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/](http://www.jmir.org/2011/4/e126/) | doi: 10.2196/jmir.1923 |
| PMID: 22209829 | |

**Required**

Your name *
First Last

Ashley Radomski

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

University of Alberta, Edmonton, Canada

Your e-mail address *

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

[adr2@ualberta.ca](mailto:adr2@ualberta.ca)

Title of your manuscript *
Provide the (draft) title of your manuscript.

Examining the Usage, User Experience, and Perceived Impact of an Internet-Based Cognitive Behavioral Therapy Program for Adolescents With Anxiety: 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.

The Breathe Program (Being Real, Easing Anxie

Evaluated Version (if any)
  e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

  Version 2

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://web.archive.org/web/20130517073804/

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)"

Anxiety (Adolescents with)

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

This study is based on secondary outcomes fr
Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

These secondary outcomes are not necessarily the outcomes of this manuscript, as we present the outcomes of only select analyses from the RCT. However, the RCT was designed with the following secondary outcomes: To explore mediators and moderators of the Internet-based CBT program, to determine the user experience with the Internet-based CBT program compared to the usual self-help intervention, to determine the effectiveness of a self-guided Internet-based CBT program in improving quality of life as compared to a usual self-help intervention, to determine adherence to a self-guided Internet-based CBT program, and to determine the cost-effectiveness of the Internet-based CBT program.

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: The effectiveness outcomes of the Breathe program will be presented in a fort
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: A manuscript based on select secondary outcomes (not all outcomes) has been submitted to a journal but not reviewed yet

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

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

- Pilot/feasibility
- Fully powered

Manuscript tracking number *

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

- no ms number (yet) / not (yet) submitted to / published in JMIR
- Other: 15795

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.

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-based" is included 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").

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 the intervention description we mention that "Brief Web-based and telephone support was also provided....Participants were assigned a Breathe coach, a trained paraprofessional, who initiated an optional telephone coaching session after session 1."
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

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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

In the title we specify that the study is conducted with "Adolescents With Anxiety"

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)

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subitem not at all important  ○ ○ ○ ● ○ 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

In the abstract under Objectives we included identification of the 2 study groups, "Within a randomized controlled trial comparing a six-session iCBT program for adolescent anxiety, Being Real, Easing Anxiety: Tools Helping Electronically (Breathe), with anxiety-based resource webpages..."

Due to space restrictions, other than the number of sessions of the Breathe program (6 sessions), we do not report the features of the interventions in the abstract. However, these details can be found in The Breathe Program and Resource-Based Webpages subsections of the Methods section in the body of the manuscript.

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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)

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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

Due to space restrictions, the level of human involvement is not reported in the abstract. However, information about human involvement can be found in The Breathe Program and Resource-Based Webpages subsections of the Methods section in the body of the manuscript.
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 indicate 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)

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.

Due to space restrictions, we do not mention recruitment, assessment or blinding details in the abstract. However, information can be found in the Participant Recruitment and Eligibility, Procedures for Informed Consent and Assent, and Data Collection subsections of the Methods section in the body of the manuscript.

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)

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_OimqcS64RdfIAFvmrTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGlKd2… 12/56
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.

"Intervention use was low for adolescents allocated to Breathe (mean 2.2 sessions, SD 2.3; n=258) or webpages (mean 2.1 visits, SD 2.7; n=278), but was higher for Breathe (median 6.0, range 1-6; 81/258) and webpage respondents (median 2.0, range 1-9; 148/278)."

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 ○ ○ ○ ○ ○ 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.

"Respondents reported positive experiences and changes in their anxiety with Breathe; however, their reports were not correlated with program use. Breathe respondents identified program design and delivery factors that help explain their experiences and use of iCBT and inform program improvements."

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)

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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

We included information about the problem and population of interest in the Background. For example, "Anxiety disorders are the most prevalent mental health concern in children and adolescents, affecting about 8% to 11% of youth [1-3]…", "Understanding options for treatment delivery and for whom it may be best suited is a key area in CBT research, as face-to-face CBT is not always accessible [8], and there are high dropout rates of children and adolescents in traditional outpatient therapy treatment, ranging from 20% to 70% [9]…", and "These discordant outcomes contribute to a lack of clarity about how program usability, credibility, satisfaction, and usage relate to each other as part of an adolescent’s iCBT experience…". We present the goals of the intervention and our study in the Objectives section. For example, "We conducted a prospective study of iCBT users’ experiences in the context of a large-scale randomized controlled trial (RCT)."

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.

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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

In the Background section we provide an overview of relevant literature and demonstrate the motivation for our study as well as how this study could be impactful. For example, "An adolescent-defined MCID could inform user-centered treatment planning and advance methodological approaches in studies of iCBT effectiveness by framing the estimation of treatment effects [35-37]."

In the Objectives section we introduce our comparator and provide a brief justification for our use of it, "The large-scale trial was designed to evaluate the effectiveness of an iCBT program developed by our research team, Being Real, Easing Anxiety: Tools Helping Electronically (Breathe), in reducing anxiety symptoms among adolescents aged 13 to 19 years compared with webpages detailing anxiety resources (resource-based webpages, a usual self-help intervention)."

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 the Objectives section we list each specific objective as well as describe the overall intent of our objectives, "Within this trial, we had four distinct objectives for the user experience study: (1) to determine the adolescents’ usage of the Breathe program and resource-based webpages, (2) to define the adolescents’ user experiences with the Breathe program and the resource-based webpages and examine whether experiences differ between program and webpage use, and (3) to have adolescent users of the Breathe program define an MCID for anxiety symptoms after program use, and (4) to explore relationships among the user experiences, program usage, and the MCID among those adolescents who used the Breathe program."

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.

Details of the trial design are included in the Objectives and Procedures for Informed Consent and Assent sections. For example, "We conducted a prospective study of iCBT users’ experiences in the context of a large-scale, parallel design, randomized controlled trial (RCT)."

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

Does your paper address CONSORT subitem 3b? *

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

No changes to eligibility criteria were made after trial commencement.

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].

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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 no important changes made to the intervention during the trial.

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 eligibility criteria for participants is included in the Participant Recruitment and Eligibility subsection of the Methods. For example, "Inclusion criteria were as follows: (1) a minimum score of 25 on the Screen for Child Anxiety Related Disorders [41], indicating the presence of clinical anxiety symptoms; (2) the ability to read and write English; (3) regular access to a telephone and a computer system with high-speed internet service; and (4) the ability to use the computer to interact with Web material."

4a-i) Computer / Internet literacy
Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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|---|---|---|---|---|
| ○ | ○ | ☄ | ○ | ○ |

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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.

As part of our eligibility criteria, we have participants indicate if they have "(4) the ability to use the computer to interact with Web material" as a means to assess their computer/Internet literacy.

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.

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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.

We have included details about recruitment, assessments, human support, security/privacy measures of our study throughout the Methods section. For example, "Recruitment was conducted through the trial's social media platforms (Facebook, Twitter, Tumblr, and Instagram) with posts and paid advertisements across Canada and through health care professionals who provided study pamphlets to prospective participants seeking mental health care in specialty care clinics, primary care clinics, and schools in Edmonton, Alberta; Hamilton, Ontario; and Halifax, Nova Scotia", "In brief, the program was delivered via Intelligent Research and Intervention Software (IRIS), a secure, password-protected website", "Data collection was embedded in IRIS to allow for electronically captured, securely stored, encrypted, and password-protected data", and "Brief Web-based and telephone support was also provided".
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.

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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.

We have included relevant information in the Participant Recruitment and Eligibility subsection of the Methods. For example, "Advertisements and pamphlets directed adolescents to view the trial website [127], which provided details on the trial, including eligibility criteria, the screening and enrollment process, information on anxiety, and the research team's contact information."

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.

We included details about how and when data were collected in the Participant Recruitment, Intervention descriptions and Eligibility and Data Collection subsections of the Methods section. For example, "Adolescents interested in participation were screened for eligibility using a secure Web-based application, Research Electronic Data Capture (REDCap)", "In brief, the program was delivered via Intelligent Research and Intervention Software (IRIS), a secure, password-protected website", and "Data collection was embedded in IRIS to allow for electronically captured, securely stored, encrypted, and password-protected data".
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.

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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

We included information about self-assessment questions in the Measures subsection of the Methods section. For example, "We developed the User Experience Questionnaire for Internet-based Interventions (UEQII) to evaluate and compare adolescents’ self-reported user experience across internet-based interventions (Multimedia Appendix 1)."

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
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.

Although not made explicit in the manuscript, we have included in the Participant and Recruitment and Eligibility subsection of the Methods that, "Advertisements and pamphlets directed adolescents to view the trial website [127], which provided details on the trial, including eligibility criteria, the screening and enrollment process, information on anxiety, and the research team's contact information." By viewing the team's contact information, they could see our institutional affiliations.

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).

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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.

In the Breathe Program subsection of the Methods section we refer to a previously published manuscript with more details about the development of the Breathe program, "The Breathe program for mild-to-moderate anxiety symptoms among adolescents is described in detail elsewhere [45]."
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.

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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.

In the Breathe Program subsection of the Methods section we refer to a previously published manuscript with more details about the development of the Breathe program, "The Breathe program for mild-to-moderate anxiety symptoms among adolescents is described in detail elsewhere [45]." In previous and forthcoming publication we mention that the Breathe program has undergone usability testing, a pilot trial, and a process of updating the program based on previous users’ feedback.

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).

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subitem not at all important   ○ ○ ○ ○ ☐ 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.

We do not clearly mention the version number of the Breathe program or whether the program remained "frozen" during the evaluation. Instead, another manuscript (O'Connor et al., 2020) discusses how we updated the Breathe program to reflect feedback from users of our pilot trial.

No changes were made to the program during the trial. If changes were made, we would have reported them in our manuscript.

5-iv) Quality assurance methods

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

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subitem not at all important ○ ○ ○ ○ ○ 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.

We have noted that the Breathe program is based on cognitive behavioural therapy and incorporates persuasive system design strategies, both approaches are evidence-based.
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

In the The Breathe Program and Resource-Based Webpages subsections of the Methods we provide screenshots of the interventions. See Figures 1-5.

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.
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.

We have archived our research webpage here: http://archive.today/2020.02.03-185253/https://thebreathestudy.weebly.com/ or see https://thebreathestudy.weebly.com/

We are currently in the process of making the Breathe Program (the actual intervention) accessible through another platform. The intervention will be restored and available through the Strongest Families Institute in the near future.

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).

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.

In the Procedures for Informed Consent and Assent subsection of the Methods we state, "This was an open-label trial, and adolescents were notified of their assigned intervention via an email that included instructions for logging into the study website." In other parts of the Methods section we describe the intervention platform as a "a secure, password-protected website."
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].

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 Breathe Program subsection of the Methods section we describe the number of sessions, content of each session (see Table 1) and the CBT principles used, features based on persuasive systems design that were included. For example, "Features based on persuasive systems design [46] were employed to promote program engagement and use: tailoring (provided customized content based on preferences or actions), self-monitoring (progress was tracked and presented virtually to encourage self-reflection), suggestions (key information was provided to help meet users' goals or needs), and reminders (weekly emails were provided to help users continue with the program and provide notifications of the release of new sessions)."

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
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.

In The Breathe Program subsection of the Methods section we discuss the suggested use of the intervention. For example, "it was suggested that participants complete one session per week in a location convenient for them" and "reminders (weekly emails were provided to help users continue with the program and provide notifications of the release of new sessions)".

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.

In The Breathe Program subsection of the Methods section we present details on the human support provided in the program. For example, "Participants were assigned a Breathe coach, a trained paraprofessional, who initiated an optional telephone coaching session after session 1. The telephone call was not designed as a therapy session but was offered to answer any program-specific questions and to help participants prepare to complete program activities (ie, exposure activities)" and "If a safety issue was flagged (eg, decompensation in anxiety symptoms between sessions and thoughts of self-harm), there was a trigger in IRIS to notify the research assistant to contact the adolescent (and potentially the parent(s) depending on the concern) by phone within 36 hours to assess whether the adolescent required more immediate care and to provide emergent or nonemergency resources."
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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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.

In The Breathe Program subsection of the Methods section we present details on the reminders, emails, or other forms of communication provided throughout the intervention. For example, "reminders (weekly emails were provided to help users continue with the program and provide notifications of the release of new sessions)."

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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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.

No co-interventions were designed to be a part of the study. However, as this was a true effectiveness trial, participants were not excluded from the study if they were seeking or engaged in concurrent treatments or supports. We collected this self-report information and will present it in a forthcoming manuscript.

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.

In the Data Collection and Measures subsections of the Methods, we outline what measures were collected and when. In the Data Analysis section we detail how data was managed and the a prior analyses that were planned and how they were carried out. For example, "We defined intervention usage as adolescent’s use of the Breathe program or the resource-based webpages during the 6-week intervention period. Intervention usage was automatically recorded in IRIS using the number of Breathe sessions completed per allocated adolescent (a maximum of six sessions) and webpages visited per allocated adolescent (no maximum)."

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

In the Data Collection and Measures subsections of the Methods we provide some information about the design and deployment of the online questionnaire we developed for the current study. For example, "We developed the User Experience Questionnaire for Internet-based Interventions (UEQII) to evaluate and compare adolescents’ self-reported user experience across internet-based interventions (Multimedia Appendix 1). UEQII items were informed by previously published questionnaires and key literature on user experiences [50-52]. Items were tested for face and content validity [53]" and "Adolescents who completed outcome measures at the postintervention time point were given a token of appreciation (Can $25 electronic gift card)."

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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essential

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

In the Measures subsection of the Methods we define how intervention usage was defined and measured: "We defined intervention usage as adolescent’s use of the Breathe program or the resource-based webpages during the 6-week intervention period. Intervention usage was automatically recorded in IRIS using the number of Breathe sessions completed per allocated adolescent (a maximum of six sessions) and webpages visited per allocated adolescent (no maximum)."
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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| subitem not at all important |   |   |   |   | ![Essential](https://docs.google.com/uc?export=download&id=1FAIpQLSfZBSUp1bwOc_Oimqcs64RdfIFvmerTSkZQL2-3O8O9hrL5Sw) |

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

In the Measures subsection of the Methods we described what, when and from whom we obtained qualitative feedback. For example, For the UEQII, "Items 35 and 36 were also open text boxes where adolescents could describe what they considered to be the most challenging and enjoyable aspects of the Breathe program, respectively."

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

Not applicable as no changes were made after 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.

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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

Information about how the sample size was calculated will be presented in the forthcoming manuscript. However, by referring to a previous publication by O’Conner et al., 2020 readers can see the pilot trial data that was used to inform the sample size calculation for this full-scale RCT.

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. We carried out the trial with the sample size parameters that were calculated a priori. These details will be provided in a forthcoming manuscript.

8a) Method used to generate the random allocation sequence

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

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_OimqcS64RdfIAFvmrTShkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGlKd2… 32/56
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.

Details about the random allocation sequence were included in the Procedures for Informed Consent and Assent subsection of the Methods: "Once consent and assent were obtained, adolescents were enrolled in the trial and randomly assigned using a computer-generated sequence with a 1:1 allocation ratio to either the Breathe program or the resource-based webpages."

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

Does your paper address CONSORT subitem 8b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

The computer-generated sequence included a permuted block size of 4.

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

Details about the random allocation sequence were included in the Procedures for Informed Consent and Assent subsection of the Methods: "Once consent and assent were obtained, adolescents were enrolled in the trial and randomly assigned using a computer-generated sequence with a 1:1 allocation ratio to either the Breathe program or the resource-based webpages."

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.

In the Procedures for Informed Consent and Assent subsection of the Methods section we mention, "This was an open-label trial, and adolescents were notified of their assigned intervention via an email that included instructions for logging into the study website." And under the Data Collection subsection we state that, "Data collection was embedded in IRIS to allow for electronically captured, securely stored, encrypted, and password-protected data", meaning that no person was involved in the data collection or assessment process; therefore, blinding was irrelevant.

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”.

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subitem not at all important ○ ○ ○ ○ ● 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

In the Procedures for Informed Consent and Assent subsection of the Methods we describe that, "Adolescents were provided an information sheet on the trial and asked several yes/no questions to ensure consent/assent was informed." The information sheet contained details about the two interventions (Breathe program or resource webpages) and were given the option to continue with study participation knowing that they have a 50/50 chance of being allocated to either intervention.

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 for this study

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.

In the Data Analysis subsection of the Methods section we outline each a priori analysis planned for the study and what statistical methods we used for within-group and between-group comparisons. For example, "To compare differences and explore relationships between variables, we conducted independent t tests and Pearson correlations (r) for parametric data, and Spearman rank-order correlation coefficients (Spearman rho) and point-biserial correlations for nonparametric data (Pearson product-moment correlation, rpb)."

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]).

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.

In the Data Analysis subsection of the Methods section we mention that no data imputation strategies were used: "All enrolled participants were included in the analysis of demographic, MASC-2, and intervention usage data; no data imputation strategies were used."

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.

In the Data Analysis subsection of the Methods section we outline each a priori analysis planned for the study and what statistical methods we used for subgroups analyses. For example, "For analysis of UEQII and GRCS data, including the MCID calculation, we included adolescents who accessed their assigned intervention at least once during the trial intervention period (ie, those allocated to the Breathe program completed at least one session and those allocated to the resource-based webpages visited at least one webpage)."

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

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X26-i) Comment on ethics committee approval

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| subitem not at all important | ✗ | ✗ | ✗ | ✗ | ✗ |

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.

In the Study Design subsection of the Methods section we noted, "The Research Ethics Boards at the University of Alberta approved the trial (ClinicalTrials.gov Identifier: NCT02970734; Evaluating an Internet-Based Program for Anxious Adolescents)."
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.

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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

We provide a description of the informed consent procedure in the Procedures for Informed Consent and Assent subsection of the Methods. For example, "The consent/assent process took place in REDCap. Adolescents were provided an information sheet on the trial and asked several yes/no questions to ensure consent/assent was informed."

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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RESULTS

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

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

Does your paper address CONSORT subitem 13a? *

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

In each subsection of the Results section we the numbers of participants who were randomly assigned, received intended treatment, and were analysed for each outcome. For example, "The total number of adolescents enrolled in the trial was 536 (258 allocated to the Breathe program and 278 allocated to the resource-based webpages)"; "The average number of iCBT sessions completed by all 258 allocated adolescents to Breathe was 2.2 (SD 2.3)"; and "Among 258 adolescents allocated to the Breathe program, 81 (31.4%) provided postintervention user experience data and accessed the program at least once (herein referred to as Breathe respondents)."
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

We did not provide a CONSORT diagram indicating participants' flow through the study process. This will be included in a forthcoming manuscript.

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

In the Intervention Usage subsection of the Results we have included the number of participants who used their respective intervention across the sessions (Breathe program) or webpages visited (resource webpages) and have displayed these numbers in Table 4 and 5, respectively.

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

In the Participant Recruitment and Eligibility subsection of the Methods we state that "Adolescents were recruited for trial participation between November 21, 2016, and July 1, 2018." In the Data Collection subsection we discuss when the data was collected (no follow-up): "We collected user experience data at the preintervention (baseline) and postintervention (6 weeks following enrollment) assessment time points of the trial (Table 2)."

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

There were no significant secular changes that we were aware of that may have affected our study.

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

We did not address why the trial ended in the current manuscript as this relates to meeting our target sample size and will be discussed in a forthcoming manuscript.

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

In the Participant Demographics subsection of the Results we present the characteristics of our participants in Table 3.

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.

We did not inquire with participants if they experienced any digital divide issues (other than having computer with Internet access as an exclusion criteria); thus, no demographics in this case are provided.

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.

Throughout the Results section the denominator for each analysis is provided. For example, "The average age of participants was 16.6 years (SD 1.7), and most participants identified themselves as female (382/536, 71.3%)."
16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with
the appropriate caveats that this is no longer a randomized sample (see 18-i).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ 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

Not applicable for the current manuscript.

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 was not applicable for the current manuscript.
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  O  O  O  O  essential
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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.

Your answer

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

Does your paper address CONSORT subitem 17b? *

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

Not applicable for the current manuscript.

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 of our analyses are outlined in the Data Analysis subsection of the Methods. In the Results section we describe the participants that were included for each analysis/measure. For example, "Among the 258 Breathe respondents, 80 (30.6% of allocated adolescents) reported their change in anxiety using the GRCS (score range -5 to +5, with 0=no change). Among these adolescents, 75% (60/80) reported that their anxiety level improved after they had used the program with an average improvement of 2.3 (somewhat better; SD 0.8)."

---

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).

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.

All of our analyses are outlined in the Data Analysis subsection of the Methods, including within-group or subgroup analyses. In the Results section we describe the participants that were included for each analysis/measure, and if this involved a subgroup of the entire sample. For example, "Among the 258 Breathe respondents, 80 (30.6% of allocated adolescents) reported their change in anxiety using the GRCS (score range -5 to +5, with 0=no change). Among these adolescents, 75% (60/80) reported that their anxiety level improved after they had used the program with an average improvement of 2.3 (somewhat better; SD 0.8)."
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.

There were no important harms or unintended effects that we were aware of to report. The subgroup of Breathe participants who experience a worsening of self-reported anxiety were described in the Breathe User Ratings of Changes in Anxiety subsection of the Results section: "For the 5% (4/80) of adolescents who reported that their anxiety was worse after the program, the average worsening rating was 1.3 (mostly same/hardly worse; SD 0.5)."

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].

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.

Your answer
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  0  0  4  0  essential

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

Your answer

DISCUSSION

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

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

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

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

The Discussion section was divided into subsections of main findings (discussed in more detail); however, we begun the Discussion section with the Principal Findings which provided a brief overview of the results as they related to our study objectives. We did not restate the study questions.

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

1  2  3  4  5

subitem not at all important ○ ○ ○ ○ ○ essential

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.

Throughout the Strengths and Limitations subsection of the Discussion section we wove in how future studies might be able to address the unanswered questions or approach solving the problems we identified differently. For example, "Disadvantages of the anchor-based method, however, include the selection of the anchor itself (ie, GRCS) and the potentially arbitrary nature of the MCID cut point for a small change in anxiety (ie, somewhat better), although the GRCS change is consistent from other studies [60]. Thus, the MCID estimate calculated can vary between samples with different participant characteristics (eg, baseline severity and previous treatment experiences) [57,61,120]. Moving forward, we recommend that MCIDs be calculated using the same measures (GRCS and MASC-2) for adolescent users of other iCBT programs."

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                    |   |   |   |   |   |

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.

We included a Strengths and Limitations subsection in the Discussion section. Here we acknowledged what we considered to be the most important limitations to our study, but also what the implications of those limitations may be. For example, "Sample characteristics, such as most adolescents identifying as female, may limit the generalizability of our findings to other adolescents who seek self-help, technology-based interventions to manage their anxiety."

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.

In the Strengths and Limitations subsection of the Discussion section we discuss some limits to the generalizability of our study's findings or how study characteristics may/not explain our findings. For example, "Additional adolescent demographic (eg, urban or rural residence) or clinical information (eg, psychological comorbidities) could help explain the differences in attrition between respondents and nonrespondents or be used to explore mediators or moderators of study participation, but these data were not collected as part of this study. Sample characteristics, such as most adolescents identifying as female, may limit the generalizability of our findings to other adolescents who seek self-help, technology-based interventions to manage their anxiety."

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting
Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

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

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

Your answer

OTHER INFORMATION
23) Registration number and name of trial registry

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

In the Study Design subsection of the Methods we state the ClinicalTrials.gov Identifier as NCT02970734.

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

We did not publish the protocol for the full-scale effectiveness trial, but did publish the protocol to the pilot trial of the intervention. We referred to the protocol in The Breathe Program subsection of the Methods in this way: "The Breathe program for mild-to-moderate anxiety symptoms among adolescents is described in detail elsewhere [45]."

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 is no applicable for this manuscript.
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

We have included a Conflicts of Interest section but have none to declare.

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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 *

Approximately 3 hours

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

- [ ] yes
- [ ] no
- [ ] Other:

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

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

- [ ] yes
- [ ] no
- [ ] Other:

Any other comments or questions on CONSORT EHEALTH

Your answer
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