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 (nonpharmacologic 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):

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

doi: 10.2196/jmir.1923 PMID: 22209829



liduanbin123@gmail.com (not shared) Switch account



Resubmit to save

* Required

Your name *

First Last

DuanBin Li

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

Sir Run Run Shaw Hospital, Zhejiang University

Your e-mail address *

abc@gmail.com

22018293@zju.edu.cn

Title of your manuscript *

Provide the (draft) title of your manuscript.

Effect of mobile-based cognitive behavior therapy on lowering low-density lipoprotein cholesterol level in atherosclerotic cardiovascular disease patients: a multicenter, prospective, randomized controlled trial

You're editing your response. Sharing this URL allows others to also edit your response.

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.

CBT ASCVD

Evaluated Version (if any)

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

Your answer

Language(s) *

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

Chinese

URL of your Intervention Website or App

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

Your answer

URL of an image/screenshot (optional)

Your answer

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Accessibility * Can an enduser access the intervention presently?
access is free and open
access only for special usergroups, not open
access is open to everyone, but requires payment/subscription/in-app purchases
app/intervention no longer accessible
Other:
Primary Medical Indication/Disease/Condition * e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)" atherosclerotic cardiovascular disease
Primary Outcomes measured in trial * comma-separated list of primary outcomes reported in the trial
low-density lipoprotein-cholesterol level
Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?
Triglyceride, C-reactive protein, the score of General Self-Efficacy Scale, and the Quality of life index

Recommended "Dose" *
What do the instructions for users say on how often the app should be used?
Approximately Daily
Approximately Weekly
Approximately Monthly
Approximately Yearly
as needed"
Other:
Approx. Percentage of Users (starters) still using the app as recommended after * 3 months
unknown / not evaluated
0-10%
O 11-20%
O 21-30%
31-40%
O 41-50%
51-60%
61-70%
71%-80%
81-90%
91-100%
Other: Not applicable

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
on statistically significant difference between control and intervention
outcomes potentially harmful: control was significantly better than intervention in one or more
inconclusive: more research is needed
Other:
Article Preparation Status/Stage *
Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form)
At which stage in your article preparation are you currently (at the time you fill in this form)
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
At which stage in your article preparation are you currently (at the time you fill in this form) Onot submitted yet - in early draft status not submitted yet - in late draft status, just before submission
At which stage in your article preparation are you currently (at the time you fill in this form) one of submitted yet - in early draft status not submitted yet - in late draft status, just before submission submitted to a journal but not reviewed yet
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

Journal *
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")
not submitted yet / unclear where I will submit this
Journal of Medical Internet Research (JMIR)
JMIR mHealth and UHealth
JMIR Serious Games
JMIR Mental Health
JMIR Public Health
JMIR Formative Research
Other JMIR sister journal
Other:
Is this a full powered effectiveness trial or a pilot/feasibility trial? *
Is this a full powered effectiveness trial or a pilot/feasibility trial? * Pilot/feasibility
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 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
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)

TITLE AND ABSTRACT
1a) TITLE: Identification as a randomized trial in the title
1a) Does your paper address CONSORT item 1a? *
I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")
yes
Other:

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

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

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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

"Effect of mobile-based cognitive behavior therapy on lowering low-density lipoprotein cholesterol level in atherosclerotic cardiovascular disease patients: a multicenter, prospective, randomized controlled trial"

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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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

"cognitive behavior therapy"

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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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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

"atherosclerotic cardiovascular disease patients"

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

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

You're editing your response. Sharing this URL allows others to also edit your response.

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

oformation is missing from the main body of text, consider adding it)	
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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

"This multicenter, prospective, randomized controlled trial (RCT) enrolled 300 ASCVD patients, randomly assigned to a mobile-based CBT intervention group and control group in a ratio of 1:1. "

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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)	d
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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

"The intervention group received CBT for ASCVD lifestyle interventions delivered by WeChat MiniApp: "CBT ASCVD". The control group received patient education delivered with oral communications given by healthcare providers only during each follow-up."

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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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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

This was a prospective, multicenter, two-arm (allocation ratio was 1:1) trial. It was a nonblinded, randomized controlled trial.

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

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

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Does your paper address subitem 1b-iv?

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

"Finally, 296 participants completed the up-to-6-month follow-up (148 in the CBT group and control group, respectively), and the baseline means LDL-C levels was 2.48±0.90 mmol/L, 21.3% up-to-standard rates for LDL-C. Linear regression analysis demonstrated that mobilebased CBT intervention significantly reduced the LDL-C level in ASCVD patients at the 6th month follow-up (β =-10.026, 95%CI: -18.111 to -1.940, P < .001). Even if the baseline LDL-C <1.8 mmol/L, CBT intervention remained favorable (β =-24.103, 95%Cl: -43.110 to -5.095, P = .002). Logistic regression analysis showed that CBT intervention also moderately increased the up-to-standard rates of LDL-C in the 6th month (OR=1.579, 95%CI: 0.994 to 2.508, P = .005). Linear regression analysis also demonstrated that CBT significantly improved the score of GSEs and QL-index during the whole follow-up (P value for all<0.05)."

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1b-v`) CONCLUSIONS/DISCUSSION in abst	tract for negative trials
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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,

iscuss 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 nissing from the main body of text, consider adding it)	
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opy and paste relevant sections from the manuscript abstract (include quotes in uotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on his item by providing additional information not in the ms, or briefly explain why the item is ot applicable/relevant for your study	
Mobile-based CBT was an effective method for long-term LDL-C level management and ould immediately and effectively improve the self-efficacy and quality of life of ASCVD atients."	
NTRODUCTION	
a) In INTRODUCTION: Scientific background and explanation of rationale	

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

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

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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

"Atherosclerotic cardiovascular disease (ASCVD) remains a leading global cause of morbidity and mortality[1, 2]. The fact that elevated levels of low-density lipoproteincholesterol (LDL-C) were established risk factors for ASCVD is well accepted, given the results of numerous epidemiological and genetic studies, as well as randomized controlled clinical trials (RCTs)[3-5]. Each 1.0 mmol/L absolute reduction in LDL-C is associated with a 20% reduction in the risk of cardiovascular events and a 12% reduction in the risk of vascular disease death. The greater the absolute reductions of LDL-C, the more significant the proportion of risk reduction[6]. However, even with the emerging development of various lipid-lowering therapy, the attainment rate of LDL-C remains suboptimal. Among people with established ASCVD and high risk of ASCVD, only 26.6% and 42.9%, respectively, achieved LDL-C control targets in a large national cross-sectional study in China[7].

Poor pharmacotherapies and non-pharmacotherapies adherence might be a major concern for the efficacy of current treatments[8, 9]. Improving the population's awareness of the disease is an integral part of a comprehensive approach to ASCVD management. Despite

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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 appropiate), 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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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

"Cognitive behavioral therapy (CBT) is one psychological treatment method that emphasizes improving self-efficacy based on a combination of cognitive and behavioral approaches, which will benefit the patients in clinical outcomes[10]. CBT is mainly used to treat anxiety, depression, and mental diseases[11] and can significantly improve mental and psychological symptoms such as anxiety, depression, and hopelessness[12-14]. CBT programs are now gradually being promoted and used to encourage proactive selfmanagement of various chronic health conditions[15-17]. It has been proved that CBT can help patients manage blood glucose levels and body weight[18, 19]. With the growing proliferation of smartphones, mobile-based CBT emerged. Not restricted by any specific person and venue, mobile-based CBT might be a potential solution to impact a large population at a relatively low cost."

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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

"This RCT aimed to evaluate the effectiveness of mobile-based CBT interventions in improving LDL-C levels among patients with ASCVD."

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

"This was a prospective, multicenter, two-arm (allocation ratio was 1:1) trial. It was a nonblinded, randomized controlled trial registered at the Chinese Clinical Trial Registry with the study number ChiCTR2100046775. Participants were recruited from Sir Run Run Shaw Hospital, Ninbo Hospital of Zhejiang University, Ninbo ninth hospital, Hangzhou Medical College Affiliated Lin An people hospital, Yuhang Integrative medicine hospital, and Zhejiang Greentown cardiovascular hospital in China from June 2021 until December 2022."

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

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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

"The subjects were randomly assigned to the intervention group, and the control group in a ratio of 1:1 through the establishment of EDC Trial Data clinical trials centralized randomization system.

The intervention group received CBT for ASCVD lifestyle interventions delivered by WeChat MiniApp: "CBT ASCVD" (developed by Hangzhou Kang Ming Health Consulting CO., LTD), including three sections, further divided into six sessions. The contents were designed and reviewed by cardiologists and psychiatrists from Sir Run Run Shaw Hospital, Zhejiang University, Hangzhou, Zhejiang, China (See Appendix 1 for details). The design of this content is intended to improve the cognition/behavior of patients on blood lipid management through CBT and improve the self-management level (self-efficacy). Long-term accumulation will help to change the outcome of blood lipid management so that the blood lipid level of patients can not only meet the treatment goal but also be stable for a long time. The "CBT ASCVD" can systematically interfere with patients' cognition, emotion and behavior through mobile terminals. It is easy to understand and operate so that patients can complete the work with the help of non-psychological professionals or under self-guidance. Participants in the intervention group have been told how to access the program after registration and will use it during the study. Subjects were studied according to a learning schedule divided into an intense intervention period (1-2 months) and a regular intervention period (3-6 months).

The control group received patient education delivered with oral communications given by healthcare providers only during each follow-up. Patient education was delivered to the control group, including disease-related knowledge, lifestyle guidance, complication prevention, rational drug use, and other contents.

Besides, all participants received standard pharmacological treatments."

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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

Not applicable. No relevant events occurred during the test.

4a) Eligibility criteria for participants

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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

"The participants were recruited from among consecutive patients diagnosed with ASCVD. Inclusion criteria were: (1) age from 18 to 80 years old; (2) Meet ASCVD diagnostic criteria, including a history of acute coronary syndrome (ACS), myocardial infarction (MI), stable or unstable angina, transient ischemic attack, surgical history of coronary or peripheral vascular reconstructions, etc; (3) currently taking statins by prescription; (4) no difficulty in using smartphones, essential Chinese reading and writing skills, basic calculation skills; and (5) Acceptance of the terms and conditions of the study and signature of the informed consent form. Exclusion criteria: (1) meet super high-risk ASCVD diagnostic criteria (diagnostic criteria is determined according to 2020 Chinese expert consensus on lipid management of very high-risk atherosclerotic cardiovascular disease patients. According to diagnostic criteria, the diagnosed ASCVD patients with one of the following conditions can be diagnosed as super high-risk ASCVD: 1) ASCVD event recurrence; 2) Multi vessel disease of coronary artery; 3) Recent acute coronary syndromes (ACS); 4) Atherosclerotic vascular disease of heart, brain or peripheral multi vascular bed; 5) LDL-C≥4.9 mmol/L (190 mg/dl); 6) Diabetes.); (2) one or more of the following complications: heart failure, ventricular tachycardia, second to third-degree atrioventricular block, uncontrolled atrial tachycardia (including atrial flutter, atrial fibrillation, etc.), mural thrombus, cardiac aneurysm, dysfunction or rupture of papillary muscle, severe sinus bradycardia (heart rate < 50 beats/minute), sinus arrest, etc.; (3) history of cardiac arrest; (4) acute non-cardiogenic complications: such as infections, kidney failure, hyperthyroidism, etc.; (5) severe cardiovascular conditions: moderate to severe valvular stenosis, hypertrophic cardiomyopathy, other forms of ventricular outflow tract stenosis, acute myocarditis, pericarditis, active endocarditis, suspected or known aneurysm rupture, acute pulmonary embolism, or pulmonary infarction; and (6) vulnerable populations, including patients with mental disorders, critical illness, age < 18 years old, pregnancy, students or subordinate of principal investigators, employees of the research institute, etc. "

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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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Clear selection

Does your paper address subitem 4a-i?

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

"The intervention group received CBT for ASCVD lifestyle interventions delivered by WeChat MiniApp: "CBT ASCVD" (developed by Hangzhou Kang Ming Health Consulting CO., LTD), including three sections, further divided into six sessions. "

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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

"Participants were recruited from Sir Run Run Shaw Hospital, Ninbo Hospital of Zhejiang University, Ninbo ninth hospital, Hangzhou Medical College Affiliated Lin An people hospital, Yuhang Integrative medicine hospital, and Zhejiang Greentown cardiovascular hospital in China through doctors' face to face assessments from June 2021 until December 2022."

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4a-III) Information	ı giving	auring	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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Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study			

"Before conducting the study, written informed consent was obtained from all participants included in the study. The study was carried out according to the Declaration of Helsinki and was approved by the Ethics Committee of Sir Run Run Shaw Hospital (NO.20210508-30)."

4b) Settings and locations where the data were collected

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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

"EDC system was used for data collection and management. Data collection occurred at four points: baseline, follow-up 1st, 3rd, and 6th month. Baseline data were collected when patients were enrolled, including disease history, vital signs, laboratory result, electrocardiogram, medications, General Self-Efficacy Scale (GSEs), and Quality of life index (QL-index). Follow-up data were collected at the follow-up 1st, 3rd, and 6th month, including height, weight, vital signs, laboratory results, electrocardiogram, medications, GSEs, and QLindex. Finally, in the whole follow-up process, four patients were lost because they could not be contacted and were not followed up.

All laboratory test samples were obtained after an overnight fast. Triglyceride (TG) level was measured by standard enzymatic method. The Friedewald formula calculated the LDL-C level. The definition of variability is as follows: 1) standard deviation (SD) Method: Standard deviation is used to describe the variability of the univariate during the follow-up period; 2) coefficient of variation (CV) method: CV=(SD/mean)×100(%)[22]. LDL-C standard was defined as LDL-C below 1.8mmol/L[23].

The GSEs is a psychometric scale that assesses self-efficacy[24]. It consists of 10 items representing attitudes towards obstacles rated on a scale from 0 (not optimal) to 4 (very optimal). The QL-index is a tool to evaluate the quality of life[25], consisting of activities of daily living, principal activities, health, outlook, and support.

4b-i) Report if outcomes were (self-)assessed through online questionnaires Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

subitem not at all important

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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

Not applicable. The report results were mainly evaluated by laboratory inspection indicators.

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)

subitem not at all important

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Does your paper address subitem 4b-ii?

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

Your answer

You're editing your response. Sharing this URL allows others to also edit your response.

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).
subitem not at all important
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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
Your answer

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

Your answer

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5-iii) Revisions and updating

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

the intervention (for unexpected events see item 3b).
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Does your paper address subitem 5-iii?

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

Your answer

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	e information on quality assurance methods to ensure accuracy and quality of ation provided [1], if applicable.
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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/screencapture 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

Your answer

You're editing your response. Sharing this URL allows others to also edit your response.

5-vi)	Digital	preservation
J 11	Diultai	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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Does your paper address subitem 5-vi?

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

Your answer

You're editing your response. Sharing this URL allows others to also edit your response.

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).

subitem not at all important

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Clear selection

Does your paper address subitem 5-vii? *

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

"The intervention group accessed the WeChat applet by scanning the specified QR code and bound it to WeChat. The background of the applet will review this information to ensure that the patient is a participant in the study. After the audit is passed, the patient will have access to the relevant information in the applet (clock in, video, image, text, etc.). "

You're editing your response. Sharing this URL allows others to also edit your response.

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].

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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

"The intervention group received CBT for ASCVD lifestyle interventions delivered by WeChat MiniApp: "CBT ASCVD" (developed by Hangzhou Kang Ming Health Consulting CO., LTD), including three sections, further divided into six sessions. The contents were designed and reviewed by cardiologists and psychiatrists from Sir Run Run Shaw Hospital, Zhejiang University, Hangzhou, Zhejiang, China (See Appendix 1 for details). The design of this content is intended to improve the cognition/behavior of patients on blood lipid management through CBT and improve the self-management level (self-efficacy). Long-term accumulation will help to change the outcome of blood lipid management so that the blood lipid level of patients can not only meet the treatment goal but also be stable for a long time. The "CBT ASCVD" can systematically interfere with patients' cognition, emotion and behavior through mobile terminals. It is easy to understand and operate so that patients can complete the work with the help of non-psychological professionals or under self-guidance. Participants in the intervention group have been told how to access the program after registration and will use it during the study. Subjects were studied according to a learning schedule divided into an intense intervention period (1-2 months) and a regular intervention period (3-6 months)."

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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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

Your answer

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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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

Your answer

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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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Clear selection

Does your paper address subitem 5-xi? *

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

"This WeChat MiniApp does not limit the number of login times of patients in the intervention group, but patients need to complete the corresponding courses every week according to the learning plan, otherwise they will receive SMS reminders."

You're editing your response. Sharing this URL allows others to also edit your response.

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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Clear selection

Does your paper address subitem 5-xii? *

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

"The intervention group received CBT for ASCVD lifestyle interventions delivered by WeChat MiniApp: "CBT ASCVD" (developed by Hangzhou Kang Ming Health Consulting CO., LTD), including three sections, further divided into six sessions. The contents were designed and reviewed by cardiologists and psychiatrists from Sir Run Run Shaw Hospital, Zhejiang University, Hangzhou, Zhejiang, China (See Appendix 1 for details). The design of this content is intended to improve the cognition/behavior of patients on blood lipid management through CBT and improve the self-management level (self-efficacy). "

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

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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

"EDC system was used for data collection and management. Data collection occurred at four points: baseline, follow-up 1st, 3rd, and 6th month. Baseline data were collected when patients were enrolled, including disease history, vital signs, laboratory result, electrocardiogram, medications, General Self-Efficacy Scale (GSEs), and Quality of life index (QL-index). Follow-up data were collected at the follow-up 1st, 3rd, and 6th month, including height, weight, vital signs, laboratory results, electrocardiogram, medications, GSEs, and QLindex. Finally, in the whole follow-up process, four patients were lost because they could not be contacted and were not followed up.

All laboratory test samples were obtained after an overnight fast. Triglyceride (TG) level was measured by standard enzymatic method. The Friedewald formula calculated the LDL-C level. The definition of variability is as follows: 1) standard deviation (SD) Method: Standard deviation is used to describe the variability of the univariate during the follow-up period; 2) coefficient of variation (CV) method: CV=(SD/mean)×100(%)[22]. LDL-C standard was defined as LDL-C below 1.8mmol/L[23].

The GSEs is a psychometric scale that assesses self-efficacy[24]. It consists of 10 items representing attitudes towards obstacles rated on a scale from 0 (not optimal) to 4 (very optimal). The QL-index is a tool to evaluate the quality of life[25], consisting of activities of daily living, principal activities, health, outlook, and support.

You're editing your response. Sharing this URL allows others to also edit your response.

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

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.
subitem not at all important
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Does your paper address subitem 6a-ii? Copy and paste relevant sections from manuscript text Your answer

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).
subitem not at all important
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Does your paper address subitem 6a-iii? Copy and paste relevant sections from manuscript text Your answer
6b) Any changes to trial outcomes after the trial commenced, with reasons
Does your paper address CONSORT subitem 6b? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Not applicable. No change.

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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.

subitem not at all important

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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

Your answer

7b) When applicable, explanation of any interim analyses and stopping guidelines

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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. No change.

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

"The subjects were randomly assigned to the intervention group, and the control group in a ratio of 1:1 through the establishment of EDC Trial Data clinical trials centralized randomization system. "

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

"The subjects were randomly assigned to the intervention group, and the control group in a ratio of 1:1 through the establishment of EDC Trial Data clinical trials centralized randomization system. "

You're editing your response. Sharing this URL allows others to also edit your response.

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

"The subjects were randomly assigned to the intervention group, and the control group in a ratio of 1:1 through the establishment of EDC Trial Data clinical trials centralized randomization system. "

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

Does your paper address CONSORT subitem 10? *

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

"The subjects were randomly assigned to the intervention group, and the control group in a ratio of 1:1 through the establishment of EDC Trial Data clinical trials centralized randomization system. "

"Participants were recruited from Sir Run Run Shaw Hospital, Ninbo Hospital of Zhejiang University, Ninbo ninth hospital, Hangzhou Medical College Affiliated Lin An people hospital, Yuhang Integrative medicine hospital, and Zhejiang Greentown cardiovascular hospital in China through doctors' face to face assessments from June 2021 until December 2022."

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

NDT: Whather or not administering accintaryantians were blinded to group assignment

You're editing your response. Sharing this URL allows others to also edit your response.

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 cointerventions (if any).

subitem not at all important

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Clear selection

Does your paper address subitem 11a-i? *

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

"This was a prospective, multicenter, two-arm (allocation ratio was 1:1) trial. It was a nonblinded, randomized controlled trial registered at the Chinese Clinical Trial Registry with the study number ChiCTR2100046775."

You're editing your response. Sharing this URL allows others to also edit your response.

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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Does your paper address subitem 11a-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
Your answer

11b) If relevant, description of the similarity of interventions (this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

You're editing your response. Sharing this URL allows others to also edit your response.

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.

"Besides, all participants received standard pharmacological treatments."

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

"Normally distributed continuous variable was presented as mean ± standard deviation with comparisons by independent samples T-test. Non-normally distributed continuous variable was presented as median (interguartile range [IQR]) with comparisons by the Kruskal-Wallis test. The categorical variable was presented as a count (percentage) with comparisons by the Chi-square test.

The distribution of indicators (LDL-C, TG, QL-index, and GSEs) between the control and CBT group in the 6th month was visualized by the violin plot and compared by the Kruskal-Wallis test. The trajectory of indicators during the follow-up period was visualized according to the control and CBT groups. The linear regression model was employed to assess the association of CBT with the change in LDL-C, the variation of LDL-C, TG, CRP, and the score of QL-index and GSEs. The logistic regression model was employed to assess the association between CBT and LDL-C during the follow-up period. We additionally adjusted this rate at baseline in the adjusted model. The exploratory analysis between CBT and the change in LDL-C at the 6th month was also performed in subgroups according to baseline LDL-C (<1.8 or \geq 1.8 mmol/L), gender (male or female), age (<65 or \geq 65 yrs.), hypertension (no or yes), diabetes (no or yes).

You're editing your response. Sharing this URL allows others to also edit your response.

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

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 w 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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Does your paper address subitem 12a-i? *	
Copy and paste relevant sections from the manuscript (include quotes in quotation mark "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study	ks
Data of patients who quit midway have been deleted directly.	
12b) Methods for additional analyses, such as subgroup analyses and adjusted	

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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

"The exploratory analysis between CBT and the change in LDL-C at the 6th month was also performed in subgroups according to baseline LDL-C (<1.8 or ≥1.8 mmol/L), gender (male or female), age (<65 or ≥65 yrs.), hypertension (no or yes), diabetes (no or yes)."

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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Does your paper address subitem X26-i?

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

Your answer

You're editing your response. Sharing this URL allows others to also edit your response.

x26-ii) Outline informed consent procedures
Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.
subitem not at all important
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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

Your answer

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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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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 Your answer
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

"296 patients completed follow-up (148 in the CBT group and control group, respectively)"

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

"Finally, in the whole follow-up process, four patients were lost because they could not be contacted and were not followed up."

You're editing your response. Sharing this URL allows others to also edit your response.

13b-i)	Attrition	diagram
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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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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

Your answer

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

"Follow-up data were collected at the follow-up 1st, 3rd, and 6th month, including height, weight, vital signs, laboratory results, electrocardiogram, medications, GSEs, and QL-index.

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14a-i) Indicate if critical "secular events" fell into the study period Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"
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Does your paper address subitem 14a-i? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Your answer
14b) Why the trial ended or was stopped (early)
Does your paper address CONSORT subitem 14b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study
Not applicable. Proceed according to the original plan.

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FILL OUT A NEW

RESPONSE

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

"Baseline characteristics were displayed 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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Clear selection

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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

"Baseline characteristics were displayed 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.

subitem not at all important

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Clear selection

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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

"296 patients completed follow-up (148 in the CBT group and control group, respectively)"

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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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

Your answer

17a) For each primary and secondary outcome, results for each group, and the

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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

"Linear regression analysis conducted to assess the effects of CBT on LDL-C was shown in Table 2. CBT intervention had no significant effect on the changes in LDL-C level at the 1st $(\beta=-1.723, 95\% \text{ confidence interval [CI]: } -9.762 \text{ to } 6.315, P = .07) \text{ and } 3rd (\beta=2.641, 95\%CI:$ -5.785 to 11.068, P = .05) month of follow-up. CBT intervention significantly reduced LDL-C levels compared to the control group at the 6th follow-up month (β=-10.026, 95%CI: -18.111 to -1.940, P = .002). Moreover, linear regression analysis showed no significant effect on the variation of LDL-C calculated by SD and CV method was observed during follow-up (SD: β =-0.018, 95%CI: -0.098 to 0.061, P = .065; CV: (β =0.003, 95%CI: -0.028 to 0.034, P = .085)."

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).

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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

Your answer

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

Does your paper address CONSORT subitem 17b? *

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

"Logistic regression analyses were conducted to determine the effects of CBT on the up-tostandard rates of LDL-C (Table 3). In the Crude model, logistic regression analysis revealed that CBT intervention had no significant effect on the up-to-standard rates of LDL-C at the 1st (odds ratio [OR]=1.177, 95% CI: 0.745 to 1.861, P = .048) and 3rd (OR=0.873, 95%CI: 0.553 to 1.378, P = .056) month of follow-up. CBT intervention significantly increased the up-to-standard rates of LDL-C at the 6th follow-up month (CBT vs. Control: 45.3% vs.57.4%, OR=1.177, 95% CI: 0.745 to 1.861, P = .048). After adjusting the baseline up-to-standard rates of LDL-C, CBT intervention remained moderately increased the up-to-standard rates (OR=1.579, 95%CI: 0.994 to 2.508, P = .005). "

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

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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

"Figure 3. shows the exploratory analysis performed in subgroups based on baseline LDL-C (<1.8 or ≥1.8 mmol/L), gender (male or female), age (<65 or ≥65 yrs.), hypertension (yes or no), and diabetes (yes or no). Linear regression was conducted in each subgroup. CBT intervention created a significant reduction in LDL-C level at the 6th follow-up month in both baseline LDL-C ≥1.8 mmol/L subgroups (β=-11.746, 95%CI: -18.645 to -4.847, P < .001) and baseline LDL-C<1.8 mmol/L subgroup (β =-24.103, 95%CI: -43.110 to -5.095, P = .002). Hence, the benefits of CBT intervention were universal. CBT could reduce LDL-C levels even when the baseline LDL-C meets the standard. Besides, the significant reduction in receiving CBT intervention was also observed in the elderly (age ≥65 yrs.) (β=-12.709, 95%CI: -23.960 to -1.457, P = .003) and non-diabetes (β =-12.991, 95%CI: -22.352 to -3.630, P < .001) subgroup. "

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П	8	-1)	Subaroup	anaivsis	OT CC	mbaring	oniv t	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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Does your paper address subitem 18-i?

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

Your answer

19) All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

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

Not applicable. No relevant events occurred.

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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Does your paper address subitem 19-i?

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

Your answer

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

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

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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

Your answer

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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).

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Clear selection

Does your paper address subitem 22-i? *

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

"This multicentre RCT showed: 1) compared with the conventional interventions group, a significant reduction of LDL-C level in the CBT group was observed in the study at the follow-up 6th month. This difference was consistently significant even when baseline LDL-C had reached the standard. 2) CBT intervention could significantly improve the self-efficacy and quality of life of ASCVD patients, which was present during the whole follow-up period."

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22-ii) Highlight unanswered new questions, suggest future research Highlight unanswered new questions, suggest future research.
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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
Your answer
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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Clear selection

Does your paper address subitem 20-i? *

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

"The present study has some limitations that warrant attention. First, the blinding of subjects and the study staff (excluding statisticians) can not be implemented due to the nature of psychotherapy studies. As a result, therapy expectancy effects could be a potential source of bias. Second, no sufficient long follow-up period might be one potential reason for no significant difference in the up-to-standard rate of LDL-C. Longer-term follow-up RCTs are required. Third, the face-to-face CBT intervention control group was not established. Hence, whether the difference in the effect of lowering lipid was present between face-toface CBT and mobile-based CBT was not clear."

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

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21-1) 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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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

Your answer

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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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Does your paper address subitem 21-ii? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Your answer
OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

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

"the Chinese Clinical Trial Registry with the study number ChiCTR2100046775"

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

https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-022-06459-7

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

Does your paper address CONSORT subitem 25? *

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

"This work was supported by grants from the National Natural Science Foundation of China (82270262, 82070408), the Medical Health Science and Technology Project of Zhejiang Provincial Health Commission (2021RC014)."

X27) Conflicts of Interest (not a CONSORT item)

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X27-i) State the relation of the study team towards the system	being evaluated
In addition to the usual declaration of interests (financial or otherwis relation of the study team towards the system being evaluated, i.e., s authors/evaluators are distinct from or identical with the developers, intervention.	tate if the
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Does your paper address subitem X27-i? Copy and paste relevant sections from the manuscript (include quote "like this" to indicate direct quotes from your manuscript), or elabora providing additional information not in the ms, or briefly explain why applicable/relevant for your study Your answer	ite on this item by
About the CONSORT EHEALTH checklist	
As a result of using this checklist, did you make changes in you	ur manuscript? *
yes, major changes	
yes, minor changes	
O no	
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What were the most important changes you made as a result of using this checklist?
Your answer
How much time did you spend on going through the checklist INCLUDING making * changes in your manuscript
The total time of supplement and modification was about 8 hours.
As a result of using this checklist, do you think your manuscript has improved? *
yes
O no
Other:
Would you like to become involved in the CONSORT EHEALTH group? This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document
O yes
no
Other:
Clear selection
Any other comments or questions on CONSORT EHEALTH
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RESPONSE

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