

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

*必填

Your name *

First Last

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Title of your manuscript *

Provide the (draft) title of your manuscript.

Effectiveness of a smartphone-based mindfulness training on maternal perinatal depression: 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.

Spiritual Healing

Evaluated Version (if any)

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

您的回答

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.

您的回答

URL of an image/screenshot (optional)

您的回答

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
- 其他:

Primary Medical Indication/Disease/Condition *

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

Perinatal depression (pregnant women with pc

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Perinatal depression measured by Edinburgh F

Secondary/other outcomes

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

Anxiety, stress, positive affect, negative affect, sleep, fatigue, prospective memory, retrospective memory and fear of childbirth.

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"
- 其他:

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%

其他:

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
- 其他:

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
- 其他:

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
- 其他:

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

其他:

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

其他:

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

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

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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

清除所选内容

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, it's "a smartphone-based mindfulness training".

1a-ii) Non-web-based components or important co-interventions in title

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

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

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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, we provided only basic health consolation for participants in both intervention and control group, which are not an important component for this trail.

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

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

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

清除所选内容

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 is "maternal perinatal depression".

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

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

1b-i) Key features/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 essential

清除所选内容

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 is "fully automated 8-week smartphone-based mindfulness training during pregnancy", and the comparator is "attention-controlled group".

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

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

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subitem not at all important essential

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Does your paper address subitem 1b-ii?

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

Yes. The intervention is "fully automated".

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

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

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subitem not at all important essential

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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. Participant were recruited offline. "Pregnant adult women with potential risk of perinatal depression were recruited from obstetrics clinics." This was a purely web-based trial and only usergroups that were recruited were accessible to the application. Baseline data were collected in person while follow-up data were self-assessed through questionnaires. "Maternal mental health indicators were measured over four time points through postpartum by online self-assessed surveys." Through the procedure, only "the assessor who collected the follow-up data was blind to the assignment."

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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subitem not at all important essential

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Does your paper address subitem 1b-iv?

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

Yes. "A total of 168 pregnant women were randomly allocated to MTPG (n = 84) or ACG (n = 84). Overall dropout rate of this study is 34.5%, and completion rate of MTP is 52.4%."

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

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

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Does your paper address subitem 1b-v?

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

Yes. "Parity did not show significantly moderating effect on intervention effect. But for nulliparous women, participants who received MTP showed significantly improved depression symptoms than those who received ACG (Group × Time effect: $2 = 18.114$, $p = 0.001$)."

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

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Does your paper address subitem 2a-i? *

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

Yes.

The main problems in this area are:

1) "Low-and middle-income countries (LAMICS) had a higher prevalence of prenatal depression than that in high-income countries (19-25% vs. 7-15%) [4]. However, the prevention and treatment of perinatal depression in LAMICS remains under-recognized, in part, due to limited resources to mental health services, greater priority to prevent obstetric complications and fetal anomaly [6] and fear of stigmatization [7]. Against this context, to provide accessible, low-cost and effective mental health services in LAMICS is a basic but significant way to improve perinatal depression."

2) Long distance is a major reason of refusal in previous intervention studies [8, 9]. Smartphone, nowadays, providing a right platform to solve this problem and disseminate accessible mental health services [10]. Smartphone applications were reported helpful for treating depression [11]."

3) "In the past three years, MBIs through internet or mobile devices were introduced into perinatal care. But for now, these studies either were in protocol and preliminary stage [22-25], or aimed at postpartum period only [26], or treated mindfulness as one component of integrated interventions [27], or used only pre-post-test design [28]. Well-design smartphone-based RCT using large sample size and long-term follow-ups and aiming at improving perinatal depression was barely conducted yet."

The target population of this study is pregnant women with potential risk of perinatal depression.

Goal of the intervention is "to provide accessible, low-cost and effective mental health services in LAMICS."

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

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

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

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Does your paper address subitem 2a-ii? *

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

Yes.

What we have know about mindfulness intervention in perinatal care: "For pregnant women, prenatal mindfulness-based trainings (MBIs), such as Mindfulness-Based Childbirth and Parenting [17] and MindBabyBody [18] programs, were utilized to reduce maternal depression, anxiety and negative affect [19], enhance maternal nurturing behaviors, and improve childhood outcomes [20]. However, there is insufficient evidence in this emerging area because majority used small sample size and non-randomized design [19, 21] and few studies conducted in LAMICS was reported while mostly were conducted in high-income countries [21]. In the past three years, MBIs through internet or mobile devices were introduced into perinatal care. But for now, these studies either were in protocol and preliminary stage [22-25], or aimed at postpartum period only [26], or treated mindfulness as one component of integrated interventions [27], or used only pre-post-test design [28]. Well-design smartphone-based RCT using large sample size and long-term follow-ups and aiming at improving perinatal depression was barely conducted yet."

Motivation for the study:

1)"Low-and middle-income countries (LAMICS) had a higher prevalence of prenatal depression than that in high-income countries (19-25% vs. 7-15%) [4]. However, the prevention and treatment of perinatal depression in LAMICS remains under-recognized, in part, due to limited resources to mental health services, greater priority to prevent obstetric complications and fetal anomaly [6] and fear of stigmatization [7]. Against this context, to provide accessible, low-cost and effective mental health services in LAMICS is a basic but significant way to improve perinatal depression."

2)"Long distance is a major reason of refusal in previous intervention studies [8, 9]. Smartphone, nowadays, providing a right platform to solve this problem and disseminate accessible mental health services [10]. Smartphone applications were reported helpful for treating depression [11]." "Even more encouraging, smartphone-based interventions may be particularly adapted by pregnant women because recent studies found that majority expectant mother searched pregnancy-related information through internet and performed high appreciations [13, 14]."

The comparator in the current study is attention-controlled group, which can partly eliminated the social component bias and provided solid findings.

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 aim of the current study is to evaluate the effectiveness of mindfulness on depression remission at post-intervention in pregnancy women with potential high risk of perinatal depression compared to ACG. The second aim is to evaluate the longer-term difference on perinatal depression, and secondary outcomes (anxiety, perceived stress, positive and negative emotions, fatigue, sleep, memory and fear of childbirth) between mindfulness training in pregnancy group (MTPG) and ACG. And the third aim is to test whether the intervention effect will differ in nulliparous and multiparous women."

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 a single-center, two-parallel-armed, assessor-blinded, 1:1 allocated, randomized controlled study with 32-week follow up. Pregnant women who scored at or above the threshold for positive depressive symptoms were randomly assigned to intervention group (receiving 8-week smartphone-based MTP) or control group (receiving 8-week regular WeChat health consultation)."

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

Yes. "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].

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Does your paper address subitem 3b-i?

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

Yes. "The Spiritual Healing was debugging-fixed for three times due to the adaptation of phone systems during this trial, but 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.

"Inclusion criteria for women to participate in the study: 1) aged 18 years and over; 2) in the 12th to 20th week of gestation; 3) singleton pregnancy; 4) no plan to terminate pregnancy; 5) receiving antenatal care and planning to deliver in the study hospital; 6) completion of junior high school education or above; 7) positive depressive symptoms screen with Edinburgh Postnatal Depression Scale (EPDS) > 10 or Patient Health Questionnaire-9 (PHQ-9) > 5; 8) able to use application on smartphone for the study; 9) able to understand the questionnaire.

Exclusion criteria were: 1) at risk of suicide or self-harm; 2) currently receiving psychiatric treatment or use psychiatric medications; 3) history of substance abuse or addiction in the past 6 months; 4) prior experience with mindfulness meditation; 5) decline to participant."

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit “de facto” eligibility criterion - this should be explicitly clarified.

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Does your paper address subitem 4a-i?

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

Yes. Participants need to be "able to use application on smartphone for the study."

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

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

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Does your paper address subitem 4a-ii? *

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

Yes.

"According to the national policy requirements of the National Health Commission of China, all pregnant women are recorded as pregnant in the 12 gestational week and then should start prenatal visits regularly. Pregnant women were recruited from the pool of women recorded as pregnant, all of whom were required to report pregnancy-related information and to receive depression screening and baseline evaluation (T1) at their first regular visit in the obstetric clinic where the study was based. Informed consent for psychological assessment was firstly obtained and then printed questionnaires including socio demographics, pregnancy-related characteristics and mental health indicators were distributed, and participants were required to complete and return them. All pregnant women were screened according to the inclusion and exclusion criteria, and eligible participants were then contacted by WeChat (a popular instant social networking software) or by phone within two weeks. Research assistants introduced them to the procedure and objectives of the trial, and obtained online informed consent if they agreed to participant this trial. Recruited participants were randomly assigned to intervention group (MTPG) or control group (ACG), where MTPG received 8-week MTP and ACG to received 8-week regular WeChat health consultations as attention control. Data collection and assessment of intervention effect took place over four time points in the follow-up period. T2 assessment took place at 4 weeks after allocation (intermediate period of intervention), T3 at 8 weeks after allocation (endpoint of intervention), T4 at 18 weeks after allocation (before childbirth), and T5 at 6 weeks after delivery. Follow-up assessments were collected by computer/smartphone assisted self-administered surveys. All participants were awarded 2 yuan when completing an assessment."

The use of instant communication software, WeChat, made it impossible to hide behind anonymity for the participants.

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

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subitem not at all important essential

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Does your paper address subitem 4a-iii?

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

您的回答

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 conducted between March 2018 to January 2020 and participants were recruited in the obstetric clinic of a tertiary hospital in Jinan, Shandong, a city located in east of China. The hospital provides perinatal services for around 5,000 pregnant women each year."

4b-i) Report if outcomes were (self-)assessed through online questionnaires

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

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

清除所选内容

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. "Depression screening and baseline evaluation (T1) was conducted through printed questionnaire in the obstetric clinic where the study was based." "Follow-up assessments were collected by computer/smartphone assisted self-administered surveys."

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention.(Not a required item – describe only if this may bias results)

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

清除所选内容

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

您的回答

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

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

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

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subitem not at all important essential

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Does your paper address subitem 5-i?

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

No. The intervention content used in the current study was developed by our team and a technology company was hired to transfer the content into application.

5-ii) Describe the history/development process

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

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subitem not at all important essential

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Does your paper address subitem 5-ii?

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

您的回答

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

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subitem not at all important essential

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Does your paper address subitem 5-iii?

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

您的回答

5-iv) Quality assurance methods

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

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

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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

您的回答

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

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

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Does your paper address subitem 5-v?

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

We only provide the screenshots of our application, but we do not keep the source code because that's a technical problem.

5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

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subitem not at all important essential

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Does your paper address subitem 5-vi?

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

The URL of the application is expired now.

5-vii) Access

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

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subitem not at all important essential

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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 who were allocated to MTPG received the URL of the application through WeChat. They can use the application as long as they sign up. An assistant will assist with registering and activating the intervention." The application is free and they do not need to be a member of specific group because the URL of the application is not open. Logs of practice on formal mindfulness training were recorded in the backstage.

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

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

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

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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.

"Pregnant women who agreed to participate in the trial were randomly allocated to intervention group or control group. We provided basic perinatal health consultations in the entire perinatal period by WeChat app for all participants allocated. Additionally, participants in the intervention group received 8-week smartphone-based MTP (described below as mindfulness training during pregnancy group or MTPG), and those allocated to control group received 8-week regular WeChat health consultations (described below as attention-controlled group or ACG).

Mindfulness training during pregnancy group (MTPG)

MTP was delivered through a custom-built mobile application named Spiritual Healing that was available in both Android and iOS version in China mainland. The Spiritual Healing app provided reading, audio and video content, and recording or journal functions. MTP was developed based on Mindfulness Behavioral Cognitive Therapy (MBCT), consisting of formal training and informal training, with eight

sessions including: To know mindfulness, Focus on the moment, Coping with negative emotions mindfully, Learn to accept difficulty, Thoughts are thoughts, Feel happiness, Mindful childbirth and Continuous mindful practice. In each session, the general scope of the subject was introduced through text, audio and visual materials. Then formal mindfulness training techniques were introduced, and users were invited to practice following the audios and record their feelings within the app. Formal mindfulness training contained mindfulness breathing, body scan, mindfulness stretching, mindfulness meditation, and lasted 15-25 minutes per day. Informal training, such as exercises for mindful eating, mindful walking, routine awareness and 3-minute breathing practices, were recommended every day. MTP lasted 8 weeks, with content provided 6 days per week. An essay related to mindfulness was pushed to participants in the last day per week. The training in MTP updated automatically every day and participants practiced according to their own schedules. A message to remind participants to follow the MTP was sent every week by WeChat. Participants were awarded 2 yuan for completion of each one-week of training. The APP were debugging-fixed for three times due to the adaptation of phone systems during this trial, but no change related to intervention content was made. For safety and de-stigmatization, participants were reminded that this APP is not equivalent psychotherapy and professional supports need to be reached when necessary.

Attention-controlled group (ACG)

Pregnant women allocated to ACG received 8-week regular WeChat health consultation as attention control. Health consultations were provided by a professional nursing assistant with experience in prenatal care using the WeChat app. The schedule of routine prenatal care was sent to participants at the time they were assigned. The assistant contacted participants in the ACG every week to ask about recent health status using a sentence "Hello, Ms. X. How are you feeling this week?", for eight weeks. Their consultations were mainly relevant to medical examination, outpatient appointments, and arrangement of inpatient care."

5-ix) Describe use parameters

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

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subitem not at all important essential

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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. "MTP lasted 8 weeks, with content provided 6 days per week and 15-25 minutes per day. A message to remind participants to follow the MTP was sent every week." "The training in MTP updated automatically every day and participants practiced according to their own schedules. A message to remind participants to follow the MTP was sent every week by WeChat."

5-x) Clarify the level of human involvement

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

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subitem not at all important essential

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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. The 8-week mindfulness training used in the current study is fully automated.

5-xi) Report any prompts/reminders used

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

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

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Does your paper address subitem 5-xi? *

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

Yes. "A message to remind participants to follow the MTP was sent every week by WeChat."

5-xii) Describe any co-interventions (incl. training/support)

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

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

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Does your paper address subitem 5-xii? *

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

Yes. "We provided basic perinatal health consultations in the entire perinatal period by WeChat app for all participants allocated."

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. "Depression assessed by the EPDS was the primary outcome in this study. EPDS is a self-report scale which assesses depressive symptoms experienced within the last week during both pre- and postnatal periods [29]. It contains 10 items with response to 4-point Likert-scales ranging from 0 to 3, where higher scores represent greater intensity of depressive symptom. EPDS was recommended as a valid depression screening tool across different cultures and different trimesters in a validation study review [30] and the cut-off score of 9/10 was used to identify positive depressive symptoms for screening purposes in the present study. Additionally, another commonly used depression screening tools, the PHQ-9, developed on the basis of DSM-IV criteria, was also used in the screening period with a cut-off of 4/5 indicative of minor depression criteria [31]. Secondary outcomes were multidimensional health issues in perinatal women, including anxiety, stress, positive affect (PA), negative affect (NA), sleep, fatigue, prospective memory (PM), retrospective memory (RM) and fear of childbirth (shown in Multimedia Appendix 3). Socio-demographics, such as age, gestational days, BMI, education level, work status, marriage and family economic level, and pregnancy-related characteristics were self-reported by participants at baseline. Study researchers were allowed to collect additional clinical data on participants from medical records following birth.

Depression screening and baseline evaluation (T1) was conducted through printed questionnaire in the obstetric clinic where the study was based. Data collection and assessment of intervention effect took place over four time points in the follow-up period. T2 assessment took place at 4 weeks after allocation (intermediate period of intervention), T3 at 8 weeks after allocation (endpoint of intervention), T4 at 18 weeks after allocation (late pregnancy, before childbirth), and T5 at 6 weeks after delivery. Follow-up assessments were collected by computer/smartphone assisted self-administered surveys."

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].

subitem not at all important 1 2 3 4 5 essential

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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

您的回答

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.

subitem not at all important 1 2 3 4 5 essential

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Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Yes. "Logs of practice on formal mindfulness training were recorded and used to evaluate the fidelity of mindfulness training. At least 3 days of practice per week in this study was considered a completed training week. And at least 4 completed training weeks were considered as completing the MTP. Completion rate in this study is the percentage of participants who completed the MTP divided by participants who received intervention."

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

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

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subitem not at all important essential

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Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

您的回答

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

Yes. No important change related trail outcomes was made in the trail. However, 14 participants in MTPG and 11 participants in ACG lost to follow up at T2 due to researcher's omission, which was marked in flow chart.

7a) How sample size was determined

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

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

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

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subitem not at all important essential

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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. "In the above meta-analysis of self-help mindfulness [33], on average 27% of participants were lost to follow up in the post-intervention assessment. Considering a 30% attrition in the follow-up, a final sample size should reach 168 with 84 individuals in each group."

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. We have conducted a pilot study. Then no interim analyses was made in the formal 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."This trial used a simple randomization approach. The random number sequence was generated by a researcher who didn't participate this study using Random Number Generators function in SPSS 23.0. Random number sequence was kept in sealed, opaque, numbered envelopes. When each participant was enrolled, a research assistant opened the envelop in sequence and assigned the participant. Participants received allocation according to the order of enrollment."

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

Yes. "This trial used a simple randomization approach."

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 sequence was generated by a researcher who didn't participate this study using Random Number Generators function in SPSS 23.0. Random number sequence was kept in sealed, opaque, numbered envelopes. When each participant was enrolled, a research assistant opened the envelop in sequence and assigned the participant."

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 sequence was generated by a researcher who didn't participate this study." The person who enrolls participants and assigns participants is the same person. "When each participant was enrolled, a research assistant opened the envelop in sequence and assigned the participant. Participants received allocation according to the order of enrollment."

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

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

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

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

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

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Does your paper address subitem 11a-i? *

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

Yes. "Throughout the RCT procedure, the assessor who collected the follow-up data did not know the assignment. Considering the use of smartphone application, the participants were able to infer the assignment."

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

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

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subitem not at all important essential

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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

Yes. The participants were informed that this trial contained two groups: application group and WeChat group. The WeChat is a popular instant communicating software in China, which is not special for the participants. Then, the participants might be able to infer the intervention of interest.

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. Because the two interventions are different in this study.

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

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

Does your paper address CONSORT subitem 12a? *

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

Yes. "Statistical analyses were performed with SPSS 23.0. The primary analysis used intention-to-treat (ITT) approach. Normality of outcomes at baseline were visually examined, and NA, sleep and PM were transformed by log due to non-normal data distribution. No more than five individuals for each measure at T1 had single entry missing, which were considered as missing at random and were imputed with median of item. Independent sample t test and chi-square test were used to compare the baseline characteristics between MTPG and ACG. In order to assess the intervention effect on depression remission at post-intervention (T3), positive depressive symptoms at T3 and EPDS reductions from T1 to T3 were compared between intervention and control groups using logistic regression models, adjusting EPDS score at baseline and between-group imbalanced factor (intended pregnancy) after randomization. To assess MTPG vs ACG intervention effect on longer-term outcomes, multilevel linear models within Generalized Estimating Equations (GEE) were performed. In GEE, the participants and assessment timepoints were designated as subject variables and within-subject variable, respectively, with exchangeable working correlation matrix and full maximum likelihood estimation applied. The continuous outcome variables in five timepoints were the dependent variable. Main effects of group, time, and Group × Time interaction effect were examined."

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

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

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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

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Does your paper address subitem 12a-i? *

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

Yes.

For the single entry missing: "no more than five individuals for each measure at T1 had single entry missing, which were considered as missing at random and were imputed with median of item." "For T2 and above, the web-based survey included rules that eliminated missing items on questionnaires. So, no item missed at follow-up due to the requirement of web-based survey."

For lost-to follow-up data: "To address our second aim on MTPG vs ACG intervention effect on longer-term outcomes, multilevel linear models within Generalized Estimating Equations (GEE) were performed. This approach has been recommended because it is able to handle missing data appropriately and can keep stable in different correlation matrix."

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. "As [35] suggested, several sensitivity analyses were conducted. Firstly, the longer-term between-group differences were analyzed in ITT group, per-protocol (PP) group and as-treated (AT) group (referred as the PP-IC group in the current study; IC: "intervention completed"). Secondly, adjusted GEE models with baseline imbalanced factor (intended pregnancy) were also performed. Thirdly, longer-term intervention effect based on GEE were also conducted in participants who completed different times of follow-up. In addition, subgroup analysis by parity (primipara/multipara) were also conducted. In the subgroup analysis, p value of less than 0.025 was considered statistically significant after Bonferroni multiple-corrected."

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

X26-i) Comment on ethics committee approval

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subitem not at all important essential

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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

您的回答

x26-ii) Outline informed consent procedures

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

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

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Does your paper address subitem X26-ii?

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

您的回答

X26-iii) Safety and security procedures

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

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

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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

Yes. "For safety and de-stigmatization, participants were reminded that this APP is not equivalent psychotherapy and professional supports need to be reached when necessary."

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 1140 pregnant women were reached and a final sample of 168 was allocated." "Of the 84 participants allocated to MTPG, 10 of them did not activate the Spirit Healing, which was considered refusing the allocation." Details are shown in flow chart.

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. This is shown in flow chart.

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.

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subitem not at all important essential

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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. "Of the 84 participants allocated to MTPG, 10 of them did not activate the Spirit Healing, which was considered refusing the allocation. All the remaining participants received MTP. On the basis of ITT sample, the mean number of completed training weeks was 3 weeks (SD: 2.701). As a whole, 44/84 participants completed at least 4 weeks training and the total completion rate was 52.4%. In all, 7/84 (8.3%) participants completed the whole 8-week training."

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. "Recruitment begun in March 2018 and ended in June 2019, and follow-up assessments ended in January 2020."

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

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

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

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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

您的回答

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

No. The trial did not stop halfway. It ended as long as the sample size reached 168.

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 1.

15-i) Report demographics associated with digital divide issues

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

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subitem not at all important essential

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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. Age, education, gender and social-economic status were reported in Table 1.

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

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

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

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subitem not at all important essential

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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. "During the whole follow-up period for the 168 participants, 24/84 (28.6%) participants dropped out in MTPG and 34/84 (40.5%) dropped out in ACG with the overall dropout rate reached 34.5%. More than half of the participants completed at least 3 follow-up (55.9%) and 72/168 (42.9%) of participants completed all follow-up."

"Of the 84 participants allocated to MTPG, 10 of them did not activate the Spirit Healing, which was considered refusing the allocation. All the remaining participants received MTP. On the basis of ITT sample, the mean number of completed training weeks was 3 weeks (SD: 2.701). As a whole, 44/84 participants completed at least 4 weeks training and the total completion rate was 52.4%. In all, 7/84 (8.3%) participants completed the whole 8-week training."

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).

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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

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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. ITT group, per-protocol (PP) group and as-treated (AT) group (referred as the PP-IC group in the current study; IC: "intervention completed") were all used to analyze in the current study.

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. Estimated effect size and its precision were reported in appendix.

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

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Does your paper address subitem 17a-i?

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

您的回答

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. "For binary EPDS at T3, fewer participants reported positive depressive symptom (EPDS ≥ 10) in MTPG than in ACG [15/63 (23.8%) vs. 24/54 (44.4%), $\chi^2 = 5.571$, $p = 0.018$]. Logistic regression model resulted that MTPG had a 0.609 times reduction (OR: 0.391, 95%CI: 0.164~0.930) on risk of positive antenatal depressive symptom than ACG (shown in Table 2)."

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. Results related to subgroup analysis (parity) and three kinds of sensitivity analyst were conducted.

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).

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

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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

您的回答

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. Only one pregnant woman in MTPG reported psychological burden caused by mindfulness training after 2 days practice, and discontinued the training. No other adverse event was reported associating with MTP directly.

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].

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subitem not at all important essential

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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

Yes. Of all the MTPG participants, two did not complete the training due to APP bug, and one discontinued the training due to the phone being damaged, and one uninstalled the APP due to insufficient phone storage.

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.

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subitem not at all important essential

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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

您的回答

DISCUSSION

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

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

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

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

1 2 3 4 5

subitem not at all important essential

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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. "Responding to the need of depression remission for pregnant women with potential risk of perinatal depression, smartphone-based mindfulness training led to lower rate of positive depression at post-intervention and greater decline in depression symptoms from baseline to post-intervention relative to attention control group. Results also support the longer-term effects of smartphone-based mindfulness training for the reduction of prenatal depression and anxiety and enhancement of positive affect. However, parity is only suggested as a potential moderator due to its deficient statistical significance. The results of this study firstly provided robust evidence on the effect of self-help smartphone-based mindfulness training on perinatal depression using RCT design, relatively large sample size and 32-week follow-up through postpartum."

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

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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

Yes. "In the current study, we tried to distil the moderating effect of parity. However, the non-significance of the three-way interaction test suggests that parity is only a potential factor to affect intervention effect. Mindfulness interventions were previously reported less accessible and easily dropped-out for women who already had children [19]. Often lacking of time and existing family commitments are important reasons for women fail to persist with longitudinal research [45]. This context is supportive for the ineffectiveness of mindfulness training in parous women, which also suggests that parity is a promising factor in terms of the significant improvement on mental health for pregnant women who received MTP in nulliparous participants. Reduction of depression for primipara who received MTP was found only at post-intervention, pointing out a future direction of the moderating effect at short-term effect but not longer-term effect. Further studies are still in need for vulnerable populations of receiving mental health service."

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.

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subitem not at all important essential

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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. "Second, we have to notice that 10 of 84 participants in intervention group did not activate mindfulness training even after they have signed the informed consent and agreed to participate this program. The high proportion of inactive participants in intervention group weakens the strength of RCT design. Third, participants in this study are able to infer their allocation and are unblinded. And the multiple assessment of outcomes increases risk for a Type I error."

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

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subitem not at all important essential

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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. This intervention is good to generalize outside of a RCT setting. "This study expands on the findings of mindfulness training in pregnancy in several key areas. First, it shows that the prenatal mindfulness training can be extended through smartphone-based delivery, which is able to lead reductions in both demand on therapists and service costs [46]. It is especially a preferable choice for LAMICS." However, on the other hand, the intervention content in the current study contains some professional knowledge related to pregnancy and perinatal care, which are not applicable to general internet population.

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

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

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subitem not at all important essential

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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

您的回答

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. "This trial is retrospectively registered in Chinese Clinical Trial Registry (Registration number: ChiCTR1900028521) due to unawareness of requirements for trial registration before enrollment." We had obtained the ethical approval before the first enrollment but they did not address the registration before enrollment. We were confused that to register at any time was acceptable. So we did not register prospectively but did it before analyzing the data.

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

No. The protocol of this study was not published. This is the first study that introduce this trail in English. We have described the trail as specific as possible in the current study.

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

Yes. "This study was funded by the Chinese National Funding of Social Sciences (Grant Number: 17BSH054). The funders had no role in study design, data collection and analysis, decision to publish or preparation of the manuscript. We also thank the China Scholarship Council for the support in one of our authors' (Yaoyao Sun) studying aboard."

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

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

1 2 3 4 5

subitem not at all important essential

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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

您的回答

About the CONSORT EHEALTH checklist

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

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

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

To add more details related to the application and the implementation process.

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

Six hours.

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

- yes
- no
- 其他:

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

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

yes

no

其他:

清除所选内容

Any other comments or questions on CONSORT EHEALTH

您的回答

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