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

* Required

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Title of your manuscript *

Provide the (draft) title of your manuscript.

Evaluating optional web-based videoconferencing in addition to added to office-based care for women receiving psychotherapy during the postpartum period: A pilot 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.

OTNhub

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://otnhub.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)"

Postpartum mood and anxiety disorders

Primary Outcomes	measured i	in trial *

comma-separated list of primary outcomes reported in the trial

Recruitment, retention, uptake, therapy att

Secondary/other outcomes

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

Symptom outcomes (postnatal depression, generalized anxiety, parental stress)

	Recommended "Dose" * What do the instructions for users say on how often the app should be used?						
0	Approximately Daily						
0	Approximately Weekly						
0	Approximately Monthly						
0	Approximately Yearly						
•	"as needed"						
0	Other:						

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

o unknown / not evaluated
O-10%
O 11-20%
21-30%
31-40%
O 41-50%
51-60%
O 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
on statistically significant difference between control and intervention
o potentially harmful: control was significantly better than intervention in one or more outcomes
inconclusive: more research is needed
Other: Not applicable based on primary outcomes
Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form)
onot submitted yet - in early draft status
onot 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
O 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")
onot 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)
on ms number (yet) / not (yet) submitted to / published in JMIR
Other: 13172

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
	yes

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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	0	\circ	\circ	\circ	\circ	essential

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

"Web-based videoconferencing" is in the title.

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 O O o 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

"In addition to office-based care" is in the title.

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 O O O essential

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

"For women receiving psychotherapy during the postpartum period" is in the

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	\circ	\circ	0	\circ	0	essential

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

"We conducted a pilot randomized controlled trial with 1:1 randomization to officebased care (treatment as usual; TAU) or office-based care with the option of VC (TAU-VC) for psychotherapy during the postpartum period."

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	0	\circ	\circ	\circ	\circ	essential

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

"The objective of the pilot RCT was to assess the feasibility, acceptability, and preliminary effectiveness of adding the option of VC in addition to usual office-based psychotherapy with a psychotherapist during the postpartum period."

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)

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subitem not at	\circ	\circ	0	0	0	essential

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

Since the intervention involves providing patients with access to videoconferencing psychotherapy with a psychotherapy, it was not possible to blind either the participants or psychotherapists.

We mentioned the participants were recruited "from a specialized mental health clinic".

"We also compared therapy attendance using therapist logs and symptoms between groups. Symptoms were assessed at baseline and 3-months post randomization with the Edinburgh Postnatal Depression Scale (EPDS), Generalized Anxiety Disorder 7-Item (GAD-7), and Parental Stress Scale (PSS)."

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	0	\circ	\circ	\circ	\circ	essential

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

"We enrolled 38 participants into the study; 19 in each treatment group. Attendance data were available for all participants, with follow-up symptom measures available for 25 (65.8%). Among the 19 TAU-VC participants, 14 (74%) utilized VC at least once. The majority of participants were highly satisfied with the VC option, and reported an average savings of \$26CAD and 2.5 hours in travel and childcare expenses and time per appointment. There were no significant differences between the two groups for psychotherapy attendance or symptoms."

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)

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subitem not at all important	0	\circ	\circ	0	\bigcirc	essential

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

Not applicable, not negative.



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 standalone 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	0	\circ	\circ	\circ	\circ	essential

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

"Up to 15% of women experience postpartum mood disorders, with most preferring psychotherapy over medication for the treatment of their mental illnesses. However, childcare responsibilities and physical recovery, particularly after a surgical birth, create barriers for regular therapy attendance. Barriers to care often lead to delayed care, treatment discontinuation, and the lack of follow-up on recommendations. Untreated symptoms of perinatal mental illness can last for months or years, leading to persistent mental health problems and decreased quality of life for both the woman and child."

"By overcoming the barriers to care that can be present in varying ways across a course of treatment, the addition of VC to an office-based treatment program could provide a very patient-centred option to receive care. This could lead to improved therapy adherence and completion rates, and possibly better outcomes as a result"

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 appropiate), 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	0	\circ	\circ	\circ	\circ	essential

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

"They (virtual care tools) can address many barriers associated with in-person care, such as travel distance and time, travel costs, and stigma."

A study by Maloni and colleagues [6] found that among postpartum women with depression and "who experienced pregnancy complications, over 90% demonstrated interest in Internet-based interventions, with 40% indicating a specific interest in chatting virtually with a provider with expertise in postpartum depression." Studies on VC-based psychotherapy have demonstrated similar treatment outcomes when directly compared to the face-to-face option"

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

"In this study, we assessed the acceptability, uptake and preliminary effectiveness of adding the option to receive psychotherapy delivered by VC to standard office-based psychotherapy for women experiencing mood and anxiety problems during their first vear postpartum."

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 was a pilot randomized controlled trial comparing usual office-based care (treatment as usual; TAU) to office-based care with the option of VC on a personal device (TAU-VC) for psychotherapy for mood or anxiety problems in the postpartum period."

"Participants were randomized 1:1 into one of the two treatment arms..."

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

"Participation was initially just offered to only new referrals to the clinic, but was expanded to include patients already in treatment after trial commencement to increase recruitment rate."

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	\circ	\circ	0	0	0	essential

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

There were not any changes made on the intervention or comparator, or any "unexpected events", that influenced study design.

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 for this study were patients in the program, 18 years of age or older, referred to psychotherapy for mood and/or anxiety symptoms, who had access to and ability to use a web-enabled personal device or computer with the required audiovisual communication capability, and had a functioning email address (a requirement for the VC platform). Patients could be approached when pregnant if they intended to continue or start psychotherapy postpartum, but the study protocol was not initiated until after the woman returned for therapy postpartum. For postpartum patients, only women less than 9 months post-partum were included, to allow a minimum of 3 months of treatment before they reached 1 year postpartum and were discharged from the program. Patients with acute mania or psychosis, or severe suicidal ideation with planning and intent were excluded."

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	0	\circ	\circ	\circ	\circ	essential

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

"...who had access to and ability to use a web-enabled personal device or computer with the required audiovisual communication capability..."

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	0	\circ	\circ	\circ	\circ	essential

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

"Participation was initially just offered to only new referrals to the clinic, but was expanded to include patients already in treatment after trial commencement to increase recruitment rate."

"Psychotherapists introduced the study to newly referred patients during the initial call about treatment, and to existing patients during a therapy session."

We believe it is clear that there is a face-to-face component from the following: "In the TAU-VC group, participants had access to TAU with the added option of having any of their treatment sessions over VC."

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	0	\circ	\circ	\circ	\circ	essential

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

Your answer

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

"Psychotherapists introduced the study to newly referred patients during the initial call about treatment, and to existing patients during a therapy session."

"Therapists provided the contact information of interested patients to a Research Assistant. The Research Assistant contacted interested patients to introduce and explain the study. If the patient was still interested, the Research Assistant obtained and documented informed verbal consent over the phone, and emailed a copy of the completed consent form to the patient."

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

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

	1	2	3	4	5	
subitem not at	\circ	0	0	\circ	0	essential

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

"Participants were recruited from a specialized mental health program in an ambulatory hospital within an urban city in Ontario, Canada that provides publicly-funded individual psychotherapy for mood, anxiety, obsessive-compulsive, or trauma or stressed-related disorders in pregnancy and up to one year postpartum delivered by highly trained psychotherapists with Master of Social Work qualifications. The program accepts referrals from primary care, midwifery, obstetricians and psychiatrists from across Ontario, although the vast majority of women who receive care reside in the greater Toronto region (population ~ 6.4 million)."

"Baseline symptom and function measures were administered by web-based survey."

"The psychotherapists completed a therapy log for each of their participants, which documented the length of time [in minutes] and format [in-person, VC, or telephone] of each session, along with cancellations and no-shows, and how often a child was present for the session."

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	0	\bigcirc	\circ	\circ	\circ	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

"Baseline symptom and function measures were administered by web-based survey. Participants provided an email address and were sent a link to a survey hosted on FluidSurveys™ [which was later transitioned to SurveyMonkey® after an institutional change in survey host]. All participants received another survey link by email to complete follow-up measures two weeks prior to reaching three months, and again at 3 months if it had not been completed."

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	\circ	\circ	\circ	\circ	0	essential

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

Since the participants are all new or existing patients of the clinic within the hospital, they are aware of the affiliation. The hospital logo is also on the consent form.

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	0	\circ	\circ	\circ	\circ	essential

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

Not applicable.

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	\circ	\circ	0	0	0	essential

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

None of the above occurred throughout the study.

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	\circ	\circ	\circ	0	0	essential

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

Not applicable.

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	0	\circ	\circ	\circ	\circ	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

We do not have this information as we were not involved with the development of the technology. Use the link provided in the next question to get in touch with someone who can provide this information. We cannot provide screenshots as it is a videoconferencing platform.

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, 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	\circ	\circ	\circ	0	0	essential

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

https://otnhub.ca/

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	0	\circ	\circ	\circ	\circ	essential

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

"To access the web-based platform, participants had to download a plugin for their computer which required a webcam and microphone, or an application for their mobile phone or tablet. The therapists all had unique accounts to log into the portal on their office computers. Therapists were able to schedule a therapy session and invite the participant by emailing them a personal link that included the date and time. Participants could attend sessions from their desired location, but were encouraged to ensure the location was private enough that they could participate fully in the session. When the appointment time arrived, participants and therapists could enter the virtual session. In addition to video and audio sharing, therapists had the ability to share their screens which allowed them to show worksheets or other visual materials during the session."

We do not have access to a demo account. Please contact othhub.ca.

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].

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

"In the TAU group, participants received the standard form of psychotherapy available in the clinic. In the program, psychotherapists provide first-line evidence-based treatments for depression and anxiety, including cognitive behaviour therapy and interpersonal therapy, adapted for the postpartum context. This treatment is provided mostly in-person, although sessions are sometimes delivered by telephone on an ad-hoc basis if a patient is unable to attend in person due to medical or last-minute childcare problems. Patients may also receive psychiatric care, including medication management, from the program psychiatrist until approximately 1 year postpartum. At this point, patients are referred back to their primary care provider for ongoing management."

"In the TAU-VC group, participants had access to TAU with the added option of having any of their treatment sessions over VC."

"Therapists were able to schedule a therapy session and invite the participant by emailing them a personal link that included the date and time. Participants could attend sessions from their desired location, but were encouraged to ensure the location was private enough that they could participate fully in the session. When the appointment time arrived, participants and therapists could enter the virtual session. In addition to video and audio sharing, therapists had the ability to share their screens which allowed them to show worksheets or other visual materials during the session."

"During the study, participants in the TAU-VC group were encouraged, but not required, to use VC for their therapy sessions and were still able to access in-person therapy sessions and phone support as per standard care. Participants were also informed that therapists could, at their discretion, recommend an in-person visit if they felt it was warranted for clinical reasons."

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.

	1	2	3	4	5	
subitem not at all important	0	0	\circ	0	\circ	essential

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

"During the study, participants in the TAU-VC group were encouraged, but not required, to use VC for their therapy sessions and were still able to access in-person therapy sessions and phone support as per standard care. Participants were also informed that therapists could, at their discretion, recommend an in-person visit if they felt it was warranted for clinical reasons."

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	0	\circ	0	0	0	essential

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

"All participants receiving access to VC received an instruction pamphlet by email and had a brief test call with the Research Assistant to ensure their device met the required technical specifications, demonstrate the platform, and to troubleshoot any initial technical issues."

"For technical support during the study, participants were provided with the Research Assistant's contact information."

"In the TAU-VC group, participants had access to TAU with the added option of having any of their treatment sessions over VC." TAU is defined as "first-line evidence-based treatments for depression and anxiety, including cognitive behaviour therapy and interpersonal therapy, adapted for the postpartum context. This treatment is provided mostly in-person, although sessions are sometimes delivered by telephone on an ad-hoc basis if a patient is unable to attend in person due to medical or last-minute childcare problems."

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	\circ	\circ	\circ	0	\circ	essential

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

"Baseline symptom and function measures were administered by web-based survey. Participants provided an email address and were sent a link to a survey hosted on FluidSurveys™ [which was later transitioned to SurveyMonkey® after an institutional change in survey host]. All participants received another survey link by email to complete follow-up measures two weeks prior to reaching three months, and again at 3 months if it had not been completed. A follow-up phone call was made to any outstanding surveys at 2 weeks post the 3-month time point."

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 standalone 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.

	1	2	3	4	5	
subitem not at all important	0	\circ	\circ	\circ	\circ	essential

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

"In the TAU-VC group, participants had access to TAU with the added option of having any of their treatment sessions over VC."

"All participants receiving access to VC received an instruction pamphlet by email and had a brief test call with the Research Assistant to ensure their device met the required technical specifications, demonstrate the platform, and to troubleshoot any initial technical issues."

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

"We documented the number and rate of referrals, and the proportion of participants who provided follow-up data at the outcome time points."

"The psychotherapists completed a therapy log for each of their participants, which documented the length of time [in minutes] and format [in-person, VC, or telephone] of each session, along with cancellations and no-shows, and how often a child was present for the session."

"Descriptive statistics were generated to examine uptake of the intervention as defined as number and percentage of sessions attended."

"Session attendance variables were summarized as group means or medians and compared between groups with unpaired t-tests or non-parametric tests where medians were reported."

"Edinburgh Postnatal Depression Scale (EPDS). The EPDS is a self-report depression screening measure that has been validated for use in pregnancy [22]. EPDS scores > 12 are predictive of a diagnosis of major depressive disorder. The EPDS has better ability to detect women with depression in the perinatal period than traditional depression measures because of the increased weight given to anxiety symptoms that appear to be more common in perinatal than in non-perinatal depression [22].

Generalized Anxiety Disorder 7-Item (GAD-7). The GAD-7 assesses symptoms of general anxiety. It has 7 items rated on a 4-point scale from 'never' to 'nearly every day,' as well as one perceived impairment rating. A score of \geq 10 is highly suggestive of a problem with anxiety. A reduction of 5 points corresponds to a clinically meaningful improvement with a reduction in score of 50% representing response [23].

Parental Stress Scale (PSS). The PSS is an 18-item questionnaire that was developed to measure the level of stress associated with raising children. All items are scored on a 5-point Likert scale from 'strongly disagree' to 'strongly agree.' The questionnaire has shown good reliability and internal consistency [24]. It has been used to study parenting stress in a variety of parent-child circumstances and is correlated with measures of depression [25]. A total score is obtained by summing all items.

"Baseline symptom and function measures were administered by web-based survey."

"All participants received another survey link by email to complete follow-up measures two weeks prior to reaching three months, and again at 3 months if it had not been completed. A follow-up phone call was made to any outstanding surveys at

2 weeks post the 3-month time point."

"At follow-up, participants in the TAU-VC group were asked additional questions about their use of and satisfaction with VC."

Telemedicine Satisfaction Questionnaire (TSQ). The TSQ was originally developed and studied by Yip et al. [26] to assess satisfaction with telemedicine. It has 15 items rated on a 5-point Likert scale from 'strongly disagree' to 'strongly agree.' The authors reported good internal validity and consistency. A factor analysis yielded 3 components: quality of care provided [8 items], similarity to in-person face-to-face interaction (5 items), and perception of the interaction (1 item). This study uses the original TSQ with the term 'telemedicine' substituted with 'video visits.' An overall score can be created by summing all items, or subscale scores can be calculated for the component domains. Individual items may also be examined to assess the positive and negative aspects of the intervention [26]. In this study, 2 additional items were added: "I am going to miss the equipment when the project ends," and "I would be willing to pay for video visits privately." These latter questions were added to gather additional data regarding interest in the intervention.

Patient Reported Costs Questionnaire (PRCQ). This questionnaire was developed by the research team to assess the participant costs and cost savings associated with access to PCVC. Respondents were asked to estimate the amount and source of time and money they saved when they attended a session of therapy with VC compared to in-person.

"TSQ and PRCQ items were analyzed descriptively."

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].

	1	2	3	4	5	
subitem not at all important	0	\circ	\circ	\circ	\circ	essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

The questionnaires were not validated for online use.

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	0	\circ	\circ	\circ	\circ	essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Since participants in the intervention group were provided with the option of using VC but were not required, this is not applicable.

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	0	\bigcirc	\circ	\circ	\circ	essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

We conducted semi-structured qualitative interviews with the therapists and select participants. We are currently analyzing the data.

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

There were no changes to trial outcomes after the trial commenced.

7a) How sample size was determined



NPT: When applicable, details of whether and how the clustering by care provides 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	0	\circ	\circ	\circ	\circ	essential

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

"We aimed to recruit 40 participants, as has been recommended for pilot studies of an intervention where the goal is to have sufficient variability to examine processes in the implementation of the protocol."

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.

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

"For randomization, 20 slips of paper labelled with "TAU" and 20 with "TAU-VC" were placed in opaque envelopes by a research staff member not involved with this study. Upon documentation of informed consent, the Research Assistant opened one of the envelopes, revealed the group allocation and communicated it to the participant and psychotherapist. If a participant withdrew prior to being informed of their allocation, the paper was returned to an envelope and put back in the pile."

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

"Participants were allocated 1:1 to the intervention and control groups using simple randomization"

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 allocated 1:1 to the intervention and control groups using simple randomization."

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

"For randomization, 20 slips of paper labelled with "TAU" and 20 with "TAU-VC" were placed in opaque envelopes by a research staff member not involved with this study. Upon documentation of informed consent, the Research Assistant opened one of the envelopes, revealed the group allocation and communicated it to the participant and psychotherapist. If a participant withdrew prior to being informed of their allocation, the paper was returned to an envelope and put back in the pile."

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	0	\circ	\circ	\circ	0	essential

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

"Participants and therapists were unblinded; data analyses were blinded to group allocation."

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	0	\bigcirc	\circ	\circ	\circ	essential

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

We did not inform participants about the arm that was the intervention of interests, but participants may have understood that TAU+VC was the intervention of interests as it included an additional component (i.e. access to VC) compared to TAU.

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 applicable

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

"Descriptive statistics were generated to examine uptake of the intervention as defined as number and percentage of sessions attended."

"TSQ and PRCQ items were analyzed descriptively."

"Session attendance variables were summarized as group means or medians and compared between groups with unpaired t-tests or non-parametric tests where medians were reported. Endpoint EPDS, GAD-7 and PSS total scores at 3 months were separately compared between groups with intention-to-treat linear mixed effects models including the relevant baseline score as a covariate. We conducted the same analyses in the subgroup of participants with baseline EPDS scores >12 to examine those participants with baseline symptoms suggestive of a major depressive disorder."

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	0	0	0	\circ	\circ	essential

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

It did not matter whether the participants randomized to TAU+VC used VC or not during the course of the study as it was optional.

We used intention to treat linear mixed effects.

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

"We conducted the same analyses in the subgroup of participants with baseline EPDS scores >12 to examine those participants with baseline symptoms suggestive of a major depressive disorder."

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	\circ	\circ	\circ	\circ	\circ	essential

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

"Research ethics approval was obtained from the Women's College Hospital Research Ethics Board."

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	\circ	\bigcirc	\circ	\circ	\circ	essential

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

"If the patient was still interested, the Research Assistant obtained and documented informed verbal consent over the phone, and emailed a copy of the completed consent form to the patient."

The consent form was a standard consent form approved by the Women's College Hospital Research Ethics Board.

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	0	0	\circ	\circ	0	essential

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

"Participants could attend sessions from their desired location, but were encouraged to ensure the location was private enough that they could participate fully in the session."



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

"43 individuals were referred to the study and provided consent to participate, but 5 did not complete baseline measures and so were not allocated to a treatment condition. A total of 38 participants were therefore included in the study; 19 in each group. At 3 months post-randomization, therapy attendance data were available for all participants (n=38, 100%), and 25 out of 38 (65.8%) completed symptom scale scores, with a slightly higher completion rate in the TAU-VC (n=14, 77.8%) than the TAU (n=11, 61.1%) condition."

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

"This information is demonstrated in Figure 1, the CONSORT flow diagram."

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	0	0	0	0	0	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

Not applicable.

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 took place from June 2016 to July 2017."

"A follow-up phone call was made to any outstanding surveys at 2 weeks post the 3month time point."

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	0	0	0	0	0	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

There were no critical secular events that fell into the study period.

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

Not applicable as the trial was not ended or stopped early.

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

This information is included in 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	\circ	\circ	\circ	\circ	0	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

Data on SES or race/ethnicity was not collected as they are not consistently documented in our assessments or the hospital's electronic medical record. However, this specialized mental health program is available to all women across Ontario with no catchment area, with demographics that reflect the population of the province. Examining this in future studies would be important as SES may reflect ability to use the VC platform (access to equipment and internet), and there could be ethnicity factors affecting treatment seeking and utilization of VC.

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	\circ	\circ	\circ	0	0	essential

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

This information is included in Figure 1, CONSORT Flow Diagram. Usage was not relevant in this study because we didn't require amount of VC use among participants in TAU-VC; it was optional.

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	\circ	0	0	\circ	0	essential

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

"We also compared therapy attendance using therapist logs and symptoms between groups. Symptoms were assessed at baseline and 3-months post randomization with the Edinburgh Postnatal Depression Scale (EPDS), Generalized Anxiety Disorder 7-Item (GAD-7), and Parental Stress Scale (PSS). Three-month scores were compared between groups with intention-to-treat linear mixed effects models controlling for baseline score."

"Endpoint EPDS, GAD-7 and PSS total scores at 3 months were separately compared between groups with intention-to-treat linear mixed effects models including the relevant baseline score as a covariate. We conducted the same analyses in the subgroup of participants with baseline EPDS scores >12 to examine those participants with baseline symptoms suggestive of a major depressive disorder."

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

"At 3 months post-randomization, therapy attendance data were available for all participants (n=38, 100%), and 25 out of 38 (65.8%) completed symptom scale scores, with a slightly higher completion rate in the TAU-VC (n=14, 77.8%) than the TAU (n=11, 61.1%) condition."

"PCVC was used at least once by 14 (74%) of the participants in the TAU-VC group. On average, users attended 50% of their sessions with VC, with four participants using VC for 100% of their therapy sessions and four participants using it for none of their sessions."

"Eleven of the 14 VC users completed the TSQ. Of them, nine (82%) agreed or strongly agreed that they felt it allowed them to attend therapy sessions more frequently. The average item score was 4.7 out of 5, with average scores of 4.7 (SD=.43), 4.7 (SD=.31) and 4.6 (SD=.67) in the domains of quality of care provided, similarity to in-person face-to-face interaction, and perception of the interaction, respectively."

"All participants who used VC at least once reported saving money and time when attending therapy sessions with VC compared to in-person. Specifically, the average cost savings was \$26CAD (SD=19.7, range \$7-70CAD) in travel, child care, and other expenses per session, and the average time savings was 2.5 hours (SD=1.6, range 1 – 7 hours) in preparation and transportation per session."

"There were no significant differences between the two groups for the total number of sessions attended, the average length of time per session, the number of no-shows or cancellations, and the number of sessions with a child in attendance (Table 2)."

"Similarly, there were no significant differences in 3-month EPDS, GAD-7, or PSS between groups (see Table 3). When analyses were restricted to those with baseline EPDS > 12 (n=10 in the TAU-VC group, and n=9 in the TAU group), there were again no significant differences between groups for 3-month EPDS (F(1,9) = .058, P = .81), GAD-7 (F(1,9) = .004, P = .95), or PSS (F(1,9) = .003, P = .96)."

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	0	\circ	\circ	\circ	\circ	essential

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

Not applicable.

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

We had no binary outcomes.

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

"Similarly, there were no significant differences in 3-month EPDS, GAD-7, or PSS between groups (see Table 3). When analyses were restricted to those with baseline EPDS > 12 (n=10 in the TAU-VC group, and n=9 in the TAU group), there were again no significant differences between groups for 3-month EPDS (F(1,9) = .058, P = .81), GAD-7 (F(1,9) = .004, P = .95), or PSS (F(1,9) = .003, P = .96)."

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	0	\circ	\circ	\circ	\circ	essential

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

Not applicable due to small sample size.

19) All important harms or unintended effects in each group



(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

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

Not applicable, as there were no important harms or unintended effects in each group.

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	0	\circ	\circ	0	0	essential

Does your paper address subitem 19-i?

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

Not applicable, as there were no privacy breaches or technical problems. The Research Assistant did not receive many technology-related queries from participants beyond initial onboarding.

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	0	\bigcirc	\circ	\circ	\circ	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

We conducted semi-structured qualitative interviewed with the therapists and select participants. We are currently analyzing the data.



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

d

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	0	\circ	0	\circ	0	essential

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 pilot study, we demonstrated feasibility of recruitment and retention of participants from a program providing psychotherapy to postpartum women with mood and/or anxiety symptoms into a study offering VC as an adjunct to office-based care. We also showed that participants used the intervention, and reported high satisfaction and substantial savings in time and money. We found no statistically significant differences in total number of sessions attended, and, while the number of participants was small, there was no evidence that symptom outcomes differed between those with the option of VC compared to those attending office-based appointments only."

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	0	0	0	0	\circ	essential

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

"We would hypothesize that by overcoming barriers to care, VC would increase attendance. However, this finding was not observed statistically between groups. A larger study would be better able to determine if access to optional VC impacts therapy attendance overall, or for certain subgroups."

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	\circ	\circ	\circ	\circ	\circ	essential

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

"This pilot study used a sample of 38 participants recruited from an academic ambulatory hospital in an urban city, so its patients may have access to more resources than other parts of the province where access barriers are more pronounced. Our program is unique in that it offers specialized care in a hospital that provides access to free child care during appointments, which eliminates some of the barriers to care in the postpartum population. Additionally, we have access to a secure government-funded VC platform. In this setting, we evaluated the option of VC for treatment, which in some areas may not be feasible when there is no access to office-based treatment and VC is the only option. Over 80% of the participants in the study had had some therapy experience prior to being referred to our program, so results may not be as generalizable to a therapy-naïve cohort. That said, we have demonstrated the feasibility of recruiting and retaining postpartum women receiving psychotherapy for mood and anxiety difficulties to receive the option of VC in addition to office-based care. Additionally, uptake and acceptability of the intervention were high and there were no indications of significant differences in outcomes, supporting that a larger study is warranted."

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	0	\circ	\circ	\circ	\circ	essential

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

"This pilot study used a sample of 38 participants recruited from an academic ambulatory hospital in an urban city, so its patients may have access to more resources than other parts of the province where access barriers are more pronounced. Our program is unique in that it offers specialized care in a hospital that provides access to free child care during appointments, which eliminates some of the barriers to care in the postpartum population. Additionally, we have access to a secure government-funded VC platform. In this setting, we evaluated the option of VC for treatment, which in some areas may not be feasible when there is no access to office-based treatment and VC is the only option. Over 80% of the participants in the study had had some therapy experience prior to being referred to our program, so results may not be as generalizable to a therapy-naïve cohort."

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	\circ	\circ	\circ	\circ	\circ	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

Not applicable, there were no elements in the RCT that would be different in a routine application setting. The reminders from the Research Assistant were only for survey completion, not for engagement with the VC platform.



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

This study was not registered as it is a pilot RCT with a very small sample size.

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

The full trial protocol is not available.

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 study was funded by a project grant awarded to Dr. Hensel from the Women's College Hospital Academic and Medical Services Group/Association of Fundraising Professionals Innovation Fund."

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 O O O 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

The study team has no relationship with the system being evaluated.

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

O no

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

Your answer

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

5 hours.

improved? *
O 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
O yes
O no
Other:
Any other comments or questions on CONSORT EHEALTH Your answer
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