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 !!!

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FILL OUT A NEW RESPONSE

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and

Mobile Health Interventions J Med Internet Res 2011;13(4):e126 URL: <u>http://www.jmir.org/2011/4/e126/</u> doi: 10.2196/jmir.1923 PMID: 22209829

* Required

Your name *

First Last

Won Kyung

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

Inha University, Incheon, Korea

Your e-mail address * abc@gmail.com

bluewhale65@inha.ac.kr

Title of your manuscript *

Provide the (draft) title of your manuscript.

Mobile health interventions for lifestyle and risk factor modification in coronary heart disease: A 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.

TEXTME-K [the Tobacco, Exercise, and Diet Me

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")

Korean

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)"

coronary heart disease

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

LDL cholesterol, systolic blood pressure, body

Secondary/other outcomes

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

HDL-C, total cholesterol, and healthy lifestyle: smoking cessation, PA, fruit and vegetable intake $\geq 2/day$, and medication adherence

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Recommended "Dose" * What do the instructions for users say on how often the app should be used?	
• Approximately Daily	
O Approximately Weekly	
O Approximately Monthly	
O Approximately Yearly	
O "as needed"	
O Other:	

Approx. Percentage of Users (starters) still using the app as recommended after 3 months * unknown / not evaluated 0-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71%-80% 81-90% 91-100% ()You're editing your response. Sharing this URL allows others to also **FILL OUT A NEW RESPONSE** edit your response.

Overall, was the app/intervention effective? *									
O yes: all primary outcomes were significantly better in intervention group vs control									
O partly: SOME primary outcomes were significantly better in intervention group vs control									
O no statistically significant difference between control and intervention									
O potentially harmful: control was significantly better than intervention in one or more outcomes									
O inconclusive: more research is needed									
• Other: positive in secondary outcomes, negative in primary outcomes									
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
- o not submitted yet in late draft status, just before submission
 - submitted to a journal but not reviewed yet
- submitted to a journal and after receiving initial reviewer comments
- submitted to a journal and accepted, but not published yet
-) published
-) Other:

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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")

- onot submitted yet / unclear where I will submit this
- Journal of Medical Internet Research (JMIR)
- JMIR mHealth and UHealth

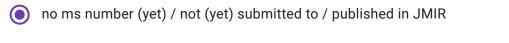


-) JMIR Mental Health
- JMIR Public Health
- JMIR Formative Research
- Other JMIR sister journal
- Other:

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



) Other:

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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")
ves
Other:

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

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

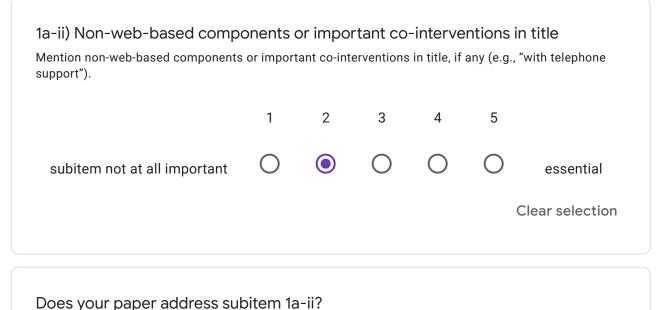
	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential
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Does your paper address subitem 1a-i? *

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

"Mobile health interventions for lifestyle and risk factor modification in coronary heart

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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

"Mobile health interventions for lifestyle and risk factor modification in coronary heart disease: A randomized controlled trial"

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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 Clear selection

Does your paper address subitem 1a-iii? *

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

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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)



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

"The primary outcomes were LDL cholesterol (LDL-C), systolic blood pressure (SBP), and body mass index (BMI). The secondary outcomes were the change in lifestyle and the adherence to the recommended health behaviors."

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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)

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subitem not at all important	0	۲	0	0	0	essential
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Does your paper address subitem 1b-ii?

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

"In addition to standard care, the intervention group received access to a supporting website and four text messages per week for six months regarding a healthy diet, physical activity, smoking, and cardiovascular health. Random allocation at study enrollment and text messaging after hospital discharge was performed automatically using a computer program."

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

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

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subitem not at all important	0	۲	0	0	0	essential				
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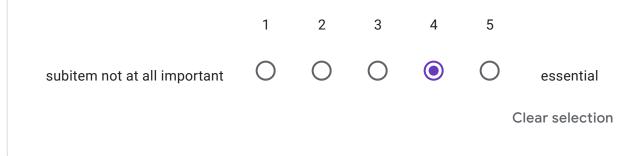
Does your paper address subitem 1b-iii?

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

"A parallel, single-blinded, 1:1 random allocation clinical trial was conducted on 879 patients treated by PCI, who were recruited during hospital admission from April 2017 to May 2020"

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)



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

"Of the eligible population, 440 and 439 patients who underwent PCI were assigned to the intervention and control groups, respectively. "

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

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it) $1 \quad 2 \quad 3 \quad 4 \quad 5$

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Does your paper address subitem 1b-v?

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

"Lifestyle-focused text messages were effective in the self-management of a healthy diet, exercise, and medication adherence, but their influence on physiological measures was modest and limited."

INTRODUCTION

2a) 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) $1 \quad 2 \quad 3 \quad 4 \quad 5$

subitem not at all important	0	0	۲	0	0	essential
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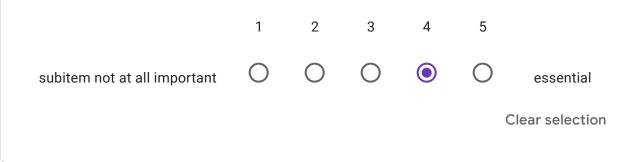
Does your paper address subitem 2a-i?*

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

"A healthy lifestyle, risk factor modification, and medication adherence are vital for preventing the recurrence of coronary heart disease (CHD). On the other hand, self-management of cardiovascular risk factors is often challenging. "

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

"Early research suggested the possible benefit of mobile phone messaging on lifestyle modification [6]. On the other hand, a Cochrane review pointed out that the evidence was not strong because of the small number of participants and the risk of bias."

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

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

"Therefore, this study examined whether a text message program could enhance selfmanagement on lifestyle and risk factor modification with objective and subjective measures in a randomized controlled trial."

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 study conducted a parallel_single-blind_randomized clinical trial enrolling 879 patients

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

Does your paper address CONSORT subitem 3b? *

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

"The participants were eligible if they were diagnosed with CHD and underwent percutaneous coronary intervention (PCI) for the first time and provided informed consent. Those younger than 18 were excluded. Initially, acute myocardial infarction was targeted as the inclusion criterion, but the criteria were extended to CHD, including angina pectoris, treated by PCI after the participating hospitals were confirmed at one month of recruitment.

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].



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

Your answer

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4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

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

"The participants were eligible if they were diagnosed with CHD and underwent percutaneous coronary intervention (PCI) for the first time and provided informed consent."

4a-i) Computer / Internet literacy

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

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subitem not at all important	0	۲	0	0	0	essential
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Does your paper address subitem 4a-i?

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

"The patients were excluded if they had no mobile phone or difficulty in reading text messages."

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

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 webbased 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.



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 who underwent the first PCI were recruited after face-to-face assessment during hospital admission."

4a-iii) Information giving during recruitment

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

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subitem not at all important	0	۲	0	0	0	essential
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Does your paper address subitem 4a-iii?

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

Your answer

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

"The participants were enrolled at two tertiary and university teaching hospitals in Chungcheongbuk-Do and Incheon, South Korea. The study areas, Chungcheongbuk-Do and Incheon, had a population of 1,590,372 and 2,922,121 in 2020. Both hospitals had Regional Cardiocerebrovascular Centers (RCCVCs) established by the Ministry of Health and Welfare to prevent and treat cardiovascular disease."

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

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

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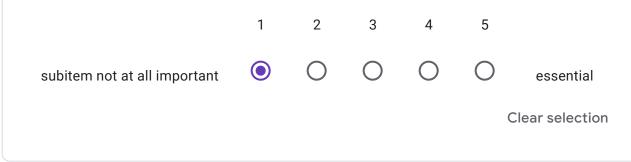
Does your paper address subitem 4b-i?*

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

"The smoking status, physical activity, diet, and medication adherence were acquired using a questionnaire. The physical activity was assessed using a Korean version of the International Physical Activity Questionnaire (IPAQ) short form. IPAQ is a commonly used tool to assess physical activity, and total hours per week for walking, moderate PA, and vigorous PA using metabolic equivalent (MET) values are computed."

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)



Does your paper address subitem 4b-ii?

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

Your answer

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

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).

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subitem not at all important	0	۲	0	0	0	essential
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Does your paper address subitem 5-i?

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

"In the intervention group, access to a supporting website and text messages regarding lifestyle modification were sent for six months. The contents of the text messages were based on the Tobacco, Exercise, and Diet Messages (TEXTME) study and the Australian Heart Foundation Healthy Living Guidelines [10, 12]. The cardiologists, nurses, clinical nutritionists, and preventive medicine experts reviewed the text messages in the TEXTME trial and modified them considering the Asian diet and culture. The text messages consisted of anti-smoking, diet, physical activity, and general cardiovascular health, including medication adherence. The number of messages was 25 and 27 for the category of anti-smoking and physical activity, respectively. The diet category consisted of 27 and 99 messages for vegetarian and non-vegetarian, respectively. The general cardiovascular health categories A and B were composed of 24 messages for the participants and non-smokers. The message-sending program delivered semi-personalized text messages considering the smoking status and diet pattern of the participants –vegetarian or not – with their names."

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

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

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

5-iv) Quality assurance methods

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

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subitem not at all important	۲	0	0	0	0	essential
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Does your paper address subitem 5-iv?

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

Your answer

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

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms								
used								
Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.								
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Does your paper address subitem 5-v?

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

Your answer

5-vi) Digital preservation

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

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subitem not at all important	۲	0	0	0	0	essential
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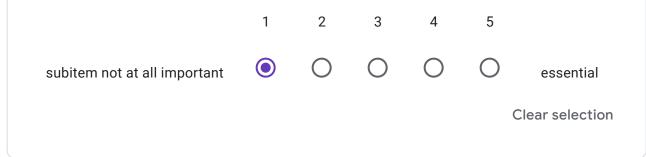
Does your paper address subitem 5-vi?

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

Your answer

5-vii) Access

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



Does your paper address subitem 5-vii? *

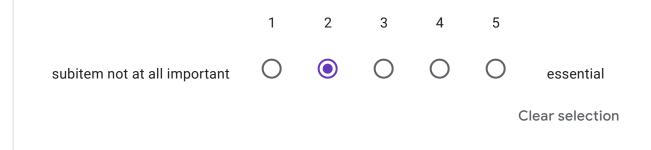
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Participants in the intervention group received four messages per week for 24 weeks in addition to standard care. The message-management program selected a message randomly from each of the four categories for a week: anti-smoking, physical activity, diet, and general cardiovascular health A for smokers, and physical activity, diet, and general cardiovascular health A for non-smokers. The messages were sent on 4 of 5 randomly selected weekdays and at randomly selected times (9 AM, 12 PM, 3 PM, and 5 PM) of the day. Every participant in the intervention group received 96 messages in the 6-month prevention program. The algorithm of message management was developed according to the pre-specified rule on selecting the categories and text messages and the frequency and timing of text sending. The study personnel explained to all the participants that they could request to stop the text message program through the phone number of the caller when they wanted to withdraw."

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].



Does your paper address subitem 5-viii? *

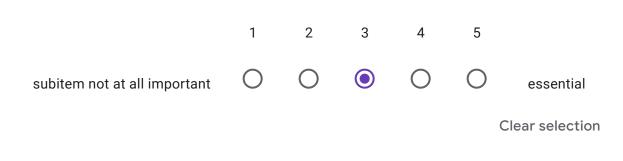
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"In the intervention group, access to a supporting website and text messages regarding lifestyle modification were sent for six months. The contents of the text messages were based on the Tobacco, Exercise, and Diet Messages (TEXTME) study and the Australian Heart Foundation Healthy Living Guidelines [10, 12]. The cardiologists, nurses, clinical nutritionists, and preventive medicine experts reviewed the text messages in the TEXTME trial and modified them considering the Asian diet and culture. The text messages consisted of anti-smoking, diet, physical activity, and general cardiovascular health, including medication adherence. The number of messages was 25 and 27 for the category of anti-smoking and physical activity, respectively. The diet category consisted of 27 and 99 messages for vegetarian and non-vegetarian, respectively. The general cardiovascular health categories A and B were composed of 24 messages for the participants and non-smokers. The message-sending program delivered semi-personalized text messages considering the smoking status and diet pattern of the participants –vegetarian or not – with their names."

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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.



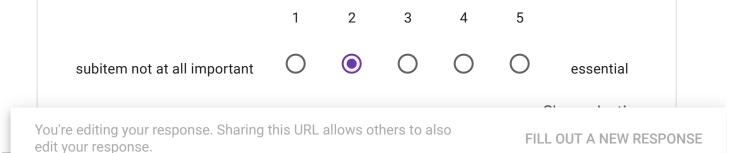
Does your paper address subitem 5-ix?

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

"Participants in the intervention group received four messages per week for 24 weeks in addition to standard care. The message-management program selected a message randomly from each of the four categories for a week: anti-smoking, physical activity, diet, and general cardiovascular health A for smokers, and physical activity, diet, and general cardiovascular health A for non-smokers. The messages were sent on 4 of 5 randomly selected weekdays and at randomly selected times (9 AM, 12 PM, 3 PM, and 5 PM) of the day. Every participant in the intervention group received 96 messages in the 6-month prevention program."

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).



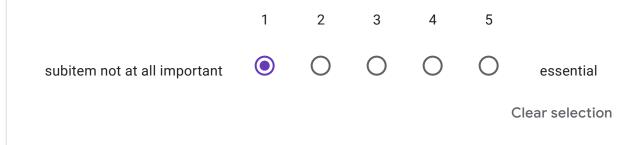
Does your paper address subitem 5-x?

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

"A web-based interface was developed for computerized randomization and a text messagesending program. When the study personnel entered the information of the participants in the secure web interface, the participants were assigned randomly to the intervention or control group. If they were assigned to the intervention and discharged from hospitals, the computer program automatically sent a text message for six months after hospital discharge."

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? *

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

Text-messages were used as an intervention method and no other prompt/reminders were used in this study.

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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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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

"Except for text messages, both groups received guideline-directed standard care for CHD."

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

Does your paper address CONSORT subitem 6a? *

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

"The primary outcome of the study was the LDL-C, systolic blood pressure (SBP), and BMI at six months considering the baseline level. The secondary outcomes were the HDL-C, total cholesterol, and healthy lifestyle: smoking cessation, PA, fruit and vegetable intake \geq 2/day, and medication adherence. Moreover, the secondary outcomes included the proportion achieving the guideline levels of five modifiable risk factors: LDL-C <70mg/dL, blood pressure <140/90 mm Hg, 30 minutes of moderate exercise \geq five days/week, smoking cessation, and BMI <25"

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If outcomes were obtained through c and apply CHERRIES items to descril				-		
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Does your paper address su Copy and paste relevant sections fro						
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6a-ii) Describe whether and defined/measured/monitore Describe whether and how "use" (inc logins, logfile analysis, etc.). Use/ac	d luding inte	ensity of u	se/dosage	e) was def	ined/meas	sured/monitored
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Your answer 6a-ii) Describe whether and defined/measured/monitore Describe whether and how "use" (inc (logins, logfile analysis, etc.). Use/ac reported in any ehealth trial.	d luding inte loption me	ensity of u etrics are i	se/dosage	e) was def process of	ined/meas utcomes t 5	sured/monitored hat should be

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained								
Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).								
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subitem not at all important	۲	0	0	0	0	essential		
Clear selection								

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

It was a one-way text-message program which did not allow interaction.

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

trial outcomes were not changed.

7a) How sample size was determined

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

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7a-i) Describe whether and h calculating the sample size	iow exp	ected a	ttrition	was take	en into	account when	
Describe whether and how expected attrition was taken into account when calculating the sample size.							
subitem not at all important		2		4		essential	
						Clear selection	

Does your paper address subitem 7a-i?

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

"A sample size of 880 was calculated considering a 15% loss to follow-up, 90% power (two-tailed and at the 5% significance level) to detect a difference in the three primary outcomes between the two groups: 10 mg/dL in LDL-C, 5 mmHg in SBP, and 1.2 kg/m2 in BMI [10]. "

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

Does your paper address CONSORT subitem 7b? *

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

"No interim analysis was planned or conducted."

8a) Method used to generate the random allocation sequence

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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

"After a pilot study, a computerized randomization program was developed for a random 1:1 allocation whose sequence was generated in a block size of 8. A web-based interface was developed for computerized randomization and a text message-sending program."

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

"After a pilot study, a computerized randomization program was developed for a random 1:1 allocation whose sequence was generated in a block size of 8. A web-based interface was developed for computerized randomization and a text message-sending program."

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

"After a pilot study, a computerized randomization program was developed for a random 1:1 allocation whose sequence was generated in a block size of 8. A web-based interface was

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

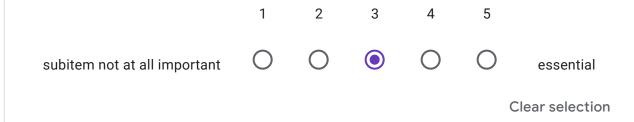
Does your paper address CONSORT subitem 10? *

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

"After a pilot study, a computerized randomization program was developed for a random 1:1 allocation whose sequence was generated in a block size of 8. A web-based interface was developed for computerized randomization and a text message-sending program."

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).



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

neovidar and autoama avaluator ware blinded to the acaimm

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11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"								
Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".								
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subitem not at all important	0	0	۲	0	0	essential		
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Does your paper address subitem 11a-ii?

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

Your answer

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

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

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

This item is not relevant for this study which was a mhealth trial.

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

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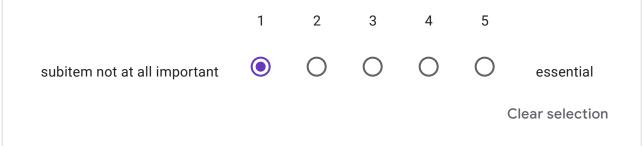
Does your paper address CONSORT subitem 12a? *

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

"The continuous variables at the baseline were presented as the means and standard deviations if they were distributed normally, while categorical variables are presented as frequencies and percentages. The baseline characteristics between the intervention and the control groups were compared using a t-test and Chi-squared test. The primary analysis was an analysis of covariance (ANCOVA) and robust Poisson regression with the baseline values of the analyzed parameters used as covariates, where continuous and binary outcomes were evaluated, respectively."

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]).



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

"Statistical analysis was conducted by an independent biostatistician and an epidemiologist not involved in the study. All evaluations of the intervention were performed on the principle of an intention to treat."

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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

"Subgroup analyses were specified in the statistical analysis plan by age, sex, smoking status, recruiting hospital, LDL-C tertile, and disease category: acute myocardial infarction and angina pectoris. No interim analysis was planned or conducted."

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



Does your paper address subitem X26-i?

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

"This protocol was approved by the institutional review boards of the Inha University Hospital (IRB number: 2017-03-008-001) and the Chungbuk National University Hospital (IRB number: 2017-05-016)"

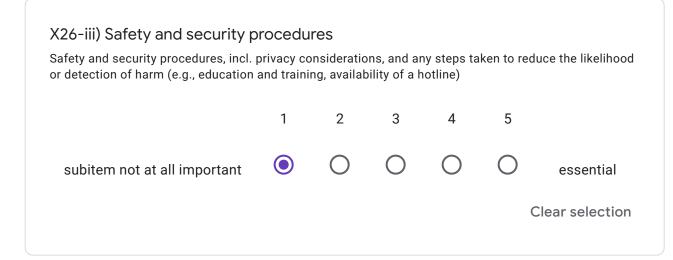
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x26-ii) Outline informed cons Outline informed consent procedures etc.?), and what information was prov consent documents.	e.g., if co	onsent was	obtained			
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Does your paper address subitem X26-ii?

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

"informed consent was provided by patients who participated in this study."



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

Vour answer

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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 the 1,130 screened for eligibility, 879 patients, who were admitted with CHD and underwent PCI from April 2017 to May 2020, were enrolled in this study (Figure 1). Two hundred and forty-one patients were excluded: 28 patients who did not have a mobile phone, 78 patients who have difficulty in reading text messages, 65 patients who declined to participate in the study, and 70 patients with other reasons, including in-hospital mortality. Of the 879 eligible patients, 440 and 439 patients were assigned randomly to the intervention and control group, respectively." and Figure 1

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) *

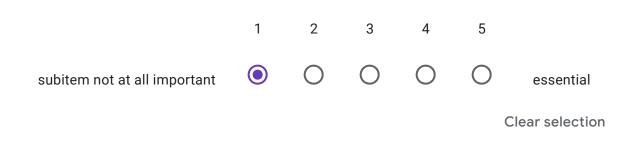
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Follow-up loss was 48, including four patients who died before the six-month follow-up in the intervention group, while 71 patients in the control group were lost to follow-up, including one death. The recruitment closed when our study sample size was achieved, and

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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

Your answer

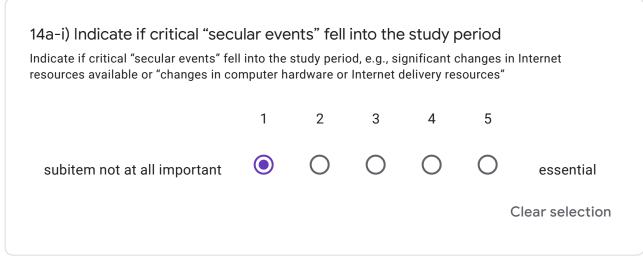
14a) Dates defining the periods of recruitment and follow-up

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

"Of the 1,130 screened for eligibility, 879 patients, who were admitted with CHD and underwent PCI from April 2017 to May 2020, were enrolled in this study (Figure 1). The recruitment closed when our study sample size was achieved, and the follow-up period was form October 2017 to November 2020."

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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

"The recruitment closed when our study sample size was achieved, and the follow-up period was form October 2017 to November 2020."

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

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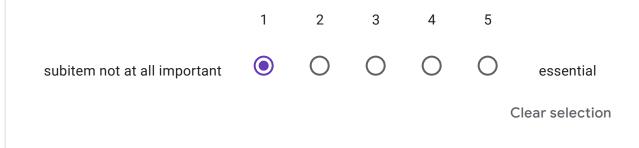
Does your paper address CONSORT subitem 15?*

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

"Table 1 compares the baseline characteristics of the study participants. The mean age of the enrolled participants was 60.4 years, and 83.3% of the subjects were male. The mean LDL-C, SBP, and BMI were 110.3 mg/dL, 125.3 mmHg, and 24.9 kg/m2, respectively. The baseline characteristics were similar in the intervention and control groups except for the angiotensin-converting enzyme inhibitors (ACEi)/ angiotensin receptor blockers (ARB); the control group was more likely to take ACEi or ARB before hospital admission."

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.



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

"Two hundred and forty-one patients were excluded: 28 patients who did not have a mobile phone, 78 patients who have difficulty in reading text messages, 65 patients who declined to participate in the study, and 70 patients with other reasons, including in-hospital mortality."

16) For each group, number of participants (denominator) included in each

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

16-i) Report multiple "denominators" and provide definitions

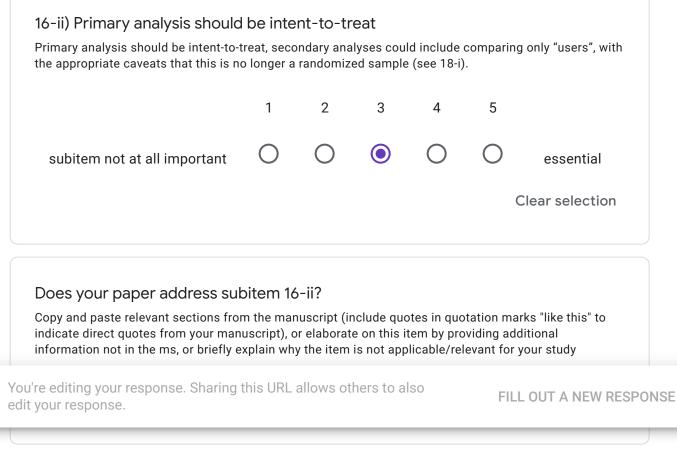
Report multiple "denominators" and provide definitions: Report N's (and effect sizes) "across a range of study participation [and use] thresholds" [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants "used" the intervention/comparator at specific pre-defined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

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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

All the tables showed denominators in the tables.



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

Table 2 and 3 had the effect size and 95% confidence interval.

17a-i) Presentation of process outcomes such as metrics of use and intensity of

use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

	1	2	3	4	5	
subitem not at all important	۲	0	0	0	0	essential
					C	Clear selection

Does your paper address subitem 17a-i?

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

Your answer

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

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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

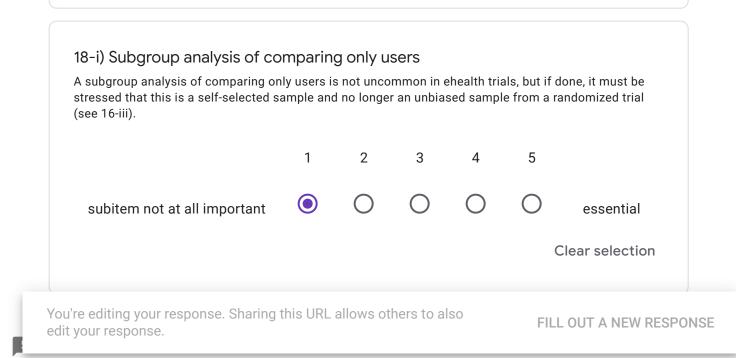
Table 2 and 3 had the effect size and 95% confidence interval.

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

"Figures 2 and 3 present the results of the subgroup analysis on the primary and secondary outcomes. Regarding the objective measures of the primary outcomes, the difference between the intervention and control groups was not significant (Figure 2). On the other hand, regarding three secondary outcomes showing a significant difference between the intervention and control groups, the text messages were more likely to be effective in males, young adults, current smokers, or patients with acute myocardial infarction (Figure 3)."



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

It was not mentioned because it was based on the text message-based program and it could cause little harm.

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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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	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

Your answer

DISCUSSION

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

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

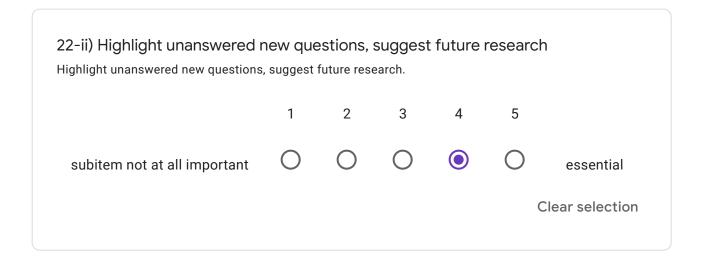
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22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)						
Restate study questions and summan outcomes and process outcomes (us		iswers sug	gested by	the data,	starting wi	th primary
	1	2	3	4	5	
subitem not at all important	0	0	۲	0	0	essential
					C	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 study found that a one-way text message program could enhance physical activity and encourage a healthy diet and medication adherence in patients who underwent PCI. Therefore, more people were likely to follow the lifestyle and risk factor modification as recommended. On the other hand, it could not induce a significant decrease in each objective measure of the risk factors: LDL-C level, SBP, and BMI. Most participants found the text message program to be a helpful motivation to change their lifestyle."



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Does your paper address subitem 22-ii?

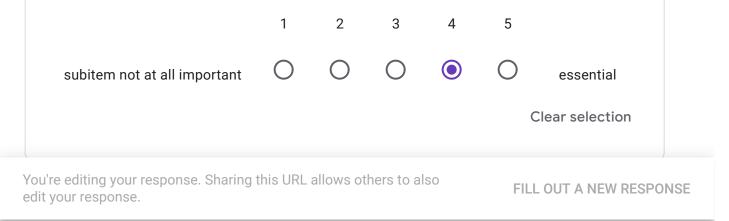
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Furthermore, a method is needed to enhance the self-management of lifestyle and risk factors in patients with CHD. In this study, only a small proportion of patients who underwent PCI achieved the guideline level of all five risk factors: 12.7% for the intervention group and 7.7% for the control group. The text message was chosen in this study because it was the most affordable and accessible to the elderly, and it required lower cost and effort with and without an automatic computer program compared to alternative methods. On the other hand, this study showed that its effect was modest. Therefore, it is important to enhance it by trying other methods, such as interactive text messaging, more personalized messaging, smartphone applications, and wearable devices [19]. For example, previous studies suggested that smartphone application could help lower calories, lower fat, increase PA, and reduce more weight in the general and obese population [8, 20]. When applying digital health technology to the self-management of CHD, the impairment of dexterity, vision, and cognition in older adults should be considered [21]. Self-management of the cardiovascular risk factors can be improved by integrating it with each component of the chronic care model framework: decision support, self-management support, delivery system design, clinical information system, and community resources [22]."

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.



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

"This study had some limitations. First, this trial was conducted in two tertiary hospitals, which were cardiovascular referral centers, which may limit its generalization. The observed effects might also depend on the accessibility of health care and cardiac rehabilitation. Second, although a text message is simple, easy, and more accessible than a smartphone application, a text message program could also be a barrier to illiteracy, elderly who do not have a mobile phone, and residents with foreign nationality. This study was conducted using a single-blind design. On the other hand, the risk of bias appears minimal because the computer program was developed for random allocation and text messaging after hospital discharge. Moreover, the study personnel who collected the data at the six-month follow-up were blinded to the allocation and the objective measures of the primary outcomes."

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations



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Does your paper address subitem 21-i?

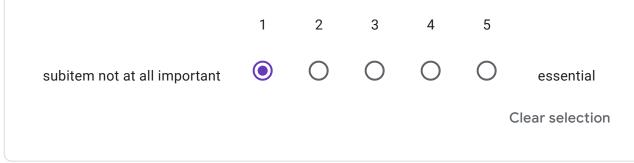
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"First, this trial was conducted in two tertiary hospitals, which were cardiovascular referral centers, which may limit its generalization. The observed effects might also depend on the accessibility of health care and cardiac rehabilitation."

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.



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

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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

Trial registration Clinical Research Information Service (CRiS) at https://cris.nih.go.kr, Identification: KCT0005087

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

Trial registration Clinical Research Information Service (CRiS) at https://cris.nih.go.kr, Identification: KCT0005087

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

"W.K.L. received funding for this work from the National Research Foundation of Korea (NRF) (NRF-2017R1C1B5017736). The funders had no role in study design, data collection, analysis, decision to publish, or manuscript preparation."

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X27-i) State the relation of the In addition to the usual declaration of study team towards the system being identical with the developers/sponso	f interests g evaluate	s (financial d, i.e., stat	or otherw e if the au	vise), also	state the r	elation of the
	1	2	3	4	5	
subitem not at all important	۲	0	0	0	0	essential
					C	Clear selection
Does your paper address subitem X27-i? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study						

"The author(s) declare no competing interests."

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yes, major changes



) no

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

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

I spent 3 hours in going through the checklist.

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

🕘 yes

) no

Other:

Would you like to become invo	lved in the CONSORT EHEALTH group?
This would involve for example becomin	ng involved in participating in a workshop and writing an

"Explanation and Elaboration" document

) yes

) no

) Other:

Clear selection

Any other comments or questions on CONSORT EHEALTH

Your answer

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