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

*必須

Your name *
First Last
Daisuke Sato

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

Your e-mail address *
whi@gmail.com
daisuke-sato@umin.ac.jp

Title of your manuscript *
Provide the (draft) title of your manuscript.
Effectiveness of Unguided Internet-based Cognitive Behavioral Therapy and the Three Good Things Exercise for Insomnia: A Three-arm 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.
III P, Insomnia Improvement Internet Program
【Evaluate Version (if any)

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

【Language(s)

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

Japanese

【URL of your Intervention Website or App

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

【URL of an imagescreen shot (optional)

【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
○ その他

【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 who)", "Alzheimer's (Informal Caregivers of)

patients with mild or severe sleep disorder

【Primary Outcomes measured in trial

coma-separated list of primary outcomes reported in the trial

Pittsburgh Sleep Questionnaire

【Secondary/other outcomes

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

sleep onset latency, total sleep time, sleep efficiency, Athens Insomnia Scale, Generalized Anxiety Disorder-7, PHQ-9, Patient Health Questionnaire 9, Center for Epidemiologic Studies Depression Scale

【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"
○ その他

回答を入力

https://docs.google.com/forms/d/e/1FAIpQLSJZBSUp1bwOc_OimqcS64RdfIAFvrmrTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&hl=en_US&ed... 2/24
| Unknown / Not Evaluated | 0-10% | 11-20% | 21-30% | 31-40% | 41-50% | 51-60% | 61-70% | 71-80% | 81-90% | 91-100% |
|-------------------------|-------|--------|--------|--------|--------|--------|--------|--------|--------|---------|

**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

**Article Preparation Status/Stage**
- 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

**Journal**
- Not submitted yet / unclear where I will submit this
- Journal of Medical Internet Research (JMIR)
- JMIR mHealth and U-Health
- JMIR Serious Games
- JMIR Mental Health
- JMIR Public Health
- JMIR Formative Research
- Other JMIR sister journal

**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).  

- no ms number (yet) / not (yet) submitted to / published in JMIR  
- その他 28747  

TITeL 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  
- その他  

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 “mobiles” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.  

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | essential |

1a-ii) Non-web-based components or important co-interventions in title  
Mention non-web-based components or important co-interventions in title, if any (e.g., “with telephone support”).  

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | essential |

1a-iii) Primary condition or target group in the title  
Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”).  
Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial  

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | essential |
Does your paper address subitem 1a-iii? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks “like this”) to indicate direct quotes from your manuscript, or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study


effectiveness for 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)

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. “physician/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)

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 user group trial), and clarify if this is 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-enroll). (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)

Outcomes were measured by online self-assessment.

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

“unguided internet cognitive behavioral therapy (ICBT) or the three good things (TGT) exercise”

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

“self-help internet interventions without e-mail support”

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

Answering questions is a continuous process. This URL will allow others to contribute to your answer.
INTRODUCTION

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

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

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

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.

2b-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., attendance/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).

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).

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.

"312 met the eligibility criteria and were randomly assigned to one of the three groups."

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.

This study was not a negative trial.

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).

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.

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., attendance/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).

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).

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).

1b) In INTRODUCTION: Scientific background and explanation of rationale

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., attendance/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).

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).

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).

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.

https://docs.google.com/forms/d/e/1FAIpQLS5ZBSUp1bwOc_OimqcS64RdfIFvrmrTsKZQL2-3O8O9hrL5Sw/viewform?hl=en_US&hl=en_US&ed... 6/24
Guided Internet-based Cognitive Behavioral Therapy for insomnia increased sleep quality. Three Good Things exercise increased self-reported levels of happiness and decreased depression.

2b) In INTRODUCTION: Specific objectives or hypotheses

This study aimed to clarify whether unguided Internet cognitive behavioral therapy or the three good things exercise could improve insomnia symptoms compared to a waiting list control group.

METHODS

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

an exploratory, parallel-group (3 groups), randomized, open-label, controlled study

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

There is no change to methods 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].

4a) Eligibility criteria for participants

Potential participants were provided to meet all the inclusion criteria at the time of the preliminary survey.
4a-i) Computer / Internet literacy
Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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

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

"access to internet use with personal computers, smartphones, and tablets"

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:
Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

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

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

"An e-mail was sent to the registered monitors owned by the internet research company that commissioned the research, and a preliminary survey was conducted on the internet."

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 X25), as this information may have an effect on user self-selection, user expectation and may also bias results.

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

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

"Members voluntarily underwent a preliminary survey after explanation and agreement following distribution of the recruitment materials."

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

"Case registration was performed via the trial website."
4b-i) Report if outcomes were (self-)assessed through online questionnaires
Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

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

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

"Outcomes were measured by online self-assessment."

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 manuscript, or briefly explain why the item is not applicable/relevant for your study

"Among the registered monitor members (candidate subjects) of monitors owned by the internet research company, those who met the conditions were automatically assigned subject identification codes when they accessed the servers."

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

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners
Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of Interest" section or mentioned elsewhere in the manuscript).

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

Does your paper address subitem 5-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the manuscript, or briefly explain why the item is not applicable/relevant for your study

"The study period was four weeks. "The intervention programs consisted of unguided ICBT program and TGT program."

5-ii) Describe the history/development process
Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

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

Does your paper address subitem 5-ii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the manuscript, or briefly explain why the item is not applicable/relevant for your study

"The study period was four weeks. "The intervention programs consisted of unguided ICBT program and TGT program."
### 5-ii) 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).

| Item | 1 | 2 | 3 | 4 | 5 |
|------|---|---|---|---|---|
| subitem not at all important | ☐ | ☐ | ☐ | ☐ | ☑ |
| essential | | | | | |

Does your paper address subitem 5-ii?

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

### 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).

| Item | 1 | 2 | 3 | 4 | 5 |
|------|---|---|---|---|---|
| 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.

### 5-iv) Quality assurance methods

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

| Item | 1 | 2 | 3 | 4 | 5 |
|------|---|---|---|---|---|
| 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.

### 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.

| Item | 1 | 2 | 3 | 4 | 5 |
|------|---|---|---|---|---|
| subitem not at all important | ☐ | ☐ | ☐ | ☐ | ☑ |
| essential | | | | | |

Does your paper address subitem 5-v?

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

### 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.

| Item | 1 | 2 | 3 | 4 | 5 |
|------|---|---|---|---|---|
| subitem not at all important | ☐ | ☐ | ☐ | ☑ | ☑ |
| essential | | | | | |

Does your paper address subitem 5-vi?

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

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For more information, visit the CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form at https://docs.google.com/forms/d/e/1FAIpQLSIZBSUp1bwOc_OimqcS64RdfIFvMr7SksKQLZ2-3O809hrL5Sw/viewform?hl=en_US&hl=en_US&… 10/24.
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.

**5-vi) Access**

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained “access to the platform and Internet” [1]. To ensure access for editors/reviewers/readers, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | essential |

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.

“Subjects accessed the ICBT site and performed the tasks autonomously.”

**5-vii) 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 information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

| 1 | 2 | 3 | 4 | 5 |
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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.

“The subjects who accessed the site received the prompt by e-mail.”

**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.

“The ICBT group underwent an unguided ICBT program for four weeks, the TGT group underwent a TGT exercise program for four weeks, and the non-intervention group (WLC) waited for four weeks without intervention.”
5-a) 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 co-intervention (local supply 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-a?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

*self-help internet interventions*

5-x) 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-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 subjects who accessed the site received the prompt by e-mail."

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

"The subjects who accessed the site received the prompt by e-mail."

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

There were no additional treatments to add to the unguided, online self-help intervention.

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

"The primary outcome was the change in PSQI from baseline in the post-intervention survey at four weeks."

https://docs.google.com/forms/d/e/1FAIpQLSjZBSU1bw0C_OimqcS64RdfiAFvmtTSkZQL2-3O8OSnrl5Sw/viewform?hl=en_US&hl=en_US&... 12/24
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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| not at all important | | | | essential |

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

"Web-based assessments was administered."

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 (logs, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

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| not at all important | | | | essential |

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

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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| not at all important | | | | essential |

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

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

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

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care 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 |
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| 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.

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

The stopping guidelines: (1) When an adverse event occurs, and the investigator determines that the subject has difficulty continuing the study; (2) When there is a request for cancellation from the subject; (3) When it is found that the subject abused the system of the Internet research company.

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 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.

"Allocation modifiers included baseline PSQI scores and gender."

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 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

Randomization was balanced.

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 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

SAS, Statistical Analysis Software, was used to carry out random grouping and the allocated sequence was kept by the administrator.

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

回答を記入する機能を用いて、他のユーザーもあなたの回答を編集できるようにします。
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).

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

This is non-blinded study.

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

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

Does your paper address subitem 11a-ii?

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

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

The item is not applicable as our study is an ehealth trial.

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

"We estimated the difference in PSQI score change between the test group and the control group and the 95% two-sided confidence interval. "No adjustment for multiplicity was made in the analysis of secondary efficacy outcomes. The significance level of the hypothesis test was set at 5% (two-sided), and the two-sided 95% confidence interval was calculated."
### 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).

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**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 study did not include incomplete data in the analysis.

### 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.

“Secondary evaluation items of effectiveness were analyzed to supplement the primary analysis results.”

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

#### X26-i) Comment on ethics committee approval

**Does your paper address subitem X26-i?**

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

“This study was approved by the Clinical Trials Ethics Review Board of the Chiba University Hospital.”

#### X26-ii) Outline informed consent procedures

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

**Does your paper address subitem X26-ii?**

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

“A document explaining consent was presented to subjects on a web page, accompanied by a verbal explanation as part of a video animation by the principal investigator.”
RESULTS

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

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

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

"270 subjects (ICBT; n = 79, TGT; n = 88, WLC; n = 103) completed a post-intervention survey at four and eight weeks."

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.

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

"Of the 106 people assigned to ICBT, 23 people did not start the ICBT program at least once, and 4 people who performed the ICBT program at least once were classed as trial deviations, leaving 79 individuals with a FAS."

"Shown in Figure 1, CONSORT diagram of participant flow throughout the study."
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

"A four week program was implemented." "The primary outcome measure was Pittsburgh Sleep Questionnaire score at four weeks compared to baseline."

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 secular events.

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

Follow-up of all subjects ended.

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

Table 1 shows baseline demographic and clinical characteristics for the three groups.

15-i) Report demographics associated with digital divide issues
In e-health 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

The demographics associated with digital divide issues were reported.

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
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 manuscript, or briefly explain why the item is not applicable/relevant for your study

The multiple denominators and provided definitions were reported, as shown in Table 2 and 3.

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 manuscript, or briefly explain why the item is not applicable/relevant for your study

Statistical analysis and reporting of this trial was conducted in accordance with CONSORT guidelines, with primary analyses based on the intention-to-treat principle.

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 manuscript, or briefly explain why the item is not applicable/relevant for your study

The results of the three groups' primary and secondary outcome were shown in Tables 3 through 6.

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 manuscript, or briefly explain why the item is not applicable/relevant for your study

Shown in Tables 3 through 6.

Does your paper address subitem 17a-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 manuscript, or briefly explain why the item is not applicable/relevant for your study

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

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

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 (doses, exposures) 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).

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

https://docs.google.com/forms/d/e/1FAIpQLSIZBSUp1bwOc_OimqcS64RdIAFvmrTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&hl=en_US&e... 19/24
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 manuscript, or briefly explain why the item is not applicable/relevant for your study.

The results of other analyses performed, such as subgroup analyses, were consistent with pre-specified from exploratory.

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 manuscript, or briefly explain why the item is not applicable/relevant for your study.

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).

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 manuscript, or briefly explain why the item is not applicable/relevant for your study.

There were no harm or unintended effects during the study.

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 manuscript, or briefly explain why the item is not applicable/relevant for your study.

There was no privacy breach or severe technical problem.
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).

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

Highlight unanswered new questions, suggest future research.

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
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.

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subitem not at all important o o o o 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

"The number of subjects who received more than 75% of the intervention in the ICBT group was 55 of 79 subjects, compared to 79 of 88 subjects who received more than 75% of the intervention in the TGT group. This could have been due to difficulties with regular participation in the ICBT program."

22) Registration number and name of trial registry

OTHER INFORMATION

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

UMIN Clinical Trial Registry Number: UMIN000034927
24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

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

The entire trial protocol is not open access.

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

Does your paper address CONSORT subitem 25? *

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

"This study was funded by the Research Institute of Economy, Trade and Industry (RIETI), Japan, and supported in part by the Grant-in-Aid for Scientific Research (B) from the Japan Society for the Promotion of Science (JSPS) (grant KAKENHI 17H04091 to S. E.), the Grant-in-Aid for Scientific Research (C) from JSPS (grant KAKENHI 18K10716 to S. D.) and Grants from Chiba Foundation for Health Promotion & Disease Prevention."

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

All authors have no conflicts of interest to declare.

About the CONSORT EHEALTH checklist

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

○ yes, major changes
○ yes, minor changes
○ no

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

回答を入力

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

The limitation of this study.
As a result of using this checklist, do you think your manuscript has improved? *
- yes
- no
- その他:

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
- その他:

Any other comments or questions on CONSORT EHEALTH
回答を入力

STOP - Save this form as PDF before you click submit
To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select "print" and then select "print as PDF") before you submit it.
When you submit your (revised) paper to JMIR, please upload the PDF as supplementary file. Don't worry if some text in the textboxes is cut off, as we still have the complete information in our database. Thank you!

Final step: Click submit!
Click submit so we have your answers in our database!