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

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating webbased 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 III

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

*Vereist

Your name

First Last Dennis de Ruijter Primary Affiliation (short), City, Country * University of Toronto, Toronto, Canada Maastricht University, Maastri Your e-mail address * abc@qmail.com d.deruijter@maastrichtuniver: Title of your manuscript * Provide the (draft) title of your manuscript. The effectiveness of a computer-tailored e-learning program for practice nurses to improve their adherence to smoking cessation counseling guidelines: a randomized controlled trial

Article Preparation Status/Stage *

At which stage in your article preparation are you currently (at the time you fill in this fo	rm)
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- onot submitted yet in early draft status
- not submitted yet in late draft status, just before submission
- submitted to a journal but not reviewed yet
- submitted to a journal and after receiving initial reviewer comments
- submitted to a journal and accepted, but not published yet
- published
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TITLE AND	ABSTRACT
1a) TITLE: I	dentification as a randomized trial in the title
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yes	
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Does your paper address subitem 1a-iii? *

"for practice nurses"	
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1b) ABSTRACT: Structured summary of tri	al design.
methods, results, and conclusions	ar accigin,
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 com-	inarator in the abstract. If
possible, also mention theories and principles used for designing the site. Ket systematic reviewers and indexers by including important synonyms. (Note: O	p in mind the needs of
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Clarify the level of human involvement in the abstract, e.g., use phrases like "fi therapist/nurse/care provider/physician-assisted" (mention number and expeany). (Note: Only report in the abstract what the main paper is reporting. If this the main body of text, consider adding it)	ertise of providers involved, i
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"Data collection was fully automated"	
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Ib-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face METHODS section of the ABSTRACT	assessments in the
Mention how participants were recruited (online vs. offline), e.g., from an oper	
clinic or a closed online user group (closed usergroup trial), and clarify if this vor there were face-to-face components (as part of the intervention or for asse	ssment). Clearly say if
outcomes were self-assessed through questionnaires (as common in web-ba: offline trials, an open trial (open-label trial) is a type of clinical trial in which bo	
participants know which treatment is being administered. To avoid confusion, to indicated the level of blinding instead of "open", as "open" in web-based tria	
access" (i.e. participants can self-enrol). (Note: Only report in the abstract whe f this information is missing from the main body of text, consider adding it)	at the main paper is reportin
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"a web-based randomized controlled trial was conducted"	

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

Does your paper address subitem 1b-iv?

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

"an intervention group (N = 147) with full access to the e-learning program for six months was compared to a control group (N = 122) without access"

"121 practice puress in the intervention group (42.4%) and 103 in the

"121 practice nurses in the intervention group (43.4%) and 103 in the control group (36.9%) completed the follow-up questionnaire"

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)

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

"Mixed linear regression analysis revealed that counseling experience moderated the program's effect on practice nurses' overall guideline adherence (β = 0.610; 95% CI 0.132 – 1.089; P = .013), indicating a positive program effect on adherence for practice nurses with a more than average level of counseling experience. Mixed logistic regression analyses regarding adherence to individual guideline steps revealed a trend towards moderating effects of baseline levels of behavioral predictors and counseling experience."

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)

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

Problem: "also to subsequent steps of evidence-based smoking cessation guidelines, PNs' adherence is suboptimal "

Solution: "Therefore, we developed and tested a novel web-based CT elearning program for PNs to support them to improve their smoking cessation counseling guideline adherence "

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

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

Does your paper address subitem 2a-ii? *

could be targeted through intervention programs aimed to improve PNs guideline adherence. Previously tested CT programs proved to be effective in changing various (determinants of) health behaviors, including smoking cessation. Therefore, by targeting PNs' behavioral predictors via a web-based CT support program, positive behavior change can be achieved among PNs, meaning that they improve their smoking cessation guideline 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 the study described here was to assess the effects of the CT elearning program on PNs 'smoking cessation guideline adherence in a randomized controlled trial (RCT). We hypothesized that PNs' guideline adherence would significantly improve as a result of exposure to the CT e-**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 "We conducted an RCT to investigate the effectiveness of the CT elearning program on PNs' smoking cessation guideline adherence, compared to no intervention." Figure 2 in de manuscript illustrates group allocation via a flowchart. 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 Changes made as a result of pilot and usability tests are described in the design paper. 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].

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Does your paper address subitem 3b-i?

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

No changes were made during the trial.	

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4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

"Eligible PNs were actively engaged in smoking cessation counseling in a Dutch general practice, had Internet access and an active email account, and were sufficiently proficient in Dutch."
4a-i) Computer / Internet literacy Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.
1 2 3 4 5 subitem not at all important
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
Participants were required to have "Internet access and an active email account".
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 (onlin 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 measure (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these. 1 2 3 4 5
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Does your paper address subitem 4a-ii? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study www.sterstudie.nl, Self-Archived at Web-Cite® on 26 July 2016 [http://www.webcitation.org/6]HiDBycb]) and social media platforms (i.e. Twitter, LinkedIn, Facebook). Additionally, individual PNs were contacted by the research team via telephone through their general practice." Assessment: "PNs were prompted to visit the CT e-learning program to complete an online informed consent form, were randomized (i.e. allocation by a computer software randomization device) and filled out the web-based baseline questionnaire."
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 ite X26), as this information may have an effect on user self-selection, user expectation and may also bias results.
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Does your paper address subitem 4a-iii? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study "Upon interest and obtaining important project information via telephone
and email, PNs were prompted to visit the CT e-learning program to complete an online informed consent form"

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

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aa aa	xplain why the item is not applicable/relevant for your study ions concerning demographic characteristics,
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Revisions ar (and compa during the e Describe dy	ons and updating d updating. Clearly mention the date and/or version number of the application/intervention ator, if applicable) evaluated, or describe whether the intervention underwent major changes valuation process, or whether the development and/or content was "frozen" during the trial. lamic components such as news feeds or changing content which may have an impact on the of the intervention (for unexpected events see item 3b).
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Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate 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 website that includes the e-learning intervention is self-archived via WebCite: "project website (i.e. www.sterstudie.nl, Self-Archived at WebCite® on 26 July 2016 [http://www.webcitation.org/6jHiDBycb])" 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). 1 2 3 4 5 subitem not at all important O O O O essential Does your paper address subitem 5-vii? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Participants could access the intervention by entering a personal username and password (described in design paper). Access: "During a six-month time period all PNs were free to visit the modules of the CT e-learning program as many times as they wanted. PNs could directly print content from the modules and save this content on their computer. 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] subitem not at all important O O O essential Does your paper address subitem 5-viii? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study during the intervention period (21). The content of advice modules was tailored to several respondent characteristics theoretically grounded in the I-Change Model (ICM (24)), which were previously demonstrated to be effective in achieving behavior change (25-28): demographics (e.g. gender), pre-motivational factors (e.g. knowledge), motivational factors (e.g. self-efficacy), post-motivational factors (e.g. coping planning), intention (to use a smoking cessation guideline), and behavior (i.e. selfreported application of smoking cessation guideline steps). ' 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. 1 2 3 4 5 subitem not at all important \bigcirc \bigcirc \bigcirc \bigcirc 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 "During a six-month time period all PNs were free to visit the modules of the CT e-learning program as many times as they wanted" 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)

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].

subitem not at all important \(\bigcap \) \(\bigcap \) \(\infty \) essential

primary outcome measure in the effect analyses.

Does your paper address subitem 6a-i? Copy and paste relevant sections from manuscript text
"Baseline and six-month follow-up questionnaires for PNs were informed by the ICM (24), and were based on questionnaires previously used among health care professionals to assess smoking cessation activities "
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.
1 2 3 4 5
subitem not at all important 🔘 🔘 🔘 essential
Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text "program usage (i.e. number of modules visited) "
program usage (i.e. number of modules visited)
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 emai feedback forms, interviews, focus groups).
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Does your paper address subitem 6a-iii?
Copy and paste relevant sections from manuscript text "Qualitative post-trial interviews with PNs (N = 17) "
Details about these interviews are described in the design paper
6h) Any changes to trial outcomes after the trial
6b) Any changes to trial outcomes after the trial commenced, with reasons
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
"Our intention was to triangulate data on PNs' guideline adherence from both smokers' and PNs' perspectives to compute the primary outcome
measure (21). Unfortunately, only 33.3% of smokers counseled by PNs (391/1,175) also participated in the trial themselves, i.e. completed the
baseline smoker questionnaire. As a result, conducting effect analyses with these data would be unreliable due to substantial loss of power and
selective inclusion of smokers."
///
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?

"We calculated the required sample size based on the possibility to detect a difference of medium effect size (i.e. adherence to two additional guideline steps) between intervention and control group PNs (α = 5%; β = 10%). As a result, at least 95 PNs per condition at the end of the trial would be sufficient. Considering 30% attrition, we aimed to include 272 PNs at baseline "
More details in the design paper.
7b) When applicable, explanation of any interim analyses and stopping guidelines
Does your paper address CONSORT subitem 7b? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study Not applicable.
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 "randomized (i.e. allocation by a computer software randomization device)"
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 Not applicable.
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

"randomized (i.e. allocation by a computer software randomization device)"	

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 you "randomized (i.e. allocation by a computer software randomization device)"	r study
	Z
11a) If done, who was blinded after assign	
nterventions (for example, participants, ca	are providers,
those assessing outcomes) and how NPT: Whether or not administering co-interventions were blinded to grou	un accienment
	ap assigninent
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 varticipants [1, 3] (this should be clearly acknowledged), but it may be possibl hose doing data analysis or those administering co-interventions (if any).	
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Does your paper address subitem 11a-i? * Copy and paste relevant sections from the manuscript (include quotes in quot ndicate direct quotes from your manuscript), or elaborate on this item by proviot in the ms, or briefly explain why the item is not applicable/relevant for you	viding additional information
participants were aware of allocation after randomization (not explicitly mentioned in paper).	
,	
participants knew which intervention was the "intervention of interest" and when the second of the s	iich one was the "comparator"
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Does your paper address subitem 11a-ii? 20py and paste relevant sections from the manuscript (include quotes in quot dicate direct quotes from your manuscript), or elaborate on this item by provot in the ms, or briefly explain why the item is not applicable/relevant for you Informed consent was provided online and participants were aware of the intervention.	iding additional information
111-116	
11b) If relevant, description of the similarit	ty of
nterventions	
, , , , , , , , , , , , , , , , , , , ,	
nterventions this item is usually not relevant for ehealth trials as it refers to similarity intervention to a active medication/intervention) Does your paper address CONSORT subitem 11b? * Copy and paste relevant sections from the manuscript (include quotes in quot indicate direct quotes from your manuscript), or elaborate on this item by proviot in the ms, or briefly explain why the item is not applicable/relevant for you	of a placebo or sham tation marks "like this" to riding additional information
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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? *

to the CT e-learning program on PNs' smoking cessation guideline adherence. Both PNs' overall adherence score (range 0-9) was used as outcome measure, and their adherence score for each guideline step separately (i.e. step-based adherence; 0 = non-adherent, 1 = adherent). Therefore, both linear and logistic mixed models were run, including the same covariates. Effect moderators were tested by including interaction effects with PNs' group allocation (i.e. intervention or control) to the regression models tested."

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

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

Does your paper address subitem 12a-i? *

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

"Since 211 PNs (78.4%) completed at least one checklist (which was needed to calculate the primary outcome measure), it meant that 58 PNs were excluded from effect analyses. For this reason, sensitivity analyses were conducted by replacing missing values on the primary outcome measure, guideline adherence, with scores assuming some dependency between the score being missing and the adherence score itself, either following an optimistic or a pessimistic scenario."

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

"Upon finding a significant interaction effect, subsequent subgroup analyses were conducted to determine the nature of the moderation, using adjusted alpha levels (Holm-Bonferroni method) to correct for multiple testing.

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

X26-i) Comment on ethics committee approval

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

"No medical ethical clearance for this study was needed according to the Medical Ethics Committee Atrium-Orbis-Zuyd (14-N-17). "

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 \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc essential

Does your paper address subitem X26-ii?

X26-iii) Safety and	security procedu	ires				
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Attrition rates are described in a flowchart. Data on intervention use are not reported in an attrition diagram.
**
14a) Dates defining the periods of recruitment and follow
JD qu
Ooes your paper address CONSORT subitem 14a? *
copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to
ndicate direct quotes from your manuscript), or elaborate on this item by providing additional informatio ot in the ms, or briefly explain why the item is not applicable/relevant for your study
Dates not defined, as recruitment and enrollment took place during a period of 6 months.
period of 6 months.
h
4a-i) Indicate if critical "secular events" fell into the study period
ndicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources vailable or "changes in computer hardware or Internet delivery resources"
variable or changes in computer naroware or internet delivery resources
ubitem not at all important 🔘 🌘 💿 💮 essential
Opes your paper address subitem 14a-i? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to
ndicate direct quotes from your manuscript), or elaborate on this item by providing additional informatio
ot in the ms, or briefly explain why the item is not applicable/relevant for your study Not applicable.
That applicable.
(early) Why the trial ended or was stopped (early)
Ooes your paper address CONSORT subitem 14b? * Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to
ndicate direct quotes from your manuscript), or elaborate on this item by providing additional informatio ot 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
IPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.)
and centers (volume) in each group
Ooes your paper address CONSORT subitem 15? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to ndicate direct quotes from your manuscript), or elaborate on this item by providing additional informatio
to the ms, or briefly explain with the item is not applicable/relevant for your study
current smokers. Nearly half (47.2%) worked in more than one general practice and PNs worked on average almost 26 hours a week. Many
PNs (66.9%) were listed in the Dutch Stop Smoking Quality Register and the mean reported PN counseling experience was 5.6 years. Finally,
almost half of PNs (47.6%) worked in a general practice with designated
smoking cessation consulting-hours and nearly all (92.6%) reported to systematically register their patients' smoking status in their patient
files."
5-i) Report demographics associated with digital divide issues
n ehealth trials it is particularly important to report demographics associated with digital divide issues,
uch as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the articipants, if known.

subitem not at all important \(\bigcirc \) \(\omega \) \(\omega \) \(\omega \) essential

1 2 3 4 5

"The baseline sam vast majority was	ple of PNs (Table 1) had a mean age of 47.3 years, the emale (97.8%) "
included in	ch group, number of participants (denominator each analysis and whether the analysis was b signed groups
Report multiple "der study participation used more than y w	ole "denominators" and provide definitions ominators" and provide definitions: Report N's (and effect sizes) "across a range of and use] thresholds" [1], e.g., N exposed, N consented, N used more than x times, N eks, N participants "used" the intervention/comparator at specific pre-defined time absolute and relative numbers per group). Always clearly define "use" of the
	1 2 3 4 5
subitem not at all in	portant 🔘 🔘 📵 🄘 essential
follow-up measure	254 PNs remained in the trial and were invited for the ment, which was completed by 88.9% (121/136) of and 87.3% (103/118) of control group PNs respectively "
Primary analysis sh	ysis should be intent-to-treat ould be intent-to-treat, secondary analyses could include comparing only "users", with ats that this is no longer a randomized sample (see 18-i).
subitem not at all in	portant 🔘 🔘 🌘 🌚 essential
Copy and paste rele indicate direct quot not in the ms, or brin pessimistic imputa adherence were n based adherence, steps 1, 6, 8 and 8 baseline adherenc significant. Main a 5 and 7 were no lo	Idress subitem 16-ii? vant sections from the manuscript (include quotes in quotation marks "like this" to s from your manuscript), or elaborate on this item by providing additional information fly explain why the item is not applicable/relevant for your study ion scenario, main and interaction effects for overall olonger or only marginally significant. Regarding stepsimilar results were found for adherence to guideline whereas regarding step 4 only main effects of e to step 4 and perceived advantages remained interaction effects concerning guideline steps 2, 3, nger or only marginally significant after conducting ensitivity analyses."
,	nch primary and secondary outcome, results fo , and the estimated effect size and its precisio
(such as 9	5% confidence interval)
Copy and paste rele indicate direct quot not in the ms, or bri	idress CONSORT subitem 17a? * rant sections from the manuscript (include quotes in quotation marks "like this" to s from your manuscript), or elaborate on this item by providing additional information fly explain why the item is not applicable/relevant for your study s showed that for PNs with more than average
counseling experie allocation to the in program) resulted to the control grou Bonferroni = .039)	nce (i.e. mean + 1 SD = 9.4 years of experience), ervention group (i.e. access to the CT e-learning n a significantly higher overall adherence compared (β = 0.610; 95% CI 0.132 – 1.089; PHolm-
Tables in the pape	report regression coefficients or ORs, including 95%
•	n of process outcomes such as metrics of use and intensity of use y/secondary (clinical) outcomes, the presentation of process outcomes such as

1 2 3 4 5

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

Not reported in results section, as this was not the aim of the paper. Intervention use is mentioned when discussing the results: "However, although more frequent users were more adherent in the present trial, program usage (i.e. number of modules visited) was not significantly associated with PNs' guideline adherence, nor did we identify that more experienced PNs were more frequent users (data not shown)."

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

Tables in the paper report ORs for binary outcomes.

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

"Detailed results on subgroup analyses for each significant interaction effect are presented in the supplement. Overall, the results show that higher adherence scores on individual guideline steps of intervention group PNs, compared to control group PNs, occur for 1) high levels of counseling experience and perceived social support; and 2) low levels of perceived (dis)advantages, self-efficacy and social modelling and little social norms."

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 harms expected (described in design paper) or unintended effects determined (not explicitly described).

				tenc 4		effects" also includes unintended positive effects [2].
subitem not at all important			•		0	essential
indicate direct quotes from	tion	s fro	om t	he n), or	uscript (include quotes in quotation marks "like this" to relaborate on this item by providing additional informatio not applicable/relevant for your study
19-ii) Include qualitative	eed	hac	k fr	om	nar	ticipants or observations from staff/researchers
Include qualitative feedback strengths and shortcomings	fror of t	n pa	artic appl	ipan icati	ts o on, o	robservations from staff/researchers, if available, on especially if they point to unintended/unexpected effects y people did or did not use the application as intended by
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"Qualitative post-trial intenthe design paper.	/iews	s wi	th P	Ns (N =	17) " details are described in
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"Another potential method to collect data on PNs' guideline adherence could be to ask PNs to respond to simulated practice situations or clinical vignettes (i.e. case studies of smokers visiting their practice for cessation support) to assess their application of evidence-based guideline steps. Research with such clinical vignettes among PNs is needed to determine the potential value of using vignettes to reliably measure PNs' smoking cessation guideline adherence."

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

20-i) Typical limitations in ehealth trials

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

Does your paper address subitem 20-i? *

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

both smokers' and PNs' perspectives to compute the primary outcome measure (21). Unfortunately, only 33.3% of smokers counseled by PNs (391/1,175) also participated in the trial themselves, i.e. completed the baseline smoker questionnaire. A second limitation was that 58 PNs (21.6%) did not manage to recruit and counsel smokers during the intervention period resulting in lacking data on these PNs' guideline adherence during consultations. As a result, these PNs could not be included in the effect analyses."

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

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

learning programs.

"a process evaluation could inform improving alterations to program's tailored content to extend the program's effectiveness beyond experienced PNs. When such strategies would be combined with program implementation among a larger population of PNs, this could further substantiate the impact of the CT e-learning program on the quality of smoking cessation care in the Netherlands."

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

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

Does your paper address subitem 21-ii?

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

Not explicitly mentioned in the paper.

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 "The study is registered with the Dutch Trial Register (NTR4436)." 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 "A full description of the design of the RCT can be found elsewhere (21)." Reference: de Ruijter D, Smit ES, de Vries H, Hoving C. Web-based computer-tailoring for practice nurses aimed to improve smoking cessation guideline adherence: A study protocol for a randomized controlled effectiveness trial. Contemporary clinical trials. 2016;48:125-32. 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 "This study was funded by a grant from the Dutch Cancer Society (UM2013-6107). 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 O O 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 "DdR, ES, HdV & CH were involved in developing the content of the elearning program. About the CONSORT EHEALTH checklist

As a result of using this checklist	, did you	make	changes	in your	manuscrip	t? *
ves major changes						

yes, minor changes

no no

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

Clarifying the description of 'program use automated'. Websites saved via WebCite were adder acknowledgements were expanded.	d as reference and
How much time did you spend on goin manuscript *	ng through the checklist INCLUDING making changes in your
5 hours	
	you think your manuscript has improved? *
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