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

suchan.victoria@gmail.com (not shared) Switch account
Draft saved
* Required

Your name *
First Last
Victoria Suchan

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
University of Regina

Your e-mail address *
abc@gmail.com
suchan.victoria@gmail.com
Title of your manuscript *
Provide the (draft) title of your manuscript.

Transdiagnostic Internet-Delivered Cognitive Behavioral Therapy for Symptoms of Postpartum Anxiety and Depression: Feasibility 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.

Wellbeing Course for New Moms

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.

Your answer
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 anxiety and depression

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial
Edinburgh Postnatal Depression Scale, Genera
Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

Depression and Anxiety Stress Scale, Postnatal Bonding Questionnaire, Dyadic Adjustment Scale-7, Treatment Satisfaction Questionnaire, Adverse Effects Questionnaire, Credibility and Expectancy Questionnaire, Working Alliance Inventory-Short Revised, Service Utilization Questionnaire

Recommended "Dose" *
What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- "as needed"
- Other:
Approx. Percentage of Users (starters) still using the app as recommended after 3 months

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

Overall, was the app/intervention effective? *

- yes: all primary outcomes were significantly better in intervention group vs control
- partly: SOME primary outcomes were significantly better in intervention group vs control
- no statistically significant difference between control and intervention
- potentially harmful: control was significantly better than intervention in one or more outcomes
- inconclusive: more research is needed
- Other:
Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

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

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

- not submitted yet / unclear where I will submit this
- Journal Formative Research
- JMIR mHealth and UHealth
- JMIR Serious Games
- JMIR Mental Health
- JMIR Public Health
- Journal of Medical Internet Research (JMIR)
- Other JMIR sister journal
- Other:
Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- [ ] Pilot/feasibility
- [ ] Fully powered

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

- [ ] no ms number (yet) / not (yet) submitted to / published in JMIR
- [ ] Other: 37216

TITLE AND ABSTRACT

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

1a) Does your paper address CONSORT item 1a? *
I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- [ ] yes
- [ ] Other:
1a-i) Identify the mode of delivery in the title
Identify the mode of delivery. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if Intervention includes non-web-based Internet components (e.g. email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.

Clear selection

Does your paper address subitem 1a-i? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Internet-Delivered Cognitive Behavioral Therapy"

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”).

Clear selection
Does your paper address subitem 1a-ii?

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

Your answer

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”) Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ 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 Symptoms of Postpartum Anxiety and Depression"

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/functionalties/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalties/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 

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 

Largely not included in abstract due to word limitations. Does state: "Clients endorsing the symptoms of PPD or PA (N=63) were randomized to an 8-week transdiagnostic ICBT course (Wellbeing Course for New Moms) or to treatment as usual (TAU)."
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.

In the objectives section we state: "This pilot study aimed to examine the impact of a therapist-assisted, transdiagnostic ICBT program on symptoms of PPD and PPA..."

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)

subitem not at all important  ○ ○ ○ ○ ○ essential
Clear selection

Does your paper address subitem 1b-iii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Not included in abstract due to word limitations
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 ○ ○ ○ ○ ○ 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

"Clients endorsing the symptoms of PPD or PPA (N=63) were randomized to an 8-week transdiagnostic ICBT course (Wellbeing Course for New Moms) or to treatment as usual (TAU)."

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials
Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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

Clear selection
Does your paper address subitem 1b-v?

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

"Time-by-group interactions for proportional reductions between groups over time were only significant after treatment and at the 1-month follow-up for the primary anxiety measure (P=.006). This study was underpowered for detecting small or medium effects."

INTRODUCTION

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

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

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

1 2 3 4 5

subitem not at all important ● ○ ○ ○ essential

Clear selection
Does your paper address subitem 2a-i? *

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

"The aim of this pilot study, which was planned before the abovementioned study was published, was to examine the efficacy of a therapist-assisted transdiagnostic program (ie, the Wellbeing Course for New Moms) for new mothers experiencing symptoms of PPD or PPA when delivered by a clinic specializing in the provision of ICBT and providing services on a continuous basis funded by the government. Examining the program in a routine care setting allows for greater generalizability of findings outside the initial research setting in which a program is developed [19,20]."

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

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

1 2 3 4 5
subitem not at all important       essential

Clear selection
Does your paper address subitem 2a-ii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To date, the vast majority of postpartum mental health research has focused on postpartum depression (PPD), leaving postpartum anxiety (PPA) poorly understood and underresearched, despite the high levels of comorbidity between these concerns [3]. The detrimental impacts associated with untreated PPD and PPA, such as impairments in mother-infant bonding [4] and infant development [5] and high economic costs [6], underscore the importance of efficacious treatment options. Cognitive behavioral therapy (CBT) has the largest evidence base for treating symptoms of PPD and PPA [7], and historically, researchers have taken a disorder-specific approach to treatment wherein they focus on a singular disorder in their trials (eg, PPD). Unfortunately, even with effective treatment options available, less than half of the new mothers experiencing symptoms seek treatment [8] because of a myriad of barriers (eg, childcare difficulties, time concerns, stigma, and transportation difficulties [9]). To address the gap between those who require and receive treatment, it is worthwhile to consider alternative treatment modalities such as internet-delivered CBT (ICBT)."

2b) In INTRODUCTION: Specific objectives or hypotheses
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

"Before recruitment for this study, the primary investigator (VS) generated a random allocation sequence using a randomizer website and specified a 1:1 ratio in blocks of 50. The sequence was produced in the form of a Microsoft Excel file, which was then uploaded directly to the website hosting the web-based screening (REDCap [Research Electronic Data Capture]; Vanderbilt University)."
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

Not included as there were no changes to methods after trial was launched.

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 ○ ● ○ ○ ○ essential

Clear selection

Does your paper address subitem 3b-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No changes occurred to the intervention once it was launched.
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

"To be eligible for this study, potential clients had to (1) be aged ≥18 years, (2) be female, (3) have given birth and have a child aged <1 year, (4) have a score ≥10 on the Edinburgh Postnatal Depression Scale (EPDS; [22]) or score ≥9 on the 7-item Generalized Anxiety Disorder (GAD-7) questionnaire [23], (5) be a resident of Saskatchewan, (6) be comfortable using technology, (7) have access to a secure computer and the internet, and (8) be willing to provide a medical contact as an emergency contact. Potential clients were excluded if they did not meet the abovementioned inclusion criteria or if they (1) were hospitalized in the prior year for mental health concerns or suicidality; (2) had unmanaged alcohol or drug use, mania, or psychosis; or (3) started a new psychotropic medication within the past month."

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  ○ ○ ○ ○ ○ essential
Clear selection
Does your paper address subitem 4a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"be comfortable using technology" was an explicit criteria for eligibility

---

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 ○ ☐ ○ ○ ○ essential
Clear selection

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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.

"Clients were recruited through web-based advertisements, presentations to health care professionals, and printed promotional materials over a span of 6 months (September 2019 to March 2020). Clients began by visiting the Online Therapy Unit website, where they completed a web-based consent form, initial eligibility questions, and a web-based screening questionnaire."
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  ○  ○  ○  ○  ○ essential

Clear selection

Does your paper address subitem 4a-iii?

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

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

"This pilot study was conducted through the Online Therapy Unit at the University of Regina. The Online Therapy Unit is a publicly funded specialized clinic that offers free ICBT to residents of Saskatchewan experiencing symptoms of anxiety or depression."
4b-i) Report if outcomes were (self-)assessed through online questionnaires

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

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● 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

"Outcome measures were administered before treatment, after treatment, and at the 1-month follow-up. Clients who were assigned to ICBT also completed the outcome measures at the 6-month follow-up. The measures took approximately 15 minutes to complete."

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 ● ○ ○ ○ ○ essential

Clear selection
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

Participants were made aware at several points that this research was affiliated with the University of Regina.

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  ○  ○  ○  ●  ○  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

Each author's affiliations are denoted
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.

Does your paper address subitem 5-ii?

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

"The Wellbeing Course for New Moms is a transdiagnostic course based on the principles of CBT. It was adapted from the Wellbeing Course [24] to reflect the common concerns faced by new mothers."

"The resource was created by one of the authors (VS) and then revised before use based on feedback from the coauthor (HH), 2 psychologists with young children, and 8 mothers recruited from the community."
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 ○ ○ ○ ○ ○ essential

Clear selection

Does your paper address subitem 5-iii?

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

There were no revisions/updates once the trial began.

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 ○ ○ ○ ○ ○ essential

Clear selection
Does your paper address subitem 5-iv?

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

"Each therapist message was personalized but included several important elements: warmth and concern, feedback on symptom measures, highlighting key skills, answering client questions about the lessons, acknowledging any stated areas of difficulty, providing encouragement reinforcing progress, managing risk, and reminding clients about course instructions (see the study by Hadjistavropoulos et al [25] for more details)."

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.

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

The materials developed for this study are copyrighted and not able to be widely disseminated to protect intellectual property.
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 ○ ○ ○ ○ ○ 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

Your answer

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 ○ ○ ○ ○ ○ essential

Clear selection
Does your paper address subitem 5-vii? *

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

"The Online Therapy Unit is a publicly funded specialized clinic that offers free ICBT to residents of Saskatchewan experiencing symptoms of anxiety or depression."

"Clients accessed the course through the Online Therapy Unit web platform."

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5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

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

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| subitem not at all important |   |   |   |   |   |
| essential |   |   |   |   |   |

Clear selection
Does your paper address subitem 5-viii? *

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

"The Wellbeing Course for New Moms is a transdiagnostic course based on the principles of CBT. It was adapted from the Wellbeing Course [24] to reflect the common concerns faced by new mothers. Clients accessed the course through the Online Therapy Unit web platform. The content of any messages and questionnaire responses were encrypted using Advanced Encryption Standard encryption with 256-bit key length. Clients completed 5 web-based lessons spanning over the course of 8 weeks, with weekly support from a therapist. The lessons resemble a Microsoft PowerPoint presentation, which participants can read through independently and move through at their own pace. Lesson 1 (1 week) provides psychoeducation about anxiety and depression in general and in postpartum populations; description of symptoms; and explanation of the relationship between unhelpful thoughts, physical symptoms, and unhelpful behaviors. Lesson 2 (2 weeks) provides information on unhelpful thoughts in relation to the CBT model and strategies for monitoring and challenging thoughts. Lesson 3 (1 week) comprises psychoeducation on physical symptoms in relation to the CBT model and strategies for managing both under- and overarousal (eg, controlled breathing). Lesson 4 (2 weeks) focuses on information related to unhelpful behaviors in relation to the CBT model and guidelines about behavioral activation and graded exposure. The fifth and final lesson (2 weeks) includes information about relapse prevention, normalization, and creation of relapse prevention plans. Each lesson includes case stories and do-it-yourself guides that were modified to be relevant to new mothers to promote the practice of strategies from the course, as well as additional resources that could be accessed at any point throughout the course (ie, assertiveness, managing beliefs, communication, mental skills, managing panic attacks, managing posttraumatic stress disorder, sleep hygiene, problem-solving and worry time, and balancing new motherhood). A new resource (ie, balancing new motherhood) was created for the purpose of this study to specifically provide information about PPD and PPA, as well as common struggles that new mothers face (eg, limited sleep, new roles, isolation, and low self-esteem)."
5-ix) Describe use parameters

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

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subitem not at all important   essential

Clear selection

Does your paper address subitem 5-ix?

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

Clients were aware of the timing of each lesson (i.e., that some lessons should be completed over 1 week and some lessons over 2). During the online screening, they were informed that the course typically takes several hours per week.

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).

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subitem not at all important   essential

Clear selection
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 clients assigned to ICBT received weekly therapist support from a master-level, registered social worker trained in the provision of ICBT. The therapist contacted clients on the same day each week throughout the 8-week course using secure emails on the Online Therapy Unit’s platform."

“Phone calls were made to clients in specific cases (ie, heightened risk of suicide, significant increase in symptoms of anxiety or depression, or to clarify client concerns). The clients also received automated messages as reminders of new lessons or questionnaires to complete.”

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).

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subitem not at all important ○ ○ ● ○ ○ essential

Clear selection
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

"The clients also received automated messages as reminders of new lessons or questionnaires to complete."

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

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subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

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

There were not any other training/support sessions required.

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.

"Outcome measures were administered before treatment, after treatment, and at the 1-month follow-up. Clients who were assigned to ICBT also completed the outcome measures at the 6-month follow-up. The measures took approximately 15 minutes to complete." All primary and secondary measures are clearly described in the manuscript.

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

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

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subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

This information was not included in the manuscript; however, these measures had all been previously used, and in most cases validated with online dissemination.
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.

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subitem not at all important | essential

Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

"Table 4 includes details about treatment adherence, acceptability, and satisfaction. In the ICBT treatment group, 75% (21/28) of the participants completed at least four of the five lessons, and 50% (14/28) of the participants completed all 5 lessons."

Table 4 contains information regarding other “use” variables such as number of logins, messages sent, etc.

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).

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Clear selection
Does your paper address subitem 6a-iii?
Copy and paste relevant sections from manuscript text

Qualitative feedback was gathered from participants; however, this information was not published within the current manuscript and therefore was not discussed.

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

"Owing to the timing of the trial, approximately half of the clients were enrolled in the Wellbeing Course for New Moms during the COVID-19 pandemic; of note, research indicates that the COVID-19 pandemic has led to a substantial increase in the rates of PPD and PPA [42]. Clients commented on some of the challenges of engaging with ICBT during the pandemic and noted that opportunities to practice strategies (eg, pleasant activity scheduling or graded exposure) may have been limited by public health recommendations for physical distancing and self-isolation."

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.

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subitem not at all important ☐ ☐ ☐ ☐ ☐ 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

This information was not included in the manuscript. In the proposal stages of this study, a power analysis was conducted to be sensitive to medium within-between group effect sizes using G*Power 3.1.9.2 (Faul, Erdfelder, Lang, & Buchner, 2007). To achieve sufficient power at 90% (\(\alpha = .05\)) to detect a medium within-between group effect size (\(f = .25\)), 23 participants per group was recommended. Given the anticipated dropout rate of approximately 20% (Hadjistavropoulos et al., 2017; Pugh et al., 2016) we initially wanted to recruit 56 participants. Ultimately, based on a post hoc power analysis, the current study was found to be unreliably powered to detect small and medium between-group effects due to the sample size.

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

We did not have interim analyses or stopping guidelines.

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

"Before recruitment for this study, the primary investigator (VS) generated a random allocation sequence using a randomizer website and specified a 1:1 ratio in blocks of 50. The sequence was produced in the form of a Microsoft Excel file, which was then uploaded directly to the website hosting the web-based screening (REDCap [Research Electronic Data Capture]; Vanderbilt University). After this point, the researchers were unable to view the allocation sequence. Randomization was performed after participants were deemed eligible for this study to limit the possibility of bias in conducting the telephone screen in the event that the randomization group was known."

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

"Before recruitment for this study, the primary investigator (VS) generated a random allocation sequence using a randomizer website and specified a 1:1 ratio in blocks of 50. The sequence was produced in the form of a Microsoft Excel file, which was then uploaded directly to the website hosting the web-based screening (REDCap [Research Electronic Data Capture]; Vanderbilt University). After this point, the researchers were unable to view the allocation sequence. Randomization was performed after participants were deemed eligible for this study to limit the possibility of bias in conducting the telephone screen in the event that the randomization group was known."

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

"Before recruitment for this study, the primary investigator (VS) generated a random allocation sequence using a randomizer website and specified a 1:1 ratio in blocks of 50. The sequence was produced in the form of a Microsoft Excel file, which was then uploaded directly to the website hosting the web-based screening (REDCap [Research Electronic Data Capture]; Vanderbilt University). After this point, the researchers were unable to view the allocation sequence. Randomization was performed after participants were deemed eligible for this study to limit the possibility of bias in conducting the telephone screen in the event that the randomization group was known."
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

"Before recruitment for this study, the primary investigator (VS) generated a random allocation sequence using a randomizer website and specified a 1:1 ratio in blocks of 50. The sequence was produced in the form of a Microsoft Excel file, which was then uploaded directly to the website hosting the web-based screening (REDCap [Research Electronic Data Capture]; Vanderbilt University). After this point, the researchers were unable to view the allocation sequence. Randomization was performed after participants were deemed eligible for this study to limit the possibility of bias in conducting the telephone screen in the event that the randomization group was known."

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).

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subitem not at all important ○ ○ ○ ○ ○ 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.

"Before recruitment for this study, the primary investigator (VS) generated a random allocation sequence using a randomizer website and specified a 1:1 ratio in blocks of 50. The sequence was produced in the form of a Microsoft Excel file, which was then uploaded directly to the website hosting the web-based screening (REDCap [Research Electronic Data Capture]; Vanderbilt University). After this point, the researchers were unable to view the allocation sequence. Randomization was performed after participants were deemed eligible for this study to limit the possibility of bias in conducting the telephone screen in the event that the randomization group was known."

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”.

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.

"At the end of the telephone screen, the screener informed participants of their allocation."
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 specifically addressed as the control group did not have a 'sham' treatment provided

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 calculated for demographic and clinical characteristics to summarize the sample and check for pretreatment differences between the conditions. Changes in outcome measures over time were modeled using generalized estimating equations (GEEs; [35]). For all GEE models, we used an exchangeable working correlation and robust “sandwich” estimates of SEs. Gamma distributions were used to accommodate the observed skewed responses. We used a log-link function, which leads to regression coefficients and hypothesis tests assuming that changes are proportional to pretreatment measures. Modeling changes as proportional reductions from pretreatment has been recommended to provide a better model fit and reduce measurement error. To compare improvements from before treatment to after treatment and at the 1-month follow-up, we calculated proportional improvements from the pretreatment time point and within-group and between-group Cohen d effect sizes. Proportional improvements and within-group Cohen d effect sizes are also reported for the ICBT treatment group at the 6-month follow-up. Hypothesis tests of differences in improvements between groups were performed using Wald tests on the estimated time×group interaction coefficients from the GEE models."

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]).

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subitem not at all important ○ ○ ○ ○ essential ○

Clear selection
**Does your paper address subitem 12a-i?**

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

"Therefore, we used multiple imputation to replace missing outcome measures, controlling for pretreatment symptom severity and course completion rates. In the TAU, course completion was not available; rather, we controlled for pretreatment symptom severity and whether the client accessed other mental health supports (ie, general practitioner, mental health worker, or other support groups), treating the mental health support access as a proxy measure for course engagement."

**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.

Due to our small sample, subgroup analyses were not able to be completed.

**X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)**
X26-i) Comment on ethics committee approval

Does your paper address subitem X26-i?

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

"Ethics approval was obtained from the University of Regina Ethics Board (approval number: 2019-077), and the trial was registered at ClinicalTrials.gov (NCT04012580)."

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.
Does your paper address subitem X26-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"Participants provided consent at various points during the study, including completing a consent form before filling out the web-based screening, providing verbal consent during the telephone screening, and before initiating the Wellbeing Course for New Moms."

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)

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subitem not at all important  ○  ○  ○  [●]  ○  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.

"The content of any messages and questionnaire responses were encrypted using Advanced Encryption Standard encryption with 256-bit key length."
As per eligibility criteria, participants have to "have access to a secure computer and the internet" to help protect their privacy.

RESULTS
13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome.

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center.

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

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.

This information is available in Figure 1 (participant flow).

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 available in Figure 1 (participant flow).
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.

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

Participants did not have access to this intervention indefinitely, so much of this information is not available.

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

"Clients were recruited through web-based advertisements, presentations to health care professionals, and printed promotional materials over a span of 6 months (September 2019 to March 2020).".... "Outcome measures were also completed at the 6-month follow-up for clients who completed the ICBT course."
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"

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subitem not at all important ○ ○ ○ ○ ○ 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

The onset of the COVID-19 pandemic during this study was discussed.

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

Does your paper address CONSORT subitem 14b? *

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

The trial did not end or stop early, it was concluded after a pre-determined number of participants were recruited.
15) A table showing baseline demographic and clinical characteristics for each group
NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This information is available 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.

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subitem not at all important ○ ○ ○ ● ○ 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

This information is available in Table 1
16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple “denominators” and provide definitions

Report multiple “denominators” and provide definitions: Report N's (and effect sizes) “across a range of study participation [and use] thresholds” [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants “used” the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define “use” of the intervention.

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subitem not at all important o o o o 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

The two groups (i.e., intervention vs. control) are clearly described including their denominators. We hope that in referencing analyses completed on each group, it implies that set of participants were included.
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).

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

All post-questionnaires and follow-up analyses employed an intention-to-treat (ITT) design. ITT principles have been developed to address and advise researchers that encounter missing data in RCTs (Gupta, 2011). Researchers assert that aspects of certain treatments may contribute to missing data, and thereby if data from those participants is excluded, the generalizability of the research results is limited (e.g., Montori & Guyatt, 2001). As such, data from all participants who consented and accessed the first lesson, regardless of whether they completed treatment, were included in the analyses; missing data was imputed (Armijo-Olivo, Warren, & Magee, 2009).

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

This information is available in Table 2

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).

subitem not at all important  ○  ○  ○  ○  ○  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

Information about intervention usage (e.g., number of logins, number of messages sent to therapist) is available in Table 4. Unfortunately we were not able to track how long participants spent engage in each lesson due to platform limitations at the time.

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.

Binary outcome measures were not utilized in this study.

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.

All analyses that were completed were included within the manuscript.

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
- essential

Clear selection
Does your paper address subitem 18-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

We did not do subanalyses on the users only.

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.

"After the treatment, clients were asked to indicate whether they experienced any negative effects, new psychological symptoms, or unwanted events (eg, family member death or loss of a job) during the course. If clients answered yes to these questions, they were asked to explain further. Clients were also asked to indicate whether that event negatively affected their participation, engagement, or benefit from the program."

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

No breaches or technical concerns were identified.

19-ii) Include qualitative feedback from participants or observations from staff/researchers
Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

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

Qualitative from participants were gathered; however, it was not included in the current manuscript as it may serve as a stand-alone manuscript in the future.

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

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

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

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

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

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

"Medium between-group Cohen d effects were observed in favor of the ICBT condition on most measures of anxiety and depression after treatment and at the follow-ups, with the exception of the depression subscale of the DASS-21. However, when examining the time-by-group interaction comparing differences in proportional reductions from before treatment between ICBT and TAU, the differences were only significant for the GAD-7 both after treatment and at the 1-month follow-up. Owing to the small sample size, this study was underpowered to detect significant differences in recovery rates between the treatment and TAU conditions, which may help explain the difference in findings based on effect sizes compared with time-by-group interactions of the proportional reductions. Improvements on all primary (EPDS, GAD-7, and PHQ-9) and most secondary measures (DASS-21 and PBQ) were maintained at the 6-month follow-up in the ICBT group. Finally, clients were satisfied with the ICBT course, perceived it as credible, and expressed high levels of alliance with their therapists."
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  O  O  O  X  O  essential

Clear selection

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

" It will be important to assess whether the findings from this study are replicated after the pandemic."

"Future trials of the Wellbeing Course for New Moms should include larger sample sizes to ensure sufficient power for additional analyses. In future trials, it would be interesting to explore the extent to which individuals with PPA or PPD use additional resources."

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
20-i) Typical limitations in ehealth trials

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

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

Clear selection

Does your paper address subitem 20-i? *

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

"Owing to the timing of the trial, approximately half of the clients were enrolled in the Wellbeing Course for New Moms during the COVID-19 pandemic; of note, research indicates that the COVID-19 pandemic has led to a substantial increase in the rates of PPD and PPA [42]. Clients commented on some of the challenges of engaging with ICBT during the pandemic and noted that opportunities to practice strategies (eg, pleasant activity scheduling or graded exposure) may have been limited by public health recommendations for physical distancing and self-isolation."

"An additional limitation of this pilot study was its small sample size, which meant that it was not reliably powered to detect small to medium between-group effects. Furthermore, the small sample size limited the types of analyses that could be conducted and prevented us from being able to determine moderators of symptom change (eg, relationship satisfaction, symptom severity and onset, use of medication, and access to other mental health supports)."

"Finally, this study relied on self-report symptom measures as opposed to engaging participants in structured clinical interviews to ascertain information about their symptoms."
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  ○  ○  ○  ●  ○  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

Your answer
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.

[Scale: 1-5]

[1] subitem not at all important
[2]
[3] 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

This was not specifically addressed. Of note, this study took place out of a specialized ICBT clinic that has a routine ICBT course. We utilized the same protocols (e.g., prompts/human involvement) as we do for the routine ICBT course.

OTHER INFORMATION

23) Registration number and name of trial registry
24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

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 is not an additional appendix or reference to include a full trial protocol.

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

"The Online Therapy Unit receives funding from the Saskatchewan Ministry of Health to provide internet-delivered cognitive behavior therapy services. The coauthors NT and BD are funded by the Australian Government to operate the national MindSpot Clinic. The funders had no involvement in the study design, collection, analysis, or interpretation of the data."
X27) Conflicts of Interest (not a CONSORT item)

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

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

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

Your answer

About the CONSORT EHEALTH checklist

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

☐ yes, major changes
☐ yes, minor changes
☒ no
What were the most important changes you made as a result of using this checklist?

Your answer

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

2 hours

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

- [ ] yes
- [ ] no
- [ ] Other: This checklist was not completed until after the manuscript was accepted

Would you like to become involved in the CONSORT EHEALTH group?

This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- [ ] yes
- [ ] no
- [ ] Other: Clear selection
Any other comments or questions on CONSORT EHEALTH

Your answer

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