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 e-health 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
Liangkun Ma

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
Peking Union Medical College Hospital, Beijing

Your e-mail address *
abc@gmail.com
MaLiangKun@pumch.cn

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

Comparing the blood glucose control efficacy of telemedicine with that of standard prenatal care in women with gestational diabetes mellitus: a randomized controlled trial

Name of your App/Software/Intervention *
If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

WeChat
## Evaluated Version (if any)

E.g. “V1”, “Release 2017-03-01”, “Version 2.0.27913”

## Language(s) *

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

Chinese

## URL of your Intervention Website or App

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

### Your Answer

## URL of an image/screenshot (optional)

### Your Answer

## Accessibility *

Can an enduser access the intervention presently?

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

- [ ] Other: Our intervention was conducted through group chat, not a specific web
| 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)" |

Gestational diabetes mellitus

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

Glycemic qualification rate (The glycemic qual

| Secondary/other outcomes |
|--------------------------|
| Are there any other outcomes the intervention is expected to affect? |

"Delivery mode, premature rupture of the membranes, preterm birth, birthweight, and postpartum hemorrhage"

| 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%

Other: Our health management project conducted during third trimester, last

Overall, was the app/intervention effective? *

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

Other:
Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

- not submitted yet - in early draft status
- not submitted yet - in late draft status, just before submission
- submitted to a journal but not reviewed yet
- submitted to a journal and after receiving initial reviewer comments
- submitted to a journal and accepted, but not published yet
- published
- 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: JMU ms#22881

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.

1 2 3 4 5

subitem not at all important    ○ ○ ○ ○ ○ essential

Does your paper address subitem 1a-i? *

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

"telemedicine". WeChat is a kind of instant messaging platform in China. Not all country use this platform for messaging, but the protocol for management can be transplant, so we use a broader term "telemedicine".

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

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

1 2 3 4 5

subitem not at all important    ○ ○ ○ ○ ○ essential

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

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

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ◯ | ◯ | ◯ | ◯ | ◯ | essential |

subitem not at all important

Does your paper address subitem 1a-iii? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"in women with gestational diabetes mellitus"

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 |
|---|---|---|---|---|
| ◯ | ◯ | ◯ | ◯ | ◯ | essential |

subitem not at all important
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

We conducted disease management through WeChat group chat, that is, we performed group chat based on a protocol described in main text. This part was a too much words to write in abstract.

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT
Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5

subitem not at all important  ○  ○  ○  ○  ○  essential

Does your paper address subitem 1b-ii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Disease management through WeChat group chat were conducted by doctors and health managers based on a protocol described in main text. This part was a too much words to write in abstract.
1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

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

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

Does your paper address subitem 1b-iii?

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

Open, combined offline prenatal care and online management.

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)

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

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

"A total of 309 women with GDM participated in the trial, with 162 women randomized to the control group and 147 to the intervention group. No significant differences in baseline characteristics were found between the control and intervention groups."
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 ◯ ◯ ◯ ◯ ◯ essential

Does your paper address subitem 2a-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Women with GDM who are on insulin therapy receive more attention from doctors and researchers, and women with GDM with mild dysglycemia who control their condition with diet alone receive much less attention, although this group may account for the majority of GDM patients." "Given the limited intervention time window, the importance of continuous patient education and self-management supervision during the periods between antenatal care visits should be strongly emphasized." "A large-sample randomized controlled study is needed to further explore the application value of mobile medicine regarding BG control, health management and clinical outcomes."

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

1  2  3  4  5

subitem not at all important ◯ ◯ ◯ ◯ ◯ essential
"For GDM women, online management can potentially improve the likelihood of following medical advice and keep GDM patients alert to the harm of poor BG control, further achieving continuous disease management. Research has demonstrated the acceptability and feasibility of mobile medical management of GDM women through social software platforms, instant messaging applications, web pages and regular e-mail alerts or telephone visits. Some of the related studies did show a slight correlation between mhealth applications and BG levels, as well as greater demand and better self-efficacy of patients. However, so far, telemedicine approaches have failed to show significant advantages over standard prenatal care, especially in terms of clinical outcomes, when used for GDM. Possibly due to the limited sample size and immature intervention paths, it is difficult to identify whether a relationship between technology use and clinical outcomes exists [15-23]." 

"This randomized control trial was conducted to verify this hypothesis by comparing the BG control efficacy of health education and lifestyle management conducted through the WeChat group chat with standard clinical prenatal care in women with GDM."
3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Eligibility criteria was decided before recruitment and did not change during the process.

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other “unexpected events” that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].
4a) Eligibility criteria for participants

"The inclusion criteria were as follows: 1) Aged between 18 and 45 years; 2) Singleton pregnancies of less than 31 gestational weeks; 3) GDM diagnosis according to the 75 g oral glucose tolerance test (OGTT) [24] and no requirement of insulin treatment according to multidisciplinary consultation; 4) Ability to use a smartphone for chatting, reading and writing basic Chinese; and 5) Voluntary participation in research. Pregnant women with a diagnosed chronic disease and other pregnancy complications except GDM as well as those who had recent trauma or treatment with glucocorticoids were excluded."

4a-i) Computer / Internet literacy

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

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential
Does your paper address subitem 4a-i?

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

您的回答

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.

subitem not at all important  ○ ○ ○ ○ ○ essential

Does your paper address subitem 4a-ii? *

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

"Patients in the intervention group received WeChat group management in addition to maternity schools and standard clinic prenatal care. In the WeChat group chat, participants received management on a weekly basis. "

4a-iii) Information giving during recruitment

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

subitem not at all important  ○ ○ ○ ○ ○ essential
Does your paper address subitem 4a-iii?

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

"Eligible patients according to assessment by clinic doctors based on the above mentioned criteria received detailed information about the project from the research team. Those interested completed questionnaires after signed informed consent and were randomized to a group. During the study, all subjects could withdraw at any time without providing any reason. All participants would receive postpartum counseling clinic for free as program reward."

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

"Participants were randomly allocated to two groups: intervention (WeChat group management) or control (standard clinical prenatal care). A random number table was used to generate the grouping envelope. Participants were grouped according to the information in the grouping envelope, ensuring randomized allocation. After the results of the grouping were announced, the subjects were not allowed to switch groups."

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

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

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important |  |  |  |  |
| essential |  |  |  |  |  |
Outcomes were not (self-)assessed through online questionnaires.

4b-ii) Report how institutional affiliations are displayed
Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item – describe only if this may bias results)

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

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

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

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

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

"In the WeChat group chat, participants received management on a weekly basis. In particular, researchers would issue a briefing to encourage patients to take an active part in their GDM control and a task card to pinpoint the basic requirements, including diet advice, demonstration of meals from other group members, exercise rules, etc., on Monday. Patients conducted self-management according to the basic criteria provided according their actual situation and shared photos of their meals and additional meals, daily exercise, and experience regarding BG control. Researchers would give individualized guidance for self-management or use a group member’s situation as an example for others. In this way, participants could learn not only from their personalized guidance but also from the situation of the other group members. On weekends, we prepared lessons and articles for group members to learn about pregnancy and GDM in several respects, including rudimentary knowledge, disease management, psychology and past cases. We encouraged the sharing of learning experiences and notes in the form of peer interactions and support groups. If there were any questions regarding the project, pregnancy or GDM, they could seek answers from the group chat. This weekly management would persist until delivery."

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.

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).

```
| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | essential |
```

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

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.

```
| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | essential |
```

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

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.

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

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

您的回答

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.

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

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

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

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

WeChat is open and free to cell phones.

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework
Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1], “whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback” [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].
Does your paper address subitem 5-viii? *

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

No application.

5-ix) Describe use parameters

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

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

Does your paper address subitem 5-ix?

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

您的回答

5-x) Clarify the level of human involvement

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

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

Does your paper address subitem 5-xi? *

"Participants visited the obstetrical clinic for prenatal care and follow-up every two weeks beginning at the time of enrollment, and this period of two weeks is referred to as a T. We asked the participants in both groups to record their fasting, post-breakfast, post-lunch, post-dinner and pre-sleep BG values for 6 days in one T. In other words, within a T, we obtained 30 monitored values. For example, if someone enrolled at 24 gestational weeks and delivered at 40 gestational weeks, she would provide eight follow-up records; 24 gestational weeks would be recorded as T0, and the follow-up records would be recorded from T1 to T8. Then, if a participant enrolled at 30 gestational weeks and delivered at 38 gestational weeks, she would have only four follow-up T periods, namely, T0 would be the enrollment visit, and T1 to T4 would be the follow-up period."
5-xii) Describe any co-interventions (incl. training/support)

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

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 5-xii? *

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

"All women diagnosed with GDM were asked to attend GDM management lesson for one time in maternity schools organized by prenatal care institutions, which were established standardly according to Beijing Municipal Health Commission. Participants were taught the basic knowledge about GDM and how to do self-management including how to conduct BG monitoring, what the BG values were supposed to be, the form of lifestyle diaries and so on. The routine prenatal care appointment during pregnancy was changed to once every two weeks when GDM was diagnosed. Doctors generally asked GDM women to record 5 BG values, fasting and before-sleep BG, and two-hour postprandial BG (post-breakfast, post-lunch, post-dinner BG) a day and at least 3 days between two visits. When patients came to visit, doctors checked the details of their records including daily diet, exercise, weight, BG, and blood pressure, and lifestyle guidance was provided according to their records. The guidance involved simple principles of lifestyle intervention like increasing food diversity, recommending coarse cereals, avoiding eating outside, take more exercises for weight control, etc. If they failed to present their diaries, the doctors asked them to return with the records on the following week. If the BG could not be controlled after general lifestyle guidance, medicine-based intervention was considered after multidisciplinary consultation."

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
"The primary outcome is the glycemic qualification rate. The glycemic qualification rate was calculated as the number of BG levels within the control range/30*100%. The BG control ranges were fasting BG (fasting and before-sleep BG) <95 mg/dL (5.3 mmol/L) and two-hour postprandial BG (post-breakfast, post-lunch, post-dinner BG) <120 mg/dL (6.7 mmol/L). Secondary outcomes, including delivery mode, premature rupture of the membranes, preterm birth, birthweight, and postpartum hemorrhage, were compared."

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].

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.

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

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

您的回答

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

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

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

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


7a) How sample size was determined
NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

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

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

Does your paper address subitem 7a-i?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"This was a superiority trial and the sample size was calculated as \( N = (Z_\alpha + Z_\beta)^2 \left[ PC(1-PC)+PT(1-PT)\right] / \left[ (PT-PC)^2 \right]. \) \( PC \) and \( PT \) were the blood glucose control rates in the control group and the expected blood glucose control rates in the test group (referring to clinical data). As there are no published estimates of glycaemic control rates, which makes sample size calculations more challenging. Therefore, we decided to assume that the control rate in the control group was about 75% according to our clinical experience, and the experimental group was expected to be 15% higher than the control group, and the sample size was calculated to be 104 cases in each group at the significance level of 0.05 (bilateral) and 80% assurance. Considering the dropout rate of up to 20%, the final sample size was determined to be 125 people 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

Not applicable.

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

"A random number table was used to generate the grouping envelope."

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

"Participants were randomly allocated to two groups: intervention (WeChat group management) or control (standard clinical prenatal care). A random number table was used to generate the grouping envelope. Participants were grouped according to the information in the grouping envelope, ensuring randomized allocation. After the results of the grouping were announced, the subjects were not allowed to switch groups."
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

We assigned the participants at the time they signed informed consent.

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

Statistician generated the random allocation sequence. Doctors enrolled participants. Research assistant assigned participants to interventions by envelope.

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
NPT: Whether or not administering co-interventions were blinded to group assignment
11a-i) Specify who was blinded, and who wasn’t

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

| 1 | 2 | 3 | 4 | 5 | essential |
|---|---|---|---|---|-----------|
| O | O | O | O | O |          |

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

Open label.

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

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

| 1 | 2 | 3 | 4 | 5 | essential |
|---|---|---|---|---|-----------|
| O | O | O | O | O |          |

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

您 的 回 答

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)
Does your paper address CONSORT subitem 11b? *

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

Not applicable.

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

"Data analysis was carried out by SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). The descriptive statistics of continuous data are expressed as the mean ± standard deviation (SD). For comparisons between two groups, if each group fulfilled the criteria of the test of normality and homogeneity of variance, the t-test was used for comparison. Otherwise, the non-parameter Wilcoxon rank sum test was used. N (%) was used for descriptive statistics, and differences in categorical variables were assessed by the chi-square test. Boxplots were used to indicate changes in blood sugar during pregnancy. The differences in outcomes between the two groups were compared using chi-square analysis. P<0.05 was considered statistically significant."

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

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

1 2 3 4 5

subitem not at all important 0 0 0 0 0 essential
Does your paper address subitem 12a–i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We didn't address the attrition / missing values.

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

Not applicable.

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

X26-i) Comment on ethics committee approval

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

Does your paper address subitem X26-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The trial received ethical approval from the Peking Union Medical College Hospital Medical Ethics Review Committee (ID: JS-1012). "

x26-ii) Outline informed consent procedures
Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

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

Does your paper address subitem X26-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Written informed consent was obtained from each participant. All researchers involved had been trained uniformly before the trial started, and all centers received site instruction when they enrolled the first several participants."

X26-iii) Safety and security procedures
Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

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

Does your paper address subitem X26-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

您的回答

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

"Of 309 GDM women who met the recruitment criteria and signed informed consent, 162 were randomized to the control group, and 147 were randomized to the intervention group."

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

"As shown in Figure 1, 365 women were screened when they came to prenatal clinic to check OGTT results; 56 of them were excluded because they did not meet inclusion criteria (n=22) or declined to participate (n=34). Of 309 GDM women who met the recruitment criteria and signed informed consent, 162 were randomized to the control group, and 147 were randomized to the intervention group. Eleven women in the control group and 6 in the intervention group did not record any BG values. Fifteen women in the control group and 8 in the intervention group changed their delivery hospital; thus, delivery records were not available. None of our participants switched to insulin therapy during the program because of persistently severe glucose abnormality or disappoint maternal-infant progressing during pregnancy. Data from 136 women in the control group and 133 in the intervention group were included in the analysis."
13b-i) Attrition diagram

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

Does your paper address subitem 13b-i?

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

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

Does your paper address CONSORT subitem 14a? *

"Participants visited the obstetrical clinic for prenatal care and follow-up every two weeks beginning at the time of enrollment, and this period of two weeks is referred to as a T. We asked the participants in both groups to record their fasting, post-breakfast, post-lunch, post-dinner and pre-sleep BG values for 6 days in one T. In other words, within a T, we obtained 30 monitored values. For example, if someone enrolled at 24 gestational weeks and delivered at 40 gestational weeks, she would provide eight follow-up records; 24 gestational weeks would be recorded as T0, and the follow-up records would be recorded from T1 to T8. Then, if a participant enrolled at 30 gestational weeks and delivered at 38 gestational weeks, she would have only four follow-up T periods, namely, T0 would be the enrollment visit, and T1 to T4 would be the follow-up period."
14a-i) Indicate if critical “secular events” fell into the study period
Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"

subitem not at all important  ○  ○  ○  ○  ○  essential

Does your paper address subitem 14a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

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

Not applicable.

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

"No significant differences were found between the control and intervention groups at baseline (Table 1, Appendix Table 1-4). Of all participants, 56 (20.8%) women were over 35 years old, 71 (26.4%) were overweight, 37 (13.8%) were obese. The OGTT results at enrollment were as follows: OGTT-fasting BG 4.98 (±0.78) mmol/L, OGTT-1 hour 10.20 (±1.84) mmol/L, and OGTT-2 hour 8.90 (±1.69) mmol/L. Participants could be further divided into four stages according to gestational weeks at enrollment: 66 women in Group I (enrolled between 23-24+6 gestational weeks), 113 women in Group II (enrolled between 25-26+6 gestational weeks), 66 women in Group III (enrolled between 27-28+6 gestational weeks), and 24 women in Group IV (enrolled between 29-30+6 gestational weeks)."

15-i) Report demographics associated with digital divide issues

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

1 2 3 4 5
subitem not at all important essential

Does your paper address subitem 15-i? *

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

Not applicable.

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
16-i) Report multiple “denominators” and provide definitions

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 16-i? *

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

"Of 309 GDM women who met the recruitment criteria and signed informed consent, 162 were randomized to the control group, and 147 were randomized to the intervention group."

16-ii) Primary analysis should be intent-to-treat

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

1 2 3 4 5

subitem not at all important essential

Does your paper address subitem 16-ii?

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

您 的 回 答
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.

"The glycemnic qualification rate of the intervention group was higher than that of the control group at nearly all time points in Group I - Group III, among which 3 time points reached statistical significant. That is, Group I at T3 (54.8% vs. 83.3%) and Group II at T3 (62.5% vs. 80.0%) and T7 (75.0% vs. 100%) (Table 2). In respect with intervention period, at T1, when participants began to receive health management, the BG qualification rate of the control group and the intervention group were similar. At T2, the BG qualification rate in the control group and the intervention group both began to rise, which were (53.3% vs 75.0%) and (62.5% vs. 70.0%) in group 1 and group 2, respectively. At T3, when management was conducted about a month, the BG control rate were (54.5% vs. 83.3%), (62.5% vs. 80.0%) and (80.0% vs 62.5%) in group 1-3, respectively.

With regards to gestational week of enrollment, the intervention started earlier, the BG controlled better. That is, in Group I (enrolled between 23 and 24+6 gestational weeks), the control rate was not different between the two group at T1. But once the intervention started, the BG control rate of intervention group became much higher than that of control group (75.0% vs 53.3%) at T2. The difference existed until T5, and decreased lower than 10% after that. In Group II (enrolled between 25 and 26+6 gestational weeks), the trend was between T2-T4. However, in Group IV, a difference between the two groups was not observed.

Furthermore, the glycemnic qualification rate gradually increased as gestational weeks progressed in both groups, regardless of the intervention method (Table 2, Figure 2-5).

Secondary outcomes were not significantly different between the control and intervention groups, including delivery mode, premature rupture of the membranes, preterm birth, birthweight, and postpartum hemorrhage (Appendix Table 5)."
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).

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

Not applicable.

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

Does your paper address CONSORT subitem 17b? *

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

Not applicable.

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

Same as main results.

18-i) Subgroup analysis of comparing only users
A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

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

Does your paper address subitem 18-i? 
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

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

Not applicable.
19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical “harm” to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects” also includes unintended positive effects [2].

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

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

您的回答

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

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

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

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

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

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

"This randomized control trial indicated that the use of instant messaging platforms such as WeChat in China for health education and lifestyle intervention in women with GDM, during the whole GDM management period, were associated with a higher rate of BG falling within the optimal range than standard clinical prenatal care, although these results were not statistically significant. Clinical pregnancy outcomes were not significantly different between the two groups. Additionally, the increasing trend in the qualified BG rate was seemingly more stable in the WeChat management group than in the control group, which supports the nonnegligible role of continuous management. Additionally, regardless of when patients enrolled in the study, GDM management was beneficial for improving the BG qualification rate in both groups, which means that when the intervention starts earlier, optimal BG is maintained longer and maternal benefits are more extensive. This highlights the importance of starting health management when GDM is diagnosed. "

https://docs.google.com/forms/d/e/1FAIpQLSIZBSUp1bwOc_OimqcS64RdlAFvmrTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dG
### 22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

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

essential
"Telemedicine, concentrating on the intervals between obstetric clinic visits, makes GDM management more comprehensive and complete in the limited time window. This can make pregnant women who are unconcerned or overwhelmed by guilt and anxiety feel more confident to manage the disease. WeChat group chat provides a platform for effective education to ensure clear understanding of medical principles and to provide active pregnancy consultations instead of women having to wait for clinic visits every few weeks. This continuous BG and lifestyle management provides more individualized and adequate practical support than doctors’ recommendations and medical guidelines and makes doctors’ orders more feasible in practice, which results in better adherence [15, 26]. In other words, greater self-efficacy results in better patient management. In addition, among all kinds of patient education and lifestyle interventions, diet change is the most difficult recommendation to follow [14]. Factors that impede the implementation of medical recommendations include social activities such as eating out, cultural factors such as the consumption of specific kinds of food, family impacts such as the rejection of the concept of an individual serving size, obsolescent views on pregnancy, women's family-centered value and role commitment [27, 28]. The WeChat group brings together a group of people with specific but similar needs and provides moral support, opportunities for peer communication and family education, making it easier to follow patient management principles. Furthermore, telemedicine has the potential to save time and costs by reducing the number of hospital appointments for women with GDM and increase clinical pressure for doctors. This concept is underexplored.

Many studies have explored the effect of online health education and lifestyle management methods on women with GDM. This article is, to our knowledge, the first to interpret BG data from this perspective. Prior studies have indicated that online education and management can help improve BG control [20, 29-31]. Our findings confirmed this, although the result of this trial was not statistically significant. The rate of glycemic qualification rates remained higher at nearly all time points regardless of the gestational weeks when participants started being managed. This trend became less obvious and stable as the enrollment time drew closer to delivery, which was observed especially in Group IV and can be attributed to the decreased sample size of participants who had delivered in this group. Some of the previous studies showed no improvement in BG control but only better patient satisfaction [15]. Regardless of the management methods, BG control improved during the entire period of pregnancy, as shown in our results and previous research [15]. However, a more detailed glycemic qualification rate revealed that trends did not always improve. We observed that the glycemic
qualification rate in the control group did not always increase as that in the intervention group did in Groups I-IV. As studies have reported the harm of BG variability for both mothers and infants [32], this discovery emphasizes that continuous management may help decrease BG variability and result in better outcomes. Regarding pregnancy outcomes, a few studies showed relationships between telemedicine interventions and longer gestational periods and fewer preterm births [15], reduced odds of cesarean section and pregnancy-induced hypertension [33], higher Apgar scores and reduced neonatal hospitalization [29]. We failed to investigate these relationships. A common result was that it was difficult to demonstrate differences between groups in pregnancy outcomes [21, 23, 31]. The same is true for systematic reviews and meta-analyses [34, 35]. Compared with previous work, we added an analysis on intervention duration. The glycemic qualification rate increased gradually after GDM management was initiated in both the intervention and control groups regardless of the enrollment time, although the rate in the WeChat group was always higher than that in the control group. It might be interpreted that the earlier that education and lifestyle interventions start, the less time the pregnant woman and fetus are exposed to hyperglycemia and the greater the likelihood of better outcomes."

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.

|   |   |   |   |   | essential |
|---|---|---|---|---|-----------|
| 1 |   |   |   |   | subitem not at all important |
"General management of women with noninsulin-dependent GDM requires lifestyle intervention to realize glycemic control and weight gain management. If we are to implement a more convenient intervention method, comprehensive assessment needs to be done, for example, by assessing its effects on weight change, BG control, sleep quality and psychological status. Assessment of indicators of adherence is required to confirm the management effect. A larger sample size may help investigate the impact of telemedicine use on the pregnancy outcomes of GDM women. This investigation is indispensable, as the aim of GDM management is to reduce negative outcomes of the pregnant woman and fetus through BG and weight control. Therefore, the lack of statistically significant results should be further explored in a larger population. A continuous management system for women with GDM to be implemented between prenatal clinics, allowing professional education to be more accessible, is considered to have the potential to reduce clinic visits and improve medical service quality. In the long run, this management method can be extended to GDM prevention at the beginning of pregnancy and GDM follow-up postpartum, emphasizing the continuity of a healthy lifestyle education and intervention [37, 38]."
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.

您的回答

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

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

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

Does your paper address subitem 21-ii?

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

您的回答

OTHER INFORMATION

23) Registration number and name of trial registry
**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

Not applicable.

**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

"The study was supported by Beijing Municipal Science and Technology Commission (grant reference Z161100000516117)."

**X27) Conflicts of Interest (not a CONSORT item)**
X27-i) State the relation of the study team towards the system being evaluated
In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

1 2 3 4 5
subitem not at all important          essential

Does your paper address subitem X27-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

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?

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

3 hours.

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

- yes
- no
- other: As the article has been reviewed and not allow too much change, we

Would you like to become involved in the CONSORT EHEALTH group?
This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- yes
- no
- other:

Any other comments or questions on CONSORT EHEALTH

您的回答

STOP - Save this form as PDF before you click submit
To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select "print" and then select "print as PDF") before you submit it.

When you submit your (revised) paper to JMIR, please upload the PDF as supplementary file.

Don't worry if some text in the textboxes is cut off, as we still have the complete information in our database. Thank you!
Final step: Click submit!
Click submit so we have your answers in our database!

提交

切勿通过 Google 表单提交密码。

此内容不是由 Google 所创建，Google 不对其作任何担保。 举报滥用行为 - 服务条款 - 隐私权政策

Google 表单