UNIVERSITY OF AMSTERDAM

UvA-DARE (Digital Academic Repository)

The PAS study: A Randomized Controlled Trial evaluating the effectiveness of a web-based multiple tailored smoking cessation programme and tailored counselling by practice nurses

Smit, E.S.; de Vries, H.; Hoving, C.

DOI
10.1016/j.cct.2010.03.001

Publication date
2010

Document Version
Author accepted manuscript

Published in
Contemporary clinical trials

Link to publication

Citation for published version (APA):
Smit, E. S., de Vries, H., & Hoving, C. (2010). The PAS study: A Randomized Controlled Trial evaluating the effectiveness of a web-based multiple tailored smoking cessation programme and tailored counselling by practice nurses. *Contemporary clinical trials*, *31*(3), 251-258. https://doi.org/10.1016/j.cct.2010.03.001

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: https://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.

UvA-DARE is a service provided by the library of the University of Amsterdam (https://dare.uva.nl)

Download date:20 Jun 2024

NOTICE: this is the author's version of a work that was accepted for publication in Contemporary Clinical Trials. Changes resulting from the publishing process, such as peer review, editing, corrections, structural formatting, and other quality control mechanisms may not be reflected in this document. Changes may have been made to this work since it was submitted for publication.

A definitive version was subsequently published as:

Smit, E.S., de Vries, H., Hoving, C. (2010). The PAS study: A Randomized Controlled Trial evaluating the effectiveness of a web-based multiple tailored smoking cessation programme and tailored counseling by practice nurses, *Contemporary Clinical Trials, 31*, 251-258. DOI: 10.1016/j.cct.2010.03.001

Study protocol

The PAS study: A Randomized Controlled Trial evaluating the effectiveness of a web-based multiple tailored smoking cessation programme and tailored counselling by practice nurses

Eline S. Smit*, Hein de Vries, Ciska Hoving

Department of Health Promotion, School for Public Health and Primary Care (Caphri), Maastricht University, P.O. Box 616, 6200 MD Maastricht, the Netherlands. Telephone: +31 43 3882397. Fax +31 43 3671032. E-mail: es.smit@gvo.unimaas.nl; hein.devries@gvo.unimaas.nl; c.hoving@gvo.unimaas.nl

* Corresponding author. Tel.: +31 43 3882397; fax: +31 43 3671032.
E-mail address: es.smit@gvo.unimaas.nl (Eline S. Smit)

Abstract

Background: PAS (Personal Advice in Stopping smoking) combines two of the most effective smoking cessation interventions: multiple computer tailoring and tailored counselling by a practice nurse in the general practice.

Methods/Design: Since May 2009, practice nurses are recruiting smoking patients. Each practice nurse is asked to recruit 15 adult smokers willing to quit within six months and having access to the Internet. Smokers can sign up for PAS through the PAS website and are then randomized into one of three groups receiving multiple tailoring and counselling (MTC), multiple tailoring (MT) or usual care (UC), respectively. All groups receive questionnaires at baseline, 2 days after a set quit date and at 6 weeks, 6 months and 12 months follow-up. The MT group receives tailored, iterative feedback letters at the first four measurements points. At 12 months follow-up biochemical validation will take place amongst respondents reporting to have quit. The three groups will be compared with regard to quit attempt rate, point prevalence abstinence and continued abstinence by means of logistic multilevel regression analyses. Linear multilevel regression analyses will be used to compare the three groups regarding smoking related beliefs.

Discussion: The present paper provides an extensive description of the development of PAS and of the design of the study towards its effectiveness. This might provide insight into PAS' potentially effective working mechanisms. The results concerning effectiveness may contribute to knowledge about the effectiveness of smoking cessation interventions aimed at smoking adults.

Trial registration: Dutch Trial Register NTR1351

Keywords: smoking cessation, computer tailoring, counselling, practice nurse, randomized clinical trial

Background

The smoking of tobacco is the most preventable cause of illness and premature death in the world [1, 2]. To aid smokers to quit successfully, effective smoking cessation interventions are essential. Computer tailored programmes have shown their efficacy [3-5]: a single tailored intervention resulted in significantly more quit attempts compared to no intervention [6, 7] and the impact of tailored interventions even increased when providing tailored information on more than one occasion (multiple tailoring) [8, 9]. But, outside scientific studies, multiple tailored smoking cessation feedback is not yet available to the Dutch general public.

A brief smoking cessation advice from a general practitioner (GP) also results in a small though significant effect on quit rates [10, 11]. GPs consider smoking cessation activities as part of their work and value these as most important in health promotion [12]. However, they also report a lack of time and skills as barriers in assisting smokers to quit on a larger scale [13, 14]. If GPs can delegate preventive tasks to others within the general practice, time constraints could diminish and the adoption of smoking cessation advice will be more likely. One possibility would be to shift our focus from GPs to practice nurses, a relatively new profession in the Netherlands. A practice nurse takes over certain tasks of the GP, such as consultation hours with patients having chronic diseases, e.g. diabetes, asthma, or hypertension. The additional value of practice nurses has been recognized, as they increase the quality of care and relieve GPs by providing care and counselling to these specific patient groups [15]. In 2007, 62% of all Dutch general practices employed a practice nurse [16].

Although computer tailoring and counselling are two of the few effective smoking cessation interventions developed so far [4], stand-alone interventions are known mostly to have only limited success [17]. Within PAS (Personal Advice in Stopping smoking), multiple computer tailoring and a counselling session with a practice nurse are combined, as the combination of two effective stand-alone interventions can be expected to achieve higher abstinence rates than either of the two alone. Supporting this approach, earlier studies showed that combining a

single tailored intervention with counselling has an additional effect compared with tailoring alone, when aiming at smoking cessation [18, 19].

This paper aims to thoroughly describe the PAS programme, its development and the intervention components it consists of, in order to facilitate the discovery of its effective working mechanisms and to make replication possible.

Methods/Design

PAS was approved by the Medical Ethics Committee of Maastricht University and the University Hospital Maastricht (MEC 08-3-037; NL22692.068.08), and is registered with the Dutch Trial Register (NTR1351). The approval covers all participating general practices in the study.

Recruitment of practice nurses

From January until March 2009, practice nurses working in general practices in the Netherlands were invited to fill out a short web-based questionnaire concerning the adoption of PAS. They were encouraged to discuss the adoption of PAS with GP(s) and practice nurses they were working with before filling out this questionnaire. Besides aiding in recruitment, this questionnaire also served as a means to assess characteristics of adoptive and non-adoptive practice nurses. Practice nurses who reported to be willing to adopt the intervention or who required more information to make a decision were contacted by telephone in order to be recruited for participation in the effectiveness study. In the first half of 2009, recruited practice nurses were visited by a member of the PAS research team. This visit aimed to explain both study procedures and the PAS counselling protocol and to secure a working relationship with each practice nurse.

Recruitment of smoking respondents

From May 2009 on, practice nurses started recruiting smoking respondents from their practices. Following procedures used in previous experiments [13, 20], a recruitment period of six months is used for each practice nurse to collect

smoking participants from their general practice. Each practice nurse is asked to recruit 15 participants for the study (five for each of the study arms). During the PAS research team's visit, practice nurses were instructed on the information to be given to each potential smoking participant before referring them to the PAS website. In addition, a Frequently Asked Questions (FAQ) section is included in the PAS counselling protocol, providing answers to numerous possible questions patients might ask their practice nurse about the study. To further assist practice nurses in recruiting enough patients, several recruitment materials are made available (e.g. desk displays and PAS business cards).

Inclusion and exclusion criteria for smokers

Respondents can be included in the study when they currently smoke, are motivated to quit within six months, are 18 years or older and are sufficiently proficient in Dutch. Moreover, they have to have access to the Internet. There are no explicit exclusion criteria.

Randomization

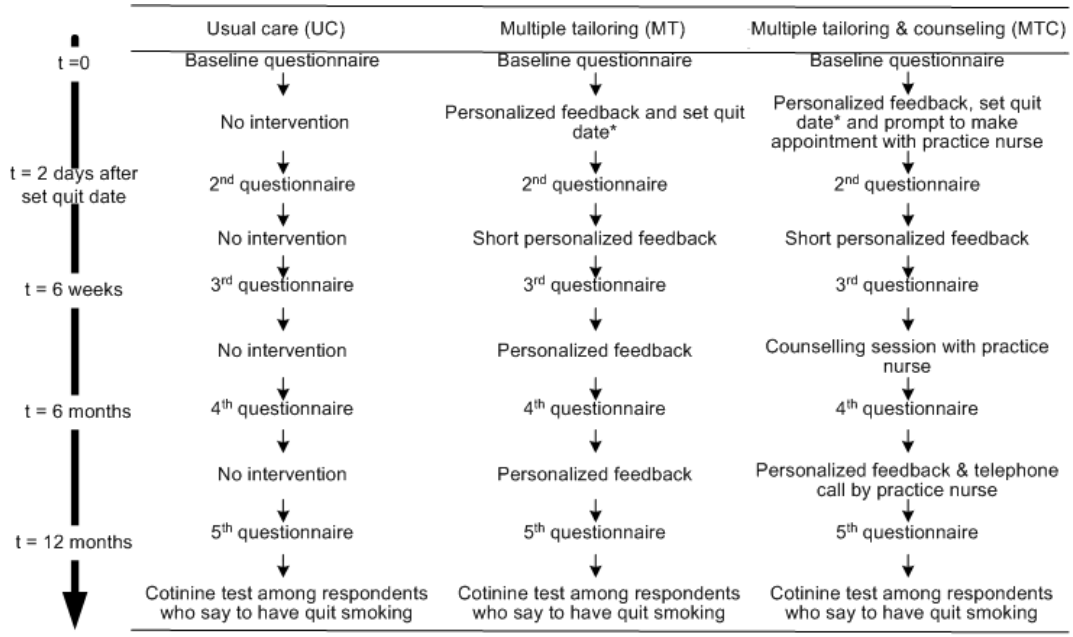
Interested smokers are directed by their practice nurse to the PAS website (www.persoonlijkstopadvies.nl), where they can sign up for the study with their own username and password. No one but the PAS research team is able to retrieve these passwords. Subsequently, after signing the online informed consent form, participants will be randomly allocated to either the control condition or one of the two experimental conditions. Randomization takes place at respondent level by means of a computer software randomization device. Blinding of respondents and practice nurses is not possible due to recruitment procedures and the requirement that respondents take notice of whether or not they are receiving an intervention.

Study design

Participants are randomly allocated to either the control condition or one of two experimental conditions (figure 1).

1. Control group (usual care; UC): Respondents receive care as usual from their general practice. They are thus able to receive any method that is usually used in their general practice to aid patients to quit smoking.
2. Multiple tailoring (MT): Respondents receive four personalized feedback letters at different time points.
3. Multiple tailoring and counselling (MTC): Respondents receive three tailored feedback letters, like the MT group, but one letter (the third) is replaced by a counselling session with a practice nurse. Also, the last tailored feedback letter (at six months follow-up) is accompanied by a telephone call from the practice nurse involved.

Figure 1. Flow-chart of the randomized controlled trial testing the effectiveness of PAS: multiple tailoring & counselling by practice nurse



Questionnaires

In all three study groups, respondents are prompted by e-mail to fill in an online questionnaire at five points in time: at baseline, two days after the quit date each

respondent sets at baseline, and then at six weeks, six months and 12 months after filling out the baseline questionnaire. One reminder is sent by e-mail each time that, one week after receiving the invitation, a respondent has still not filled out the particular questionnaire he or she was invited to complete.
Questionnaires are based on the I-Change model [21] and have been tested experimentally among Dutch smoking adults in previous studies [6, 22, 23]. Each questionnaire (except the questionnaire two days after the set quit date) consists of questions concerning smoking behaviour, addiction level, attitude, self-efficacy, social influence, action and coping planning and intention to quit smoking and/or to maintain non-smoking [21]. At baseline, respondents are asked to plan a quit date within the upcoming 4 weeks. The questionnaire two days after this quit date only consists of questions concerning smoking behaviour and implemented action and coping plans, as we want to minimize the burden of filling out a questionnaire by smokers who have recently quit. For smokers who have quit at follow-up, measurements, questions and feedback about action plans are skipped, as preparatory plans become redundant once the respondent has actually quit. For these respondents, emphasis is laid on coping plans.

Web-based multiple tailored smoking cessation advice

With tailored health communication, the content of the health message is adapted to the specific characteristics of a particular individual with a view to attracting and keeping the individual's attention [24, 25]. Baseline computerized feedback messages of the present tailoring programme are based on a previously tested effective theory based single computer-tailored intervention [6]. The feedback respondents will receive later on during the programme is created by the PAS research team. Feedback letters are personalized and based upon the answers provided by respondents in the questionnaires, as personalization and feedback are both shown to be working mechanisms of tailoring [26, 27]. Messages are tailored to several respondent characteristics, based on the I-Change model [21]: gender, cognitive variables (attitude, social influence and self-efficacy), intention to quit smoking, goal and relapse prevention strategies

(action and coping plans), and smoking behaviour. Feedback is item based in order to provide more detailed feedback and to improve personalization of the feedback messages. Moreover, feedback will be iterative, in that the second, third and fourth feedback letters not only concern the respondent's present state, but also refer to changes (in behaviour, but also in beliefs) made by the respondent compared with earlier measurements.

Questions are alternated with feedback in order to improve retention rates. Feedback messages ultimately form a complete feedback letter that is presented to respondents after completion of the questionnaire. All feedback letters, except the one two days after the set quit date, are 4-5 pages in length and consist of seven components:

1. Introduction, including specific *behavioural feedback* and feedback on the respondent's level of *intention* to quit smoking or to maintain non-smoking.
2. Feedback on the *advantages (pros) and disadvantages (cons)* of smoking and quitting smoking. Feedback is given on the respondent's scores on 12 items measuring the pros and cons of smoking.
3. Feedback on the respondent's perceived *social influence* (perceived social norms, social modelling and social support).
4. Feedback on level of *self-efficacy* not to smoke in potentially difficult situations, varying from not smoking when just having had dinner to not smoking when being offered a cigarette.
5. Feedback on *action plans* on the extent to which respondents are planning to undertake specific actions (e.g. telling others about one's quit attempt) while preparing their quit attempt.
6. Feedback on how to deal with difficult situations (*coping plans*). For the same situations as included in the questions on self-efficacy, respondents can choose to formulate a specific plan in order not to smoke when these situations occur. Respondents are asked to formulate these plans in the form of if-then statements, as these have proven to be successful in significantly reducing long-term relapse to smoking [28].

7. *Ending*, in which the PAS research team wishes each respondent good luck during their quit attempt/maintaining their non-smoking behaviour.

The feedback letter respondents receive 2 days after the quit date they set at baseline consists of only one page as this feedback letter is based on a shorter questionnaire. This feedback provides respondents with relapse prevention strategies, as recent studies show that 70-80% of ex-smokers relapse within 3 months time [29, 30].

Respondents can access their personal feedback in three ways: it is directly made available online, feedback letters are sent to the respondent by email and they can be printed.

The computer tailoring programme was pilot tested among both researchers specialized in smoking cessation research and among our target population of current smokers [31]. Researchers were consulted for their expertise in translating theoretical concepts into questions, whereas smokers were asked about several characteristics of the questions and tailored feedback letters (e.g. Do you understand what is meant by each question?; Do you perceive the advice given as interesting?; Do you think the feedback messages are annoying?). The results from this pilot test indicated, among other things, that the questions were understandable and easy to answer and that the feedback given was clear and perceived as personally relevant. However, some minor technical changes had to be made in the tailoring programme (e.g. some people received feedback not completely matching their answers to the questions).

Tailored counselling by practice nurses

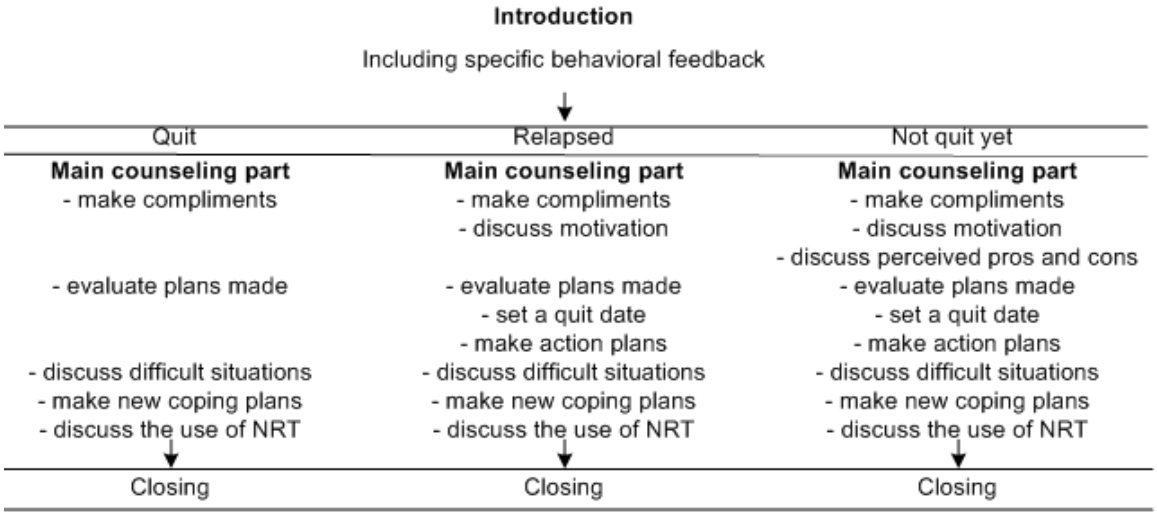
After receiving the first tailored feedback, respondents in the MTC group are prompted to schedule a counselling meeting with their practice nurse within 6-8 weeks. As shown in figure 1, the MTC group receives this counselling session at the same time as respondents in the MT group receive their third tailored feedback letter. Practice nurses are provided with a summary of the answers MTC respondents gave in the questionnaire at 6-week follow-up. The PAS

counselling protocol and this summary together provide a framework for the counselling session.

To assist practice nurses in guiding counselling sessions, a counselling protocol has been developed. This protocol is based on interviews held with practice nurses (N=16), to gain insight into their expectations and desires concerning the content and structure of such a counselling protocol. The final PAS counselling protocol consists of three main chapters guiding counselling sessions with three different types of patients: smokers who have quit, smokers who have quit but relapsed, and smokers who have not quit yet. For these three types of patients, different issues are to be discussed during the counselling session, but the structure of all sessions is the same. A pilot test has been conducted among practice nurses and smoking cessation counselling experts and has been modified based on their feedback. Both the content and structure of the different counselling sessions are visually displayed in figure 2.

After each counselling session, practice nurses are asked to fill out a checklist, so that we can monitor what has been discussed in each session and investigate whether the PAS counselling protocol was used correctly. These checklists may be used by practice nurses during counselling sessions as a mnemonic device to prevent oversight. Practice nurses can return the checklists either by mail or e-mail. Pre-addressed and pre-paid envelopes have been included in the protocol for the practice nurses to return the checklists by mail. Moreover, general information about PAS and about the study being conducted, advice on how to recruit smoking patients for the study, a section with frequently asked questions and the PAS research team's contact information are also included in the counselling protocol.

Figure 2. Flow-chart of the three different types of counselling sessions by practice nurses



In addition, we provide practice nurses with a PAS CD-ROM. The CD-ROM visually supports the counselling protocol. Besides information about PAS, the CD-ROM also provides short exemplary videos presenting different types of smokers/quitters a practice nurse may encounter in the general practice.

Biochemical validation

When conducting intervention studies, biochemical validation is warranted to test whether self-reported behaviour is accurate [32]. Mostly used is the cotinine assessment, as it is accurate and sample collection is simple: a sample of saliva can be collected with a swab stick.

Practice nurses will be responsible for conducting cotinine tests in their general practice. As this test has to be undergone four days after filling out the last questionnaire at twelve months follow-up, the PAS research time will provide practice nurses with a sufficient number of cotinine tests beforehand. Once the respondent has filled out the twelve months follow-up questionnaires and indicated that he or she has quit smoking, the practice nurse will be instructed to invite the participant for a voluntary appointment to conduct the cotinine test. If respondents refuse to undergo the test, practice nurses are instructed to ask for their main reason for refusing.

After the saliva is collected with a swab stick, it should be applied to a test strip, on which the test result will appear within 20 minutes. Results can be either negative (no cotinine measurable) or positive (cotinine detected in the saliva). Practice nurses will register test results for each patient and report the findings to the PAS research team both by e-mail and regular mail. After having combined the results with data previously gathered for the particular respondent, the saliva sample will be destroyed.

Cohort retention

To retain participating practice nurses, a range of strategies is used. Some of these are targeted, for instance calling them regularly to investigate their progress in recruiting patients and to discuss possibilities for improvement, and sending chocolate telegrams to each practice nurse who has recruited their first five smoking patients. Other strategies are more general, like sending newsletters outlining study progress and practice nurses' and patients' experiences with PAS.

To retain respondents participating in the smoking cessation programme, each respondent will get a 10 euro voucher after filling in the last questionnaire. This is mentioned at the beginning of each questionnaire in order to keep participants motivated to complete their participation in our study.

Outcome measures

The primary outcome measure is *prolonged abstinence*. Prolonged abstinence is defined as not having smoked since filling in the baseline questionnaire, taking into account a grace period of 4 weeks (0=no; 1=yes). A grace period is considered the initial period directly after the intervention delivery, in which quitting and re-initiating smoking behaviour will not be counted as such [33, 34].

Secondary outcome measures

Secondary outcome measures are *having made a serious quit attempt* (at least 24 hours of abstinence*) since the previous measurement point* (0=no; 1=yes),

24-hour point prevalence abstinence (having refrained from smoking during the last 24 hours; 0=no; 1=yes), *7-day point prevalence abstinence* (having refrained from smoking during the last 7 days; 0=no; 1=yes), *continued abstinence* (having refrained from smoking since the previous measurement point; 0=no; 1=yes) and changes in overall tobacco consumption, intention to quit smoking and/or to maintain non-smoking, attitude, self-efficacy and social influence.

Overall tobacco consumption is measured using five open-ended questions regarding the quantity of cigarettes, shag, cigars, cigarillo's and pipes respectively, smoked per day. The answers to these five questions are then converted into one overall score (in number of cigarettes) representing tobacco consumption.

Intention to quit smoking is measured by one item asking the respondent whether or not he or she is intending to quit smoking, on a 7-point Likert scale (1=very surely not; 7=very surely yes). This question is only asked when respondents indicate that they still smoke.

Intention to maintain non-smoking is measured by one item asking the respondent whether or not he or she is intending to maintain non-smoking, also on a 7-point Likert scale ranging from 1=very surely not, to 7=very surely yes. This question is only asked when respondents have quit smoking.

Attitude is measured by twelve items, with which a respondent can agree or disagree, measured on a 5-point Likert scale (e.g. When I do not smoke, my condition will improve; 1=no, does not improve; 2=do not know; 3=yes, will improve a bit; 4=yes, will improve; 5=yes, will improve a lot; When I do not smoke, it is harder for me to relax; 1=no, it is not harder to relax; 2=do not know; 3=yes, it is a bit harder to relax; 4=yes, it is harder to relax; 5=yes, it is a lot harder to relax).

Self-efficacy is measured by nine items measured on a 5-point Likert scale (e.g. Do you think you will manage not to smoke when taking a break or when you are being offered a cigarette?; 1=surely not; 2=probably not; 3=maybe yes, maybe no; 4=probably yes; 5=surely yes).

Social influence is measured by nine items: three items measuring social norms (e.g. My partner…; 1=thinks that I should not smoke; 2=probably thinks that I should not smoke; 3=neutral/do not know; 4=probably thinks I should smoke; 5=thinks that I should smoke; 9=not applicable), three items measuring social support (e.g. My children support my not smoking; 1=no, my children do not support me; 2=do not know; 3=yes, my children support me a little; 4=yes, my children support me; 5=yes, my children support me a lot; 9=not applicable) and three items measuring social modelling (e.g. How many of your friends smoke?; 1=none of them; 2=the minority; 3=half of them; 4=the majority; 5=all of them; 9=not applicable). All three constructs take into account the respondent's partner, children and friends.

Statistical analyses

Sample size and power

We expect 10% point prevalence abstinence in the control condition [6, 7]. Power estimations are based on the ability to detect differences of 10% with a power of .95 and p-value of .05. We estimate that the multiple tailoring intervention will lead to 20% and the combination with counselling to 30% point prevalence abstinence. To be able to detect this difference significantly, almost 300 respondents per intervention arm are necessary at the end of the trial (900 respondents in total) [35]. Including 20% attrition over the trial period, 1100 respondents need to be recruited. As we expect an additional attrition of 20% in the multiple tailoring and counselling arm (as some respondents randomized in this arm might refuse to or do not show up), we aim to include around 1200 respondents in the study; 400 respondents in each of the study arms. As practice nurses will be recruiting 15 participants each, we have recruited 80 practice nurses. Given the high response rates in previous studies, the number of smoking participants and the number of practice nurses to be recruited are reasonable.

Analysis

As we randomize smoking patients within their general practices, to assess the effect of PAS on both main and secondary outcome parameters, multilevel analyses will be used. Conducting multilevel analyses will enable us to correct for the effect different practice nurses and/or general practices may have on the outcomes measured at patient level. As our main outcome parameters are dichotomous variables, logistic multilevel regression analyses will be conducted when it concerns these outcome measures. To assess the effect of PAS on secondary outcome measures, linear multilevel regression analyses will be conducted, as these are continuous variables. Intention-to-treat (ITT) analysis will be conducted as well as complete case analysis. Results will be corrected for baseline variables (e.g. demographics, attitude, intention and smoking behaviour) by adding these variables to the multilevel model. Moreover, the likelihood of chance findings will be considered and if needed, Bonferonni corrections will be applied.

Subgroup analyses will be conducted to analyze differences in the importance of the predictors in gender and SES (socio-economic status) subgroups, also using multilevel analyses. These will be corrected for baseline variables (demographics, cognitions, intention and behaviour) by means of ANOVA. Bonferonni corrections will be applied if necessary.

Data will be analyzed using Mplus version 5.

Additional studies

In addition to the effect study extensively described in this paper, three other studies will be conducted regarding PAS, which will be described briefly.

Process evaluation A process evaluation will be conducted among respondents, practice nurses and GPs to assess their respective experiences with PAS. In addition, this study will aim at identifying potential alterations that would improve the implementation of PAS. For respondents, questions about the intervention received will be added to the questionnaire they receive at 12-months follow-up. Practice nurses and GPs will be invited to fill in a process

evaluation questionnaire included in the debriefing letter they receive at the end of the study.

Feasibility analysis Among those practice nurses initially labelled as non-adopters, a study will be conducted towards the feasibility of the diffusion of the PAS counselling protocol on a large scale. Additionally, we aim to identify possible improving alterations to the protocol in order to facilitate implementation. Within this study, practice nurses do not need to recruit participants, but are asked to use the PAS protocol for the duration of three months. After this period, they will be interviewed by telephone concerning their experiences, perceived advantages of the protocol and the difficulties encountered while using it. Moreover, the number of counselled smokers will be assessed.

Cost-effectiveness analysis In the end, a study will be conducted to assess the cost-effectiveness of the multiple computer tailoring programme and tailored counselling protocol, together entailing PAS.

Discussion

This paper described the development of PAS and the design of the study testing its effectiveness. PAS aims to evaluate the effectiveness of a web-based multiple tailored smoking cessation programme combined with tailored counselling by practice nurses, compared with multiple tailoring alone and both compared with usual care. It is hypothesized that the combination of two effective stand-alone interventions will result in higher abstinence rates than either of these two alone. Within PAS the counselling session was provided by practice nurses instead of by GPs, as GPs have often reported a lack of time and skills to help smokers who want to quit [13, 14]. If counselling given by a practice nurse in combination with web-based computer tailoring is as effective, or even more effective, than counselling given by GPs, the GPs' time constraints could be reduced and practice nurses could permanently adopt the task of providing smoking cessation advice.

(Potential) strengths of the study

The present study had several potential strengths:

- Motivation as an inclusion criterion

Only smoking patients are eligible to take part in PAS who are motivated to quit within 6 months. As there is only limited time and manpower available within the present study and as motivating smokers to quit can be very time-consuming when motivation is still low, this has led us to use motivation as an inclusion criterion. This is in accordance with inclusion criteria used in previous studies on the effect of online smoking cessation programmes [7, 36]. Moreover, smokers unmotivated to quit were not expected to be willing to set a quit date within the near future, one of the key elements of PAS.

- Randomization approach

An important strength of our study is the randomization approach, in which allocation is covered and done by an automated computerized process. Randomization is done on patient level, because of statistical considerations. Moreover, randomization on practice nurse level seemed unfavourable because it is likely that practice nurses who would have been allocated to the control group would have difficulties including and, more importantly, retaining, sufficient patients [37].

- Use of checklists & audiotapes

All participating practice nurses are given the same instructions on how to use the PAS counselling protocol. However, there is a possibility that not all practice nurses will use the protocol in exactly the same way, due for example to previously existing counselling habits or unfamiliarity with the new protocol. To be able to gain insight into the content of the consultations, all practice nurses are asked to fill out a checklist of each consultation they have according to the PAS protocol. This can be considered in line with the use of intervention cards in a previous study, a strategy proven to be an important predictor of adherence to a minimal-contact smoking cessation intervention [38]. Similarly to the so-called intervention cards, the PAS checklists can function not only as a registration system, but also as a schematic summary of the counselling protocol and as a reminder of all topics needing to be discussed. In addition, each practice nurse is

asked to audiotape one of the PAS counselling sessions, to enable us to get insight into the quality of these sessions as well. Together, the checklists and audiotapes can be used to search for factors increasing or diminishing the effectiveness of the intervention.

(Potential) limitations of the study

The present study also had some potential limitations:

- Participant selection

A selection bias may limit generalization of the results of this study. Those patients who do not have access to the Internet are excluded from participation, which could result in selection bias. However, in the Netherlands, almost 90% of the population has access to the Internet at home, which is the highest percentage of all countries in the European Union [39]. In addition, practice nurses are provided with a variety of recruitment materials, in order to make participation attractive for as wide a variety of patients as possible. Moreover, selective refusal of practice nurses is possible. To limit such bias' influence on the results and to create a relatively heterogeneous sample of practice nurses, a national sample of practice nurses has been recruited.

- Sample size calculation

The sample size needed was calculated on the base of a Chi-square analysis, while for the main analyses regression analyses will be used. However, sample size calculations based on Chi-square analysis often overestimate the sample size needed, even though this will be (partly) undone by the multilevel structure of this study.

- Randomization on patient level

Randomization on patient level could lead to contamination bias, as it is possible that practice nurses have consultations according the PAS protocol with patients from the MT or UC group. To minimize such bias, clear instructions to only use PAS intervention materials in the MTC group are given to each practice nurse before they start recruiting patients. When notifying practice nurses of a new

patient participating in PAS, the group to which this patient has been allocated and what this implies for the care he or she should receive is indicated.

Conclusion

This extensive description of the development of PAS is provided in order to offer insight into its potentially effective working mechanisms. The results regarding the effectiveness of PAS, which will be reported in other papers, may contribute to the knowledge about effective elements of smoking cessation interventions aimed at smoking adults and about the possibilities of multiple computer tailoring combined with tailored counselling by practice nurses.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CH and HdV developed the concept and design of the study. ESS designed the interventions and coordinated the implementation of the interventions and data collection of the study. HdV and CH provided support during the development and execution. ESS and CH significantly contributed to writing this manuscript, while HdV was involved in revising the manuscript. All authors have read and approved the final version of the manuscript.

Appendix

Example of a tailored smoking cessation advice for someone who did not quit yet at 6-months follow-up and whose self-efficacy has decreased since baseline.

Step 3. Do you feel confident that you will succeed?

You are now less confident than the last time that you will succeed in not smoking. That's a pity, because when you feel more confident that you will succeed, it will become easier for you to quit smoking. Therefore, we will go

through those situations again, in which you indicated it will be hard for you not to smoke. And on the next pages, we will once more give you the opportunity to make specific plans for these difficult situations. By making specific plans on how to make sure you will not smoke in these situations, the chances will increase that you will succeed in permanently not smoking anymore.

- You are not sure whether you will succeed not to smoke when someone offers you a cigarette. And you are right, it is indeed very hard to say 'no' in such a situation. Perhaps you can re-read the advice we have you last time. In this advice, we extensively described how you can learn to **say 'no'** in such situations. You will find your previous feedback letter by clicking on the **'my advice'** button in the left menu.
- You indicate that you do not think you will manage not to smoke when you're taking a break. For many smokers, is has become a habit to smoke while taking a break. But why don't you try not to stick around your smoking colleagues, when you often smoke during breaks at work? There are probably many other people who do not smoke and with whom you can have a nice chat.

Acknowledgements
This study was funded by the Dutch Cancer Society (UM 2007-3834).

The authors would like to thank:

- Participating practice nurses and smokers;
- Vincent Cox, for visiting many practice nurses to give them instructions about PAS and for his advice in the development of the PAS intervention materials.

References

[1] United States Department of Health and Human Services. The health consequences of smoking: a report of the Surgeon General. 2004. http://www.surgeongeneral.gov/library/smokingconsequences. Aug 16, 2009.

[2] World Health Organization. WHO Report on the Global Tobacco Epidemic. 2008. http://www.who.int/tobacco/mpower/mpower_report_full_2008.pdf. Aug 16 2009.

[3] Borland R, Balmford J, Hunt D. The effectiveness of personally tailored computer-generated advice letters for smoking cessation. Addiction 2004; 99:369-77.

[4] Lancaster T, Stead LF. Self-help interventions for smoking cessation. Cochrane Database Syst Rev 2005.

[5] Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychol Bull 2007;133:673-93.

[6] Dijkstra A, De Vries H, Roijackers J. Long-term effectiveness of computer-generated tailored feedback in smoking cessation. Health Educ Res 1998; 13:207-14.

[7] Hoving EF. The feasibility of a smoking cessation computer tailored expert system in Dutch general practice and community pharmacy setting [dissertation]. Maastricht: Maastricht University; 2007.

[8] Brug J, Glanz K, van Assema P, Kok G, van Breukelen GJP. The impact of computer-tailored feedback and iterative feedback on fat, fruit, and vegetable intake. Health Educ Behav 1998;25:517-31.

[9] Dijkstra A, De Vries H, Roijackers J, van Breukelen G. Tailoring information to enhance quitting in smokers with low motivation to quit: Three basic efficacy questions. Health Psychol 1998;17:513-19.

[10] Lancaster T, Stead L. Physician advice for smoking cessation. Cochrane Database Syst Rev 2005;Cd000165.

[11] Stead LF, Bergson G, Lancaster T. Physician advice for smoking cessation. Cochrane Database Syst Rev 2008;Cd000165.

[12] McAvoy BR, Kaner EF, Lock CA, Heather N, Gilvarry E. Our Healthier Nation: are general practitioners willing and able to deliver? A survey of attitudes to and involvement in health promotion and lifestyle counseling. Br J Gen Pract 1999;49:187-90.

[13] Yarnall K, Pollak K, Krause K, Michener J. Primary care: Is there enough time for prevention? Am J Public Health 2003;93:635-41.

[14] Hoving C, Mudde AN, de Vries H. Intention to implement a smoking cessation expert system in Dutch general practice. Health Educ 2007; 107:307-15.

[15] Lamkaddem M, de Bakker D, Nijland A, de Haan J. [The influence of general practice support on the GP's workload]. 2004. http://www.nivel.nl/pdf/invloed-praktijkondersteuning-op-werklast-huisartsen.pdf. Aug 16 2009.

[16] Nederlands Instituut voor onderzoek in de gezondheidszorg. Cijfers uit registratie van huisartsen, peiling 2007. 2007. http://www.nivel.nl/pdf/cijfers-uit-de-registratie-van-huisartsen-peiling-2007.pdf. Aug 16 2009.

[17] Lancaster T, Stead L, Silagy C, Sowden A. Effectiveness of interventions to help people stop smoking: findings from the Cochrane Library. British Medical Journal 2000; 321(7257): 355-358.

[18] Curry SJ, McBride C, Grothaus LC, Louie D, Wagner EH. A randomized trial of self-help materials, personalized feedback, and telephone counseling with nonvolunteer smokers. J Consult Clin Psychol 1995; 63:1005-14.

[19] Sutton S, Gilbert H. Effectiveness of individually tailored smoking cessation advice letters as an adjunct to telephone counseling and generic

self-help materials: randomized controlled trial. Addiction 2007; 102:994-1000.

[20] Prochaska JO, Velicer WF, Redding C, Rossi JS, Goldstein M, DePue J, et al. Stage-based expert systems to guide a population of primary care patients to quit smoking, eat healthier, prevent skin cancer, and receive regular mammograms. Prev Med 2005;41:406-16.

[21] De Vries H, Mudde A, Leijs I, Charlton A, Vartiainen E, Buijs G, et al. The European Smoking prevention Framework Approach (EFSA): an example of integral prevention. Health Educ Res 2003;18:611-26.

[22] Dijkstra A, de Vries H, Bakker M. Pros and cons of quitting, self-efficacy, and the stages of change in smoking cessation. J Consult Clin Psychol 1996;64:758-63.

[23] Hoving C, Mudde AN, de Vries H. Effect of recruitment method and setting on the composition of samples consisting of adult smokers. Patient Educ Couns 2007;65:79-86.

[24] Kreuter M, Farrell D, Olevitch L, Brennan L. Tailoring Health Messages: Customizing Communication with Computer Technology. Mahwah, New Jersey: Lawrence Erlbaum Associates; 2000.

[25] de Vries H, Brug J. Computer-tailored interventions motivating people to adopt health promoting behaviors: introduction to a new approach. Patient Educ Couns 1999;36:99-105.

[26] Dijkstra, A. The Psychology of Tailoring-Ingredients in Computer-Tailored Persuasion. Social and Personality Psychology Compass 2008; 2(2): 765-84.

[27] Dijkstra, A. Working mechanisms of computer-tailored health education: evidence from smoking cessation. Health Educ Res 2005; 20(5): 527-39.

[28] van Osch L, Lechner L, Reubsaet A, Wigger S, de Vries H. Relapse prevention in a national smoking cessation contest: effects of coping planning. Br J Health Psychol 2008;13:525-35.

[29] Hoving EF, Mudde AN, de Vries H. Predictors of smoking relapse in a sample of Dutch adult smokers; the roles of gender and action plans. Addict Behav 2006;31:1177-89.

[30] Zhou X, Nonnemaker J, Sherrill B, Gilsenan AW, Coste F, West R. Attempts to quit smoking and relapse: factors associated with success or failure from the ATTEMPT cohort study. Addict Behav 2009;34:365-73.

[31] Damoiseaux VMG, van der Molen HT. Gezondheidsvoorlichting en gedragsverandering. Assen: Van Gorcum; 1998.

[32] Patrick DL, Cheadle A, Thompson DC, Diehr P, Koepsell T, Kinne S. The validity of self-reported smoking: a review and meta-analysis. Am J Public Health. 1994;84:1086-93.

[33] Hughes JR, Keely JP, Niaura RS, Ossip Klein DJ, Richmond RL, Swan GE. Measures of abstinence in clinical trials: issues and recommendations. Nicotine Tob Res 2003;5:13-25.

[34] West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. Addiction 2005;100:299-303.

[35] DSS Research. Researcher's toolkit. http://www.dssresearch.com/toolkit/sscalc/size.asp. Jan 13, 2010.

[36] Te Poel F, Bolman C, Reubsaet A, de Vries H. Efficacy of a single computer-tailored e-mail for smoking cessation: results after 6 months. Health Educ Res 2009; 24:930-40.

[37] Lindstrom D, Sundberg-Petersson I, Adami J, Tönnesen H. Disappointment and drop-out rate after being allocated to control group in a smoking cessation trial. Contemp Clin Trials 2009; doi:10.1016/j.cct.2009.09.003.

[38] Segaar D, Willemsen MC, Bolman C, De Vries H. Nurse adherence to a minimal-contact smoking cessation intervention on cardiac wards. Res Nurs Health 2007; 30: 429-44.

[39] Centraal Bureau voor de Statistiek. http://www.cbs.nl/nl-NL/menu/themas/vrije-tijd-cultuur/publicaties/artikelen/archief/2008/2008-2641-wm.htm. Feb 19 2010.