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

* Required

Your name *

First Last

Daniel Ehlman

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

Centers for Disease Control and Prevent

Your e-mail address *

abc@gmail.com

dehlman@cdc.gov

Title of your manuscript *

Provide the (draft) title of your manuscript.

Evaluating a Personalized, Automated Caregiver Mobile Phone Delivered Text Message Reminder Intervention to Reduce Infant Vaccination Drop-out in Arua, Uganda: Protocol for a Randomized Controlled Trial

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

SMS immunization reminders sent from

Evaluated Version (if any)

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

Version 2.26

Language(s) *

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

English, Lugbara

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

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: DHIS2 is currently free and open but the specific modification for ou

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)"

Vaccine preventable diseases

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Vaccination coverage at 12 months of a

Secondary/other outcomes

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

Your answer

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- ☐ Approximately Daily
- ☐ Approximately Weekly
- ☐ Approximately Monthly
- ☐ Approximately Yearly
- ☒ "as needed"
- ☐ Other:

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- ☒ unknown / not evaluated
- ☐ 0-10%
- ☐ 11-20%
- ☐ 21-30%
- ☐ 31-40%
- ☐ 41-50%
- ☐ 51-60%
- ☐ 61-70%
- ☐ 71%-80%
- ☐ 81-90%
- ☐ 91-100%
- ☐ Other:

Overall, was the app/intervention effective? *

- ☐ yes: all primary outcomes were significantly better in intervention group vs control
- ☐ partly: SOME primary outcomes were significantly better in intervention group vs control
- ☐ no statistically significant difference between control and intervention
- ☐ potentially harmful: control was significantly better than intervention in one or more outcomes
- ☐ inconclusive: more research is needed
- ☒ Other: This manuscript presents the protocol, not the intervention's effecti

Article Preparation Status/Stage *

At which stage in your article preparation are you currently (at the time you fill in this form)

- ☐ not submitted yet - in early draft status
- ☒ not submitted yet - in late draft status, just before submission
- ☐ submitted to a journal but not reviewed yet
- ☐ submitted to a journal and after receiving initial reviewer comments
- ☐ submitted to a journal and accepted, but not published yet
- ☐ published
- ☐ Other:

Journal *

If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- ☐ not submitted yet / unclear where I will submit this
- ☐ Journal of Medical Internet Research (JMIR)
- ☐ JMIR mHealth and UHealth
- ☐ JMIR Serious Games
- ☐ JMIR Mental Health
- ☐ JMIR Public Health
- ☐ JMIR Formative Research
- ☒ Other JMIR sister journal
- ☐ Other:

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

- ☐ Pilot/feasibility
- ☒ Fully powered

Manuscript tracking number *

If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

☒ no ms number (yet) / not (yet) submitted to / published in JMIR

☐ Other:

TITLE AND ABSTRACT

1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *

I.e. does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

☒ yes

☐ Other:

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

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

subitem not at all
important

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essential

Does your paper address subitem 1a-i? *

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

"Mobile Phone"

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").

subitem not at all
important

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essential

Does your paper address subitem 1a-ii?

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

Your answer

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

subitem not at all
important

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essential

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

"Caregiver", "Infant"

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 METHC

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)

subitem not at all
important

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essential

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

"All participants received the standard of care, defined as the health worker providing child vaccination home-based records to caregivers, as available, and providing verbal instruction of when to return for the next visit. At the end of each day, caregivers and their children were randomized by computer either to receive or not to receive personalized, automated text message reminders for their subsequent vaccination visits according to the national schedule. "

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)

subitem not at all
important

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essential

Does your paper address subitem 1b-ii?

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

Your answer

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

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)

subitem not at all
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essential

Does your paper address subitem 1b-iii?

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

Your answer

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)

subitem not at all
important

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Does your paper address subitem 1b-iv?

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

Your answer

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)

subitem not at all
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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

Your answer

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)

subitem not at all
important

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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

"...Timely vaccination with these vaccines remains low, which threatens the health of Ugandan children with morbidity and mortality from vaccine preventable diseases.

"Innovative ways are needed to increase coverage, including increasing recall rates of caregivers to bring children for timely vaccination (Kalan et al., 2014). Prompting of health seeking behavior via mobile technology interventions has been shown to improve health intervention uptake, particularly in high-income countries (Free et al., 2013). However, only a limited number of studies have evaluated the role of mobile phone short message service (SMS) reminders, also known as text message reminders, to increase vaccination coverage in low- and middle-income countries (LMIC)."

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

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

subitem not at all
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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

"A few studies in LMIC (Kaewkungwal et al., 2010) (Schlumberger et al., 2015) (Uddin et al., 2016) (Nguyen, Vu, Dao, Tran, & Nguyen, 2017) have assessed coverage improvements from the implementation of electronic immunization registers (EIRs) that had an automated SMS reminder feature. The study designs varied in terms of scientific rigor and each concluded that coverage increased; however, it was not possible to assess the impact of SMS reminders alone, as the EIRs provided the additional intervention of improving the tracking of individuals.

"Other studies (Bangure et al., 2015) (Eze & Adeleye, 2015) (Haji et al., 2016) (Domek et al., 2016) (Gibson et al., 2017) (Kazi et al., 2018) enrolled participants between birth and Penta1 and followed them through Penta3, or in some cases through 12 months of age. Most of these studies focused on coverage at 2-4 weeks after the scheduled Penta3 date, as compared to the Kenya SMS cluster randomized controlled trial (cRCT) (Gibson et al., 2017) which assessed coverage at 12 months of age, which is a typical Expanded Program on Immunization (EPI) indicator. The Gibson and colleagues (2017) study, which used a randomized controlled trial (RCT) design, did not find the SMS reminder intervention alone to significantly improve vaccination coverage at 12 months of age. However, the other studies concluded that SMS reminders did significantly improve vaccination coverage."

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

"Primary Objective:

- To evaluate a personalized, automated caregiver SMS reminder intervention to reduce vaccination drop-out for children 12 months of age and younger in select health facilities in Arua District

"Secondary Objectives:

- To measure the impact of a personalized, automated caregiver SMS reminder intervention to increase the probability that children will receive Penta3 within 12 weeks of Penta1 receipt and MCV by 10 months of age
- To assess caregiver acceptability of a personalized, automated caregiver SMS reminder intervention
- To determine the cost-effectiveness of a personalized, automated caregiver SMS reminder intervention from the provider (Ministry of Health) perspective"

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

"A two arm, multi-center, parallel groups RCT was conducted in four health facilities providing vaccination services in and around the town of Arua...
 "At the end of each day, study participants who were registered that day were randomized by computer using stratified permuted block randomization to either the control or the intervention arm, which was then recorded in the database as well. For randomization assignment, study participants were matched in order of registration to a sequence that was generated by non-field study personnel prior to the start of enrollment. Stratification and blocking occurred at the health facility level; blocks of random size were used (lengths = 2, 4, and 6) to minimize the ability to predict the next assignment. The health worker, study personnel, and participants were blinded to the randomization at assignment. However, unblinding of the intervention group occurred at the time when they received the first SMS reminder. The control group became unblinded as they realized that they were not receiving SMS reminders. Upon occasion, study participants shared their intervention status with health workers and field-level study personnel, thus unblinding them to the status of some caregivers. Non-field staff study personnel who managed the database had access to intervention status after randomization assignment."

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

"After the first two months of study recruitment (Feb-Mar 2016), enrollment was found to be lower than expected, so a fourth health facility was added as a study site."

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
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Does your paper address subitem 3b-i?

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

Your answer

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

"Caregiver participant inclusion criteria:

- Had access to a personal or household mobile phone that could receive SMS
- Was caring for a child between 6 weeks and 6 months of age at the time of Penta1 vaccination visit
- Lived in Arua district
- Was 14 years of age or older

"Caregiver participant exclusion criteria:

- Did not have access to a mobile phone number at time of enrollment
- Did not agree or was unable to consent to participate in the study
- Did not anticipate being the caregiver through the child's first birthday
- Planned to move out of Arua district in the upcoming year
- Prior enrollment of the caregiver with a different child"

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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essential

Does your paper address subitem 4a-i?

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

Your answer

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

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

subitem not at all
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Does your paper address subitem 4a-ii? *

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

"Study participants were enrolled at the four selected health facilities during vaccination sessions at the time of Penta1 vaccination. Study personnel who were stationed in the selected health facilities explained the study, obtained consent and enrolled the eligible caregivers who accepted to participate in the study. Study participants responded to a brief pre-intervention questionnaire to collect basic demographic and locating information. The health facility staff vaccinated the children, filled out the health facility immunization register, and filled out the children's HBRs, per standard practice in Uganda (Uganda National Expanded Programme on Immunization)..."

"At the time of the MCV visit, study personnel administered the post-intervention questionnaire to participants to gather information on the acceptability of the SMS reminder intervention; knowledge, attitudes, and beliefs regarding vaccination practices; and demographic information. Participants who did not return for MCV were visited or contacted by phone and interviewed at their homes. In a few cases, the study personnel met the participants in another location that was convenient to them and reimbursed them for their transportation costs. In a few other cases, the study personnel interviewed participants by phone because it was not feasible to interview in person."

4a-iii) Information giving during recruitment

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

subitem not at all
important

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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 four largest health facilities in and around Arua town"; "Arua District"; "Uganda"

"At enrollment, study personnel administered the pre-intervention questionnaire to participants (at Penta1 visit) to gather basic demographic and locating information. At the time of the MCV visit, study personnel administered the post-intervention questionnaire to participants to gather information on the acceptability of the SMS reminder intervention; knowledge, attitudes, and beliefs regarding vaccination practices; and demographic information. Participants who did not return for MCV were visited or contacted by phone and interviewed at their homes. In a few cases, the study personnel met the participants in another location that was convenient to them and reimbursed them for their transportation costs. In a few other cases, the study personnel interviewed participants by phone because it was not feasible to interview in person."

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

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

subitem not at all important ☐ ☐ ☐ ☒ ☐ essential

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

"...As part of the post-intervention questionnaire, study personnel reviewed HBRs of the child participants to extract vaccination data.

"...In addition, study personnel extracted vaccination data on the child participants from the immunization register."

4b-ii) Report how institutional affiliations are displayed

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

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 4b-ii?

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

Your answer

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).

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 5-i?

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

Your answer

5-ii) Describe the history/development process

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

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

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.

subitem not at all
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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

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-cap

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.

subitem not at all
important

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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, 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.

subitem not at all
important

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essential

Does your paper address subitem 5-vi?

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

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).

subitem not at all
important

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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

The intervention required access to a mobile phone to receive SMS reminders.

"Caregiver participant inclusion criteria:

- Had access to a personal or household mobile phone that could receive SMS"

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

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].

subitem not at all
important

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essential

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

"For each study participant, the study personnel sent an SMS to a designated short code number with information that included the caregiver's preferred first or last name, caregiver's mobile phone number, child's date of birth and the participant study ID in the following format: "Penta [ChildDOB] CN. [CaregiverName].PN.[PhoneNumber].ID.[StudyID]" (Figure 2)"

"The information in the SMS populated a centralized immunization registry database in a District Health Information System 2 (DHIS2) Software (Version 2.26) Tracker Module instance created for this study; in addition, the study personnel mobile phone number who registered the study participant and the date that the registration SMS was sent (which also served as the date of Penta1 vaccination) were recorded in the database. At the end of each day, study participants who were registered that day were randomized by computer using stratified permuted block randomization to either the control or the intervention arm, which was then recorded in the database as well. For randomization assignment, study participants were matched in order of registration to a sequence that was generated by non-field study personnel prior to the start of enrollment. Stratification and blocking occurred at the health facility level; blocks of random size were used (lengths = 2, 4, and 6) to minimize the ability to predict the next assignment."

"Following the Uganda EPI schedule and accounting for health worker practices in Arua, the DHIS2 Tracker instance was programmed to automatically schedule follow-up vaccination visits at 30 days after Penta1 (for the visit to receive Penta2, Oral Polio Vaccine (OPV) dose 2, and Pneumococcal Conjugate Vaccine (PCV) dose 2 vaccines), 61 days after Penta1 (for Penta3/OPV3/PCV3) and 274 days after the child's date of birth (for MCV). SMS reminders in both English and Lugbara (the most common local language spoken in Arua) were then automatically scheduled to be sent from DHIS2 Tracker at 7am, first to an SMS aggregator in Uganda, then on to the appropriate Uganda telecommunications service providers, which in turn sent the SMS to the appropriate participants. Penta2 SMS reminders were sent two days before, on the day of, and two days after the scheduled vaccination visit. Penta3 and MCV SMS reminders were sent on the day of and five and seven days after the scheduled vaccination visits. As an automated intervention, SMS reminders were sent regardless whether the caregiver had already visited the health facility. In the ideal system, the visit for Penta3/OPV3/PCV3 would have been scheduled 30 days after the Penta2/OPV2/PCV2 visit; however, because the DHIS2 Tracker instance was not updated after vaccination visits, we needed to schedule the visit in reference to the Penta1/OPV1/PCV1 visit date.

"Prior to the start of study enrollment, consensus decision-making with caregivers and health workers in Arua district and partners at the national level took place to finalize the pattern, timing, and exact wording of the SMS (Table 2). Because some SMS reminders would be automatically sent to caregivers either before the child was due or after a completed visit, we emphasized in the SMS that the caregiver refer to the child's HBR to confirm the date of next vaccination."

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.

subitem not at all
important

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Does your paper address subitem 5-ix?

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

Your answer

5-x) Clarify the level of human involvement

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

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 5-x?

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

Your answer

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).

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

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

The intervention was reminders.

"SMS reminders in both English and Lugbara (the most common local language spoken in Arua) were then automatically scheduled to be sent from DHIS2 Tracker at 7am, first to an SMS aggregator in Uganda, then on to the appropriate Uganda telecommunications service providers, which in turn sent the SMS to the appropriate participants. Penta2 SMS reminders were sent two days before, on the day of, and two days after the scheduled vaccination visit. Penta3 and MCV SMS reminders were sent on the day of and five and seven days after the scheduled vaccination visits."

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).

subitem not at all important ☐ ☐ ☐ ☐ ☒ essential

Does your paper address subitem 5-xii? *

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

There was no co-intervention.

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

"For the primary objective, a logistic regression model with fixed effects at the health facility level will be used to analyze differences between intervention and control groups in Penta3 and MCV coverage at 12 months of age. For the assessment of timeliness, a logistic regression model with fixed effects at the health facility level will be used to analyze differences between intervention and control groups in Penta3 coverage 12 weeks after receipt of Penta1 and in MCV coverage at 10 months of age. In addition, at 12 weeks after Penta1, 10 months of age, and 12 months of age, Cox proportional hazards models with fixed effects at the health facility level will be used to analyze time-to-event (i.e., timeliness) outcome data. The primary analyses will be based on intention-to-treat, but per-protocol analysis will also be conducted. Dates of vaccination from HBRs will be used for analysis, supplemented with dates from the immunization register extraction if HBR dates are unavailable."

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES it

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

subitem not at all
important

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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Your answer

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measure

Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

subitem not at all
important

☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Your answer

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

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

subitem not at all
important

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essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Your answer

6b) Any changes to trial outcomes after the trial commenced, with reasons**Does your paper address CONSORT subitem 6b? ***

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

No changes to report. Keep in mind that this is the protocol manuscript, not a manuscript reporting the effectiveness.

7a) How sample size was determined

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

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

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

subitem not at all
important

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essential

Does your paper address subitem 7a-i?

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

Your answer

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

"The proposed research was minimal risk and did not present significant concerns regarding ethical treatment of study participants."

"Study participants were provided details on how they could opt-out of the study at any point and thus be removed from receiving SMS reminders."

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

"At the end of each day, study participants who were registered that day were randomized by computer using stratified permuted block randomization to either the control or the intervention arm, which was then recorded in the database as well. For randomization assignment, study participants were matched in order of registration to a sequence that was generated by non-field study personnel prior to the start of enrollment. Stratification and blocking occurred at the health facility level; blocks of random size were used (lengths = 2, 4, and 6) to minimize the ability to predict the next assignment. The health worker, study personnel, and participants were blinded to the randomization at 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

"At the end of each day, study participants who were registered that day were randomized by computer using stratified permuted block randomization to either the control or the intervention arm, which was then recorded in the database as well. For randomization assignment, study participants were matched in order of registration to a sequence that was generated by non-field study personnel prior to the start of enrollment. Stratification and blocking occurred at the health facility level; blocks of random size were used (lengths = 2, 4, and 6) to minimize the ability to predict the next assignment. The health worker, study personnel, and participants were blinded to the randomization at assignment."

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

"At the end of each day, study participants who were registered that day were randomized by computer using stratified permuted block randomization to either the control or the intervention arm, which was then recorded in the database as well. For randomization assignment, study participants were matched in order of registration to a sequence that was generated by non-field study personnel prior to the start of enrollment. Stratification and blocking occurred at the health facility level; blocks of random size were used (lengths = 2, 4, and 6) to minimize the ability to predict the next assignment. The health worker, study personnel, and participants were blinded to the randomization at assignment."

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

"At the end of each day, study participants who were registered that day were randomized by computer using stratified permuted block randomization to either the control or the intervention arm, which was then recorded in the database as well. For randomization assignment, study participants were matched in order of registration to a sequence that was generated by non-field study personnel prior to the start of enrollment. Stratification and blocking occurred at the health facility level; blocks of random size were used (lengths = 2, 4, and 6) to minimize the ability to predict the next assignment. The health worker, study personnel, and participants were blinded to the randomization at assignment."

"Study personnel who were stationed in the selected health facilities explained the study, obtained consent and enrolled the eligible caregivers who accepted to participate in the study."

CDC generated the random allocation sequence. Study personnel enrolled the participants. A computer assigned participants to interventions.

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

essential

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

"The health worker, study personnel, and participants were blinded to the randomization at assignment. However, unblinding of the intervention group occurred at the time when they received the first SMS reminder. The control group became unblinded as they realized that they were not receiving SMS reminders. Upon occasion, study participants shared their intervention status with health workers and field-level study personnel, thus unblinding them to the status of some caregivers. Non-field staff study personnel who managed the database had access to intervention status after randomization assignment."

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

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”.

subitem not at all
important

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essential

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

No applicable.

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

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

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

"For the primary objective, a logistic regression model with fixed effects at the health facility level will be used to analyze differences between intervention and control groups in Penta3 and MCV coverage at 12 months of age. For the assessment of timeliness, a logistic regression model with fixed effects at the health facility level will be used to analyze differences between intervention and control groups in Penta3 coverage 12 weeks after receipt of Penta1 and in MCV coverage at 10 months of age. In addition, at 12 weeks after Penta1, 10 months of age, and 12 months of age, Cox proportional hazards models with fixed effects at the health facility level will be used to analyze time-to-event (i.e., timeliness) outcome data. The primary analyses will be based on intention-to-treat, but per-protocol analysis will also be conducted. Dates of vaccination from HBRs will be used for analysis, supplemented with dates from the immunization register extraction if HBR dates are unavailable. Data will be analyzed using statistical software such as STATA, SAS, or R."

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]).

subitem not at all
important

essential

Does your paper address subitem 12a-i? *

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

"The primary analyses will be based on intention-to-treat, but per-protocol analysis will also be conducted. Dates of vaccination from HBRs will be used for analysis, supplemented with dates from the immunization register extraction if HBR dates are unavailable."

"Data quality control was addressed at multiple stages. The first stage of quality control was by the data collectors themselves. Adequate training minimized the risk of procedural errors. Furthermore, questionnaires were formatted electronically, which limited the amount of missing data as logic patterns required the study personnel to enter all required fields. The electronic tools required the data collector to input values for each field. The second level of control was the local study coordinator. During data collection, the study coordinator ensured proper sampling and interviewing through daily periodic spot checks in the course of data gathering. The study coordinator reviewed the data entered by the data collectors and then locked each record, after which it was no longer modifiable by the data collectors. The third level of control was the principal investigator who reviewed the data to ensure that 1) the sample size was reached, 2) the eligibility requirements of each participant were met, and 3) blanks or partially completed forms were minimized."

Partially completed forms of participants who are interviewed is not expected to be a problem due electronic data entry fields requiring study personnel to enter all required fields. Interviewed participants with missing vaccination dates will be treated as unvaccinated for intention-to-treat analyses.

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses**Does your paper address CONSORT subitem 12b? ***

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

Not applicable for the manuscript protocol.

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)**X26-i) Comment on ethics committee approval**

subitem not at all
important

essential

Does your paper address subitem X26-i?

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

Your answer

x26-ii) Outline informed consent procedures

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

subitem not at all
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Does your paper address subitem X26-ii?

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

Your answer

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)

subitem not at all
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Does your paper address subitem X26-iii?

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

Your answer

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

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

Not applicable for the manuscript protocol.

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

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate 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 for the manuscript protocol.

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.

subitem not at all
important

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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

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

"Enrollment began in February 2016 and concluded in August 2016. The pre-intervention questionnaire was applied during enrollment. SMS reminders were sent to the intervention group between February 2016 and April 2017. Follow-up interviews of study participants, including data extraction from the children's vaccination cards, and focus group discussions occurred between September 2016 and December 2017. Data extraction from the health facility immunization registers, completion of the health facility records review forms and costs data collection occurred between January 2016 and September 2017. "

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

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essential

Does your paper address subitem 14a-i?

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

Your answer

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *

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

Not applicable.

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

Not applicable for the manuscript protocol.

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.

subitem not at all
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Does your paper address subitem 15-i? *

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

Not applicable for the manuscript protocol.

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

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

subitem not at all
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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

Not applicable for the manuscript protocol.

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

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

subitem not at all
important

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essential

Does your paper address subitem 16-ii?

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

Your answer

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

Not applicable for the manuscript protocol.

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).

subitem not at all
important

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essential

Does your paper address subitem 17a-i?

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

Your answer

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

Does your paper address CONSORT subitem 17b? *

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

Not applicable for the manuscript protocol.

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

Not applicable for the manuscript protocol.

18-i) Subgroup analysis of comparing only users

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

subitem not at all
important

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Does your paper address subitem 18-i?

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

Your answer

19) All important harms or unintended effects in each group

(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

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

Not applicable for the manuscript protocol.

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

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essential

Does your paper address subitem 19-i?

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

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.

subitem not at all
important

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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

22-i) Restate study questions and summarize the answers suggested by the data, starting with p

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

subitem not at all
important

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Does your paper address subitem 22-i? *

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

Not applicable for the manuscript protocol.

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

subitem not at all
important

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☐

essential

Does your paper address subitem 22-ii?

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

Your answer

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses**20-i) Typical limitations in ehealth trials**

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

subitem not at all
important

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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

Not applicable for the manuscript protocol.

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

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 21-i?

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

Your answer

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

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.

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 21-ii?

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

Your answer

OTHER INFORMATION**23) Registration number and name of trial registry****Does your paper address CONSORT subitem 23? ***

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

"Clinicaltrials.gov NCT04177485;
https://clinicaltrials.gov/ct2/show/NCT04177485"

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

Does your paper address CONSORT subitem 24? *

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

Not applicable.

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

Does your paper address CONSORT subitem 25? *

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

"we would like to thank the Bill and Melinda Gates Foundation for their financial support (grant number OPP1038011)"

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.

subitem not at all
important

essential

Does your paper address subitem X27-i?

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

Your answer

About the CONSORT EHEALTH checklist

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

- ☐ yes, major changes
- ☒ yes, minor changes
- ☐ no

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

Your answer

How much time did you spend on going through the checklist INCLUDING making changes in yo

5 hours

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

☒ yes

☐ no

☐ Other:

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

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

☐ yes

☐ no

☐ Other:

Any other comments or questions on CONSORT EHEALTH

Your answer

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