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
Ditte S Linde

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

Your e-mail address *
abc@gmail.com
dsondergaard@health.sdu.dk

Title of your manuscript *
Provide the (draft) title of your manuscript.
One-way text messages versus no text messages on attendance to follow-up cervical cancer screening among HPV-positive Tanzanian Women (Connected2Care): a parallel-group 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.
Connected2Care

Evaluated Version (if any)
e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

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

English, Kiswahili

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.

http://connected2care.org

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:

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)"

Cervical cancer (HPV-positive screening)
Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

Attendance to follow-up screening

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

Knowledge, barriers for screening attendance

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:

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)
- JMI R mHealth and UHealth
- JMI R Serious Games
- JMI R Mental Health
- JMI R Public Health
- JMI R Formative Research
- Other JMI R 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 JMI R 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 JMI R. If the paper is already published in JMI R, 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 JMI R)

- no ms number (yet) / not (yet) submitted to / published in JMI R
- Other:
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.

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").

https://docs.google.com/forms/d/e/1FAIpQLSIZBSUp1bwOc_OimqcS64RdfIAFvmsTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGlKd2Z2Q1l...
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
"versus no text messages"

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

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
"follow-up cervical cancer screening among HPV-positive Tanzanian Women"

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

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

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT
Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)
Does your paper address subitem 1b-i? *

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

"The intervention group received one-way text messages, and the control group received no text messages."

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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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

No. It is described in the methods sections of the article but not directly in the abstract as it is implicit.

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

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

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Does your paper address subitem 1b-iii?

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

"Participants were not blinded but outcome assessors were"

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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essential

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

"705 were included into this trial; 358 were allocated to the intervention group and 347 to the control group."

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 important

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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

No
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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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

"Connected2Care is a sub-study of a larger research study, Comprehensive Cervical Cancer Prevention in Tanzania (CONCEPT). The CONCEPT study is linked to the existing national cervical cancer screening programmes in Dar es Salaam and Kilimanjaro and will end in December 2021."

"One-way text message interventions – also referred to as one-way short messages service (SMS) – involve sending text messages to a recipient who cannot respond to the text message."

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 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.

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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

"The advantages of text messages are that they are easy to use, can be sent to the receivers simultaneously, and they require less staff. A recent systematic review and meta-analysis of one-way text message trials in Africa showed that one-way text messages have been tested within different clinical areas across Africa, though mainly in relation to medicine adherence and appointment attendance. The effect of one-way text messages varied across clinical areas, and overall the highest effect was found in relation to increasing attendance to a childhood immunization appointment[10]. In relation to cervical cancer screening attendance, a systematic review from 2017 concerning text message interventions on cancer screening rates[11], found one trial from Malaysia with no effect of one-way text messages improving attendance to a repeat cervical smear compared to postal letters[12]. However, recent trials from Tanzania and Kenya have shown that one-way text messages increased attendance to cervical cancer screening among screening-naïve women[13] and a repeat cervical smear[14] compared to no text messages. Yet, it is still unknown whether or not one-way text messages can increase the attendance rate of HPV-positive women who have been appointed a follow-up screening."

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

"The aim of this study (Connected2Care) was to assess the effect of one-way text messages on attendance to a provider-initiated follow-up screening appointment among women who had tested HPV-positive during a patient-initiated opportunistic screening 14 months earlier. In addition, we examined factors associated with attendance regardless of group allocation."

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.

"Connected2Care is an unblinded, multi-centre, parallel-group randomized controlled trial (RCT)"

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.

"Post-hoc we exploratively assessed factors that were associated with attendance, i.e. number of text messages received and socio-demographic characteristics, as well as assessed how attendance was increased post-intervention period via phone calls and home visits. Pre-specified secondary outcomes included the cost-effectiveness of the intervention; the intervention's effect on knowledge of cervical cancer and screening (16 item true-false questionnaire); and barriers against implementing a text message intervention in Tanzania (mixed method study). The secondary outcomes, cost-effectiveness and knowledge, have not been assessed, and barriers against implementation have been assessed in a qualitative post-invention study together with factors that influence screening attendance. The latter objective have been published elsewhere[17] whilst data on barriers related to the text message intervention is yet to be published."

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 1 2 3 4 5 essential
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

"Six months into the study – after enrolment of 38 participants – we discovered that the SMS system did not dispatch the text messages as according to the study plan. We reassigned 38 participants into a new SMS system (www.connected2care.org), and they stayed in the groups they were originally allocated to[15]. We conducted a post-hoc sensitivity analysis excluding these women and another post-hoc analysis excluding 16 participants who were misclassified as HPV-positive and erroneously included into the study."

"We encountered several obstacles while conducting this trial. Firstly, we had to switch to a new SMS system six months into trial due to the first system being unreliable. However, our sensitivity analysis found no difference in effect among the participants who had been enrolled using the first system. Secondly, a number of women were misclassified as HPV-negative or -positive in the process of transferring the laboratory reports to the CONCEPT investigators. This led to a number of women being incorrectly excluded from or included into the trial. The sensitivity analysis of the incorrectly included women showed no difference in results. Even though these issues are study-specific, they highlight a need for incorporating secure procedures when implementing a more complex screening method such as rapid HPV-testing in a setting like Tanzania."

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

"Women 25-60 years of age, who attended a patient-initiated cervical cancer screening at the study sites, were assessed by a screening nurse for overall eligibility to participate in the CONCEPT study. Eligible women gave written informed consent. Exclusion criteria were pregnancy or menstruation on day of enrolment, previous hysterectomy, cervical cancer or diagnosis of cervical precancerous lesions within the past 12 months. The sub-group of CONCEPT participants, who tested high-risk HPV-positive at the enrolment screening, were assessed for eligibility to be further included into the Connected2Care study. Women were ineligible for inclusion into Connected2Care if they did not own a private mobile phone, had provided an invalid phone number (i.e. digits missing) or were not informed of their positive HPV test result. Ineligible women were excluded prior to randomisation."

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 1 2 3 4 5 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

No relevant for this study as it is a text message intervention.

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

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

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

"Women 25-60 years of age, who attended a patient-initiated cervical cancer screening at the study sites, were assessed by a screening nurse for overall eligibility to participate in the CONCEPT study."

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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1 2 3 4 5 essential
"Eligible women were assigned an anonymous study id and interviewed by a trained nurse using a structured questionnaire. The nurse also registered their home address and phone numbers as well as provided general cervical cancer screening education and counselling as according to the national guidelines for cervical cancer screening in Tanzania."

"Eligible women gave written informed consent."

"Finally, the women were told that they may receive health educative and reminder text messages before their next screening appointment."

"Data sharing statement
All data collected for the Connected2Care study are available upon request. Individual participant data will de-identified. Additional available data includes the CONCEPT protocol, the CONCEPT eligibility and informed consent form, the CONCEPT contact information form, the CONCEPT baseline questionnaire, the protocol for how to deliver HPV-positive results to participants, the protocol for how to trace non-attendants, statistical analyses, and the content of all the text messages for the trial – in Kiswahili and English. Data will be made available upon request by contacting the first author of the study by email at dsondergaard@health.sdu.dk, who will then seek approval by the primary investigator in the CONCEPT project, Julius D. Mwaiselage."

"Connected2Care is an unblinded, multi-centre, parallel-group randomized controlled trial (RCT) conducted at three hospitals in Tanzania: Ocean Road Cancer Institute (ORCI) in Dar es Salaam, and Kilimanjaro Christian Medical Centre (KCMC) and Mawenzi Regional Hospital in Moshi. Originally, the study was designed as a double-site study (ORCI/KCMC); however, due to a slower-than-expected recruitment rate, a third study site (Mawenzi Regional Hospital) was added six months into the recruitment phase."
4b-i) Report if outcomes were (self-)assessed through online questionnaires

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

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Does your paper address subitem 4b-i? *

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

"Due to the overt nature of the text message intervention, the study participants were not concealed to their group allocation. Yet, the outcome assessors – in the form of screening nurses registering the attendance date – were blinded."

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)

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Does your paper address subitem 4b-ii?

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

Not relevant as the intervention is one-way text messages.

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

"An online text message portal (www.connected2care.org) – developed specifically for this study – automatically dispatched the messages and sent them with the id “Elimu Ya Afya” (meaning “health education” in Kiswahili)."

"We would also like to thank Andreas Hover Lundh for commenting upon the manuscript, Pia Veldt Larsen for statistical support, and Yusuph Kassim for developing SMS-system and providing technical support for the system throughout the trial."

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 | 1 | 2 | 3 | 4 | 5 | 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

"The sender id, content, timing, and number of text messages were pre-tested on screening clients as well as on screening nurses prior to the intervention starting. The rationale behind combining health education and reminders was that health education would enhance the perceived seriousness of the disease as well as the benefit of the screening and combined with reminders they would be cues to actions for screening attendance. The messages were not personalized out of privacy concerns, and they were developed in English and translated into Kiswahili using back-forth translation"

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 | ☐ | ☐ | ☐ | ☒ | ☐ | essential |

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

"An online text message portal (www.connected2care.org) – developed specifically for this study – automatically dispatched the messages and sent them with the id “Elimu Ya Afya” (meaning “health education” in Kiswahili). The portal had a ‘delivery note feature’, which showed the discrepancy between the number of text messages sent and the number received."

"Six months into the study – after enrolment of 38 participants – we discovered that the SMS system did not dispatch the text messages as according to the study plan. We reassigned 38 participants into a new SMS system (www.connected2care.org), and they stayed in the groups they were originally allocated to"
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 important: [ ]
subitem important: [ ]
subitem essential: [ ]

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

No

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.

subitem not at all important: [ ]
subitem important: [ ]
subitem 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.

Examples of content of text message intervention are given (figure 1) and under the "Data sharing statement" it is stated that all content is available upon request. The actual source code of the sms dispatching system is not available as all researchers are also blind to this.
5-vi) Digital preservation

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

1 2 3 4 5
subitem not at all important

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

"An online text message portal (www.connected2care.org) – developed specifically for this study – automatically dispatched the messages and sent them with the id “Elimu Ya Afya” (meaning “health education” in Kiswahili)."

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 “back door” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

1 2 3 4 5
subitem not at all important

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

"An online text message portal (www.connected2care.org) – developed specifically for this study – automatically dispatched the messages and sent them with the id “Elimu Ya Afya” (meaning “health education” in Kiswahili)."
5-viii) Mode of delivery, features-functionalities/components of the intervention and comparator, and the theoretical framework

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

Does your paper address subitem 5-viii? *

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

"An online text message portal (www.connected2care.org) – developed specifically for this study – automatically dispatched the messages and sent them with the id “Elimu Ya Afya” (meaning “health education” in Kiswahili)."

"The sender id, content, timing, and number of text messages were pre-tested on screening clients as well as on screening nurses prior to the intervention starting. The rationale behind combining health education and reminders was that health education would enhance the perceived seriousness of the disease as well as the benefit of the screening and combined with reminders they would be cues to actions for screening attendance. The messages were not personalized out of privacy concerns, and they were developed in English and translated into Kiswahili using back-forth translation."

"Despite the fact that we pilot-tested the text messages prior to the trial starting, it is plausible that use of a health behaviour theoretical framework and further pilot testing of the intervention and the text messaging portal could have addressed some of the study challenges."
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.

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

Does your paper address subitem 5-ix?

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

"Over a period of 10 months, 10 health educative messages and five reminders were sent to the women in the intervention 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).

| Item | 1 | 2 | 3 | 4 | 5 |
|------|---|---|---|---|---|
| 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.

"The first author (DSL) assigned participants to the trial by uploading the phone numbers of the eligible participants into the text messaging system"

"The random sequence generation was developed by the external IT-consultant, who developed the text messaging system, and it was concealed to all investigators."
5-\textit{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 | 1 | 2 | 3 | 4 | 5 | essential |
|-----------------------------|---|---|---|---|---|-----------|

\textbf{Does your paper address subitem 5-\textit{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

"Over a period of 10 months, 10 health educative messages and five reminders were sent to the women in the intervention group. The health educative messages were sent once a month and contained information about screening, risk factors, and symptoms for cervical cancer (Figure 1). The reminders were sent 14, seven, and one day prior to the 14-months follow-up screening appointment as well as one and seven days post the appointment date"

5-\textit{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 | 1 | 2 | 3 | 4 | 5 | essential |
|-----------------------------|---|---|---|---|---|-----------|

\textbf{Does your paper address subitem 5-\textit{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

Not applicable.
Does your paper address CONSORT subitem 6a? *

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

"The primary outcome was attendance to a health provider-initiated follow-up screening at 14-months. It was measured as whether or not the participants attended the follow-up screening within 30 days of their screening appointment. Pre-specified secondary outcomes included the cost-effectiveness of the intervention; the intervention's effect on knowledge of cervical cancer and screening (16 item true-false questionnaire); and barriers against implementing a text message intervention in Tanzania (mixed method study). The secondary outcomes, cost-effectiveness and knowledge, have not been assessed, and barriers against implementation have been assessed in a qualitative post-intervention study together with factors that influence screening attendance. The latter objective have been published elsewhere[17] whilst data on barriers related to the text message intervention is yet to be published. "

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

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

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Not applicable.

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/adoptions metrics are important process outcomes that should be reported in any eHealth trial.
Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

"An online text message portal (www.connected2care.org) – developed specifically for this study – automatically dispatched the messages and sent them with the id “Elimu Ya Afya” (meaning “health education” in Kiswahili). The portal had a ‘delivery note feature’, which showed the discrepancy between the number of text messages sent and the number received."

"The SMS dispatching system showed that all participants in the intervention group received at least one of the 15 text messages sent to them; 8% (n=26) received between 1-4 text messages, and 32% (n=111) received all 15 text messages (Table 2)."

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 | 1 | 2 | 3 | 4 | 5 |
|-----------------------------|---|---|---|---|---|
|                             | ○ | ○ | ○ | ○ | ● |

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

"Post-hoc we exploratively assessed factors that were associated with attendance, i.e. number of text messages received and socio-demographic characteristics, as well as assessed how attendance was increased post-intervention period via phone calls and home visits."

"Thirdly, the attendance rate was much lower than what we had anticipated, which led us to part from some of our originally pre-planned secondary outcomes and examine what affects attendance in more detail. However, we clearly specified which analyses and results were conducted post-hoc in order not to hypothesize after the results were known (i.e. avoid HARKing)[21]."

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.

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

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_OimqcS64RdfIAFvmtTskZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGIKd22ZQ... 29/53
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

"The sample size was calculated based on the methods described by Altman[18]. We estimated that the intervention would increase the attendance rate with 15 points, and that 73% in the intervention group and 58% in the control group would attend their follow-up appointment. With an allocation ratio of 1:1, a two-sided □ of 5% and 80% power, we required approximately 350 participants in each arm. At the time of design, no other text message interventions on cervical cancer had been conducted in Africa, and the estimation was based on the effect of mHealth interventions found within other clinical areas in Eastern Africa[19, 20]."

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

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

No interim analyses were conducted. Not stated in manuscript.

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The random sequence generation was developed by the external IT-consultant, who developed the text messaging system, and it was concealed to all investigators. Screening nurses enrolled participants and were concealed to the latter group allocation."
8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Participants were randomly assigned to the intervention or control group with a 1:1 ratio."

"parallel-group randomized controlled trial"

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

Does your paper address CONSORT subitem 9? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The random sequence generation was developed by the external IT-consultant, who developed the text messaging system, and it was concealed to all investigators. Screening nurses enrolled participants and were concealed to the latter group allocation."

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

"Participants were randomly assigned to the intervention or control group with a 1:1 ratio. The randomisation occurred through an incorporated algorithm in the text message system, which automatically assigned participants to the intervention or control group. The random sequence generation was developed by the external IT-consultant, who developed the text messaging system, and it was concealed to all investigators."

"The first author (DSL) assigned participants to the trial by uploading the phone numbers of the eligible participants into the text messaging system and was not concealed to the group allocation."

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

1 2 3 4 5
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

"Screening nurses enrolled participants and were concealed to the latter group allocation."

"The first author (DSL) assigned participants to the trial by uploading the phone numbers of the eligible participants into the text messaging system and was not concealed to the group allocation. Due to the overt nature of the text message intervention, the study participants were not concealed to their group allocation. Yet, the outcome assessors – in the form of screening nurses registering the attendance date – were blinded."

"The random sequence generation was developed by the external IT-consultant, who developed the text messaging system, and it was concealed to all investigators."

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

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

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

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

"Due to the overt nature of the text message intervention, the study participants were not concealed to their group allocation."

"Due to lack of blinding of participants, there is a risk of performance bias and risk of contamination, which could have affected the internal validity of the trial[22]."
11b) If relevant, description of the similarity of interventions

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

Does your paper address CONSORT subitem 11b? *

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

Not applicable.

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

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

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

"We calculated a risk ratio to determine if the proportion of participants who attended their follow-up screening differed between groups and used a relative risk regression by use of a generalised linear model with log-link function and binomial distribution as statistical family."

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

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

1 2 3 4 5

subitem not at all important

essential
15.8.2019

**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.

"After randomisation, four participants in each group developed cervical cancer and four from each group died from the disease (n=16). These participants were excluded from the analysis, leaving 689 women for analysis."

**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.

"In subgroup analyses, we assessed if the intervention had differential effect across subgroups by including an interaction term between the intervention allocation and a subgroup defining variable."

"In subgroup analyses, we assessed if the intervention had differential effect across subgroups by including an interaction term between the intervention allocation and a subgroup defining variable."

**X26) REB/IRB Approval and Ethical Considerations**

[recommended as subheading under "Methods"] (not a CONSORT item)

**X26-i) Comment on ethics committee approval**

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

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

"The study protocol has been published elsewhere[15], and joined ethical approval for all study sites was obtained from the National Institute for Medical Research in Tanzania."

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

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

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

"Eligible women gave written informed consent."

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 | ☐ | O essential |
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? *

"Altogether 4080 women were enrolled into the CONCEPT study. Of these, 705 were included into Connected2Care (Figure 2). After randomisation, four participants in each group developed cervical cancer and four from each group died from the disease (n=16). These participants were excluded from the analysis, leaving 689 women for analysis."

"The intervention and control group were comparable (Table 1), and the primary analysis showed that the intervention had no effect on attendance to a follow-up screening appointment; 24% attended in both the intervention (n=84/350) and in the control group (n=80/339); (RR: 1.02; 95% CI: 0.79-1.33)."

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

"After randomisation, four participants in each group developed cervical cancer and four from each group died from the disease (n=16). These participants were excluded from the analysis, leaving 689 women for analysis."

See figure 2: Flow chart of trial

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 | 1 | 2 | 3 | 4 | 5 | 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

"The SMS dispatching system showed that all participants in the intervention group received at least one of the 15 text messages sent to them; 8% (n=26) received between 1-4 text messages, and 32% (n=111) received all 15 text messages (Table 2). When examining factors potentially associated with attendance to screening, we found that the number of text messages received did not appear to affect the attendance rate."

See table 2.
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

"Study participants were enrolled into the study between 17 August 2015 and 6 July 2017, and the follow-up ended by 6 October 2018."

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”

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

Does your paper address subitem 14a-i?

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

Not applicable.

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.

See "Table 1: Baseline characteristics"

15-i) Report demographics associated with digital divide issues

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

1 2 3 4 5

subitem not at all important

essential

Does your paper address subitem 15-i? *

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

See "Table 1: Baseline characteristics"

See "Table 2: Factors associated with attendance"

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

16-i) Report multiple “denominators” and provide definitions

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

1 2 3 4 5

subitem not at all important

essential
Does your paper address subitem 16-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The intervention and control group were comparable (Table 1), and the primary analysis showed that the intervention had no effect on attendance to a follow-up screening appointment; 24% attended in both the intervention (n=84/350) and in the control group (n=80/339); (RR: 1.02; 95% CI: 0.79-1.33)."

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

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subitem not at all important

1 2 3 4 5 essential
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Does your paper address subitem 16-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The analysis was intention-to-treat (ITT)"

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The intervention and control group were comparable (Table 1), and the primary analysis showed that the intervention had no effect on attendance to a follow-up screening appointment; 24% attended in both the intervention (n=84/350) and in the control group (n=80/339); (RR: 1.02; 95% CI: 0.79-1.33)."

See "Figure 3. Forrest plot of subgroup analysis"
17a-i) Presentation of process outcomes such as metrics of use and intensity of use

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

Does your paper address subitem 17a-i?

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

No

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

"The intervention and control group were comparable (Table 1), and the primary analysis showed that the intervention had no effect on attendance to a follow-up screening appointment; 24% attended in both the intervention (n=84/350) and in the control group (n=80/339); (RR: 1.02; 95% CI: 0.79-1.33)."

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

See "Figure 3. Forrest plot of subgroup analysis"

See "Table 2: Factors associated with attendance"

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).

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

Not applicable.

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
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 | 1 | 2 | 3 | 4 | 5 | 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.

"Six months into the study – after enrolment of 38 participants – we discovered that the SMS system did not dispatch the text messages as according to the study plan. We reassigned 38 participants into a new SMS system (www.connected2care.org), and they stayed in the groups they were originally allocated to[15]. We conducted a post-hoc sensitivity analysis excluding these women and another post-hoc analysis excluding 16 participants who were misclassified as HPV-positive and erroneously included into the study. The sensitivity analysis for the SMS-system (RR: 0.95; 95% CI: 0.71-1.26) and misclassifications (RR: 0.98; 95% CI: 0.75-1.29) showed similar results as our main analysis."

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 | 1 | 2 | 3 | 4 | 5 | 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

"Pre-specified secondary outcomes included ... barriers against implementing a text message intervention in Tanzania (mixed method study)."

"...data on barriers related to the text message intervention is yet to be published."

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).

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

"Principal results
This trial shows that one-way text messages did not improve the attendance rate to a health provider-initiated follow-up cervical cancer screening among HPV-positive women. Overall, one-fourth of the participants attended their follow-up screening regardless of whether or not they had received text messages. Hence, the barrier of getting women to return to the clinic was not one which one-way text messages appeared to overcome. Not all text messages dispatched were received among the intervention group, yet the number of messages received did not affect the attendance rate. Once the trial had finished an additional 22% of women attended the clinic after a nurse had called them and 2% attended after a nurse home-visit. Of the remaining non-attendees, a further 30% participated via home visit and self-sampling, which led to a total follow-up rate of 78%.

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

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

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Does your paper address subitem 22-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The outcome of our trial is highly relevant, both in a larger mHealth context and in relation of how to address the cervical cancer burden in East Africa. Rapid HPV-testing is an area that has potential to improve prevention of the disease, however, this trial shows that implementation of rapid HPV-testing leads to the challenge of providing proper follow-up of the women who test HPV-positive. This is an issue which policy makers and global health clinicians should be aware of in relation to implementing rapid HPV-testing as a primary screening method in future cervical cancer screening programs in Africa. Our post-trial follow-up strategy indicates that phone calls where nurses engage with the women and emphasise the importance of re-attendance, may be more effective than a one-way text message intervention."

"How best to implement rapid HPV-tests, the overall care pathway for HPV-positive women, and the potential of phone call reminders for cervical cancer follow-up are areas worth exploring in future studies in Africa."

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

https://docs.google.com/forms/d/e/1FAIpQLSfZBSUp1bwOc_OimqeqS64RdfAFvmrTSkZQL2-3O8O9hrL5Sw/viewform?hl=en_US&formkey=dGIkKdZ2Q... 47/53
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

"Limitations
We encountered several obstacles while conducting this trial. Firstly, we had to switch to a new SMS system six months into trial due to the first system being unreliable. However, our sensitivity analysis found no difference in effect among the participants who had been enrolled using the first system. Secondly, a number of women were misclassified as HPV-negative or -positive in the process of transferring the laboratory reports to the CONCEPT investigators. This led to a number of women being incorrectly excluded from or included into the trial. The sensitivity analysis of the incorrectly included women showed no difference in results. Even though these issues are study-specific, they highlight a need for incorporating secure procedures when implementing a more complex screening method such as rapid HPV-testing in a setting like Tanzania. Thirdly, the attendance rate was much lower than what we had anticipated, which led us to part from some of our originally pre-planned secondary outcomes and examine what affects attendance in more detail. However, we clearly specified which analyses and results were conducted post-hoc in order not to hypothesize after the results were known (i.e. avoid HARKing)[21]. Despite the fact that we pilot-tested the text messages prior to the trial starting, it is plausible that use of a health behaviour theoretical framework and further pilot testing of the intervention and the text messaging portal could have addressed some of the study challenges.

Due to lack of blinding of participants, there is a risk of performance bias and risk of contamination, which could have affected the internal validity of the trial[22]. To preserve privacy, we did not personalize the text messages, and we excluded women who did not own a private mobile phone. However, this exclusion criterion affects the external validity of the trial as the participants may not represent the target population. Despite our effort to ensure privacy for the study participants, we cannot guarantee that the participants found the messages confidential enough. If this was an issue, it could have affected the acceptability and effectiveness of the messages. Our explorative subgroup analysis indicated that HIV-status may be a potential effect modifier. However, our trial was not dimensioned to assess differential effects across subgroups, and it is likely an artefact of the data and a false discovery rather than HIV-status modifying the relationship between text messages and follow-up."
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

|   | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| 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

"To preserve privacy, we did not personalize the text messages, and we excluded women who did not own a private mobile phone. However, this exclusion criterion affects the external validity of the trial as the participants may not represent the target population."

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

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

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

Not described.
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

"Trial registration: ClinicalTrials.gov; NCT02509702."

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

"The study protocol has been published elsewhere[15]."

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

"Role of the funding source
The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. DSL, JDM, and VR had access to all the data in the study, and DSL had the final responsibility for the decision to submit for publication."

"Acknowledgements
The study is funded by the Danish International Development Agency (Danida; 14-P02-Tan/A26775) and the University of Southern Denmark (internal funds)."
X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

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

1 2 3 4 5

subitem not at all important

essential

Does your paper address subitem X27-i?

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

"Declaration of Interests

There are no competing interests for any of the authors."

Further, we have attached ICMJE forms for all co-authors.

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?

Reflected upon other elements that could have been described in further detail in the manuscript.
How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

3-4 hrs

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

This checklist is highly important, however, some elements overlap, and it is very time consuming to fill in. Consider simplifying structure by only making sub-questions appear if they are applicable to the intervention. Many questions relate to internet and EHEALTH overall, and it would have been nice with questions that were more applicable specifically to MHEALTH as this is the intervention of this trial.
STOP - Save this form as PDF before you click submit

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