

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

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

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

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

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

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

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

Mandatory reporting items are marked with a red *.

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

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

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

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

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

Eysenbach G, CONSORT-EHEALTH Group

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

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

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

doi: 10.2196/jmir.1923

PMID: 22209829

* Required

Your name *

First Last

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

Your e-mail address *abc@gmail.com**Title of your manuscript ***

Provide the (draft) title of your manuscript.

Article Preparation Status/Stage *

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

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

Journal *

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

- not submitted yet / unclear where I will submit this
- Journal of Medical Internet Research (JMIR)
- Other:

Manuscript tracking number *

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

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

TITLE AND ABSTRACT

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

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

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

yes

Other:

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

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

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subitem not at all important essential

Does your paper address subitem 1a-i? *

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

"Study Protocol for a Randomized Controlled Trial to Evaluate Better Nights, Better Days, an Internet-Based Behavioural Intervention designed to Improve Psychosocial Health Outcomes in Children with Insomnia"

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").

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subitem not at all important essential

Does your paper address subitem 1a-ii?

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

This item is not applicable as there are no non-web-based components of the intervention, Better Nights, Better Days®.

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

The title specifies that the target population of the intervention is "Children with Insomnia."

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

Mention key features/functionality/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

The relevant sections of the abstract where the intervention components are described are copied below:

“Objectives: The Better Nights, Better Days® (BNBD) online program provides a readily accessible eHealth intervention to support parents in providing evidence-based care for insomnia in typically developing children aged 1- to 10-years old.

Methods: BNBD is a fully automated program, developed based on

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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subitem not at all important essential

Does your paper address subitem 1b-ii?

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

The relevant section of the abstract where the level of human involvement is defined is copied below:

“Methods: BNBD is a fully automated program, developed based on evidence-based interventions previously tested by the investigators, as well as on the extant literature on this topic.”

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

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

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subitem not at all important essential

Does your paper address subitem 1b-iii?

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

randomized controlled trial (RCT) in which participants (N = 300 primary caregivers of children with insomnia residing in Canada) are assigned to Intervention or Usual Care.
 Results: The effects of this behavioural sleep eHealth intervention will be assessed at 4- and 8-months post randomization. Assessment includes both sleep (actigraphy, sleep diary) and daytime functioning of the children, and daytime functioning of their parents. Results will be reported using the standards set out in the Consolidated Standards of Reporting Trials (CONSORT) Statement.”

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)

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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

Results: The effects of this behavioural sleep eHealth intervention will be assessed at 4- and 8-months post randomization. Assessment includes both sleep (actigraphy, sleep diary) and daytime functioning of the children, and daytime functioning of their parents. Results will be reported using the standards set out in the Consolidated Standards of Reporting Trials (CONSORT) Statement.”

As this abstract details a protocol for RCT that is currently ongoing, use data has not yet been assessed and is therefore not included.

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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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

As this abstract details a protocol for RCT that is currently ongoing, data collection is still underway and data analysis and results are not reported.

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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subitem not at all important essential

Does your paper address subitem 2a-i? *

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

The relevant sections from the paper outlining the type of problem and solution that is the object of the study is copied below:

"Pediatric Sleep Problems and Daytime Consequences
Sleep problems are highly prevalent amongst children [1, 2]. Although there is a range of physiological causes for inadequate sleep (e.g., sleep apnea, restless legs syndrome, and narcolepsy), by far the most common problem is insomnia. This condition is defined as "repeated

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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subitem not at all important essential

Does your paper address subitem 2a-ii? *

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

The Better Nights, Better Days® (BNBD) program, which is an eHealth intervention for primary caregivers of children ages 1- to 10-years who present with insomnia, can bridge this knowledge to practice gap by providing a potential solution to one of the most common treatment barriers - access to care. BNBD is an innovative, bilingual (English and French) eHealth program for parents, which aims to provide accessible and evidence-informed care for insomnia in typically developing children."

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

psychosocial health at the 8-month follow-up, evaluated using a questionnaire which identifies internalizing and externalizing behaviours and quality of life of children.

d) We hypothesize that parents randomized to the Intervention group, compared to parents randomized to the Usual Care group, will show 1) decreased daytime fatigue, 2) increased psychosocial health, and 3) improved parenting strategies at the 8-month follow-up based on questionnaires."

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

up assessment. The Consolidated Standards of Reporting Trials (CONSORT) 2010 [59, 60] guidelines and CONSORT eHealth guidelines [61] were used to design the trial and will be adhered to when reporting the results of the trial. The intervention is being delivered across Canada. The study is coordinated through Dr. Corkum's research laboratory (Corkum LABS; Learning, Attention, Behaviour and Sleep) at Dalhousie University. Both the Intervention group and Usual Care group are able to access any resources or programs and services while enrolled in the study, if they so choose."

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

As this manuscript details a protocol for a national RCT, changes to methods that may be implemented after the trial commencement are not reported in this protocol.

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

As this manuscript details a protocol for a national RCT, changes to the intervention that may be implemented after the trial commencement or events that may impact the study design are not reported in this protocol.

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

expert clinical review based on an adapted health related questionnaire.

3. Child has a mental health disorder that has required hospitalization or residential care and/or current use of psychotropic medications which are known to interfere with sleep (e.g., stimulant medication for ADHD), as determined by parent report and expert clinical review based on an adapted health related questionnaire [64].

4. Parent does not have appropriate level of English or French language skill to engage in this intervention, assessed based on a questionnaire that captures proficiency in communication [65]."

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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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

An inclusion criterion explicitly articulates that participants must “have regular access to high speed internet connection and an email account,” ensuring participants have access to, and use of the internet. Literacy is addressed as a requisite criterion that participants must be “comfortable communicating in English or French for day-to-day tasks (e.g., listening to the news on the radio or watching TV, reading books, magazines, etc.).”

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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subitem not at all important essential

Does your paper address subitem 4a-ii? *

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

screening on the REDCap website (see here, interested individuals read the inclusion/exclusion criteria in lay terms and self-assess to determine if they may be eligible. If a parent feels they may meet eligibility criteria and are interested in the study, they click a link directing them to the REDCap database to continue with screening. A Screening Information and Consent Form to participate in the screening process is presented and potential participants must consent to proceed. Participants are given an opportunity to contact research staff by email to have any questions answered and concerns addressed, if they so choose.”

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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subitem not at all important essential

Does your paper address subitem 4a-iii?

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

The relevant sections outlining how participants were briefed for recruitment and informed consent procedures are outlined below:

“Study Procedures

...

Screening and Consent

After completing the Screening Information and Consent Form, participants complete the Screening Questionnaire (author-made) to

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

All measures are available in both English and French, based on whether the participant has enrolled in the English or French language trial. All secondary and exploratory outcome measures are administered online via REDCap. All electronic questionnaires underwent technical and usability testing by research staff and external reviewers, as well as by six parents of children ages 1-10 years. All questionnaires are displayed in a sequential manner. Certain measures are age-dependent and REDCap automatically delivers them accordingly.”

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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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

Secondary Outcome Measures and Measures for Exploratory Analyses
Secondary outcome and exploratory outcomes are assessed through the administration of online questionnaires to assess children's sleep and psychosocial health, parental function, treatment barriers and predictors to successful intervention adherence. Each participant answers 13-15 questionnaires based on the group assignment (Intervention or Usual Care) and age of the child.”

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)

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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

This item is not addressed in the protocol manuscript as the institutional affiliations of the investigators were not deemed to bias recruitment or study results.

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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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

The name of the intervention software developer is addressed in the following section of the paper:

"eHealth Intervention

...

The intervention is hosted on the BeHealth Solution, LLC's proprietary technology platform [68] and can be accessed through participants' desktops, laptops, tablets, and smartphones."

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

the intervention platform in the Spring of 2016. Internal reviewers, including program developers with BeHealth Solutions, LLC, and research staff at Corkum LABS reviewed the intervention to identify technical problems. Six parents of children ages 1- to 10-years old also served as external reviewers for the program and completed five questionnaires to provide structured feedback on the technical operation of each session of the intervention. The goal of this step was to identify functional problems with the program (e.g., broken links, incorrect routing) prior to conducting the RCT.”

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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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

This manuscript outlines a research protocol of an RCT to evaluate the intervention that is currently ongoing. As such, information pertaining to the revisions and updating of the intervention during the trial are not reported.

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

the intervention platform in the Spring of 2016 for internal reviewers, including program developers with BeHealth Solutions, LLC, and research staff at Corkum LABS reviewed the intervention to identify technical problems. Six external reviewers, parents of children ages 1- to 10-years old, also reviewed the program and completed five questionnaires to provide structured feedback on the technical operation of each session of the intervention. The goal of this step was to identify functional problems with the program (e.g., broken links, incorrect routing) prior to conducting the RCT.”

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.

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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

This manuscript outlines a research protocol of an RCT to evaluate the intervention that is currently ongoing. The Better Nights, Better Days intervention is protected by a trademark registered under the Canadian Intellectual Property Office, and the intellectual property is governed by an inter-institutional agreement. As such, the source code of the intervention is not provided in this protocol.

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](http://www.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.

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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

This manuscript outlines a research protocol of an RCT to evaluate the intervention that is currently ongoing. The Better Nights, Better Days intervention is protected by a trademark registered under the Canadian Intellectual Property Office, and the intellectual property is governed by an inter-institutional agreement. As such, the URL of the intervention is not provided in this protocol. As the investigators intend to commercialize the program should the trial determine that it is effective in treating insomnia in typically developing children, the program will be

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).

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subitem not at all important essential

Does your paper address subitem 5-vii? *

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

Each care condition receive access after they complete the 6-month follow-up assessment...

The program can be used at a time that is convenient for the participants, removing barriers to care and providing services in the comfort and privacy of their own homes. The intervention is hosted on the BeHealth Solution, LLC's proprietary technology platform [68] and can be accessed through participants' desktops, laptops, tablets, and smartphones."

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

Describe mode of delivery, features/functionality/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

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

Each session provides evidence-based information to parents, strategies for implementation of best practices to address sleep problems, and access to additional help and advice through a "Roadblock" Q&A style support detailing common obstacles to implementing the recommended interventional strategies, and evidence-based methods to navigate these obstacles. There is also a "Reward Centre" where parents can develop reward programs (e.g., sticker charts) to help support the implementation of these sleep intervention strategies."

5-ix) Describe use parameters

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

1 2 3 4 5

subitem not at all important 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

strategies.

The program can be used at a time that is convenient for the participants, removing barriers to care and providing services in the comfort and privacy of their own homes. The intervention is hosted on the BeHealth Solution, LLC's proprietary technology platform [68] and can be accessed through participants' desktops, laptops, tablets, and smartphones."

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 5-x?

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

The following section addresses the level of human involvement in the full-self guided behavioural intervention:

"eHealth Intervention

...

The BNBD intervention is fully self-guided (i.e., there is no contact with coaches or clinicians), empowering parents to implement strategies independently. The program introduces evidence-based interventions,

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 5-xi? *

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

“eHealth Intervention

...

The intervention includes five sessions made available sequentially to participants. Table 2 summarizes the content of the intervention. The recommended completion time of the intervention ranges from 5-10 weeks. Participants receive an automated email reminder when a session becomes available, a prompt to complete each session, and seven notices that the recommended completion time is approaching.”

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).

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 5-xii? *

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

The intervention is designed to be fully self-guided, empowering parents of children with insomnia to implement behavioural strategies independently. Therefore no additional co-interventions, training or support for users (i.e., contact with coaches or clinicians).

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

4-Month and 8-Month Follow-up

Primary outcome measures (sleep diary and actigraphy), secondary outcome measures (questionnaires) and measures to address exploratory questions are administered to all participants at baseline and at 4- and 8-months post-randomization. Participants receive an automated invitation email from REDCap to start their 4-month follow-up after 16-weeks post-randomization, and to start their 8-month follow-up 32-weeks post-randomization.”

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

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

All measures are available in both English and French, based on whether the participant has enrolled in the English or French language trial. All secondary and exploratory outcome measures are administered online via REDCap. All electronic questionnaires underwent technical and usability testing by research staff and external reviewers, as well as by six parents of children ages 1-10 years. All questionnaires are displayed in a sequential manner. Certain measures are age-dependent and REDCap automatically delivers them accordingly.”

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

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

in advance of each subsequent module, participants are asked to record how carefully they reviewed the material, what percentage of the recommended strategies they implemented, and how successful they were in implementing these strategies, , as well as to provide an estimate of the overall percent improvement of their child's sleep problems. Second, computer-generated user statistics captured by the intervention platform software are used to assess adherence, such as the number of times the site was accessed, and the period of time taken to complete each module.”

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

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

...satisfaction with services received. The CSQ-8 items measure how parents to rate the services they received through the BNBD intervention on a 4-point Likert-scale. Participants can also elaborate and provide any additional feedback on the intervention in text-box format. Internal consistency for the CSQ-8 is reported with alphas ranging from .83 to .93 [126]. An overall score for the CQS-8 is produced by summing all item responses producing scores ranging from 8 to 32, with higher values indicating higher satisfaction. The CSQ-8 takes approximately 5 to 7 minutes to complete.”

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

This manuscript outlines a research protocol of an ongoing RCT. As such, information pertaining to the revisions to the trial outcomes implemented after the trial commenced are not reported.

7a) How sample size was determined

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

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

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

1 2 3 4 5

subitem not at all important 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

power needed to detect a significant group by time interaction with the effect size (d) = .45 and alpha set to .025, for primary outcome measures calculated from actigraphy and sleep diary from baseline to 4-month follow-up. Given that two primary outcome variables are being used (sleep efficiency from actigraphy and sleep efficiency from sleep diaries), alpha was divided by two so that P = .025, rather than P = .05 would be accepted as indication of statistical significance. This is based on the assumption that an effect size of d =.45 is clinically significant for sleep efficiency as measured by actigraphy and sleep diary [45].”

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

communicated to the Principal Investigator or her delegate (Co-Investigator) and follow-up with the participant is made to ensure their well-being. Data monitoring for adverse events or trends in outcome has not been undertaken given that this is a low risk study. An Adverse Events Committee, composed of the three members from Dalhousie University, not associated with the BNBD study, and having medical, psychology, and sleep expertise, will review adverse events if one becomes known during the course of the study."

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

Research staff members randomize participants using an automated REDCap procedure. The randomization table, created in Excel, is uploaded into the REDCap database, where it cannot be modified or accessed. Only the research associate is able to view the randomization table. Once a participant completes baseline assessment, research staff members confirm all criteria are met and "trigger" the automated randomization by clicking a button within the program. An automated email is sent to participants to notify them of the randomization result."

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

not blinded to their assignment group. Participants are stratified by age groups: Toddler (1-2 years of age); Pre-School (3-5 years of age); and School-Aged (6-10 years of age). Blocks of four are used to randomize the participants for each stratum (i.e., each age group).

The randomization table was created using the block random function in the R statistical software [94] and inputted into REDCap by a research staff member who is not associated with the management of participants."

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

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

participants. The only individuals who have access to the randomization table are not associated with participant management and include the research associate (E. Begum) who created the random allocation table based on the study design and a Co-Investigator with extensive RCT design experience (R. Stremler) and the study statistician (P. Andreou), who reviewed the randomization table. The statistician conducting the primary analysis will be blinded to participant allocation to Intervention or Usual groups (i.e., the statistician will not be given the code for this variable)."

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

Does your paper address CONSORT subitem 10? *

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

The relevant sections of the manuscript outlining who generated the random allocation sequence and enrolled participants to the intervention is outline below:

"Study Procedures

...

Randomization

After completion of baseline measures participants are randomized. A

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

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

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

1 2 3 4 5

subitem not at all important 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

Research staff members randomize participants using an automated REDCap procedure. The randomization table, created in Excel, is uploaded into the REDCap database, where it cannot be modified or accessed. Only the research associate is able to view the randomization table. Once a participant completes baseline assessment, research staff members confirm all criteria are met and "trigger" the automated randomization by clicking a button within the program. An automated email is sent to participants to notify them of the randomization result."

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

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

1 2 3 4 5

subitem not at all important 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

Participants randomized to the Intervention Group receive access to the intervention, while the Usual Care group, as the control comparator, do not receive access to the intervention until the post 8-month assessment period. Participants are therefore aware if they have been assigned to the intervention versus the comparator condition.

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

This item is not relevant to the study as the intervention comparator is the waitlist condition.

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

b) Secondary Outcome: For the secondary outcomes, we will test differences between the two groups modeling changes in the outcome variables across the three points of measurement (baseline, 4- and 8-months post randomization) to determine treatment effects at 8-months post-randomization. Again, a significant Time-X-Group interaction would indicate differential rate of change over time between groups. Differences in the estimated means at the 4-month and 8-month post-treatment time points will also be examined."

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

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 12a-i? *

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

The relevant section outlining the planned imputation techniques to deal with missing values is outlined below:

"Statistical Analysis

...

Data Analysis

...

An intent-to-treat analysis will be conducted. Multiple Imputation (MI)

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

primary outcomes (group diary and geography). Analysis is based on the methodology of the extension of the GLM for longitudinal data, namely marginal and random effects modeling which allows for varying intercepts and slopes across subjects, 'G-side' random effects, and different within person error variance covariance structure, 'R-side' random effects [103, 104]. An interaction of age group (Toddler, Preschool, School-Aged) x time (3 assessments) x randomization group (Intervention, Usual Care) would indicate differential response to treatment."

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

X26-i) Comment on ethics committee approval

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem X26-i?

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

The manuscript comments on ethical approval for the protocol within the Ethical Considerations section of the manuscript, stating: "Ethics approval was granted by IWK Health Center Research Ethics Board."

x26-ii) Outline informed consent procedures

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem X26-ii?

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

participate at any time, and they are informed of the aims, methods, benefits and risks of the study. All participants are given an opportunity to contact research staff by email or to request a phone call to have any questions answered and concerns addressed. A series of true and false questions to test a participant's knowledge of their research rights are used to ensure informed consent. A copy of both the Screening Information and Consent Form and the Information and Consent Form are available to be downloaded and saved by participants. Participants provide an electronic signature and date and click an "I Agree" button."

X26-iii) Safety and security procedures

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

1 2 3 4 5

subitem not at all important 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

communicated to the Principal Investigator or her delegate (Co-Investigator) and follow-up with the participant is made to ensure their well-being. Data monitoring for adverse events or trends in outcome has not been undertaken given that this is a low risk study. An Adverse Events Committee, composed of the three members from Dalhousie University, not associated with the BNBD study, and having medical, psychology, and sleep expertise, will review adverse events if one becomes known during the course of the study."

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

The manuscript reports on a research protocol of a national RCT that is currently ongoing. As such, results related to the participants' randomization assignment and data analysis are not reported.

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

A CONSORT schematic flow diagram is included as Figure 1 in this manuscript. However as this manuscript reports on the study protocol of an ongoing RCT, no results regarding losses and exclusions post-randomization are reported.

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 13b-i?

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

A CONSORT schematic flow diagram is included as Figure 1 in this manuscript. However as this manuscript reports on the study protocol of an ongoing RCT, no results regarding losses and exclusions post-randomization are reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding the periods of recruitment and follow-up are reported.

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

Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"

1 2 3 4 5

subitem not at all important 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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding secular events of the study period are 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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding the periods of recruitment and follow-up are reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding the baseline demographic and clinical characteristics of each group are available and are therefore not reported.

15-i) Report demographics associated with digital divide issues

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

1 2 3 4 5

subitem not at all important 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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding participant demographics are reported.

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

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

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

1 2 3 4 5

subitem not at all important 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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding participant numbers included in analysis are reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding participant numbers are reported. The protocol manuscript specifies that “Data analyses are overseen by the research team, including the statistician, using an intent-to-treat data analytic approach [100].”

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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding data analysis are reported.

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 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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding data analysis are reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding data analysis are reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding data analysis are reported.

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

Does your paper address subitem 18-i?

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

As this manuscript reports on the study protocol of an ongoing RCT, no results regarding data analysis are reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, no harms or unintended effects are reported.

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

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

As this manuscript reports on the study protocol of an ongoing RCT, no harms or unintended effects are reported.

19-ii) Include qualitative feedback from participants or observations from staff/researchers

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 19-ii?

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

As this manuscript reports on the study protocol of an ongoing RCT, no harms or unintended effects are reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, data analysis and interpretation are not reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, data analysis and interpretation are not reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, data analysis and interpretation are not reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, data analysis and interpretation are not reported.

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

As this manuscript reports on the study protocol of an ongoing RCT, data analysis and interpretation are not reported.

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

The manuscript addresses the trial registration under the section Clinical Trial Registration. The trial registration information provided is as follows: "ClinicalTrials.gov Protocol Registration and Results System (PRS), NCT02243501. Registered on 14 April 2014."

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

Does your paper address CONSORT subitem 24? *

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

This manuscript itself outlines the research protocol for the RCT.

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

Does your paper address CONSORT subitem 25? *

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

This study was supported by the Canadian Institutes of Health Research (CIHR) Team Grant FRN-TGS 109221. This information is included in the Acknowledgements section of the 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

There are no conflicts of interest to declare. This information is included in the section titled Conflicts of Interest.

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- yes, major changes
- yes, minor changes
- no

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

Additional pertinent information was included in the manuscript regarding the administration of the online questionnaires according to the CHERRIES recommendations.

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Several hours were devoted to the review of the existing manuscript and edits to the paper based on the CONSORT checklist.

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

yes

no

Other:

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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

This was a valuable exercise and the CONSORT EHEALTH checklist has been used to strengthen the manuscript.

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