CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be

- a) a guide for reporting for authors of RCTs,
- b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.

Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.

In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).

Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):

Eysenbach G, CONSORT-EHEALTH Group

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

J Med Internet Res 2011;13(4):e126

URL: http://www.jmir.org/2011/4/e126/ doi: 10.2196/jmir.1923 PMID: 22209829 yiseul.loa.choi@gmail.com 계정 전환 ፟ 초안 저장됨 🔀 비공개 * 표시는 필수 질문임 Your name * First Last Yiseul Choi Primary Affiliation (short), City, Country * University of Toronto, Toronto, Canada Yonsei University College of Dentistry, Seoul, K Your e-mail address * abc@gmail.com loa@yuhs.ac Title of your manuscript * Provide the (draft) title of your manuscript. Smartphone-based telemonitoring for better oral health with toothbrushes: A 6-month randomized controlled trial

Name of your App/Software/Intervention * If there is a short and a long/alternate name, write the short name first and add the long name in brackets. Mombrush ProCare Evaluated Version (if any) e.g. "V1", "Release 2017-03-01", "Version 2.0.27913" 내 답변 Language(s) * What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French") Korean, English 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. https://play.google.com/store/apps/details?id=com.xiu.mom_brush.rolling.advanced URL of an image/screenshot (optional) 내 답변

| 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 7 E : |
| 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)" gingivitis (Adults who are in good general heal- |
| Primary Outcomes measured in trial * comma-separated list of primary outcomes reported in the trial Fluorescent Plaque Index |
| Secondary/other outcomes Are there any other outcomes the intervention is expected to affect? Turesky Modified Quigley-Hein Plaque Index (QHI), H2S and CH3SH concentrations, the ratio of periodontal high-risk microbiota, the ratio of caries-risk/anti-caries microbiota |

| 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" |
| 이 기타: at least twice daily |
| |
| Approx. Percentage of Users (starters) still using the app as recommended after * 3 months |
| unknown / not evaluated |
| O-10% |
| O 11-20% |
| 21-30% |
| 31-40% |
| 41-50% |
| 51-60% |
| 61-70% |
| 71%-80% |
| 81-90% |
| 91-100% |
| ○ 기타: |

| 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 |
| ○ 기타: |
| |
| |
| 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) Onot 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) onot 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 |
| 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 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 |

| 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 Serious Games |
| JMIR Mental Health |
| JMIR Public Health |
| JMIR Formative Research |
| Other JMIR sister journal |
| ○ 기타: |
| |
| |
| 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 |
| |
| O Pilot/feasibility |
| O Pilot/feasibility |
| Pilot/feasibility Fully powered |
| 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

기타:

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.

2 3

subitem not at all important

essential

선택해제

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

"Smartphone-based telemonitoring" for better oral health: a 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"). | | | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | | | | |
| subitem not at all important | | 0 | 0 | 0 | 0 | essential | | | |
| | | | | | | 선택해제 | | | |
| Does your paper address sub | item 1a | -ii? | | | | | | | |
| Copy and paste relevant section: "like this" to indicate direct quot providing additional information applicable/relevant for your stud | s from n es from not in th | nanuscri _l your mai | nuscript) | , or elabo | orate on t | his item by | | | |
| No, the title does not mention any non-web-based components or important co- interventions. This is appropriate because the study does not appear to include significant non-web-based components or co-interventions such as "telephone support." The intervention relies primarily on smartphone-based telemonitoring and does not require additional non-web-based support. | | | | | | | | | |
| | | | | | | | | | |
| 1a-iii) Primary condition or target group in the title Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes") Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial | | | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | | | | |
| subitem not at all important | 0 | 0 | • | 0 | 0 | essential | | | |
| | | | | | | 선택해제 | | | |

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

Partially. The title, "Smartphone-based telemonitoring for better oral health: a randomized controlled trial," refers broadly to oral health improvement but does not specify a particular condition (e.g., "plaque reduction" or "gingivitis prevention") or target group (e.g., "adults," "patients with periodontal disease"). While the general focus on oral health is clear, the title could be more specific regarding the primary condition or population studied.

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

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

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

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

| | 1 | 2 | 3 | 4 | 5 | |
|------------------------------|---|---|---|---|---|----------|
| subitem not at all important | 0 | 0 | 0 | 0 | • | essentia |

선택해제

Does your paper address subitem 1b-i? *

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

Yes, the abstract mentions key features and functionalities:

The telemonitoring toothbrush connects to a smartphone application, provides real-time feedback, and includes weekly dental professional reviews. The oscillating-rotating power toothbrush uses smartphone-based guidance. The manual toothbrush is used without digital feedback but participants kept a brushing diary.

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 | 0 | | 0 | 0 | essential |
| | | | | | | 선택해제 |

Does your paper address subitem 1b-ii?

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

Yes, the level of human involvement is clarified.

For the telemonitoring toothbrush, weekly dental professional reviews are explicitly mentioned. The oscillating-rotating power toothbrush and manual toothbrush do not involve real-time human interaction, highlighting differences in intervention support.

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 | 0 | 0 | 0 | • | essential |
| | | | | | | 선택해제 |

Does your paper address subitem 1b-iii?

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

Yes, the methods section of the abstracr explicitly address this subitem.

Recruitment method: Participants were recruited offline, indicating a closed recruitment process rather than an open-access web-based trial.

Assessment setting: Data collection occurred in clinical settings, clarifying that the study involved face-to-face assessments, not web-based self-assessments.

| 1b-iv) RESULTS section in abstract must contain use data | | | | | | | | | |
|---|---|---|---|---|---|-----------|--|--|--|
| Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it) | | | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | | | | |
| subitem not at all important | 0 | 0 | 0 | 0 | • | essential | | | |
| | | | | | | 선택해제 | | | |
| | | | | | | | | | |
| Does your paper address subitem 1b-iv? Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Yes, results include use data indirectly by mentioning that interest in the telemonitoring toothbrush declined after 3 months. This highlights the importance of user engagement and adherence over time. | | | | | | | | | |
| 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 | 2 | 3 | 4 | 5 | | | | |
| subitem not at all important | 0 | 0 | • | 0 | 0 | essential | | | |
| | | | | | | 선택해제 | | | |

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

Not directly applicable.

This is not a "negative trial," as the primary outcomes (plaque reduction) showed significant improvements for the telemonitoring toothbrush. The abstract does note a decline in interest over time, which is a limitation discussed in the conclusions.

INTRODUCTION

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

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

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

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subitem not at all important O O O essential

선택해제

Does your paper address subitem 2a-i? *

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

Yes, the manuscript clearly describes the problem of maintaining effective oral hygiene and the potential of technologically advanced toothbrushes to address this issue. It identifies telemonitoring toothbrushes as a stand-alone intervention designed to improve oral health compliance by providing personalized feedback and monitoring.

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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subitem not at all important O O O essential

선택해제

Does your paper address subitem 2a-ii? *

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

Yes, the manuscript provides a rationale, discussing the advancements in oral hygiene technology, including smart toothbrushes, and their potential to improve brushing techniques compared to manual methods. It justifies the selection of two comparators: the oscillating-rotating power toothbrush (to compare two types of smart toothbrushes) and the manual toothbrush (to serve as a standard, non-digital control).

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

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

Yes, the manuscript states clear objectives: to compare the clinical effectiveness of a telemonitoring toothbrush, an oscillating-rotating power toothbrush, and a manual toothbrush in improving oral hygiene. It hypothesizes that the telemonitoring toothbrush will be more effective in reducing plaque and improving oral health outcomes than the other two methods.

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *

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

Yes, the trial design is clearly described as a parallel-group randomized controlled trial. The allocation ratio (1:1:1) is also specified, with 50 participants in each group.

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

Does your paper address CONSORT subitem 3b? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study No important changes to methods, such as eligibility criteria, content, or functionality of the intervention, were reported during the trial. 3b-i) Bug fixes, Downtimes, Content Changes Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2]. subitem not at all important essential 선택해제 Does your paper address subitem 3b-i? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study No significant changes to methods, such as eligibility criteria, content, or functionality of the intervention, were reported during the trial. There were no documented bug fixes or downtimes that could have influenced the study design. 4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

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

Yes, the paper addresses CONSORT subitem 4a.

The eligibility criteria for participants are explicitly stated in the Methods section: Participants had to be aged 19 or older, have at least 24 teeth, and be smartphone users. Exclusion criteria include conditions like moderate to severe periodontitis, systemic diseases affecting halitosis, and the use of orthodontic devices or removable dentures.

4a-i) Computer / Internet literacy

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

subitem not at all important O O O essential

선택해제

Does your paper address subitem 4a-i?

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

Yes, smartphone usage was explicitly included as an eligibility criterion, which inherently assumes participants have basic computer/Internet literacy. This is crucial for interacting with the telemonitoring application.

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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선택해제

Does your paper address subitem 4a-ii? *

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

Yes, recruitment was closed and conducted offline in a clinical setting. Data collection also occurred face-to-face during clinical visits, ensuring that participants were directly assessed.

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 O O O essential

선택해제

Does your paper address subitem 4a-iii?

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

Yes, informed consent was obtained from participants, and the study protocol, including objectives and procedures, was reviewed with participants before enrollment.

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

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

Yes, the paper addresses CONSORT subitem 4b.

The manuscript specifies that the study was conducted at the Department of Advanced General Dentistry at Yonsei University College of Dentistry, a clinical setting. Recruitment and data collection occurred offline and in-person, ensuring consistency in the study environment.

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

1 2 3 4 5

subitem not at all important

O O essential

선택해제

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

No online questionnaires were used. However, at the last visit, participants completed a written self-report questionnaire consisting of eight questions about their current oral care habits and perceptions of the remote monitoring toothbrush. All assessments (plaque indices, halitosis measurements, and microbiota sampling) were conducted face-to-face in a clinical setting.

4b-ii) Report how institutional affiliations are displayed

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

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

선택해제

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

Yes, the study specifies that data collection occurred at the Department of Advanced General Dentistry, Yonsei University College of Dentistry. The institutional affiliation is clearly stated, which could influence participant trust and volunteer rates but is transparently disclosed.

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

| 5-i) Mention names, credential, affiliations of the developers, sponsors, and owners | | | | | | | | | | |
|--|---|---|---|---|---|-----------|--|--|--|--|
| Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript). | | | | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | | | | | |
| subitem not at all important | 0 | 0 | 0 | 0 | • | essential | | | | |
| | | | | | | 선택해제 | | | | |
| | | | | | | | | | | |
| 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 Yes, the manuscript provides the names of the toothbrush devices used in the study: Telemonitoring toothbrush: Mombrush® (XiuSolution, South Korea). Oscillating-rotating toothbrush: Oral-B® Genius 8000 (Procter & Gamble, USA). The author/evaluators are not the owner or developer of the software. | | | | | | | | | | |
| 5-ii) Describe the history/development process Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results. | | | | | | | | | | |
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| subitem not at all important | 0 | • | 0 | 0 | 0 | essential | | | | |
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Does your paper address subitem 5-ii?

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

Partially addressed. While the manuscript describes the features and functionalities of the telemonitoring application, it does not provide details about its development process or formative evaluations such as usability testing.

5-iii) Revisions and updating

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

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subitem not at all important O O O ● essential 선택해제

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

No major revisions or updates to the application or interventions during the trial are reported.

| 5-iv) Quality assurance method | ods | | | | | | | | |
|--|-----------|----|---|---|---|-----------|--|--|--|
| 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 | 0 | 0 | 0 | 0 | 0 | essential | | | |
| Does vour naner address sub | nitem 5-i | v2 | | | | | | | |
| 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 내 답변 | | | | | | | | | |
| <u> </u> | | | | | | | | | |
| | | | | | | | | | |
| 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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| subitem not at all important | 0 | 0 | 0 | 0 | 0 | essential | | | |

Does your paper address subitem 5-v?

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

Reproducibility is supported by a detailed description of the intervention, including app features and instructions. Although source code is not provided, screenshot figures are provided in the appendix to the manuscript.

5-vi) Digital preservation

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

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Does your paper address subitem 5-vi?

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

The telemonitoring app operates as a server-side application, where brushing records and interventions are stored on a centralized server. Raw data is received and stored by the company (owners), ensuring centralized access for long-term preservation and future analysis.

For the oscillating-rotating toothbrush (ORT) group, the application used was an on-device application, limiting data accessibility. To overcome this, participants sent screenshots of brushing records via text messages to the researcher weekly. These screenshots were stored by the researcher as part of the study records, ensuring data retention for analysis despite the application's on-device limitation.

5-vii) Access

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

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subitem not at all important O O O O essential

Does your paper address subitem 5-vii? *

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

Yes, access to the telemonitoring toothbrush required participants to install the Mombrush ProCare application. Participants did not need to pay for the device or app, and they were instructed on its use during clinical visits.

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

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

1 2 3 4 5 subitem not at all important O O O O essential 선택해제

Does your paper address subitem 5-viii? *

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

Yes, the manuscript describes features such as real-time feedback, tracking brushing habits, and weekly expert reviews. The theoretical framework of improving oral health through behavioral feedback is implicit.

5-ix) Describe use parameters

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

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Does your paper address subitem 5-ix?

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

Yes, participants were instructed to brush at least twice daily and use the assigned toothbrush exclusively for six months. Weekly feedback was provided for the telemonitoring group.

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

Yes, human involvement included weekly expert feedback for the telemonitoring group and manual diary reviews for the manual toothbrush group.

5-xi) 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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Does your paper address subitem 5-xi? *

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

Yes, reminders were delivered via the telemonitoring app as notifications to encourage brushing at the recommended times.

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 Yes, co-interventions included instructional videos and feedback sessions for the telemonitoring group, ensuring users understood and adhered to proper brushing techniques. 6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed Does your paper address CONSORT subitem 6a? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Yes, outcomes are clearly defined. 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].

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subitem not at all important

| Does your paper address subitem 6a-i? Copy and paste relevant sections from manuscript text | | | | | | | |
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| Not applicable, as no online questionnaires were used. Outcomes were assessed in person using clinical measurements. | | | | | | | |
| | | | | | | | |
| 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. | | | | | | | |
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| Does your paper address sub Copy and paste relevant section Partially addressed. While the m | ns from n | nanuscrip | | y feedba | ck and ap | pp-based | |
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| Copy and paste relevant section Partially addressed. While the m brushing records, it does not inc durations. 6a-iii) Describe whether, how obtained Describe whether, how, and whe | anuscrip lude deta , and wh | nanuscrip t describ ailed met nen qual | es weekl rics such itative fe | eedback | frequence | ey or session | |
| Copy and paste relevant section Partially addressed. While the m brushing records, it does not inc durations. 6a-iii) Describe whether, how obtained Describe whether, how, and whe | anuscrip lude deta and when qualitate | nanuscrip t describ ailed met nen qual ntive feed terviews, | es weekl rics such itative fe back fro focus gr | eedback m partici | frequence from pa | ey or session | |

| | Does your paper address subitem 6a-iii? Copy and paste relevant sections from manuscript text | | | | | | |
|--|---|--|--|--|--|--|--|
| | es, participant feedback was collected through a post-study questionnaire, capturing erceptions of the telemonitoring toothbrush's effectiveness and usability. | | | | | | |
| | | | | | | | |
| | 6b) Any changes to trial outcomes after the trial commenced, with reasons | | | | | | |
| | | | | | | | |
| | Does your paper address CONSORT subitem 6b? * | | | | | | |
| | Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study | | | | | | |
| | No changes to the trial outcomes are reported. Pre-specified outcomes remained consistent throughout the study. | | | | | | |
| | | | | | | | |
| 7a) How sample size was determined NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed | | | | | | | |
| | | | | | | | |
| | 7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size Describe whether and how expected attrition was taken into account when calculating the sample size. | | | | | | |
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Does your paper address subitem 7a-i?

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

Yes, the manuscript describes how the sample size was calculated.

The sample size was 150 participants, divided into three groups of 50. The sample size was calculated using G-Power 3.1.9.2, with an effect size of 0.3, a significance level of 0.05, and a statistical power of 85%, considering a dropout rate of 15%.

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

Does your paper address CONSORT subitem 7b? *

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

Not applicable. No interim analyses or stopping guidelines were implemented or mentioned in the study design.

8a) Method used to generate the random allocation sequence NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

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

Yes, the manuscript specifies that a computerized block randomization method was used to generate the random allocation sequence, ensuring unbiased assignment.

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *

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

Yes, the manuscript states that block randomization with a block size of 5 was used.

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

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

Yes, allocation was concealed using a computerized randomization tool by two independent researchers who were not involved in the rest of the study. The participants and outcome assessors were blinded to group assignments.

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

Does your paper address CONSORT subitem 10? *

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

Yes, the manuscript explains that two independent researchers generated the random allocation sequence and assigned participants to their respective groups, ensuring proper implementation and avoiding bias.

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).

subitem not at all important O O O essential

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Does your paper address subitem 11a-i? *

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

Yes, the manuscript describes that the study was single-blind:

Blinded: Outcome assessors were blinded. Not blinded: Participants were not blinded. 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

Participants were blinded to the study hypothesis and were not informed which intervention was considered the "intervention of interest" (telemonitoring toothbrush) or which ones were comparators (oscillating-rotating toothbrush and manual toothbrush). All participants were told that the study aimed to compare the effectiveness of three different types of toothbrushes in improving oral hygiene. This minimized biases related to participant expectations about the interventions.

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

Does your paper address CONSORT subitem 11b? *

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

Not applicable. The interventions (telemonitoring toothbrush, oscillating-rotating toothbrush, and manual toothbrush) were inherently different in terms of functionality and feedback, so similarity between them is not relevant.

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

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

Does your paper address CONSORT subitem 12a? *

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

Yes, statistical methods are described in the manuscript.

All statistical analyses were performed using SPSS statistical software (SPSS for Windows, v. 25; SPSS Inc., Chicago, IL, USA). Data were tested for normality using the Kolmogorov Smirnov test. One-way analysis of variance and chi-square tests were used to analyze the demographics and questionnaire responses of the study participants. Independent sample t-tests were used to compare changes in brushing habits by group. SHS, QHI, and VSC were analyzed using repeated measures analysis of variance with Bonferroni's multiple comparison test. Changes in microbiota within groups were analyzed using a paired-samples t-test. All statistical analyses were two-tailed, and the statistical significance level was set at P< 0.05.

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

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

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| subitem not at all important | 0 | 0 | 0 | 0 | • | essential |
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Does your paper address subitem 12a-i? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Yes, the analysis included intent-to-treat principles, and participants with incomplete data were excluded from specific analyses rather than using imputation methods. 12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses Does your paper address CONSORT subitem 12b? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Yes, subgroup analyses were conducted to compare adherence levels among participants and assess differences in outcomes across time points (baseline, 1, 3, and 6 months). X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item) X26-i) Comment on ethics committee approval 1 2 3 4

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subitem not at all important

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

Yes, The Institutional Review Board (IRB) of the Dental Hospital at Yonsei University reviewed and approved the study protocol prior to the trial in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments (IRB number: 2-2020-0032). The manuscript explicitly states this.

x26-ii) Outline informed consent procedures

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

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Does your paper address subitem X26-ii?

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

Yes, participants provided informed consent offline after receiving a detailed explanation of the study objectives, procedures, and data management practices. Consent forms included information about data confidentiality and the voluntary nature of participation.

X26-iii) Safety and security procedures Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline) 1 2 3 4 5 subitem not at all important O O O ● essential 선택해제

Does your paper address subitem X26-iii?

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

Yes, all data was anonymized.

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

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

Yes, a CONSORT flow diagram is included in the manuscript, detailing the number of participants assessed for eligibility, randomized, and included in analyses, along with reasons for dropout or exclusion.

| 13b) For each group, losses and exclusions after randomisation, together with reasons | | | | | |
|---|--|--|--|--|--|
| Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Yes, a CONSORT flow diagram is included in the manuscript, detailing the number of participants assessed for eligibility, randomized, and included in analyses, along with reasons for dropout or exclusion. | | | | | |
| | | | | | |
| 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. 1 2 3 4 5 subitem not at all important O O O O essential | | | | | |
| 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 내 답변 | | | | | |
| 14a) Dates defining the periods of recruitment and follow-up | | | | | |

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Yes, recruitment and follow-up occurred between January 2021 and May 2022. 14a-i) Indicate if critical "secular events" fell into the study period Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources" subitem not at all important essential 선택해제 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 No critical secular events occurred during the study period. 14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14a? *

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. The trial ended as planned after six months of follow-up.

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

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

Yes, Table 1 shows baseline demographic and clinical characteristics for each group.

15-i) Report demographics associated with digital divide issues

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

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subitem not at all important O O O essential

선택해제

Does your paper address subitem 15-i? *

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

Yes, Table 1 shows the participants' age, education, sex, interest in IT devices, and Frequency of use of IT devices.

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

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

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

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

선택해제

Does your paper address subitem 16-i? *

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

Yes, the manuscript reports the number of participants analyzed per group at each time point.

| 16-ii) Primary analysis should Primary analysis should be intenonly "users", with the appropriate 18-i). | t-to-trea | t, second | dary anal | - | | |
|---|-----------|-----------|-----------------|-----------|---------|-----------|
| | 1 | 2 | 3 | 4 | 5 | |
| subitem not at all important | 0 | 0 | 0 | 0 | 0 | essential |
| Does your paper address sub | item 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 | | | | | | |
| 내 답변 | | | | | | |
| | | | | | | |
| 17a) For each primary and se estimated effect size and its p | - | | | | • | • |
| | | | | | | |
| Does your paper address CO | NSORT | subiter | n 17a? ' | · | | |
| Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study | | | | | | |
| Yes, results for primary outcome | s and se | condary | outcome | s are pre | sented. | |
| | | | | | | |

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 subitem not at all important 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 내 답변 17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended Does your paper address CONSORT subitem 17b? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Not applicable, as the outcomes are primarily continuous.

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

| Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate 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 presentation in the "Results" section adheres to the journal's requirements. | | | | | | | |
| 18-i) Subgroup analysis of co A subgroup analysis of compar- done, it must be stressed that the sample from a randomized trial | ing only ι nis is a se | users is n elf-select | ot uncor | | | | |
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| subitem not at all important | O | O | O | 0 | O | essential | |
| Does your paper address sul Copy and paste relevant section "like this" to indicate direct quo providing additional information applicable/relevant for your study | ns from th tes from not in th | ne manus your mai | nuscript) | , or elabo | rate on tl | nis item by | |
| 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 No important harms or unintended effects occurred during the study. 19-i) Include privacy breaches, technical problems Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2]. subitem not at all important essential 선택해제 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

No harms were reported.

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

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

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subitem not at all important O O O O 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

Yes, our paper includes qualitative feedback from participants. The qualitative feedback highlighted the usability of the telemonitoring app and the perceived effectiveness of real-time feedback.

DISCUSSION

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

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

| 22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use). | | | | | | |
|--|------------------------------------|--------------------|-----------|------------|-----------|-------------------|
| | 1 | 2 | 3 | 4 | 5 | |
| subitem not at all important | 0 | 0 | 0 | 0 | • | essential |
| | | | | | | 선택해제 |
| Does your paper address subitem 22-i? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Yes, the interpretation aligns with the results, emphasizing the benefits of telemonitoring toothbrushes while acknowledging usability challenges and potential adherence drop-offs over time. | | | | | | |
| 22-ii) Highlight unanswered n Highlight unanswered new ques | | | | | search | |
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| Does your paper address sub Copy and paste relevant section "like this" to indicate direct quot providing additional information applicable/relevant for your stud | s from the es from not in th | ne manu your ma | nuscript) | , or elabo | rate on t | his item by |

내 답변

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

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subitem not at all important O O O ● essential

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 limitations of this study are as follows. First, the restriction on the use of auxiliary oral hygiene devices, such as dental floss and interdental brushes, during the study period. Although the use of auxiliary oral hygiene devices was restricted to compare the efficacy of the smart toothbrush itself, the use of auxiliary oral hygiene devices plays an important role in oral hygiene management in interdental areas. Since auxiliary oral hygiene devices are highly recommended in clinical practice, it is necessary to evaluate plaque removal and gingival health improvement when using auxiliary oral hygiene devices together with a smart toothbrush. In addition, the nutrition practices of the participants were not recorded. Nutrition practices could affect the oral environment in addition to brushing, but this was not considered in the result analysis. Finally, right-handedness and left-handedness were not considered. Since the app showed a video guide on how to brush based on right-handedness, it could have been confusing for left-handed participants.

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

| Internet population, outside of a applicability of the study results | | • | • | patient p | opulation | n, including |
|--|--|-----------------------|------------------------------------|---------------------------------------|--------------------------------------|---|
| | 1 | 2 | 3 | 4 | 5 | |
| subitem not at all important | 0 | 0 | 0 | 0 | 0 | essential |
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| Copy and paste relevant section "like this" to indicate direct quo providing additional information applicable/relevant for your students. | tes from not in th | your mai | nuscript) | , or elabo | orate on t | his item by |
| 내 답변 | | | | | | |
| | | | | | | |
| 21-ii) Discuss if there were el application setting Discuss if there were elements setting (e.g., prompts/reminders interventions) and what impact adoption, or outcomes if the interventions. | in the RC s, more h the omis | T that wo uman inv | ould be d volvemer nese eler | ifferent i nt, trainin ments co | n a routin g sessior ould have | e application ns or other co- on use, |
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| subitem not at all important Does your paper address sub | 0 | -ii? | 0 | 0 | 0 | essential |
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OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

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

Yes, the manuscript includes the registration number (KCT0009094) and platform (Clinical Research Information Service, Republic of Korea).

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

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

Yes, the full trial protocol for this study can be accessed at the Clinical Trial Information Service (https://cris.nih.go.kr/cris; KCT0001980).

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

Does your paper address CONSORT subitem 25? *

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

Yes, funding from the Korea Health Industry Development Institute (KHIDI) is disclosed.

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

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subitem not at all important

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essential

선택해제

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

Yes, the manuscript declares no competing interests. It specifies that the authors are not affiliated with the developers of the telemonitoring application or toothbrushes used in the study.

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| As a result of using this checklist, did you make changes in your manuscript? * |
|--|
| yes, major changes |
| yes, minor changes |
| O no |
| What were the most important changes you made as a result of using this checklist? |
| |
| How much time did you spend on going through the checklist INCLUDING * making changes in your manuscript |
| 1 week spend on going through the CONSORT-EHEALTH checklist. |
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| As a result of using this checklist, do you think your manuscript has improved? * |
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| Would you like to become involved in the CONSORT EHEALTH group? This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document |
|--|
| yes |
| O no |
| ○ 기타: |
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