the eligibility screening. The consent form indicated that participants would either gain access to the full app immediately or in 30-days following completion of the final survey."

## X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

## Does your paper address subitem X26-iii?

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

Security: "Many steps were taken to ensure the privacy of participants. Each participant receives an individual account which has a unique username and password. They are then able to change this password upon logging in. Only participant email and phone number (if provided through access to peer coaching) are stored within the app, names are used only for consent and are never entered into the app. Instead, participants can create a unique username within the app which they are informed should not include their full name. Identifiable data (email and phone number) are stored in separate data files within the app backend from all the app utilization and survey data which is recorded with only a study id number."

Safety: "Anyone endorsing a current suicidal plan (i.e., answering "yes") was prevented from registering and was instead provided with a list of local crisis resources."; "An additional safety component was added so that participants screening at high risk of suicidality (i.e., plan for suicide or recent attempt, thoughts of hurting others) were asked within the survey to consent to provide their contact information and receive an expedited appointment with the university counselling services."; "An SOS button appears in the top corner of the home page and provides a list of crisis resources if needed (see Figure 1.)."

## RESULTS



13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome  
 NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? \*

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

"1489 participants completed the baseline survey and were randomized into the trial with 743 participants in the intervention group and 746 participants in the control group."

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) \*

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

"80% of participants in the intervention group (n=589) and 83% of participants in the control group (n=619) completed the 30-day follow-up survey within the specified 44-day time period to be included in analysis (i.e., 19% of participants who completed the baseline (n=279) did not complete the 30-day follow-up survey within 44 days and were therefore considered lost to follow-up)."

13b-i) Attrition diagram

Strongly recommended: An 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) or other figures or tables demonstrating usage/dose/engagement.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (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

Your answer

14a) Dates defining the periods of recruitment and follow-up



Does your paper address CONSORT subitem 14a? \*

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

"Recruitment initially began on September 4, 2022, during an on-campus student orientation event where interested students were asked to provide contact information to receive a follow-up email; however, participants were not provided with app download information and user accounts to begin the study until September 28, 2022, due to technical delays. Recruitment concluded on June 2, 2023, with the last participant beginning the trial on June 11, 2023."

14a-i) Indicate if critical "secular events" fell into the study period

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	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Does your paper address subitem 14a-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

Your answer

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? \*

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

The trial stopped once the target sample was recruited.

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group



Does your paper address CONSORT subitem 15? \*

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

Included in manuscript, Table 1.

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Does your paper address subitem 15-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

Demographic information for age, gender, and student year were included as part of the participant characteristics (Table 1.).

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple "denominators" and provide definitions

Report multiple "denominators" and provide definitions: Report N's (and effect sizes) "across a range of study participation [and use] thresholds" [1], e.g., 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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 16-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

N= 2372 consented to the study, N=2293 were invited to participate in the trial, N=1489 completed the baseline survey and were randomized into the trial (743 participants in the intervention group and 746 participants in the control group). "Among those in the intervention group (n=743), 496 (67%) accessed at least one app component during the 30 days of follow-up."

## 16-ii) Primary analysis should be intent-to-treat

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).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

## Does your paper address subitem 16-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

"The primary analysis was intention-to-treat including all participants who completed the baseline assessment and were randomized into either the control or intervention group"

## 17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

## Does your paper address CONSORT subitem 17a? \*

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

"The results of these GLMM's indicated that participants in the intervention group had significantly greater reductions in anxiety symptoms (adjusted group mean difference = -0.85 (95% CI -1.27, -0.42),  $P < .001$ , Cohen's  $d = -0.17$  (95% CI -0.26, -0.09)) and depressive symptoms (adjusted group mean difference = -0.63 (95% CI -1.08, -0.17),  $P < .001$ , Cohen's  $d = -0.11$  (95% CI -0.19, -0.03)) compared to the control group (See Table 2). Although participants in the intervention group also demonstrated a greater reduction in alcohol risk scores on the USAUDIT-C, this difference was not statistically significant (adjusted group mean difference = -0.13 (95% CI -0.34, 0.08),  $P = 0.23$ ).", "The results of these GLMMs indicated that compared to those in the control group, participants in the intervention group had significantly greater improvements in mental wellbeing (adjusted mean difference = 0.73 (95% CI 0.35, 1.1),  $P < .001$ , Cohen's  $d = 0.17$  (95% CI 0.08, 0.26) and significantly associated with 20% reductions in their frequency of cannabis use (IRR=0.80 (95% CI 0.66, 0.96),  $P = .02$ ) and a 13% reduction on typical number of drinks consumed when drinking (IRR=0.87 (95% CI 0.77, 0.98),  $P = .03$ ). No significant differences were found on frequency of binge drinking (IRR=0.98 (95% CI 0.86, 1.13),  $P = .83$ ), frequency of drinking (IRR=0.97 (95% CI 0.88, 1.06),  $P = .48$ ) and frequency of any opioid use (IRR=0.62 (95% CI 0.16, 2.31),  $P = .48$ ). The impact of the intervention on non-medical stimulant use was not able to be assessed due to the small number of non-medical stimulant users at baseline and follow-up."



17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 17a-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

"Among those in the intervention group (n=743), 496 (67%) accessed at least one app component during the 30 days of follow-up. More specifically, 453 (61%) engaged with one or more chatbot activities; 147 (20%) accessed the community component; 188 (25%) completed the services survey; and 113 (15%) accessed a peer coach."

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? \*

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 to our analysis

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? \*

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

No additional subgroup analyses or adjusted analyses were included in this paper. These will be done in future papers.





**18-i) Subgroup analysis of comparing only users**

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but 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).

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Clear selection

**Does your paper address subitem 18-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

"As outlined in our study protocol, we plan to complement these finding with additional secondary analyses to examine the impact of Minder in subgroups of participants defined by the extent of their app utilization and baseline mental health and sociodemographic characteristics."

**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

No important harms or unintended effects were identified

**19-i) Include privacy breaches, technical problems**

Include privacy 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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Clear selection

**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

See Appendix A of 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

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

Your answer

## DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: 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

"In this study, we found that participants in the intervention group who had access to the Minder app reported significantly greater average reductions in symptoms of anxiety (GAD-7) and depression (PHQ-9) compared to the control group.", "Although we did not find evidence of an effect on overall alcohol consumption risk in our primary outcome analyses of the USAUDIT-C, we did find significant reductions in cannabis use frequency and typical number of alcoholic drinks consumed in a drinking session in our analysis of secondary outcomes."



## 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	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

"Further research will be done to better understand how to optimize the Minder intervention for different needs and for additional populations. By better understanding who benefitted from the intervention and what content they utilized, we plan to make the app more personalized (including recommendations and features). Additionally, future co-development processes will be needed to further improve the utilization of the app and incorporation into existing systems of care. There were some participants who did not utilize the app outside of the surveys, so trying to make the intervention more appealing for these users will be important."

## 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	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

"As with many trials for online interventions, the participants were not blinded to what condition they were in leading to a potential for placebo effects. However, control group participants did download the app and completed the surveys within it which may have helped to mitigate these effects on the trial. There were also several minor technical issues throughout the trial which may have impacted the participants' experience with the app; however, these were resolved quickly by the research team. An explanation of these issues can be found in Appendix C. There were some participants who did not use the app at all apart from completing the surveys."



**21) Generalisability (external validity, applicability) of the trial findings**

NPT: 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 population, including applicability of the study results for other organizations

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	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

"Another strength of this study is the pragmatic trial design that included a large non-clinical sample. Remuneration was only provided to participants for completion of the baseline and follow-up surveys, not for use of the intervention itself. Participants were also not told to use the app in any specific way or for any given amount of time when starting the study. Although this approach may have contributed to the finding of small average effects, it does increase the generalizability of our findings to other populations and provides an estimate of the impact of the app if it were made available to all students."

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

**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

Your answer

**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

ClinicalTrials.gov [NCT05606601]

## 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

<https://www.researchprotocols.org/2023/1/e49364>

## 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

"This work was supported by Health Canada's Substance Use and Addictions Program (arrangement:1920-HQ-000069; University of British Columbia ID: F19-02914)."

## 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential



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

Your answer

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?

Changes to information included in title and abstract

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

Around 7 hours filling in the checklist and making changes

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

- ☒ yes
- ☐ no
- ☐ Other:

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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