

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

luckywangjuan@gmail.com [Switch account](#)



Not shared



Draft saved

* Indicates required question

Your name *

First Last

Juan Wang

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

Shandong University, Jinan, China

Your e-mail address *

abc@gmail.com

17865199596@163.com

Title of your manuscript *

Provide the (draft) title of your manuscript.

The Effectiveness and Mechanisms of a Digital Mindfulness-Based Intervention for Subthreshold to Clinical Insomnia Symptoms in Chinese Pregnant Women: A 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.

a digital mindfulness-based intervention target

Evaluated Version (if any)

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

Your answer

Language(s) *

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

Chinese

URL of your Intervention Website or App

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

Your answer

URL of an image/screenshot (optional)

Your answer

Accessibility *

Can an enduser access the intervention presently?

- ☐ access is free and open
- ☒ access only for special usergroups, not open
- ☐ access is open to everyone, but requires payment/subscription/in-app purchases
- ☐ app/intervention no longer accessible
- ☐ Other:

Primary Medical Indication/Disease/Condition *

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Insomnia symptoms (Pregnant women with)"

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

insomnia symptoms measured by the Insomni

Secondary/other outcomes

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

insomnia remission rates and reliable change rates, sleep onset latency, wake after sleep onset, total sleep time, sleep efficiency, sleep quality, fatigue symptoms, daytime sleepiness, anxiety symptoms, depressive symptoms

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- ☒ Approximately Daily
- ☐ Approximately Weekly
- ☐ Approximately Monthly
- ☐ Approximately Yearly
- ☐ "as needed"
- ☐ Other:

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

☒ unknown / not evaluated

☐ 0-10%

☐ 11-20%

☐ 21-30%

☐ 31-40%

☐ 41-50%

☐ 51-60%

☐ 61-70%

☐ 71%-80%

☐ 81-90%

☐ 91-100%

☐ Other:

Overall, was the app/intervention effective? *

- ☒ yes: all primary outcomes were significantly better in intervention group vs control
- ☐ partly: SOME primary outcomes were significantly better in intervention group vs control
- ☐ no statistically significant difference between control and intervention
- ☐ potentially harmful: control was significantly better than intervention in one or more outcomes
- ☐ inconclusive: more research is needed
- ☐ Other:

Article Preparation Status/Stage *

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

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

Journal *

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

- ☐ not submitted yet / unclear where I will submit this
- ☒ Journal of Medical Internet Research (JMIR)
- ☐ JMIR mHealth and UHealth
- ☐ JMIR Serious Games
- ☐ JMIR Mental Health
- ☐ JMIR Public Health
- ☐ JMIR Formative Research
- ☐ Other JMIR sister journal
- ☐ Other:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- ☐ Pilot/feasibility
- ☒ Fully powered

Manuscript tracking number *

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

- ☐ no ms number (yet) / not (yet) submitted to / published in JMIR
- ☒ Other: JMIR ms#68084

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.

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

Clear selection

Does your paper address subitem 1a-i? *

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

Yes, "a Digital Mindfulness-Based Intervention"

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

Clear selection

Does your paper address subitem 1a-ii?

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

No, it is not applicable.

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

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☐ ☐ ☒

Clear selection

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

Yes, the target condition or group was "sub-threshold to clinical insomnia symptoms in Chinese pregnant women"

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

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

Yes, the key intervention was "the 6-week dMBI-PI plus standardized care", the comparator was "standardized care"

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

[Clear selection](#)**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

Yes, the intervention was "self-help"

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)

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 1b-iii?

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

Yes, participants were recruited offline ("were recruited from obstetrics clinics"), and "All outcomes were self-assessed through web-based questionnaires"

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)

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☒ ☐ ☐

[Clear selection](#)**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

Your answer

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)

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☐ ☒ ☐

[Clear selection](#)

Does your paper address subitem 1b-v?

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

Yes, the conclusions were mainly focused on the significant effects of intervention on primary outcome, and the discussion about negative results of the secondary outcomes was presented in the main text.

INTRODUCTION

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

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

Does your paper address subitem 2a-i? *

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

Yes, the main problems in this area include:

- 1) "Several studies have documented the effectiveness of cognitive behavioral therapy for insomnia (CBT-I, the first-line insomnia treatment recommended by many guidelines, and most evidence comes from general population) among pregnant women, but only 34.8% to 63.8% achieved remission from prenatal insomnia symptoms [6-8]. Moreover, the accessibility of CBT-I is significantly hindered by the availability of trained clinicians and the high treatment costs..... "
- 2) ".....however, only a few pilot studies and small sample randomized controlled trials (RCT) explored the effectiveness of MBIs on prenatal insomnia symptoms [17-19]."
- 3) ".....Regrettably, although there are several theoretical and practical considerations suggesting that such flexible digital delivery may be especially attractive to pregnant women.....few studies have established whether the digital delivery of MBIs can improve prenatal insomnia symptoms. "
- 4) "However, most studies to date assessing the effectiveness of MBIs fail to include a prior hypothesis about mediators in modeling of programs effects. Moreover, several studies tend to stop the mediation testing and conclude that the mediation is not present because of a non-significant total effect [26]."
- 5) ".....However, to our knowledge, only one well-designed RCT study has investigated the mediating roles of rumination and worry in the MBIs' effects on insomnia symptoms among patients with breast cancer, which found that both of rumination and worry were significantly mediators underlying the effects of MBI on insomnia symptoms [28]."

The target population of this study is pregnant women with sub-threshold to clinical insomnia symptoms.

The goal of the intervention is "to evaluate the effectiveness of a digital mindfulness-based intervention targeted at prenatal insomnia (dMBI-PI) on reducing sub-threshold to clinical insomnia symptoms through a RCT with a relatively large sample size and long-term follow up from the second trimester to postpartum....."

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

[Clear selection](#)**Does your paper address subitem 2a-ii? ***

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

1) What is known about the mindfulness-based interventions for insomnia symptoms?

"...Accumulating evidence has suggested that mindfulness-based interventions (MBIs) may hold promise as an additional treatment option for insomnia symptoms. As Shallcross' s theoretical model for the effects of mindfulness practices on risk processes for the development and maintenance of sleep disturbances proposed [11], the core principles of MBIs, such as present-moment awareness, non-judging, and acceptance, may theoretically improve sleep by counteracting the adverse cognitive and behavioral processes implicated in insomnia. These processes have been widely suggested across various etiological models of insomnia, including sleep-specific rumination (repetitive negative thinking about the causes of current daytime symptoms associated with poor sleep, such as fatigue, poor concentration, and disturbed mood), sleep-specific worry (repetitive negative thinking towards future adverse consequences of poor sleep), pre-sleep arousal (increased pre-sleep cognitive activity, or physical arousal similar to that of the acute stress response driven by the activation of the sympathetic nervous system, e.g., increased heart rate, elevated body temperature, and muscle tension), sleep-related attentional bias (increased scanning or monitoring towards anything that could be perceived as sleep-related threats, including both internal stimuli such as bodily sensations, and external stimuli such as noise, light, or clocks) and maladaptive behaviors (subtle behaviors individuals engage in to cope with the fear of not being able to sleep and its negative consequences, e.g., consuming caffeine to prevent daytime dysfunction, going to bed early to ensure enough time to fall asleep, or looking at the clock to see how long it is taking to get to sleep [12].

Jason C. Ong and colleagues developed a mindfulness-based therapy for insomnia (MBT-I) in 2008, combining mindfulness meditation practices with behavior therapy of CBT-I (such as sleep hygiene, stimulus control, and sleep restriction) [13]. In fact, because automatic thoughts might be very resistant to change, substituting negative thoughts and beliefs with rational ones has been widely recognized as one of the most challenging steps in CBT-I. In comparison, a mindfulness-based approach emphasizes shifting from automatic reactions to a more detached, process-oriented observation and acceptance

2) The motivation for the study is:

".....digital adaptations of psychological interventions have been widely advocated over the past decade to overcome the dissemination barriers prevalent in in-person treatments (e.g., a shortage of professional practitioners, treatment costs, time/location restrictions) [22]. Preliminary research has demonstrated the effectiveness of digital MBIs on improving sleep among non-pregnant populations [23-25]. Regrettably, although there are several theoretical and practical considerations suggesting that such flexible digital delivery may be especially attractive to pregnant women (e.g., they are predominantly young adults, have relatively great eHealth literacy and technology acceptance [26], often have numerous medical appointments making it challenging to attend additional face-to-face sessions specifically for insomnia symptoms, and for whom timeliness of access to interventions is critical), few studies have established whether the digital delivery of MBIs can improve prenatal insomnia symptoms....."

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

Yes, "the first objective of this study was to evaluate the effectiveness of a digital mindfulness-based intervention targeted at prenatal insomnia (dMBI-PI) on reducing sub-threshold to clinical insomnia symptoms through a RCT with a relatively large sample size and long-term follow-up from the second trimester to postpartum. Furthermore, to better understand the mechanisms of change, our second objective was to....."

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

Yes, "This study was an evaluator-masked, two-parallel-armed RCT"; ""When eligible participants completed baseline assessments and provided informed consent, the independent researcher opened the envelope and randomly assigned participants to the dMBI-PI intervention group or the control group using a 1:1 ratio.""

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

Does your paper address CONSORT subitem 3b? *

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

No important change was conducted after enrollment.

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].

subitem not at all important 1 2 3 4 5 essential

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Clear selection

Does your paper address subitem 3b-i?

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

No change related to intervention content was made.

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

Yes. "Eligible participants had to meet the following criteria: (1) at least 18 years old; (2) singleton pregnancy; (3) between 12 and 20 weeks of gestation (according to the clinical practices of obstetrics in China, most pregnant women start to receive regular check-ups at the hospital after establishing the Maternal & Children's Health Handbook in the community around the 12th gestational week); (4) at least a junior high school education; (5) planning to receive regular check-ups and deliver at the research hospitals; (6) a score of 8 or greater on the Insomnia Severity Index (ISI; corresponding to sub-threshold to clinical insomnia symptoms)....."

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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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

Does your paper address subitem 4a-i?

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

Yes. Eligible participants had to be "having a WeChat account and, after receiving an in-person demonstration or remote guidance via WeChat messages, self-reporting the ability to use the WeChat mini-program".

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
Clear selection						

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

Yes. "The baseline (T1) and follow-up assessments (including post-intervention (T2), two months after post-intervention (T3, the third trimester), and 42 days postpartum (T4)) were conducted through an online survey platform (wjx.cn)."

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.

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☒ ☐ ☐

[Clear selection](#)

Does your paper address subitem 4a-iii?

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

Yes, but the related information was mainly presented in the Multimedia appendix (the trial protocol). "Potentially eligible pregnant women (between 12 and 20 weeks of gestation) were informed about the research by a researcher (an experienced outpatient assistant). Women interested in participating were invited to add the WeChat account of the researcher, provide the online informed consent for the screening procedures, and then complete a short questionnaire (including general information, the ISI, and EPDS) to assess their eligibility to participate.

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

Yes. "This study was an evaluator-masked, two-parallel-armed RCT conducted in two tertiary hospitals in Shandong, China from October 2021 to July 2022 (follow-up was completed in February 2023)."

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.

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☐ ☐ ☒

Clear selection

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

Yes. "the outcome assessments during the study period were administered using self-assessed questionnaires....."; ".....were conducted through an online survey platform (wjx.cn)....."

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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

[Clear selection](#)**Does your paper address subitem 4b-ii?**

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

Your answer

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).

subitem not at all important 1 2 3 4 5 essential

☐ ☒ ☐ ☐ ☐

[Clear selection](#)**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

Your answer

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.

subitem not at all important 1 2 3 4 5 essential

☐ ☒ ☐ ☐ ☐

[Clear selection](#)

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

Your answer

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).

subitem not at all important 1 2 3 4 5 essential

☐ ☒ ☐ ☐ ☐

Clear selection

Does your paper address subitem 5-iii?

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

Your answer

5-iv) Quality assurance methods

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-iv?

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

Your answer

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

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

Your answer

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](https://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.

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 5-vi?

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

Your answer

5-vii) Access

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-vii? *

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

Yes. "Participants in the dMBI-PI intervention group could access six course modules via a WeChat mini program called "Mom Sleep Well" (screenshots of the mini program are shown in Figure 1). These modules would be unlocked successively after inputting the invitation code, and for each module, the thematic course would be unlocked first, followed by the six-day home practices in turn. When each module was unlocked, research staff sent course reminders to participants using standardized WeChat messages."

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 5-viii? *

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

Yes. "The six-week dMBI-PI was adapted from the MBT-I manual by Jason C. Ong [31] and the MBCT manual by John Teasdale, Mark Williams, and Zindel Segal [32]. An experienced professor with a doctoral degree in psychological medicine, led the adaptation of the treatment content tailored to pregnant women [33-35]. For example, in the thematic courses, examples were adapted to suit pregnant women's characteristics (e.g., when addressing negative thoughts related to insomnia, an example like "If I keep experiencing insomnia symptoms, it will affect my baby's development. If my baby isn't healthy, our family will be ruined..." was provided); in the mindfulness practices, we included guidance on mindfulness-awareness of fetal movements; in the sleep restriction, following prior studies on pregnant women [6], the recommended lowest time in bed was set at 5.5 hours, unlike the general population's 5-hour suggested by the internationally standardized treatment protocol [36]. The dMBI-PI contained 6 weekly course modules. Each course module consists of a video-based thematic course and six days of audio-based formal mindfulness practices; participants were also encouraged to adhere to informal mindfulness practices (e.g., mindful eating, walking or 3-minute breathing practices) and sleep-promoting behaviors daily (details are provided in Table 1). "

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 5-ix?

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

Yes. "The dMBI-PI contained 6 weekly course modules. Each course module consists of a video-based thematic course and six days of audio-based formal mindfulness practices; participants were also encouraged to adhere to informal mindfulness practices (e.g., mindful eating, walking or 3-minute breathing practices) and sleep-promoting behaviors daily (details are provided in Table 1)."

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 5-x?

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

Yes. "When each module was unlocked, research staff sent course reminders to participants using standardized WeChat messages."

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-xi? *

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

Yes. "When each module was unlocked, research staff sent course reminders to participants using standardized WeChat messages."

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 5-xii? *

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

Yes. "the intervention group (the 6-week dMBI-PI plus standardized care) or the control group (standardized care)". "The control group received standardized care (treatment as usual [TAU]) from obstetric staff, including regular telephone follow-ups, health education, pregnancy risk assessment and management, and nutrition and lifestyle guidance. "

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

Yes.

1) primary outcome

"Insomnia symptoms were assessed using the ISI from T1 to T4. In prior research [6, 8, 37], the ISI has been validated as a reliable measure for perinatal insomnia symptoms, and a cutoff score of 8 and 11 has been widely adopted to identify participants suffering from sub-threshold and clinical insomnia symptoms, respectively. Correspondingly, a total score of less than 8 has been commonly used as the criterion for remission from insomnia symptoms. In addition, based on the formula for calculating the reliable change (the standard error of the measurement (SEM) * 2.77, while SEM =), we substituted the ISI pretest standard deviation (SD) score and a test-retest reliability of 0.887 [38] into the formula, and finally, a reliable change criterion on the ISI of 2.52 points was calculated [39]. In this trial, the continuous score of ISI was treated as the primary outcome, while the insomnia remission rates and reliable change rates were treated as the secondary outcomes."

2) Secondary outcomes

"In addition to insomnia remission rates and reliable change rates, six continuous secondary outcome measures were chosen following the recommendations for a standard research assessment of insomnia [40]: the Consensus Sleep Diary-Core for subjective sleep patterns (including sleep onset latency (SOL, the time taken to fall asleep after going to bed), wake after sleep onset (WASO, the total time spent awake after initially falling asleep), total sleep time (TST), and sleep efficiency (SE, the percentage of time spent asleep relative to the time spent in bed), which were calculated by averaging data across one week; participants who wrote diaries for at least 3 days were eligible; longer SOL or WASO, shorter TST or lower SE were all indicators of poorer sleep) [41], the Pittsburgh Sleep Quality Index (PSQI) for sleep quality [42], the Flinders Fatigue Scale (FFS) for fatigue symptoms [43], the Epworth Sleepiness Scale (ESS) for daytime sleepiness [44], the Generalized Anxiety Disorder-7 (GAD-7) for anxiety symptoms [45] and the EPDS for depressive symptoms [46]. Higher scores on the PSQI, FFS, ESS, GAD-7, and EPDS indicate poorer sleep quality, more severe fatigue symptoms, daytime sleepiness, anxiety and depression symptoms, respectively. These measures have been widely used in perinatal women and demonstrated satisfactory psychometric properties in previous research [47-49]. With the exception of sleep diaries which were only used at T1 and T2, other measures were conducted from T1 to T4."

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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Your answer

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Yes. "Adherence was assessed by the completion of thematic courses/home practices recorded in the back-end management system of the WeChat mini program. Referring to previous research among perinatal women [31, 47], a module was defined as completed when participants completed the thematic course or at least 3 days of mindfulness practices, and participants completed at least half (3/6) of the modules were considered adherent. "

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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Your answer

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

No important change related trial outcomes was made in the trail.

7a) How sample size was determined

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

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

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

Yes. "According to the medium effect of digital MBIs on prenatal depression symptoms observed in our previous study [31] and a similar or larger effect on insomnia symptoms observed in a prior RCT with small sample size [55], 160 participants were calculated to detect a moderate between-group difference via a 2-sample t test of the mean change scores in ISI from baseline to post-intervention, based on a statistical power of 80%, a two-tailed 5% significance level, and a 20% attrition rate. Considering that the mixed-effects approach used for the analysis is more efficient than 2-sample t test, our actual statistical power was expected to be higher than 80%."

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

No interim analyses was made in this trail.

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

Yes. "The random number tables were generated and stored in numbered, sealed, and opaque envelopes by a researcher independent of the research team. When eligible participants completed baseline assessments and provided informed consent, the independent researcher opened the envelope and randomly assigned participants to the dMBI-PI intervention group or the control group using a 1:1 ratio."

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

This trial used a simple randomization approach. "When eligible participants completed baseline assessments and provided informed consent, the independent researcher opened the envelope and randomly assigned participants to the dMBI-PI intervention group or the control group using a 1:1 ratio."

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

Yes. "The random number tables were generated and stored in numbered, sealed, and opaque envelopes by a researcher independent of the research team. When eligible participants completed baseline assessments and provided informed consent, the independent researcher opened the envelope and randomly assigned participants to the dMBI-PI intervention group or the control group using a 1:1 ratio. "

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

Yes. "The random number tables were generated and stored in numbered, sealed, and opaque envelopes by a researcher independent of the research team. When eligible participants completed baseline assessments and provided informed consent, the independent researcher opened the envelope and randomly assigned participants to the dMBI-PI intervention group or the control group using a 1:1 ratio. "

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

[Clear selection](#)

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

Yes. "Because the control group did not receive the same digital intervention courses, it was difficult to keep the treatment implementers and participants blinded to treatment assignment. However, one of the advantages of digital interventions is that they provide a low-touch, structured format that supports the implementation of interventions with high fidelity, that is, ensuring the intervention content is delivered as intended or designed; meanwhile, the outcome assessments during the study period were administered using self-assessed questionnaires, and the assignment was concealed from the data collectors responsible for distributing the questionnaires, which may potentially alleviate the risk of contamination from non-blind treatment implementers."

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”.

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☒ ☐ ☐

Clear selection

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

Your answer

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

No, it is not applicable.

12a) Statistical methods used to compare groups for primary and secondary outcomes

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

Does your paper address CONSORT subitem 12a? *

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

Yes. "All analyses were performed using SPSS version 25.0 and R version 4.2.2. Following the intention-to-treat (ITT) principle, linear-mixed model analysis where we included group, time, and group-by-time interactions as the explanatory variables and random intercepts to account for the within-participant correlation of repeated responses, was conducted for ISI (primary outcome), a series of continuous secondary outcomes and hypothesized mediators separately. This method allowed us to included available data from pregnant women who missed the follow-up assessments at any time point, and the group-by-time interactions were used to measure the differences in within-participant outcome changes between the dMBI-PI intervention and control group [59]. Effect sizes (Cohen d) were calculated by dividing the between-group differences at post-intervention or follow-up by the pooled standard deviations (SD) of the continuous outcomes at baseline, with 0.2, 0.5, and 0.8 corresponding to small, moderate or large effect sizes, respectively [8]. For the secondary outcomes of remission and reliable change, logistic regression models (with dropouts defined as no remission and no reliable change, respectively) were fitted to assess whether the proportions of participants with remitted insomnia symptoms and achieving reliable change differed between two groups during follow-up. We corrected for the increased probability of type I error due to multiple testing of multiple secondary outcomes or hypothesized mediators using the Benjamini-Hochberg false discovery rate (FDR) correction. To assess the robustness of the results, sensitivity analyses using datasets after performing multiple imputation, using participants who completed all follow-up assessments (complete cases analysis) or who actually received the treatment (as-treated analysis) were conducted. Moreover, we examined whether there was a difference in the treatment effect (indicated by their remission status at follow-up or reliable change status from baseline to follow-up) for adherent vs non-adherent participants in the intervention group through 2 tests. More details are available in the Multimedia Appendix 2."

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential
Clear selection						

Does your paper address subitem 12a-i? *

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

Yes. "To assess the robustness of the results, sensitivity analyses using datasets after performing multiple imputation, using participants who completed all follow-up assessments (complete cases analysis) or who actually received the treatment (as-treated analysis) were conducted."

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

Yes. "To assess the robustness of the results, sensitivity analyses using datasets after performing multiple imputation, using participants who completed all follow-up assessments (complete cases analysis) or who actually received the treatment (as-treated analysis) were conducted. Moreover, we examined whether there was a difference in the treatment effect (indicated by their remission status at follow-up or reliable change status from baseline to follow-up) for adherent vs non-adherent participants in the intervention group through 2 tests. "

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

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

Your answer

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.

subitem not at all important 1 2 3 4 5 essential

☐ ☒ ☐ ☐ ☐

[Clear selection](#)**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

Yes. "All participants provided electronic informed consent."

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)

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☒ ☐ ☐

[Clear selection](#)

Does your paper address subitem X26-iii?

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

The related information was displayed in the trial protocol. "For pregnant women who were excluded due to suspected severe depressive symptoms or active suicidality, the researcher informed their obstetricians and provided referral recommendations and assistance. This study did not place any limits on access to non-study treatments (including the use of sleep medication or non-drug treatments). At study completion, on the premise that the intervention was effective, participants in the control group were also provided access to dMBI-PI courses."

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

Yes. "A total of 980 pregnant women joined the screening process, of which 160 eligible pregnant women with a mean (SD) age of 30.54 (3.86) years were included in this trial. Most participants were excluded due to failing to meet the insomnia criteria, with further details available in Figure 2. "

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

Yes. "As shown in Figure 2, from T2 to T4, there were 14 at T2 (3 participants missed the assessment and 11 dropped out of the study), 14 at T3 (dropped out of the study), and 28 at T4 (dropped out of the study) participants who did not respond to the assessments, respectively. "

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.

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☐ ☐ ☒

Clear selection

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

Yes. The related information was shown in a CONSORT flow diagram (Figure 2).

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

Yes. "This study was an evaluator-masked, two-parallel-armed RCT conducted in two tertiary hospitals in Shandong, China from October 2021 to July 2022 (follow-up was completed in February 2023). "

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"

subitem not at all important 1 2 3 4 5 essential

☒ ☐ ☐ ☐ ☐

Clear selection

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

Your answer

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

Does your paper address CONSORT subitem 14b? *

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

The trial did not stop halfway.

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

Yes. These information was shown in Table 2.

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

Clear selection

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

Yes. Most of demographics associated with digital divide issues (such as age, education, and social-economic status) were reported in Table 2.

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
Clear selection						

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

Yes. “Participants randomized to receiving dMBI-PI completed a mean (SD) of 2.66 (2.23) modules of six total modules, with 65 of 80 (81%) completing at least one module, 37 (46%) completing at least three modules (adherent participants), and 15 (19%) completing all modules.”

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
Clear selection						

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

Yes. "Following the intention-to-treat (ITT) principle, linear-mixed model analysis where we included group, time, and group-by-time interactions as the explanatory variables and random intercepts to account for the within-participant correlation of repeated responses, was conducted for ISI (primary outcome), a series of continuous secondary outcomes and hypothesized mediators separately. "

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

Yes, the results were shown in Table 3 and Table 4.

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

Clear selection

Does your paper address subitem 17a-i?

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

Your answer

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

Does your paper address CONSORT subitem 17b? *

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

Yes, the detailed information was provided in the Table 3.

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

Yes. "Similar results were obtained when we performed repeated analyses using imputed datasets (see Multimedia Appendix 6), complete cases analysis (see Multimedia Appendix 7) or as-treated analysis (see Multimedia Appendix 8). "

"Most of these results remained robust in the sensitive analysis (see Multimedia Appendix 11-13)."

"When we fitted mediation analyses using raw difference scores from T1 to T2, similar results were obtained except that the mediating effect of SRBQ was non-significant in the single mediation analyses (Multimedia Appendix 14). Meanwhile, when we considered the temporal associations between the hypothesized mediators and outcome variable, the results showed that the indirect pathways of the intervention assignment linked to insomnia symptoms at T3 through APSQ, PSAS, SAMI-B and SRBQ at T2 were statistically significant, although the intervention effect on insomnia symptoms at T3 was non-significant (Multimedia Appendix 15)."

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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

Clear selection

Does your paper address subitem 18-i?

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

Your answer

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

Yes. "One participant in the control group experienced adverse events (induced labor due to fetal heart development problems); this was irrelevant to study participation because it occurred during the first week of the intervention and the participant received routine care."

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].

subitem not at all important 1 2 3 4 5 essential

☐ ☒ ☐ ☐ ☐

[Clear selection](#)**Does your paper address subitem 19-i?**

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

Your answer

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

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

subitem not at all important 1 2 3 4 5 essential

☐ ☒ ☐ ☐ ☐

[Clear selection](#)

Does your paper address subitem 19-ii?

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

Your answer

DISCUSSION

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

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

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

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

Yes. "To our knowledge, this was the first published RCT with a relatively large sample size to examine the effectiveness of the dMBI-PI on reducing sub-threshold to clinical insomnia symptoms....."

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

Does your paper address subitem 22-ii?

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

"Future studies are warranted to validate our findings in pregnant women diagnosed with insomnia, using more frequent practice reminders or other adherence promotion measures....."

"To promote better adherence for socioeconomically disadvantaged individuals, further digital psychological interventions should be tailored to meet the needs of lower-educated vulnerable groups....."

"This may underscore the need for future research to tailor digital MBIs specifically for postpartum women by incorporating psychological education on postpartum feeding"

"Future studies are warranted to employ more complex designs with more intensive assessments of hypothesized mediators and outcomes to delineate the temporal relationships and mechanisms through which"

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

Does your paper address subitem 20-i? *

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

Yes. "Our study also had a few limitations to be noted. First, the participants were relatively homogeneous; most lived in cities, were employed and highly educated. Second, insomnia symptoms were measured"

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential

Clear selection

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

Yes. "First, the participants were relatively homogeneous; most lived in cities, were employed and highly educated. "

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.

subitem not at all important 1 2 3 4 5 essential

☐ ☐ ☒ ☐ ☐

Clear selection

Does your paper address subitem 21-ii?

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

Your answer

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

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

Yes. "The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2100052269)
.....

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

Yes. "The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2100052269) and the detailed trail protocol is available in the Multimedia Appendix 1. "

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

Does your paper address CONSORT subitem 25? *

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

"This study was funded by a grant from the National Natural Science Foundation of China (Grant Number: 32400913 and 32071084) and the Fundamental Research Funds for the Central Universities (grant number 2022JC016). The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data....."

X27) Conflicts of Interest (not a CONSORT item)**X27-i) State the relation of the study team towards the system being evaluated**

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

[Clear selection](#)**Does your paper address subitem X27-i?**

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

Your answer

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

☐ yes, major changes

☒ yes, minor changes

☐ no

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

Your answer

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

We spent on going through the checklist at least 8 hours.

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

☒ yes

☐ no

☐ Other:

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

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

☒ yes

☐ no

☐ Other:

Clear selection

Any other comments or questions on CONSORT EHEALTH

Your answer

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