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ABSTRACT

Background: Dutch practice nurses sub-optimally adhere to evidence-based smoking cessation guidelines. Web-based computer-tailoring could be effective in improving their guideline adherence. Therefore, this paper aims to describe the development of a web-based computer-tailored program and the design of a randomized controlled trial testing its (cost-)effectiveness.

Methods: Theoretically grounded in the I-Change Model and Self-Determination Theory, and based on the results of a qualitative needs assessment among practice nurses, a web-based computer-tailored program was developed including three modules with tailored advice, an online forum, modules with up-to-date information about smoking cessation, Frequently Asked Questions (FAQs) and project information, and a counseling checklist. The program's effects are assessed by comparing an intervention group (access to all modules) with a control group (access to FAQs, project information and counseling checklist only). Smoking cessation guideline adherence and behavioral predictors (i.e. intention, knowledge, attitude, self-efficacy, social influence, action and coping planning) are measured at baseline and at 6- and 12-month follow-up. Additionally, the program's indirect effects on smokers' quit rates and the number of quit attempts are assessed after 6 and 12 months.

Discussion: This paper describes the development of a web-based computer-tailored adherence support program for practice nurses and the study design of a randomized controlled trial testing its (cost-)effectiveness. This program potentially contributes to improving the quality of smoking cessation care in Dutch general practices. If proven effective, the program could be adapted for use by other healthcare professionals, increasing the public health benefits of improved smoking cessation counseling for smokers.

1. Introduction

Smoking continues to be the leading cause of preventable disease and premature death worldwide [1,2]. In the Netherlands, smoking prevalence has been decreasing for years, but about 23% of the adult population still smokes [3]. Evidence-based smoking cessation interventions combining pharmacotherapy with behavioral counseling are effective in supporting smokers to quit [4–6]. Dutch smokers most often visit their general practice for such cessation support, which is increasingly provided by trained practice nurses (PNs) [7,8]. PNs are employed in 80% of general practices, taking over specific tasks from the GP such as chronic disease consultations and lifestyle counseling, like smoking cessation support [9].

PNs are qualified to provide smoking cessation counseling [9], but their adherence to evidence-based smoking cessation guidelines has proven to be suboptimal (i.e. partial adherence) [10–12]. Complete adherence to these guidelines is known to have better effects on patients' quit rates than only a brief quit advice or less elaborate counseling [13]. As improved guideline adherence positively contributes to the quality of smoking cessation care [9,14], it is therefore important to improve PNs' smoking cessation guideline adherence.

Dutch PNs' suboptimal guideline adherence can be explained by various perceived barriers, such as low self-efficacy to motivate smokers and use motivational interviewing techniques; difficulties finding up-to-date information about smoking cessation, compensation of counseling and high-quality training opportunities for PNs; and not considering cessation counseling as their responsibility [9,15,16]. Particularly guideline elements like 'motivating smokers to quit' and 'organizing adequate follow-up consultations' are regularly not adhered to in practice [16]. Recognizing these barriers to smoking cessation guideline adherence, Dutch PNs have recently indicated interest in a tailored, easy-to-use, web-based program that can provide them with guideline adherence support [16].

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Such guideline adherence support can be provided via web-based computer-tailored (CT) programs, providing PNs with personally relevant advice, based on their individual answers to the questions of an online questionnaire [17]. When PNs, for instance, indicate specific difficulties for adhering to evidence-based smoking cessation guidelines they subsequently receive CT advice about only those difficult situations (e.g. when patients have little time) that they individually perceive as barriers to adherence [18]. Integrating CT advice in a web-based environment makes it easily accessible, since PNs can consult it wherever and whenever they find convenient [19,20].

CT programs have proven to be effective in changing various health behaviors and their determinants [21–24]. CT programs for smokers, for example, were found to be effective in improving quit rates [25–28] and a CT intervention for physicians showed promising results regarding adherence to smoking cessation guidelines [29]. We therefore hypothesize that CT advice on applying evidence-based smoking cessation guidelines can effectively support PNs to improve their guideline adherence. Ultimately, CT advice could contribute to improving the quality of smoking cessation care in general practices, resulting in more successful quit attempts among counseled smokers and less smoking related illness and death. Nonetheless, a CT program for PNs aimed at improving their smoking cessation guideline adherence does not yet exist.

Therefore, this paper describes the development of a web-based CT adherence support program and its components for Dutch PNs. Additionally, the study design of a randomized controlled trial testing the program's (cost-) effectiveness is described.

2. Methods/design

The aim of this paper is to describe the development of a web-based CT adherence support program for PNs and the study design of the randomized controlled trial testing the effectiveness of this program in terms of guideline adherence by the PN and subsequent smoking cessation rates among their smoking patients. Evaluation by the Medical Ethics Committee Atrium-Orbis-Zuyd (14-N-17) revealed that no medical ethical clearance for this study was needed according to the rules of the Medical Research Involving Human Subjects Act (WMO). The study is registered with the Dutch Trial Register (NTR4436).

2.1. Study design effectiveness trial

In order to investigate the effects of the web-based CT program on PNs' adherence to evidence-based smoking cessation guidelines, a randomized controlled trial will be conducted. PNs in the intervention group have full access to the content of the web-based CT program (i.e. five intervention modules and three general modules), while PNs in the control group have access to the three general modules of web-based CT program only.

At the start of the trial all participating PNs are asked to fill out a baseline questionnaire. Upon completion of this questionnaire, only PNs in the intervention group receive a tailored feedback letter (which PNs can later also consult in one of the intervention modules). Immediately after receiving this feedback letter, intervention group PNs have access to five intervention modules i.e. brief tailored advice, extended tailored advice, new tailored advice, an online forum, and background information) and three general modules (i.e. project information, frequently asked questions (FAQs), and a counseling checklist). PNs are free to (re-)visit and use these modules at their convenience during a six-month period.

After completion of the baseline questionnaire, PNs in the control group receive a short thank-you message. During the subsequent six months, these PNs do not have access to the five intervention modules of the web-based CT adherence support program, but only to the three general modules: project information, the FAQs and the counseling checklist. PNs in this group can also (re-)visit and use these modules at their convenience.

Once the six-month intervention period ends and PNs in both the intervention and control group have filled out the first follow-up questionnaire, only project information, the FAQs and the counseling checklist remain accessible for both groups. Intervention group PNs will no longer have access to the five intervention modules. The three general modules remain available until PNs from both groups receive the invitation to fill out the second follow-up questionnaire, 12 months after baseline (see Fig. 1).

2.2. Recruitment of practice nurses

PNs actively engaged in providing smokers with cessation counseling and working in general practices in the Netherlands are invited to participate in the trial. Moreover, PNs are eligible when they are sufficiently proficient in Dutch, have Internet access and have an active email account.

PNs who already participated in our preliminary studies (i.e. individual interviews with PNs and an online questionnaire for PNs) and reported to be interested in participation are personally invited to participate. Further recruitment takes place via several national institutes and organizations for Dutch PNs specifically, or primary care professionals more generally. Through these institutes and organizations PNs are initially invited via email, newsletters and website messages. Additionally, social media platforms such as LinkedIn, Twitter and Facebook are used to inform as many people as possible about the research project and refer them to the project website (www.sterstudie.nl). This website has been online since September 2014, is free to visit and offers more details about the rationale and the different studies of the project, about the research team and about evidence-based smoking cessation guidelines in general. Through the website, PNs are also informed about the research objectives, the randomization procedure of the trial and the incentive for trial completion (i.e. a €50 gift voucher). They also have the opportunity to contact the research team for more information or directly register for participation in the trial via the website. In addition, a FAQs section is available on the website to directly answer questions that PNs might have. In case PNs report to be interested in participation they are subsequently contacted by telephone.

2.3. Randomization

After verbal consent is provided via telephone, PNs receive an email containing detailed information about the project and instructions for signing in to the web-based CT adherence support program (i.e. personal username-password combination and a personalized auto-login link). No one but the research team is able to retrieve these login data. After PNs access the program and start filling out the baseline questionnaire they are asked to provide online informed consent, after which they are randomly allocated to either the intervention or the control group of the trial. Group allocation takes place at respondent level by means of a computer software randomization device, which allocates approximately half of the PNs to each group. Blinding of the PNs is not possible, since they are aware of their access to the different modules of the web-based CT program after they have completed the baseline questionnaire.

2.4. Recruitment of smokers

Recruitment of smokers is important for the evaluation of smokers' abstinence rates and number of quit attempts, which is a secondary aim of the trial. Every smoking patient who visits the general practice and receives smoking cessation care from a PN participating in the trial is invited by his/her PN to participate. PNs are provided with a recruitment letter (i.e. sent to the PN via email by the research team and accessible via the module with project information of the web-based program) that can be used to inform smokers about the trial. Individuals eligible for participation should smoke at the start of the study and should receive individual smoking cessation counseling from a PN who is enrolled in the study. Furthermore, smokers must be 18 years

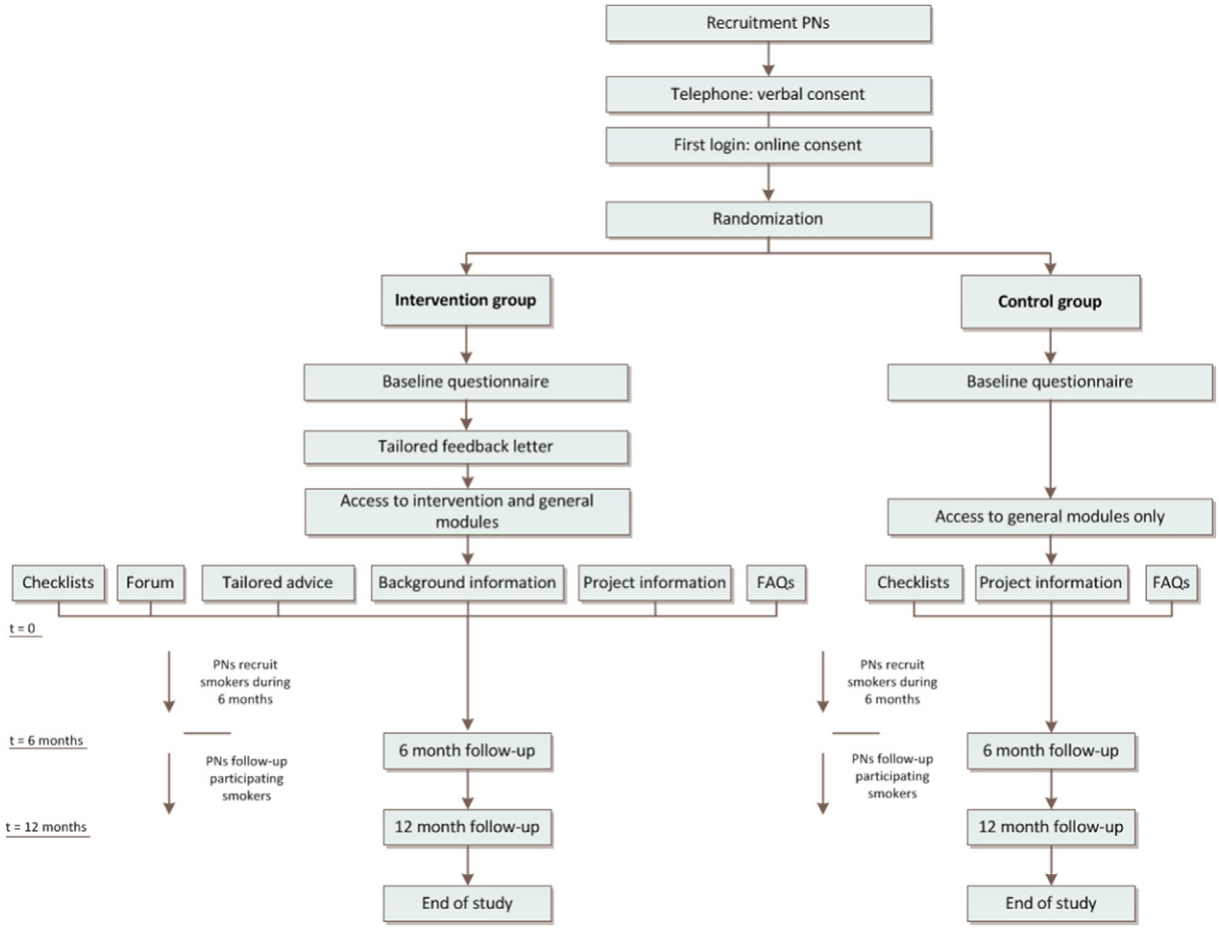

Fig. 1. flowchart of the design of the randomized effectiveness trial.

or older, sufficiently proficient in Dutch, have Internet access and have an active email account.

Interested smokers give their PN permission to provide the research team with the smoker's email address and date of birth. Subsequently, PNs can register smokers for participation in the trial via one of the general modules (i.e. the counseling checklist) of the web-based CT program. Within this module, PNs are asked to submit the smoker's email address and date of birth. This information is automatically processed by a software program to send registered smokers a personalized email invitation to participate in the trial. The content of these mails is similar for smokers that are recruited by intervention group and control group PNs. Smokers are hence unaware of their PN's group allocation. Subsequently, participating smokers receive similar automatic email invitations and reminders to fill out a total of three online questionnaires during the trial. The content of these questionnaires is also identical for all smokers, irrespective of their PN's group allocation. Completion of all questionnaires is rewarded with a €10 gift voucher.

PNs in both study groups use the counseling checklist to recruit smoking patients only during the first six months of the trial. PNs receive several phone calls and personalized emails during this period to stimulate them to recruit an adequate number of smokers. During the final six months (i.e. after the first follow-up questionnaire) PNs only fill out the checklist after consultations with smokers who already participate in the trial. Hence, no new smokers are recruited during this final period.

2.5. Web-based CT adherence support program

The content and design of the web-based CT program for PNs is based on the results from an earlier needs assessment among Dutch PNs [16]. This study, in which semi-structured individual interviews were held to discover perceived facilitators and barriers to smoking cessation guideline adherence and identify PNs' needs concerning an adherence support program, showed that PNs perceived several psychological (e.g. low self-efficacy to increase the motivation of smokers and arrange follow-up consultations) and practical barriers (e.g. lack of high-quality brochures and information about compensation by different healthcare insurers) to guideline adherence. The involvement of a general practitioner and the use of visually attractive information brochures were perceived as facilitating factors by PNs. Finally, PNs were interested in a simple program, which is easily accessible and provides individually relevant content instead of large amounts of general information [16]. Based on these results, a web-based CT adherence support program was developed, aimed to provide PNs with personalized and tailored content about evidence-based smoking cessation guidelines and their adherence to and perceptions about these guidelines. Personalized and tailored information is better at attracting and keeping the individual's attention [17]. Furthermore, PNs can directly print the content and save it on their computer. Finally, in order to make PNs' program usage more convenient, they are free to visit the program as frequently as they like and wherever and whenever they want.

2.6. Usability testing

Usability tests with behavior change experts ($N = 5$) and PNs ($N = 5$) were conducted to identify flaws in the web-based CT program and potential improving alterations. Experts assessed the program's usability using the heuristic evaluation method [40]. They assessed the program's lay-out and interaction structure according to a set of ten usability heuristics [41]. PNs used the think aloud method, which means that they were asked to visit all modules of the web-based CT program,

while verbalizing their actions and thoughts [40]. Based on the usability tests the following improving alterations to the program were made: adding more images to modules with a lot of text; adding 'return-to-home' buttons to all modules; providing instructions for using the print and save function and disabling pop-ups in the internet browser; and changing visual analogue answer scales to numerical scales. This resulted in a web-based CT program, integrated in the project website (www.sterstudie.nl), consisting of five intervention modules and three general modules that are described in the following sections.

2.7. Intervention modules

Only PNs that are enrolled in the intervention group of the trial have access to the five intervention modules of the web-based CT program: three modules with tailored advice (i.e. brief tailored advice, extended tailored advice, and new tailored advice), an online forum, and a module with background information. The aim and a PN's usage of each of the modules are described below.

2.7.1. Brief tailored advice

After completing the baseline questionnaire all PNs in the intervention group always receive a tailored feedback letter. The brief tailored advice module of the web-based CT program allows PNs to re-read this tailored feedback letter, which is based on PNs' individual answers to the questions in the online baseline questionnaire concerning their demographic characteristics, adherence to evidence-based smoking cessation guidelines and their scores on behavioral predictors (attitude, self-efficacy, social influences, knowledge, and action and coping planning).

The content of the letter is kept rather simple and visually attractive through the use of figures and graphs. First, PNs are shown a color-coded bar chart (i.e. red for poor, yellow for not yet sufficient and green for satisfactory) showing their adherence to the different guideline steps during smoking cessation trajectories of their last ten smoking patients, followed by tailored recommendations for optimal adherence. Next, PNs see a similar color-coded chart that reports back their individual scores concerning behavioral predictors. This information is then followed by tailored pieces of advice providing PNs with brief explanations for their red, yellow or green scores for every behavioral predictor (attitude, self-efficacy, social influences, knowledge, and action and coping planning). Finally, the tailored feedback letter concludes with tailored recommendations for individual PNs to visit specific other intervention modules of the web-based CT program, and to select particularly those topics where there is room for improvement (i.e. red or yellow scores). For example, a PN who perceives many disadvantages of using an evidence-based smoking cessation guideline, as reported in the baseline questionnaire, is advised to visit the module 'extended tailored advice' and choose the topic 'disadvantages of guideline use'. In this module, additional tailored advice is provided aimed to invalidate those particular disadvantages of guideline use that are perceived by this specific PN (see extended tailored advice for an example).

2.7.2. Extended tailored advice

This module provides PNs with additional, more extensive tailored advice based on their answers to the questions in the online baseline questionnaire. Whereas the brief tailored advice module contains advice tailored on a more general level (e.g. addressing PNs' attitude by reflecting on how many advantages and disadvantages of guideline use they perceive), the extended tailored advice module provides more in-depth advice on a chosen topic. PNs can choose from a drop-down list about which topic(s) they would like to receive more extended tailored advice. The following topics can be chosen:

1. Guideline adherence; with advice distinguishing between guideline steps that an individual PN either satisfactorily, not yet sufficiently or poorly reported to adhered to.
2. Knowledge of smoking cessation guidelines; with advice on guideline elements about which an individual PN does not yet have sufficient knowledge. This was assessed with true-false items, so PNs only receive advice about wrongly answered items.
3. Perceived disadvantages of using a smoking cessation guideline; with advice aimed to invalidate disadvantages that an individual PN reported to perceive.
4. Perceived advantages of using a smoking cessation guideline; with advice aimed to endorse advantages that an individual PN reported to not yet perceive.
5. Perceived social influence to use a smoking cessation guideline; with advice distinguishing between how much (i.e. low, medium, high) social modeling, social norms and social support an individual PN reported to perceive.
6. Perceived self-efficacy to use a smoking cessation guideline in potentially difficult situations; with advice on dealing with only those situations that an individual PN perceived to be difficult.
7. Action planning; with advice on how individual PNs can prepare for smoking cessation consultations and use a smoking cessation guideline by making specific action plans (e.g. printing an overview of the guideline prior to a consultation). PNs are only asked to make plans for those steps they wish to apply in their counseling.
8. Coping planning; with advice on how PNs can deal with difficult situations to use a smoking cessation guideline by making coping plans. Individual PNs only receive advice on situations they reported to be difficult.

These topics can be chosen one at a time, but PNs can choose a new topic and read the related advice as many times as they like. For example, a PN can select the topic 'disadvantages of guideline use' to receive tailored advice aimed to invalidate the individually perceived disadvantages of guideline use. For instance, if a PN perceives that adhering to a guideline is time-consuming, as indicated in the baseline questionnaire, the following advice is presented:

> *If you have recently started using a guideline, it is indeed possible that this can be more time-consuming at first. You need some time to get used to the structure of the guideline and to become familiar with the content of the different guideline steps. However, you will notice that, after working with it for a while, you are actually able to save some time. Using the guideline will become habitual, which results in working more efficiently during a smoking cessation consultation.*

2.7.3. New tailored advice

This module provides PNs with new tailored advice and is especially designed to provide advice when a PN's behavior or behavioral determinants have changed since the last time they used the program. PNs are advised to first read the modules with brief and extended tailored advice before starting to use this module. Advice in this module is similar to the advice in the module with extended tailored advice, but is updated in order to match the updated personal situation of a PN, since the last time they used the program. For this advice to be generated, PNs need to answer the questions about the subject of their choice again, which are similar to the questions of the baseline questionnaire. From a drop-down list, they can choose about which topics they would like to receive new advice and subsequently fill out the corresponding questions about this topic. Then, new tailored advice is generated based on the answers they have provided. As in the extended tailored advice module, topics can be chosen one at a time, but PNs are free to obtain new feedback on all topics and use this module as many times as they like.

2.7.4. Online forum

This module provides PNs with the opportunity to contact colleagues via an online forum to discuss issues and ask questions related to smoking cessation guidelines and consultations. PNs are free to use the forum as they like, but several threads (i.e. smoking cessation counseling, smoking cessation guidelines, motivating smokers to quit) are created in advance by the research team to provide PNs with some structure when visiting the forum for the first time. Members of the research team moderate the forum, meaning that inappropriate or incorrect messages on the forum can be commented on or deleted.

2.7.5. Background information

This module provides PNs with up-to-date information on a variety of topics relevant for smoking cessation counseling. The information includes facts and figures about smoking (cessation), Dutch rules and regulations about smoking, an overview of compensation of smoking cessation counseling by Dutch healthcare insurers, a description of the content of evidence-based smoking cessation guidelines, patient-centered materials that can be used during counseling, information about smoking related to pregnancy, and a collection of links to relevant websites for more information.

2.8. General modules

Both PNs that are enrolled in the intervention and control group of the trial have access to three general modules of the web-based CT program: project information, FAQs and the counseling checklist.

The module with project information provides general information about the research project and the web-based CT program. It also addresses aspects related to the randomized controlled trial, such as the timing of the invitations for the questionnaires, the randomization procedure, the recruitment of smokers and the incentive for trial completion.

The FAQs module provides PNs with answers to predefined questions regarding the web-based CT program and the randomized controlled trial. PNs can use this module to find immediate answers to relatively simple questions, such as 'How do I sign in to the online program?'. They can also directly contact the research team via email or telephone in case they have a question that is not covered by the FAQs module.

Finally, PNs in both groups have access to the counseling checklist. This checklist has two main goals, which are important for the randomized controlled trial testing the effectiveness of the web-based CT program. The checklist is a tool for PNs for a) the recruitment of interested smokers (see recruitment smokers) and b) registration of a PN's adherence to evidence-based smoking cessation guidelines (see data collection).

2.9. Data collection

PNs in both the control and the intervention group are prompted via email to complete three online questionnaires: at baseline (maximum 30 min required), and six months (maximum 20 min required) and 12 months (maximum 10 min required) after baseline. Email reminders are sent one week and two weeks after receiving the invitation to complete a questionnaire, each time a PN has not yet (completely) filled out that particular questionnaire. Questionnaires are based on the I-Change Model [30] and the Self-Determination Theory [31], and are based on questionnaires previously used among health professionals [11,32,33]. The baseline questionnaire for PNs consists of questions concerning demographic characteristics (e.g. age, sex, education, work experience), smoking cessation guideline adherence, and potential behavioral predictors (i.e. intention, knowledge, attitude, self-efficacy, social influence, action and coping planning), as derived from the I-Change Model [30]. Furthermore, the questionnaire includes a set of questions about PNs' motivation to use an evidence-based smoking cessation guideline, based on Self-Determination Theory [31,34]. The 6-month follow-up questionnaire again includes questions about smoking cessation guideline adherence, potential behavioral predictors and motivation. Additionally, several questions are added to this questionnaire to inform the process evaluation, based on previously used questionnaires [35,36]. The 12-month follow-up questionnaire includes questions concerning smoking cessation guideline adherence and the most proximal predictors of behavior (i.e. intention, attitude, self-efficacy, social influence) according to the I-Change Model [30]. Additionally, all PNs are asked whether they have had access to the intervention modules (i.e., brief tailored advice, extended tailored advice, new tailored advice, the online forum and background information) during the trial, as to corroborate that PNs in the control group were not exposed to intervention modules.

Smoking patients counseled by PNs from both groups are invited via email to fill out three online questionnaires (maximum 10 min required per questionnaire): at baseline, and 6 months and 12 months after baseline. The baseline questionnaire includes questions concerning demographic characteristics (e.g. age, sex, and education), smoking status, their PN's smoking cessation guideline adherence and autonomy-supportiveness, based on Self-Determination Theory [31,37]. Moreover, healthcare usage, and quality of life [38,39] are measured. The 6-month and 12-month follow-up questionnaires again address a patient's smoking status, their PN's smoking cessation guideline adherence and autonomy-supportiveness, and a patient's healthcare usage and quality of life. Additionally a few questions are included to inform the evaluation of PNs' smoking cessation consultations with patients (e.g. assessing whether a patient agrees/disagrees about their PN's advice being helpful to quit smoking).

As briefly mentioned in the description of the general modules, data about PNs' smoking cessation guideline adherence is also collected via the counseling checklist. During the entire trial period (i.e. twelve months) PNs in both groups provide smoking cessation care to their patients and are asked to fill out a counseling checklist after every consultation with a patient. Via the counseling checklist, PNs fill out the date and duration of each smoking cessation consultation, and report which guideline steps were adhered to (yes/no) during that particular consultation. The following guideline steps are assessed in the checklist: providing a quit advice, assessing smoking profile and smoking history, assessing motivation, increasing motivation, assessing barriers, discussing relevant barriers, discussing the use of cessation aids, setting a quit date and making a quit plan, and organizing consultations after the quit date. Finally, PNs can briefly describe why particular steps were not adhered to, if this was the case. When PNs fill out a checklist about the next consultation with the same patient they can select the email address of that particular smoker from a drop-down menu. This enables the researchers to register the number of consultations with each patient.

2.10. Outcome measures

The primary outcome measure of this randomized controlled trial is PNs' evidence-based smoking cessation guideline adherence, which is calculated based on three assessments:

1. By assessing PNs' adherence as perceived by participating smokers (in smokers' baseline and both follow-up questionnaires).
2. By asking PNs to self-report their adherence to each of the guideline steps during each consultation with a smoking patient (using the counseling checklist, throughout the study).
3. By at random audiotaping 10% of the consultations during which PNs engage in smoking cessation counseling with a smoking patient (throughout the study, with audiotapes scored by two independent coders).

All data concerning PNs' smoking cessation guideline adherence is collected dichotomously: has each step been adhered to (yes/no)?

This results in a score ranging from zero (none of the steps are adhered to) to nine (all steps are adhered to) for each type of assessment. PNs' self-report data and smokers' data will be triangulated and averaged for each counseled smoker [42]. Subsequently, a mean adherence score will be calculated for each PN based on all consultations conducted during the trial period (12 months). This adherence score will be used as the primary outcome measure for this study. In case large discrepancies (i.e. a difference in adherence of 3 guideline steps) between the two self-report measures are observed, both PN and smoker endpoints will be used as separate outcome measures instead of using the triangulated score.

2.10.1. Secondary outcome measures

Secondary outcome measures are counseled smokers' point prevalence smoking abstinence and number of serious quit attempts during the trial period. Point prevalence abstinence (PPA) is measured by asking whether the participant has smoked (yes/no) during the last 24 h (24 h PPA) and during the last seven days (7d PPA). A serious quit attempt is defined as a period of at least 24 h of abstinence.

2.11. Statistical analyses

2.11.1. Sample size and power calculation

One of PNs' main tasks is to counsel patients wanting to change their lifestyle; therefore, it is hypothesized that at baseline most PNs already adhere to at least one of the smoking cessation guideline steps (i.e. provide quit advice). Due to measurement effects, an increase in adherence is expected in the control group to adherence to two steps, while it is estimated that the intervention yields adherence to four steps. To be able to detect this difference significantly ($\alpha = 5\%$; $\beta = 10\%$), assuming a medium effect size [43], 95 PNs per arm are necessary at the end of the trial (190 in total). Considering 30% attrition we aim to include at least 272 PNs at baseline.

Among smokers, a 10% difference in 7 d PPA is expected between smokers in the control group (expected increase of 10%) [44,45] and intervention group (expected increase of 20%). To significantly ($\alpha = 5\%$; $\beta = 20\%$) detect this difference, using an Intraclass Correlation Coefficient of 0.06, taking into account the multilevel design of the trial and a pessimistic scenario (i.e. allowing for variation in the number of recruited smokers by different PNs) [46], the 190 PNs need to include around 1200 smokers (6–7 smokers each).

2.11.2. Data analysis

To assess the effects of the intervention and other potential predictors on adherence, linear regression analyses will be conducted. To assess effects on smoking cessation measures logistic (PPA variables) or linear (number of quit attempts) regression analyses will be done. Intention-to-treat (ITT) analysis as well as complete case analysis will be conducted. Data will be analyzed using SPSS version 21.

2.12. Additional studies

In addition to the described randomized controlled trial, several other studies will be conducted within this research project.

2.13. Process evaluation

As part of the first follow-up questionnaire, all PNs are asked about their general experiences with the web-based CT program, their opinion about the program's user-friendliness, and about possible improving alterations to the program. PNs in the intervention group also evaluate the extra modules they had access to during the trial period in terms of their usefulness and user-friendliness. Data gathered with these questions are used to develop an interview guide to conduct additional telephone interviews with PNs to obtain specific recommendations for improvement of intervention materials. The process evaluation among smokers predominantly evaluates the quality of their PN's smoking cessation care as perceived by the smokers.

2.14. Forum usage analysis

PNs' activities on the forum are monitored in order to conduct an analysis of forum usage. The following forum parameters are collected for every PN: number of visits, number of posts, number of replies and number of views. In addition, data is collected about the content of forum posts, and about interactions between forum users writing a particular post and users replying to those posts. An analysis of these parameters can be used to investigate whether the degree of forum usage and user interaction influences the study's outcome measures.

2.15. Economic evaluation

The economic evaluation study involves a combination of a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA). Data for this study is collected during the baseline and follow-up measurements as part of the trial. For both CEA and CUA the intervention costs, healthcare costs and patient costs are identified as relevant. For the CEA, the incremental cost-effectiveness ratio (ICER) is expressed as the incremental costs per additional quitter (measured as 7d PPA) in the intervention group as compared with the control group. For the CUA, the ICER is expressed as the incremental costs per quality-adjusted life year (QALY) gained, based on the quality of life measures EuroQol [39] and ICECAP [38].

3. Discussion

This paper described the development of a web-based CT adherence support program for Dutch PNs and the study design of a randomized controlled trial testing its effectiveness. It is hypothesized that CT advice can support PNs to improve their adherence to evidence-based smoking cessation guidelines during consultations with their smoking patients. Due to the tailored nature of the web-based advice, PNs only receive advice and practical tips about counseling aspects they have individually identified as being relevant to them. Furthermore, by taking into account PNs' needs regarding the design and content of the web-based CT support program, an easy-to-use program was created containing individually relevant and visually attractive information which PNs can use at their convenience wherever and whenever they want. Incorporating PNs' content and design needs was hypothesized to increase their interest in the program resulting in higher exposure to the program's content [18,47,48] and making it more likely that the program actually improves PNs' smoking cessation guideline adherence. PNs' improved guideline adherence could subsequently enhance the quality of smoking cessation care in Dutch general practices, ultimately resulting in a higher number of smokers successfully quitting smoking. If proven effective, it might hence be worthwhile to pursue widespread implementation of web-based CT adherence support for PNs, leading to increased benefits regarding the amount of smoking related illness and death.

3.1. Potential strengths of the study

This study has several potential strengths. First, triangulation is used for calculating our primary outcome measure. PNs' evidence-based guideline adherence is assessed via online questionnaires filled out by counseled smokers, via self-report questionnaires filled out by PNs (checklists), and via an assessment of audiotaped consultations by two independent coders. Assessing the same outcome measure from three different perspectives and subsequently integrating two of them into a single outcome measure improves the reliability of our primary outcome measure [49]. In this way, the influence of responding in a

socially desirable manner, which is often observed in self-report questionnaires [50], can be corrected for by assessments via smoking patients.

Secondly, the design and content of the web-based CT program is based on theory [30,31], previously developed CT programs [32,46,47] as well as on a qualitative needs assessment we conducted among Dutch PNs [16]. This helped us to match the content of the CT program to the most important factors influencing PNs' guideline adherence and to develop an adherence support program that matches PNs' needs concerning content and design features of such a program. Integrating PNs' needs in the design of the web-based CT program is likely to enhance their interest in and use of the program, aiming for maximum exposure to the program's tailored content [47] and resulting in optimal effectiveness.

Thirdly, random allocation of practice nurses to either the control or intervention group is executed by an automated computerized process. The research team has no influence on this process since they only know in which group a participant is placed after the allocation procedure has finished.

3.2. Potential limitations of the study

The present study also has some potential limitations. First, randomization on PN level might lead to PNs from the same general practice being allocated to different treatment groups. This might introduce contamination, since information transfer between different PNs could take place (i.e. from an intervention group PN to a control group PN, and vice versa). However, in only 22.4% of Dutch general practices more than one PN is employed [9], which restricts the potential for contamination bias to only these practices. Moreover, by asking PNs in both study groups at the second follow-up measurement whether they have had access to intervention group modules (i.e., brief tailored advice, extended tailored advice, new tailored advice, the online forum and background information) during the trial we are able to measure exposure to these modules — also among control group PNs. Potential access to these intervention modules by PNs in the control group can subsequently be corrected for in statistical analyses.

Secondly, participating PNs know about group allocation after they have filled out the baseline questionnaire, because they see what modules of the CT program they have access to at that moment. PNs who are allocated to the intervention group might be more likely to adhere to filling out counseling checklists, to recruit smokers and report on the consultations with smokers held during the intervention period, than PNs in the control group, because they know they have full access to all modules. In order to promote the use of the counseling checklists among all PNs, for recruiting smokers and reporting on consultations, email reminders are sent to all PNs stressing the importance of using the checklist and providing tailored feedback on how often they have used it so far. Moreover, as an extra stimulus to engage with the online program, PNs in the control group are informed that they receive access to the content of the intervention module with background information after the trial has ended. These strategies are implemented to prevent high rates of non-usage attrition, especially among PNs in the control condition [48].

A third potential limitation concerns the high rates of drop-out attrition among participants in web-based interventions, often caused by a lack of face-to-face contact and a high degree of anonymity [48]. In the present study, we try to prevent high attrition rates among participating PNs with several strategies often applied in web-based CT programs, such as providing tailored feedback, sending reminders via email, providing an incentive for study completion, minimizing usability challenges and providing personal contact [51]. By integrating PNs' needs regarding the content and design of the web-based CT program as identified in our preliminary needs assessment, we aim to make the program as personally relevant and convenient to use as possible. Moreover, usability challenges are minimized by incorporating results from usability tests among PNs and behavior change experts, which were conducted prior to the start of the trial. Finally, personal contact is ensured by contacting PNs via telephone at three time points during the trial, in order to lower the degree of anonymity and make sure PNs know the researchers involved in the study and also how to be able to contact them with problems or questions. Relatedly, in order to prevent high rates of drop-out attrition among smokers, we use strategies like minimal time investment, email reminders and an incentive for study completion [51].

4. Conclusion

This detailed description of the development of a web-based CT adherence support program for Dutch PNs offers insight into its potentially effective working mechanisms. The results of the randomized controlled trial testing the program's (cost-)effectiveness, the process evaluation study and an analysis of forum usage will be reported in other papers. These results will benefit our understanding of effective interventions supporting PNs working in the general practice setting to improve their adherence to evidence-based smoking cessation guidelines. Furthermore, when proven effective, the results from these studies might provide insight into the potential value of adapting the program's content to the work situation of other healthcare professionals involved in smoking cessation counseling. Adherence to evidence-based smoking cessation guidelines among health professionals as midwives, dentists and physical therapists is not yet optimal either and could hence also be improved [52,53]. Adaptation and implementation of an effective web-based CT adherence support program for a wider range of health professionals could lead to even greater public health benefits.

Conflicts of interest

None declared.

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