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
JMIR 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/

Your response is too large. Try shortening some answers.
doi: 10.2196/jmir.1923
PMID: 22209829

thomas2709@gmail.com (not shared) Switch account
Resubmit to save

* Required

Your name *
First Last

Thomas Günzow

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University of Toronto, Toronto, Canada

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Your e-mail address *

abc@gmail.com

thomas.gultzow@maastrichtuniversity.nl

Title of your manuscript *
Provide the (draft) title of your manuscript.

Does an Explicit Value Clarification Method with Computer-Tailored Advice Increase the Effectiveness of a Web-Based Smoking Cessation Decision Aid? Findings From a Randomized Controlled Trial.
Name of your App/Software/Intervention *
If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

VISOR

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")

Dutch

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

https://www.visor-keuzehulp.nl

URL of an image/screenshot (optional)

https://asset.jmir.pub/assets/4635c4381fdd0e35d802117e44bfb8f0.png (original text transl...
### 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: Was accessible for the RCT only at this stage

### 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)"

Smoking (cessation)

### Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

7-day point prevalence abstinence 6 months post baseline

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

7-day point prevalence abstinence 1 month post baseline, evidence-based cessation assistance use, and decisional conflict

Your response is too large. Try shortening some answers.
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: One-time use

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: n/a

Your response is too large. Try shortening some answers.
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: Only when assumed that all dropout respondents still smoke

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:

Your response is too large. Try shortening some answers.
Journal *
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

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

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

- Pilot/feasibility
- Fully powered

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

- no ms number (yet) / not (yet) submitted to / published in JMIR
- Other: JMIR 34246

TITLE AND ABSTRACT

Your response is too large. Try shortening some answers.
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.

- [ ] 1 (subitem not at all important)
- [ ] 2
- [ ] 3
- [ ] 4
- [ ] 5 (essential)

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

"Does an Explicit Value Clarification Method with Computer-Tailored Advice Increase the Effectiveness of a Web-Based Smoking Cessation Decision Aid? Findings From a Randomized Controlled Trial."
1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 1a-ii?

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

n/a; there are no co-interventions

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes")

Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

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subitem not at all important ○ ○ ○ ● ○ essential

Does your paper address subitem 1a-iii? *

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

"Does an Explicit Value Clarification Method with Computer-Tailored Advice Increase the Effectiveness of a Web-Based Smoking Cessation Decision Aid? Findings From a Randomized Controlled Trial.", ie, not developed for a certain condition, but for smoking (cessation)
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 a DA with the aforementioned elements [an 'explicit value clarification method' (VCM) paired with computer-tailored advice], the control group received the same DA without these elements. "

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)

Your response is too large. Try shortening some answers.
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.

"To test the added value of an effective element (ie, an 'explicit value clarification method' [VCM] paired with computer-tailored advice indicating the most fitting cessation assistance) of a web-based smoking cessation DA., ie, computer-tailored and web-based to indicate the online set-up of the intervention

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 indicate 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)

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

Clear selection

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 mainly recruited online (eg, social media). All data was self-reported." Also we clearly state throughout the abstract that the whole RCT and intervention was web-based.

Your response is too large. Try shortening some answers.
1b-iv) RESULTS section in abstract must contain use data

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

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Clear selection

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

"2375 participants were randomized (n = 1164 intervention, 49.01%), of which 599 completed the DAs (n = 275 intervention, 45.91%), and 276 (n = 143 intervention, 51.81%), 97 (n = 54 intervention, 55.67%), and 103 (n = 56 intervention, 54.37%) completed t=1, t=2 and t=3, respectively."

"Non-usage attrition was 34.19% higher in the intervention group than in the control group (P < .001)."

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)

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Clear selection

Your response is too large. Try shortening some answers.
"We cannot currently confidently recommend the inclusion of explicit VCMs and computer-tailored advice. In fact, they might result in higher non-usage attrition rates, thereby limiting their potential. Because a lack of statistical power may have influenced the outcomes, we recommend replicating this study with some adaptations based on lessons learned."

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

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

1. Subitem not at all important
2. Essential

Clear selection

Your response is too large. Try shortening some answers.
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

"[...] information about the effective elements of smoking cessation DAs is currently lacking and the only smoking cessation DA that has been studied in a Dutch context before [17] has shown a number of limitations: (1) was largely paper-based, thereby limiting widespread dissemination; (2) lacked an interactive design, even though interactivity has been shown to positively influence factors such as information comprehensibility and attitudinal beliefs [18,19] and; (3) did not explicitly include methods to help end users to become aware of what is important to them personally (in the DA-literature this is often referred to as value clarification [20]), even though this is regarded as an active DA-element [21,22]. Moreover, interestingly, this DA had a positive effect on smoking cessation success, but not on the uptake of cessation assistance [17]. Improving cessation assistance uptake might further increase the effectiveness of smoking cessation DAs [...]"

"VISOR was a stand-alone, one-time intervention meant to support adult smokers in the general population in their decision to use smoking cessation assistance and did not have to be used together with a healthcare professional."

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

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

subitem not at all important  ○  ○  ○  ◼  ○  essential

Clear selection

Your response is too large. Try shortening some answers.
"Previous studies showed that explicit VCMs seem to be more effective than implicit VCMs in terms of decision-making processes [23], especially in the long run [24] and when people are supported in understanding the implications of their clarified values [25,26]. One approach to facilitate understanding of the implication of clarified values is to show participants which options fit their clarified values best [25], eg, by providing computer-tailored advice based on answers provided in the explicit VCM. However, so far it has not been studied if the addition of explicit VCMs paired with such advice will also positively impact on smoking cessation outcomes. To advance our understanding of the effectiveness of smoking cessation DAs and to support more people in the Netherlands to quit smoking successfully, we have developed a web-based smoking cessation DA (called VISOR) that includes interactivity and an explicit VCM paired with computer-tailored advice and studied its effects in a randomized controlled trial (RCT)."
3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

"An RCT in line with the CONSORT-EHEALTH checklist was conducted [32].", 
[...] allocating approximately 50% of the respondents to either group."

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

See 2.7. Changes From the Study Protocol, section was too long to provide direct quotes

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].

1 2 3 4 5
subitem not at all important

Clear selection

Your response is too large. Try shortening some answers.
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

"Neither the DA received by the intervention group, nor the DA received by the control group changed throughout the trial."

"[...] due to a technical mistake, some participants who completed VISOR, but had not completed t=1 (directly after the decision aid), did not receive an automatic invite for the other follow-ups. When this mistake was discovered, some participants were already lost to follow-up. We dealt with this in 2 different ways: (1) People who had already missed t=2 but completed the DA in the 3 months prior to the discovery of the mistake received the invite to participate in t=2 regardless (n = 38 received this invitation, n = 3 made use of this); (2) people who already missed t=3 were still invited to participate in t=3 but not t=2 (n = 130 received the invitation, n = 5 made use of this)."

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

"Participants could be included if they were (1) currently smoking, (2) motivated to stop smoking within 6 months, (3) between 18–100 years old, (4) able to understand Dutch, and (5) had access to the internet and the necessary internet literacy (skills) to use the DA. The last 2 inclusion criteria were not actively screened for but were deemed inherent to participation. Participants were excluded if they did not meet these inclusion criteria and/or if they exclusively used e-cigarettes.*

4a-i) Computer / Internet literacy
Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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subitem not at all important ○ ○ ● ○ ○ essential

Your response is too large. Try shortening some answers.
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

"[...] and the necessary internet literacy (skills) to use the DA. The last 2 inclusion criteria were not actively screened for but were deemed inherent to participation."

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.

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

"As described in the study protocol [28] participants were mainly recruited online to reflect the online nature of VISOR and the entire trial was web-based (ie, there were no offline contacts)."

"30 accounts showed duplicate e-mail addresses; of those, only 8 were linked to accounts in both trial arms (ie, multiple accounts using the same e-mail address in each of the trial arms) and finished baseline with more than 1 account; of those only 2 participants filled in the follow-ups in such a way that they could have a distorting effect on the results (ie, they were first randomized into the intervention group, then in the control group and filled in the follow-ups as participants belonging to the control group even though they received the additional intervention elements) those were therefore adjusted, ie, the 'randomization variable' was changed to 1 = Intervention."
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.

Does your paper address subitem 4a-iii?

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

"Participants received no information regarding the differences between the intervention group and the control group as to not bias the results of the trial."

"Participants registered for the study via an online form, which included their provision of informed consent and the creation of an account."

Yes, see answers for 4b-i and 4b-ii
4b-i) Report if outcomes were (self-)assessed through online questionnaires

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

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

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

"All data were self-assessed."

4b-ii) Report how institutional affiliations are displayed

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

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

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

"All recruitment materials (eg, the project website) included a display of the project team's institutional affiliations in some form."

Your response is too large. Try shortening some answers.
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).

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subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 5-i?

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

"[...] VISOR was developed by a steering team (TG, ES, CD, and CH) that lead a development process [...]"

"The developers of the intervention (ie, TG, ES, CD, and CH) were also involved in this evaluation."

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.

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

Your response is too large. Try shortening some answers.
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.

"In accordance with the IPDAS guidelines for DA development [27,28], VISOR was developed by a steering team (TG, ES, CD, and CH) that lead a development process involving both professional experts and potential end users, eg, by assessing their needs and opinions before the initial development [29], and by conducting usability tests–this development process is described in detail elsewhere [28]."

The development has already been described in JMIR Research Protocols: https://doi.org/10.2196/21772

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).

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.

"Neither the DA received by the intervention group, nor the DA received by the control group changed throughout the trial."
5-iv) Quality assurance methods
Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

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

This is implicitly described by mentioning the professional experts that were involved in the development, e.g., "In accordance with the IPDAS guidelines for DA development [27,28], VISOR was developed by a steering team (TG, ES, CD, and CH) that lead a development process involving both professional experts [...]"

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

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subitem not at all important   ○   ○   ○   ○   ○
essential                      ○
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Your response is too large. Try shortening some answers.
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

We provide screenshots of different parts of the intervention, see answers earlier

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.

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

We provide screenshots of different parts of the intervention, see answers earlier

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

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

We provide screenshots of different parts of the intervention, see answers earlier
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

"[...] we used a project website with a direct access point to VISOR via a clickable button."

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

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Clear selection

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

The article includes two whole section on this; eg, 1.1 The smoking cessation DA VISOR

Your response is too large. Try shortening some answers.
5-ix) Describe use parameters

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

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subitem not at all important o o ○ o o essential Clear selection

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

"VISOR was a stand-alone, one-time intervention […]"

"Throughout the entire study, participants also received information on the duration of VISOR and the questionnaires."

5-x) Clarify the level of human involvement

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

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Your response is too large. Try shortening some answers.
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

"VISOR was a stand-alone, one-time intervention meant to support adult smokers in the general population in their decision to use smoking cessation assistance and did not have to be used together with a healthcare professional. That being said, VISOR could be used to prepare patients/clients for a healthcare consultation about smoking (cessation) and certain cessation assistance options (eg, prescription medication) did require a healthcare provider to prescribe said options. Therefore, if VISOR users chose to use a cessation assistance option that required prescription by a healthcare provider, they were advised to contact their healthcare provider to gain access to this specific option."

5-xi) Report any prompts/reminders used
Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

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

"Participants were asked to fill in each follow-up questionnaire if they made use of the entire DA, even when they did not fill in one of the other follow-up questionnaires. To avoid high attrition rates, participants received either 1 automatic reminder after a week (if they had not filled in a follow-up questionnaire at all) or 2 after 2 days and a week (if they already started filling in at least part of a follow-up questionnaire). Participants that started using VISOR or started filling in the baseline questionnaire (t=0) without finishing it also received 2 automatic reminders (after 2 days and a week)."
5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as eHealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

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Does your paper address subitem 5-xii? *

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

n/a; see our answer to 5-x

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

Your response is too large. Try shortening some answers.
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.

"After 1 and 6 month(s), participants were queried regarding the choice made (ie, the implemented decision; secondary outcome) and if they were able to abstain from smoking in the previous 7 days (ie, 7-day point prevalence abstinence; secondary and primary outcome)."

"After the DA, we measured decisional conflict (secondary outcome) using the decisional conflict scale [9] which was also verified to be unidimensional in our sample (Ω = .98, more information can be found on the OSF [35]). We employed all 16 items using the original statement format with 5 response categories (0 = strongly agree, 1 = agree, 2 = neither agree or disagree, 3 = disagree, 4 = strongly disagree) and created a composite score as described in the user manual provided by O'Connor [48]: Individuals' scores were (1) summed, (2) divided by 16, and (3) multiplied by 25. Thus, every participant had a score ranging from 0 (no decisional conflict) to 100 (extremely high decisional conflict). Scores exceeding 37.5 are generally regarded to be associated with decision delay or being unsure about decision implementation [48]."

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

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

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

"If available, we used previously validated measurements (eg, [9]) and measurements that were used in a Dutch context before (eg, [37]), if possible we used measurements that were used in self-administered online studies before [38,39]."
6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

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

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Clear selection

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

“Second, in order to find out which factors influenced non-usage attrition (ie, attrition during the intervention) and dropout attrition (ie, not returning to the follow-ups) [...]“

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

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

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subitem not at all important  ○  ○  ○  ○  ○  essential

Clear selection

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

n/a for this article, a process evaluation may follow in the future
7a) How sample size was determined

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

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

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

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subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 7a-i?

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

"Considering 50% attrition over the study period, we had aimed to include 1592 smokers at baseline."
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

n/a, as interim analyses were not conducted

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

"Before the account creation participants were automatically randomized into either the intervention or the control group by the online platform on which questionaries and VISOR were hosted, allocating approximately 50% of the respondents to either group."

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

"Before the account creation participants were automatically randomized into either the intervention or the control group by the online platform on which questionaries and VISOR were hosted, allocating approximately 50% of the respondents to either group."

Your response is too large. Try shortening some answers.
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

"Before the account creation participants were automatically randomized into either the intervention or the control group by the online platform on which questionaries and VISOR were hosted, allocating approximately 50% of the respondents to either group."

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

"Before the account creation participants were automatically randomized into either the intervention or the control group by the online platform on which questionaries and VISOR were hosted, allocating approximately 50% of the respondents to either group.", ie, this was done automatically

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

Your response is too large. Try shortening some answers.
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).

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subitem not at all important □ □ □ □ □ essential

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

"End users were blinded to which group they were allocated to."

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
subitem not at all important □ □ □ □ □ essential

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

"Participants received no information regarding the differences between the intervention group and the control group as to not bias the results of the trial."
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 an 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 manuscript, or briefly explain why the item is not applicable/relevant for your study

"Participants in the intervention group received the DA as described in the introduction (see 1.1 The Smoking Cessation DA VISOR), whereas participants in the control group received the same DA excluding the explicit VCM and computer-tailored advice, ie, for them steps 6 and 7 described in Textbox 1 were skipped. The only other (small) difference was that participants in the intervention group were immediately directed towards the end after they had chosen to use no evidence-based cessation assistance (ie, step 8–access information—was skipped), which was not the case for the control group. This way both groups had a chance to reevaluate their choice as the intervention group was offered a chance to reevaluate their choice during the additional elements."

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 manuscript, or briefly explain why the item is not applicable/relevant for your study

See 2.6. Data Analysis, sections were too long to provide direct quotes
12a-i) Imputation techniques to deal with attrition / missing values

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

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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.

See answer above, ie, 12a

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.

See answer from previous questions, ie, 12a

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

Your response is too large. Try shortening some answers.
X26-i) Comment on ethics committee approval

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subitem not at all important 〇 〇 〇 〇 〇 essential

Clear selection

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 did not fall under the scope of the Medical Research Involving Human Subjects Act as indicated by the Medical Ethics Committee Zuyderland, the Netherlands (16-N-227) [...]"

x26-ii) Outline informed consent procedures

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

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subitem not at all important 〇 〇 〇 〇 〇 essential

Clear selection

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.

"Participants registered for the study via an online form, which included their provision of informed consent and the creation of an account."
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. subitem not at all important
2. 
3. essential

Clear selection

Does your paper address subitem X26-iii?

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

Described and made clear throughout the article (albeit implicitly), eg, "Initially collected continuously but was recoded into 3 categories to comply with the privacy regulations of the University of Amsterdam."

RESULTS

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

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

Does your paper address CONSORT subitem 13a? *

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

"The total sample consisted out of 2375 participants that were randomized of which 1164 participants completed the baseline questionnaire. Subsequently, 599 participants completed the DA(s), 276 participants then filled in t=1 completely, 97 participants filled in t=2 completely and 103 participants filled in t=3 completely. The entire trial flow can be seen in Figure 3. The characteristics of participants that finished the baseline questionnaire are described and made clear throughout the article (albeit implicitly), eg, "Initially collected continuously but was recoded into 3 categories to comply with the privacy regulations of the University of Amsterdam."
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

Shown in Figure 3, which was based on the CONSORT flow diagram

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

Does your paper address subitem 13b-i?

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

Shown in Figure 3, which was based on the CONSORT flow diagram

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

Your response is too large. Try shortening some answers.
In the original study protocol, and as such described in the Netherlands Trial Register, it was planned to contact participants 4 times after having used VISOR (ie, directly after the DA, after 1 month, 6 months, and 12 months). Unfortunately, we had to extend our recruitment period due to the Coronavirus disease 2019 (COVID-19) pandemic and consequently, the recruitment period lasted for approximately 12 months, ie, 6 months longer than initially planned. Consequently, given the maximum project duration funded by the Dutch Cancer Society, we had to drop the 12-month follow-up measurement. Therefore, the original primary outcome (ie, 7-day point prevalence after 12 months) had to be adjusted and, ultimately, 7-day point prevalence after 6 months was used as the primary outcome.

In total, the study consisted out of 4 fully automated and web-based contact moments: t=0 the baseline questionnaire and VISOR, t=1 directly after participants had used VISOR, t=2 after 1 month, and t=3 after 6 months.
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

"In the original study protocol, and as such described in the Netherlands Trial Register, it was planned to contact participants 4 times after having used VISOR (ie, directly after the DA, after 1 month, 6 months, and 12 months). Unfortunately, we had to extend our recruitment period due to the Coronavirus disease 2019 (COVID-19) pandemic and consequently, the recruitment period lasted for approximately 12 months, ie, 6 months longer than initially planned. Consequently, given the maximum project duration funded by the Dutch Cancer Society, we had to drop the 12-month follow-up measurement. Therefore, the original primary outcome (ie, 7-day point prevalence after 12 months) had to be adjusted and, ultimately, 7-day point prevalence after 6 months was used as the primary outcome."

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. Participants’ characteristics of participants that finished the baseline questionnaire"

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

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subitem not at all important ○ ○ ○ ○ ● essential

Your response is too large. Try shortening some answers.
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. Participants’ characteristics of participants that finished the baseline questionnaire”, but also the findings regarding attrition, ie, 3.2. Attrition.

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.

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subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection
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 total sample consisted out of 2375 participants that were randomized of which 1164 participants completed the baseline questionnaire. Subsequently, 599 participants completed the DA(s), 276 participants then filled in t=1 completely, 97 participants filled in t=2 completely and 103 participants filled in t=3 completely. The entire trial flow can be seen in Figure 3. The characteristics of participants that finished the baseline questionnaire can be seen in Table 1."; n included for analyses are described in the respective tables.

"30 accounts showed duplicate e-mail addresses; of those, only 8 were linked to accounts in both trial arms (ie, multiple accounts using the same e-mail address in each of the trial arms) and finished baseline with more than 1 account; of those only 2 participants filled in the follow-ups in such a way that they could have a distorting effect on the results (ie, they were first randomized into the intervention group, then in the control group and filled in the follow-ups as participants belonging to the control group even though they received the additional intervention elements) those were therefore adjusted, ie, the 'randomization variable' was changed to 1 = Intervention."

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 ○ ○ ● ○ ○ essential

Does your paper address subitem 16-ii?

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

"However, we deviated from the checklist in one respect: Participants were only invited for the follow-up measurements if they completed the DA(s), that is, if they completed the intervention until the end. This was done as we wanted to ensure that the participants, that we included for the analysis, received the additional intervention elements—as those were the focus of our RCT."

Your response is too large. Try shortening some answers.
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.

See text and tables in 3.3. Hypotheses testing

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.

Next to attrition analyses (see 3.2. Attrition), we also describe insights regarding usage time; eg, “[...] available data provided by the intervention host indicates that the differences in usage times between the 2 groups were significantly different. The median usage time of the intervention group was approximately 9 minutes, while in the control group it was approximately 6 minutes (see the OSF for more information [35]).”

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

Your response is too large. Try shortening some answers.
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.

See text and tables in 3.3. Hypotheses testing

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.

"Interestingly, available data provided by the intervention host indicates that the differences in usage times between the 2 groups were significantly different. The median usage time of the intervention group was approximately 9 minutes, while in the control group it was approximately 6 minutes (see the OSF for more information [35])."

"The most plausible explanation for this is that different groups within our sample (eg, older compared to younger participants) differed in their stage of decision making (see the OSF for more information [35])."

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).

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

Clear selection

Your response is too large. Try shortening some answers.
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

"However, we deviated from the checklist in one respect: Participants were only invited for the follow-up measurements if they completed the DA(s), that is, if they completed the intervention until the end. This was done as we wanted to ensure that the participants, that we included for the analysis, received the additional intervention elements—as those were the focus of our RCT."

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

n/a

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].

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

Your response is too large. Try shortening some answers.
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

"Furthermore, due to a technical mistake, some participants who completed VISOR, but had not completed t=1 (directly after the decision aid), did not receive an automatic invite for the other follow-ups. When this mistake was discovered, some participants were already lost to follow-up. We dealt with this in 2 different ways: (1) People who had already missed t=2 but completed the DA in the 3 months prior to the discovery of the mistake received the invite to participate in t=2 regardless (n = 38 received this invitation, n = 3 made use of this); (2) people who already missed t=3 were still invited to participate in t=3 but not t=2 (n = 130 received the invitation, n = 5 made use of this)."

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.

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

n/a for this article, a process evaluation may follow in the future

DISCUSSION

Your response is too large. Try shortening some answers.
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

| Subitem | 1 | 2 | 3 | 4 | 5 |
|---------|---|---|---|---|---|
| Subitem not at all important | | | | | |
| Essential | | | | | |

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).

"The aim of this article was to report on the effects of adding an explicit VCM with computer-tailored advice to a smoking cessation DA (called VISOR) on both smoking cessation outcomes and decisional conflict. Contrary to our expectations, we did not find any effect on decisional conflict. Also, while the worst-case scenarios might suggest an effect on smoking cessation rates and cessation assistance uptake, this finding was not replicated in the either the complete case analyses or the MI-analyses. Moreover, given the fact that Blankers et al. [55] have shown that analyses based on penalized imputation can be biased when missingness is unbalanced between trial arms (as in our case), we cannot confidently speak of effects on smoking cessation success and cessation assistance uptake, despite the suggestion of effects in the worst-case scenarios. That said, all the significant and non-significant effects found were in the expected direction, ie, participants in the intervention group showed more smoking cessation, more evidence-based cessation assistance uptake, and less decisional conflict."

Your response is too large. Try shortening some answers.
22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

[1] [2] [3] [4] [5]

subitem not at all important [ ] [ ] [ ] [ ] [ ] essential

Clear selection

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

Raised throughout 4. Discussion, albeit implicitly sometimes.

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.

[1] [2] [3] [4] [5]

subitem not at all important [ ] [ ] [ ] [ ] [ ] essential

Clear selection

Does your paper address subitem 20-i? *

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

Your response is too large. Try shortening some answers.
21) Generalisability (external validity, applicability) of the trial findings
NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

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

subitem not at all important □ □ □ □ □ essential

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.

subitem not at all important □ □ □ □ □ essential

Clear selection
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

n/a; the intervention could be implemented without any changes

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: Netherlands Trial Register NL8270"

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

"Specifically, we set out to test the following hypotheses (as described in the study protocol [28] [...]", protocol has been published in JMIR Research Protocols (https://doi.org/10.2196/21772)

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

Your response is too large. Try shortening some answers.
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

"[...] the development of VISOR and the accompanying studies (eg, the aforementioned needs assessment [29]) were funded by the Dutch Cancer Society, UM2015-7744."

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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
Clear selection

Does your paper address subitem X27-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The developers of the intervention (ie, TG, ES, CD, and CH) were also involved in this evaluation."

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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?

Conflict of interest section

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

3 hours in total

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

n/a

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