Effectiveness of training general practitioners in two methods (ABC versus 5A) of providing brief stop-smoking advice: a pragmatic, 2-arm cluster randomised controlled trial

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ABSTRACT

OBJECTIVE
To assess the effectiveness of a 3.5h-training for general practitioners (GPs) in two different methods of giving brief stop-smoking advice – 5A (ask, advice, assess, assist, arrange) or ABC (ask, brief advice, cessation support) – during routine consultations with smoking patients.

DESIGN
Pragmatic 2-arm cluster randomised controlled trial with a pre-post-design for the primary outcome and cluster randomisation for secondary outcomes.

SETTING
General practices (cluster) in the Rhine-Ruhr Metropolitan Region of the German federal state of North Rhine-Westphalia. The study opened to recruitment in June 2017 and closed in July 2019, with final follow-up in February 2020.

PARTICIPANTS
General practices with their GPs were randomised (1:1) to receive training in either 5A or ABC. Tobacco smoking patients aged ≥ 18 years, who routinely consulted these GPs six weeks prior or six six following the training were eligible to participate. Non-smokers, those with limited literacy or incapability to provide informed consent, or who did not see their GP in person were ineligible.

INTERVENTIONS
Two different standardised 3.5h-trainings (ABC or 5A), in small groups of ~8 GPs, in delivering brief stop-smoking advice, moderated by a senior researcher and an experienced GP peer-trainer and including role-plays with professional actors.

MAIN OUTCOME MEASURES
Primary outcome: patient-reported receipt of GP advice to quit, measured during a face-to-face interview directly following the consultation in the GP practice. Secondary outcomes included patient-reported receipt of GP delivered recommendation/prescription of evidence-based behavioural counselling; nicotine replacement therapy (NRT); varenicline or bupropion; any pharmacotherapy (NRT, varenicline or bupropion); or a combination of behavioural support and pharmacotherapy. A further aim was to compare the effectiveness of the two methods (ABC vs. 5A) against each other regarding all outcomes. All analyses were adjusted for a priori defined potentially relevant confounders and by using imputed patient data for missing data on confounding variables. Main analyses were double-checked using complete cases patient data.

RANDOMISATION AND MASKING
Two different methods of randomisation were applied, depending on how many GPs were available for the scheduled training dates (six training cycles over the course of two years, with two trainings – 5A and ABC – per cycle): computer-generated block randomisation, or randomisation by virtue of the GPs temporal availability. GPs could not be fully blinded with respect to their training allocation. Patients were blinded to the nature and aim of the study until the end of the data collection.

RESULTS

52 GP practices (with 69 GPs) participated in the training and data collection (ABC training: 27 GP practices, 5A training: 25 GP practices). Of 5,406 unique patients who routinely consulted their GP within 5 weeks prior/post training and provided informed consent to participate, 1,937 (35.9%) were current tobacco smokers. Of these, 1,039 were interviewed prior to, and 898 following, the training. The rates of stop-smoking advice delivered by GPs (primary outcome) increased from 13.1% (n=136/1,039) to 33.1% (n=297/898) following the training (adjusted odds ratio (aOR)=3.25, 95% confidence interval (CI)=2.34 to 4.51). Overall, recommendation/prescription rates of cessation treatment were low a priori (<2%), but had increased after the training (e.g., behavioural counselling: aOR=7.15, 95%CI=4.02 to 12.74; any pharmacotherapy: aOR=7.99, 95%CI=4.11 to 15.52). The increase in rates of stop-smoking advice following the training was higher in the ABC vs. 5A group (aOR=1.71, 95%CI=0.94 to 3.12), but the difference failed to be statistically significant (p=0.08).

CONCLUSIONS

Our brief training offers a highly effective strategy to improve the delivery of evidence-based smoking cessation advice in general practice. ABC seems to be more feasible to apply for GPs during routine consultations. Approaches to further increase the delivery of stop-smoking advice, and upscaling implementation strategies for the ABC training in general practice, should be evaluated.

TRIAL REGISTRATION

German Clinical Trials Register (DRKS00012786); registered on 22th August 2017, prior to the first patient in.

Keywords

Tobacco addiction, primary care, general practitioner, brief smoking cessation advice, national clinical guideline, 5A, ABC, very brief advice
WHAT IS ALREADY KNOWN ON THIS TOPIC

- Systematic review evidence shows that brief physician stop-smoking advice increases the likelihood that smokers attempt to quit and become abstinent, particularly if offered together with evidence-based smoking cessation treatment.
- Clinical guidelines recommend such advice to be routinely delivered by primary care physicians (general practitioners, (GPs)), but the implementation of these recommendations by GPs in Germany – a country where approximately one third of the population still smokes tobacco - is low.
- A strategy is needed to overcome barriers preventing GPs from routinely providing stop-smoking advice, such as a lack in knowledge and skills. No experimental study has evaluated such a strategy in German general practice so far.
- Two methods of brief stop-smoking advice exist – 5A (ask, advice, assess, assist, arrange) or ABC (ask, brief advice, cessation support) – but it is unclear which method can be more effectively implemented by trained GPs.

WHAT THIS STUDY ADDS

- This cluster randomised controlled trial evaluated the effectiveness of a 3.5h-training for GPs in providing brief stop-smoking advice and compared two different methods (ABC vs. 5A) on the rates of delivery of such advice and recommendations of evidence-based cessation treatment in 1,937 smoking patients from 52 GP practices in Germany.
- The training, irrespective of the training method, was strongly associated with an increase in the rates of GP delivered advice and recommendation of evidence-based smoking cessation treatment.
- The data suggests that a training according to ABC is more effective than 5A in increasing the rates of GP delivered stop-smoking advice.
- Upscaling and implementation strategies should be evaluated for the ABC training in German general practice.
INTRODUCTION

Brief advice about quitting tobacco smoking, delivered by healthcare professionals is effective in provoking a quit attempt and increase the likelihood that this attempt will be successful.¹ Moreover, brief advice is highly cost-effective since it does not require any particular equipment.² However, effects of simple advice alone are relatively small.¹ Combining such advice together with evidence-based pharmacological (e.g., nicotine replacement therapy (NRT), varenicline or bupropion) or behavioural (e.g., outpatient single or group intervention) smoking cessation therapy substantially increases long-term abstinence rates.³ ⁴ National and international clinical guidelines⁵ ⁷ thus strongly recommend that healthcare professionals should routinely give brief stop-smoking advice to every smoking patient and provide evidence-based treatment. Primary care physicians play a pivotal role in smoking cessation since the majority of smokers visits their general practitioner (GP) at least once a year.⁸ Hence, from a public health perspective the routine provision of brief advice in general practice care can substantially contribute to the reduction of the absolute numbers of smokers.

However, the implementation of guideline recommendations on the treatment of tobacco addiction in Germany is rather poor. Only about 18% of smokers report the receipt of brief advice to quit smoking during their last consultation, and barely 4% report the offer of an evidence-based smoking cessation treatment.⁸ Only every fifth smoker in Germany makes at least one attempt to quit smoking per year, and barely 13% of these attempts are supported with an evidence-based cessation aid.⁹ Thus, the majority of smokers miss a prime opportunity to quit harmful tobacco consumption.

Central barriers of GPs to the provision of brief advice on smoking cessation include the lack of training or education in the delivery of effective advice to quit, and the lack of time to provide advice during routine consultations.¹⁰ ¹⁴ Such training is not implemented by default in the education of medical students in Germany, and postgraduate trainings are optional, costly, and time consuming. The lack of the opportunity to offer treatment at no costs may further lower the GPs’ motivation to deliver such advice, since evidence-based cessation therapy is not fully reimbursed in Germany.

Systematic review evidence supports the effectiveness of training health professionals in providing smoking cessation advice on the point prevalence of smoking, continuous abstinence and professional performance.¹⁵ Accordingly, guidelines for the implementation of Article 14 of the World Health Organization Framework Convention on Tobacco Control recommend the routine integration of brief stop-smoking advice into all healthcare systems, and ensuring that healthcare workers are trained to provide such advice to their smoking patients.¹⁶ However, only few trials on the effectiveness of such trainings have been conducted in general practice settings.¹⁵ These studies show positive training effects on the rates at which GPs deliver brief stop-smoking advice,¹⁷ ¹⁸ refer to smoking cessation services,¹⁹ and on GP-reported knowledge, self-efficacy, and attitude regarding the delivery of brief smoking cessation counselling.¹⁸ ²⁰
The duration of the trainings in these studies varies between 40 minutes\textsuperscript{19} and several days,\textsuperscript{18} whereby multi-day trainings demand additional time which might lower the GPs’ motivation to participate. Regarding the training effect on the rates of GP delivered smoking cessation treatment, the study of Girvalaki et al.\textsuperscript{18} showed a positive effect of a full-day training and two 3-hour refresher sessions on the rate of provided behavioural and pharmacological smoking cessation treatment, whereas the one-hour intervention of Verbiest et al. could not improve prescription rates of pharmacotherapy.\textsuperscript{17}

So far, only one cluster randomised trial on the effectiveness of a smoking cessation training for GPs has been conducted in Germany, comparing the effect of a brief training together with either financial incentives for the GPs, or for the patients’ use of pharmacological therapy on 12-month tobacco abstinence.\textsuperscript{22} From these data, no conclusion can be drawn regarding the unique effect of the training.

Brief stop smoking counselling can be structured in many ways. Very brief methods such as the 3A (ask, advice, assist/act) or the ABC method (ask, brief advice, cessation support) are often recommended internationally,\textsuperscript{23-25} whereas in Germany the 5A method is more traditionally used: ask (for the smoking status of the patient), advise (urge the smoker to quit), assess (motivation to quit), assist (provide evidence-based cessation treatment), and arrange (follow-up contacts).\textsuperscript{5} According to the 5As, only smokers willing to quit receive the final steps “assist” and “arrange”. For smokers unmotivated to quit, which applies to most smokers at the time of the consultation,\textsuperscript{26} GPs are recommended to provide an additional brief intervention to enhance the motivation to quit (the 5Rs\textsuperscript{5}). Although associations between the last two steps of 5A and success in quitting were shown to be strongest,\textsuperscript{28} both steps are only rarely applied,\textsuperscript{29} probably because discussions with smokers about their willingness to quit are too time-consuming and unsuccessful during routine consultations. Thus, many smokers would not be offered evidence-based treatment to quit smoking, and may be less likely to use such treatment when feeling motivated and attempting to quit at a later stage.

The German clinical guideline\textsuperscript{7} for treating tobacco addiction recommends the provision of either method (ABC or 5A). So far, no studies comparing the effectiveness of both methods on the rates of delivery of brief-stop smoking advice in general practice settings, and thus no recommendation can be made to favour one method over the other. Although, it can be assumed that the ABC approach is more convenient to apply for GPs in daily practice. We therefore developed and pre-tested two 3.5h-trainings for GPs in delivering such advice during routine consultations: one based on the 5As and one based on the ABC approach.\textsuperscript{31} The aim of the present study was to assess whether our trainings provide an effective strategy to improve the implementation of the clinical practice guideline recommendations for the treatment of tobacco addiction by increasing the patient-reported rates of GP delivered brief stop-smoking advice (primary outcome) and the recommendation/prescription rates for evidence-based smoking cessation treatment (secondary outcomes) A secondary aim was to compare the effectiveness of both methods (ABC vs. 5A) against each other.
METHODS

Trial design

Detailed information on the development and pilot testing of the intervention and on the results of a qualitative process evaluation have been previously published in a protocol. Non-adherence to the study protocol, if applicable, will be reported throughout this manuscript and extensions to planned statistical analyses will be reported under the corresponding “non-adherence” paragraph. In brief, we conducted a pragmatic, 2-arm cluster randomised controlled trial with a pre-post-design for the primary outcome (evaluation of the effectiveness of a training on the delivery rates of brief stop-smoking advice during routine consultations with smoking patients) and with cluster randomisation for the comparison of the effectiveness of both training methods – ABC and 5A – against each other. The study protocol was approved by the ethics committee of the Medical Faculty at the Heinrich-Heine-University (HHU) Düsseldorf, Germany (5999R). All participants (GPs, patients) gave written informed consent. GP practices were randomised between 22 June 2017 and 15 March 2019. The study has been registered at the German Clinical Trials Register (DRKS00012786).

The study consisted of six study cycles. According to the study protocol, a study cycle was initially defined as a period of eight weeks: four weeks pre-training data collection followed by the training (intervention) and then four weeks post-training data collection. In order to minimise sampling bias which might be aligned with considerable fluctuations in patient flow among different practice days or weeks (e.g., on Mondays, during a flu epidemic, or on public holidays), data collection was carried out on approximately seven varying GP office days during the four-week pre-training period and on seven days during the four-week post-training period. However, in some practices with lower daily patient visits, this period had to be extended to up to six weeks with up to 10 days of data collection prior and following the training. Per cycle, two trainings were carried out, one according to each method.

Participants

GP practices

GP practices were recruited by postal dispatch from the publicly accessible online medical register of the regional Association of Statutory Health Insurance Physicians North Rhine in the Rhine-Ruhr Metropolitan Region of the German federal state North Rhine-Westphalia: a densely populated, polycentric urban agglomeration area with a strongly intercultural shaped population structure and economic inequalities, as well as from the practice network of the Institute of General Practice of the HHU Düsseldorf, Germany. Practices interested in participation were contacted by phone and fax messages in all following conversations. According to the study protocol, all GPs from group or single practices were eligible except for those specialised in treating substance abuse or in psychotherapeutic care, or those who have been trained in providing smoking cessation support within the last five years. However, since many GPs in Germany provide psychosomatic or
psychotherapeutic care, this exclusion criterion would have substantially lowered the number of eligible GP practices. Thus, contrary to the protocol, these GPs were not excluded from participation but their patients were only recruited following routine GP consultation, never following psychotherapeutic consultations.

Patients

Data on the primary and on most secondary outcomes was collected in tobacco smoking patients consecutively consulting their GP within a period of six weeks prior and six weeks following the training by means of questionnaire-guided, face-to-face interviews in all consecutive patients immediately following GP consultation in the setting of the practice. Data collection was carried out by four part-time researchers. Per study cycle, each of them managed to collect data in two or three practices. Prior to the consultation with the GP, patients were informed about, and invited to participate in the study by the researcher. At this time, all patients (independently of their smoking status) were invited to participate, and patients did not receive full information about the real purpose of the study (detailed information on blinding in the corresponding paragraph). Although it was not intended, in several practices, the GP repeatedly asked some of the smoking patients to participate in the study. Following the GP consultation, the interviews were conducted in a separate room. All patients were asked to answer questions on their sociodemographic characteristics and their current tobacco smoking status. Current tobacco smoking was defined as smoking cigarettes (including hand-rolled or self-stuffed) daily or occasionally, or any other combustible tobacco (pipe, cigars, cigarillos, shisha). For non-smokers, the interview ended at this point, whereas for current smokers the interview was continued with questions on their smoking behaviour, and on the outcomes of this study. In current smokers, the interview took approximately 10 to 15 minutes. The full baseline questionnaire can be found here: osf.io/f2p7b/ (translated English version), osf.io/7pmr5/ (original German version).

Per protocol, patients younger than 18 years, those suffering from moderate or severe cognitive impairment, those with language barriers or of too low literacy to understand the patient informed consent form, or those who did not see their GP in person (e.g., just picking up a prescription) were not eligible to participate. Although not explicitly mentioned in the protocol, patients using only electronic cigarettes or heated tobacco products were also not eligible to participate.

Randomisation and masking

Cluster randomisation was used because the intervention (training) was delivered at the practice level. Per study cycle two small-group trainings – one per training method – were offered resulting in 12 trainings in total (six in ABC, six in 5A). GPs from the same practice were assigned to the same training. In case a GP had to cancel the training, she or he was re-assigned to the same training including post-training data collection at the following study cycle. In group practices, only patients from GPs participating in the study were included. The minimum number of participants to run the training was set at three, which occurred once due to short-term drop-outs. The maximum number was
set at ten participants, which still allows intensive practical training. However, one training was conducted with 12 GPs due to large group practices who were randomised to the same training.

To yield a maximum participation rate, three to four potential training dates were offered, outside common GPs’ practice opening hours. GPs had to register for at least two dates to participate. Depending on how many GPs were available at least at two of the proposed training dates, two different methods of randomisation were applied.31

- Eight or more GPs: computer-generated block randomisation with random permuted blocks of sizes two or four, prepared by an independent statistician (WV), and concealed from the study team.
- Fewer than eight GPs: randomisation by virtue of the GPs temporal availability, meaning that the two dates with most registrations were selected and, in a random order between the study cycles one was assigned to be an ABC and the other a 5A training.

GPs could not be fully blinded to their training allocation, but we neither give detailed information on both training methods nor on their group allocation until the end of the pre-training data collection.31 Patients were fully blinded to the nature and aim of the study until the end of the data collection. The study was masked as a study on “physician-patient communication on health behaviour” in the initial informed-consent form. Following the data collection, patients received full information on the purpose of the study, a strategy that was approved by the ethics committee.

As described in the protocol,31 it was not feasible to blind the researchers who collected the data to the GPs’ group allocation, but they were not actively involved in the trainings, and were alternately assigned to the GP practices for data collection as well as depending on the travel distance between a practice and their personal residence.

**Procedures (Interventions)**

In 2016, we developed a standardised 3.5h-training for GPs in delivering brief stop-smoking advice during routine practice consultations according to two different methodological approaches: ABC and 5A. The theoretical foundation of this training is based on the “COM-B” behaviour change model32. The training was designed to address at least two components (capability and motivation) of the COM-B model which, according to the model, influence the performance of behaviour. Since the ABC approach seems to be less difficult and less time consuming to apply for GPs during routine consultations, we assumed that the training according to ABC might also influence the third component “opportunity” of the COM-B model. We used the Behaviour Change Techniques (BCT) Taxonomy33 to describe the active components of our training which might have the potential to alter the GPs’ behaviour. BCTs are reported in the study protocol.31

According to the training manual, trainings were always led by a senior researcher of the study centre together with an experienced GP peer-trainer who both rotated between ABC and 5A trainings.
Overall, three different researchers and four GPs served as trainers. Each training session started with an introductory lecture of approximately 60 min according to national and international guidelines on smoking cessation. This lecture included the latest evidence on the development of tobacco addiction, effective smoking cessation treatments, details about the specific method of providing stop-smoking advice (either ABC or 5A), and reflexive group discussions on GPs’ experience with barriers and facilitators of the provision of stop-smoking advice. The lecture was followed by about 90 min simulated role-plays, including moderated peer feedback, with professional actors trained in patients’ specific behaviour, enabling the GPs to practice the delivery of brief stop-smoking advice according to ABC or 5A. GPs received one-page handouts on the structure the respective method, on evidence-based smoking cessation treatments, and a copy template with local outpatient programs, quit smoking websites and hotlines to which patients can be referred to. These handouts were developed as a result of the process evaluation following the pilot study. Participation in training was incentivised with five Continuing Medical Education credits.

Outcome measures

Primary outcome

We published a tabular overview of the pre-specified outcomes online together with the statistical analyses plan: osf.io/36kpc/ (version 3-3). The primary outcome is defined as the number of patients prior to and following the training who report the receipt of brief stop-smoking advice during the last consultation with their GP, irrespective of the training method, out of the total number of patients who stated to be current smokers at the time of the consultation. Brief stop-smoking advice was assessed by asking the patient whether the GP urged him or her to quit smoking during this consultation.

Secondary outcomes

Most secondary outcomes refer to the patients’ last consultation with their GP, and were measured together with the primary outcome. The following secondary outcomes were defined as the number of smoking patients prior to and following the training who, irrespectively of the training method, report the receipt of GP delivered prescription or recommendation of:

- individual or group behavioural counselling in own practice or elsewhere,
- NRT,
- varenicline or bupropion,
- any pharmacotherapy (NRT, varenicline or bupropion),
- a combination therapy of behavioural counselling and pharmacotherapy,
- and to directly compare the effectiveness of the ABC and the 5A method (interaction with pre vs. post measurement) by means of the primary and secondary outcomes.
Together with the baseline data collection data on sociodemographic characteristics (age, sex, level of education) of all patients was collected. Among current smokers, further data was collected on smoking behaviour: average number of cigarettes (or, e.g., pipes, cigars) smoked per day, week or month (for occasional smokers), motivation to stop smoking (German version of the Motivation to Stop Smoking Scale, MTSS)\textsuperscript{26}, and on their urges to smoke (German version of the Strength of Urges to Smoke Scale, SUTS)\textsuperscript{34}. Patients reporting the receipt of any brief smoking cessation advice were be asked about their satisfaction with that conversation; operationalised by ratings on a 6-point Likert scale ranging from 1 = “very satisfied” to 6 = “very dissatisfied”).

Further secondary outcomes were measured by means of brief postal follow-up questionnaires at week 4, 12, and 26 following the consultation with the GP among those who were smoker at baseline. These data included attempts to quit smoking, the use of evidence-based or non-evidence-based smoking cessation methods (e.g., acupuncture, hypnosis) used to support this attempt, and point prevalence abstinence rates, but are not subject of the present analyses.

Data on GP characteristics (including age, gender, smoking status, professional experience, and specialisation), and on characteristics of the practice (e.g., location rural vs. urban, average number of patients per calendar quarter) were collected immediately following randomisation. Data on short-term training effects on GPs’ self-reported attitude towards (motivation), opportunity, knowledge on, and practical skills (capability) in the provision of brief advice to quit tobacco consumption was collected in accordance with the “COM-B” behaviour change model\textsuperscript{32} by means of a brief questionnaire prior to and immediately following the training.

**Statistical analysis**

The primary outcome for this study was the percentage of smokers reporting the delivery of brief stop-smoking advice by their GP during routine consultation from prior to following the training. The sample size calculation was informed by data from our previous study of the German population\textsuperscript{8} showing that about 18% of smokers in Germany are currently receiving brief advice on smoking cessation during a consultation with their GP. From the pilot study\textsuperscript{31} we assumed that it would be feasible to recruit 48 GP practices in total during a period of about two years. Training GPs in either the ABC or 5A method was assumed to have a clinically relevant effect if it increases these rates by at least 10% (corresponding to an odds ratio of 1.77) between pre- and post-training. A simulation study showed that 16 patients (respectively eight prior to and eight following the training) per practice were needed to evaluate the primary outcome with a statistical power of at least 80%, and a total of 42 patients (respectively 21 prior to and 21 following the training) per practice were needed to evaluate the interaction effect between the time (pre-post training) and the group variable ABC vs. 5A (for which we assumed post-training percentages of 33% and 23%, respectively), resulting in a total study sample size of 2,016 patients (respectively 1,008 prior to and 1,008 following the training). Further details on the sample size calculation are reported in the protocol\textsuperscript{31}. 
**Descriptive statistics**

Sociodemographic baseline data of GPs and patients are described for each group separately for the pre- and post-training assessment and for both study arms (Table 1 and 2). Continuous variables are presented with means and standard deviations, whereas categorical variables are denoted in numbers and percentages together with 95% confidence intervals (95%CI).

**Analyses of primary and secondary outcomes**

To fully mask the statistician and the researchers involved in the statistical analyses of outcomes, we wrote the code for the present analyses prior to the analyses and based on a blinded dataset; i.e., with the values of the primary (pre vs. post training measurement) and secondary exposure variables (ABC vs. 5A training method) in a randomly shuffled order. All analyses were conducted using R version 3.6.1.35 The analysis plan (latest version 3.3) and R code (latest version 3.6) can be found at the Open Science Framework: osf.io/36kpe/, osf.io/zurfq/.

Data are structured hierarchically in clusters (= practices), with patients within these clusters. Since differences in rates of delivery of smoking cessation advice were expected among practices, mixed-effects logistic regression models were used to analyse the dichotomous primary outcome (received advice: yes vs. no), with a fixed effect for time (dichotomous: pre- vs. post training) and random effects for the practices and the time effect. The same model was applied to the secondary outcomes. All models were adjusted for potential confounders measured at baseline including patients’ age, sex, level of education, time spent with urges to smoke, and strength of urges to smoke.

In order to analyse differences between the ABC and 5A training, the dichotomous group variable and its interaction with time (pre-post training) were added to the models as fixed effects. In both models, the time effect and the interaction were analysed by means of Wald-type tests (level of significance .05).

All participating patients were included in an intention-to-treat analysis. Since missing data on primary and secondary outcomes was very rare, no imputation methods were applied; see also paragraph “adherence to the protocol”. Missing data of potential confounding variables in contrast was imputed by using a multiple imputation approach, with missing data imputed by chained equations using the “mice-package”36 in R with m=20 imputed datasets and 10 iterations for each dataset. Results across the imputation datasets were pooled using Rubin’s rules37. To examine the sensitivity of the results, an additional complete case analysis was performed for the primary outcome as well as for the interaction effect between group (ABC, 5A) and time (pre-post measurement).

**Adherence to the protocol**
Smaller changes to the published study protocol regarding the data collection and GPs exclusion criteria are reported in the corresponding paragraphs throughout this manuscript.

All planned statistical analyses were reported in the study protocol and in the analysis plan published prior to the conducted analyses (latest version 3.3, osf.io/36kpc/). A few changes made to planned analyses including explanations were also provided within this document. In brief, we did not adjust the analyses for the “motivation to stop smoking” since motivation was assessed following the consultation with GP and might thus already be influenced by the behaviour of the GP during the consultation. Furthermore, we did not perform a complete case analysis for the primary outcome, since missing data was very rare (only 4 cases). For all adjusted analyses, missing data of potential confounders was imputed to reduce the potential for bias compared to a complete case analysis.

Two additional secondary outcomes were assessed: an aggregate variable of all forms of patient-reported receipt of GP recommendation/prescription for pharmacotherapy (NRT, varenicline or bupropion) and the receipt of a combination therapy (pharmacotherapy and behavioural counselling). This decision was made since usage of stop-smoking medication is very low in Germany, and because the combination therapy is recommended in the national clinical guideline.

We further ran explorative subgroup analyses for the primary outcome with patient data (sex, level of education, and number of cigarettes smoked per day: ≤10 vs. >10) and GP data (sex, number of years in clinical practice, practice type, smoking status: ever vs. never smoker), but results are only reported if the interaction effect (subgroup variable x exposure variable) was statistically significant at p<0.05. Details on these group comparisons can be also found in the analyses plan (osf.io/36kpc/).

Patient and public involvement

The trial procedure and all aspects of the intervention (GP training), including the clinical vignettes for the role-plays, were developed in an interdisciplinary team of health care researchers, experienced GPs, and actors trained in professional patient-physician communication. During the pilot study, which was conducted in 13 GP practices, the intervention and methods of data collection in patients were tested and reviewed, and feedback was obtained by means of a process evaluation in participating GPs regarding barriers and facilitators to transfer the content of the intervention into their daily practice routine. Methods of data collection in patients and comprehensibility of the questions to assess the primary and secondary outcomes were also reviewed during the pilot study.

RESULTS

Figure 1 shows the trial flow of participating GPs and their smoking patients. Between June 2017 and May 2019, 5,761 study invitation letters were sent to addresses of GPs from single and group practices. A total of 106 practices responded, with at least one GP per practice who was generally
interested to participate in the study. For 26 of these practices, no initiation telephone call could be
arranged with the GP in person to provide detailed information on the study procedures. Following a
telephone call with GPs from the remaining practices, one GP did not met the inclusion criteria and 21
GPs refused to participate due to time constraints, or a lack of providing a separate room for the data
collection patient interviews. Finally, 58 practices with 78 GPs were eligible, provided informed
consent, and thus received a study ident number. Two practices with three GPs withdrew before the
start of the randomisation, hence a total of 56 practices (75 GPs) were randomly assigned to either an
ABC or 5A training, a number which was slightly higher than originally intended.

During the process of the study, further GPs had to be sporadically excluded because they did not
participate in the training or in both periods of data collection (Figure 1). A total of 52 practices (69
GPs) were finally included in the statistical analyses. Table 1 presents baseline sociodemographic and
professional characteristics of this GP sample stratified by training method.

Table 2 presents baseline sociodemographic of all patients of these GP practices who participated in
the study and who were current tobacco smokers at that time, stratified by pre-post data collection
period and by training method of the GP they had consulted. In total, 1,937 smoking patients
participated of whom 1,037 patients were interviewed prior to the GP training and 898 patients
following the GP training. The latter sample size was slightly lower than intended because some
patients, i.e. those with acute diseases, visited their GP multiple times over several weeks, minimising
the selection of unique patients within the second period of data collection.

Patients reporting the receipt of brief smoking cessation advice indicated that they were satisfied with
that conversation with their GP, and no relevant differences regarding this satisfaction and in patient
characteristics were observed between the patient samples prior to and following the GP training and
between the samples of the two GP training methods ABC and 5A (Table 2).

Primary outcomes

Table 3 presents the results for the analysis of the primary outcome. The absolute rates of patient-
reported receipt of brief advice to quit smoking delivered by their GP increased from 13.1% (n = 136)
 prior to the training to 33.1% (n = 297) following the training (adjusted odds ratio (aOR) = 3.25, 95%
confidence interval (CI) = 2.34 to 4.51, p<0.001). This result remained stable when using complete
case patient data for the analyses (aOR = 3.28, 95%CI = 2.35 to 4.59), in which patients with missing
data on potential confounding variables were excluded (missing cases per variable: age: n = 2 (0.1%),
level of education: n = 2 (0.1%), time spend with urges to smoke: n = 118 (6.1%), strength of urges to
smoke: n = 122 (6.3%)).

Secondary outcomes
Table 3 also presents the results for the analyses of secondary outcomes. Overall, the patient-reported rates of recommendation/prescription of evidence-based treatment for smoking cessation delivered by their GP were low prior to the training (<2%), but increased significantly for all types of treatment after the training, with aOR’s ranging from 7.15 (95%CI = 4.02 to 12.74) for behavioural counselling to an odds ratio of 15.45 (95%CI = 5.67 to 42.10) for NRT. Following the training, patients were also more likely to report the receipt of a recommendation/prescription for the combination of behavioural counselling and pharmacotherapy to quit smoking from their GP (aOR = 4.36, 95%CI = 2.46 to 7.73).

Regarding the effectiveness of the two training methods (ABC vs. 5A) for the primary outcome, a higher increase in the rates of stop-smoking advice following the training was observed in patients whose GP were trained in the ABC method compared to those whose GP were trained in the 5A method (aOR=1.71, 95%CI=0.94 to 3.12), although the difference failed to be statistically significant (p=0.08). This result remained stable when using complete case patient data for the analyses (OaR=1.69, 95%CI=0.91 to 3.12).

The increase in patient-reported rates of recommendations or prescriptions of single or group behavioural support delivered by the GPs following the training was higher in the ABC vs. 5A group (aOR=4.59, 95%CI=1.40 to 14.98). According to the data, no such advantage could be observed for the ABC method regarding the recommendation/prescription rates of pharmacological smoking cessation treatments or the combination of behavioural counselling and pharmacotherapy (Table 3).

One model (for recommendation of varenicline or bupropion) could not be fitted due to perfect separation (prior to the training, no such recommendation was ever provided in the ABC group, increasing to 3.1% after the training, while the pre- and post-training percentages remained relatively stable at 1.4% and 1.6%, respectively, in the 5A group).

Subgroup analyses
Explorative subgroup analyses for the primary outcome revealed a significant (p=0.025) interaction for the GPs’ number of years working in clinical practice (below group median number of years (< 12 years) vs. above group median number of years (>12 years)), showing a higher increase of reported delivery of brief stop-smoking advice following the GP training in patients who had visited a GPs with more than 12 years of working experience (OR=4.63, 95%CI=2.93 to 7.33) compared to those who had visited a GP with less than 12 years in clinical practice (OR=2.33, 95%CI=1.49 to 3.64).

GP-reported training effects
Data on short-term effects of the training on GPs’ attitude (motivation), knowledge and practical skills (capability), and opportunity to provide brief stop-smoking are reported in Supplementary Table S1. Self-reported capability and opportunity in the provision of stop-smoking advice improved following the training, with all items increased by effect sizes between 0.58 and 2.84. The largest difference
from prior to following the training was observed for self-reported knowledge of the steps of a structured brief stop-smoking advice (mean difference=2.84, p<.001, Cohen's d=2.83). No such training effect could be observed for motivation, which was already high prior to the training (mean difference=0.07 and 0.10). Following the training, 91.3% (n=63) of the GPs agreed to implement brief stop-smoking advice more frequently in their daily practice (Supplementary Table S2). The majority (79.7%, n=55) estimated their learning growth following the training to be high or very high.

**DISCUSSION**

**Principal findings of the study**

In this cluster randomised controlled trial with pre-post data collection in 1,937 smoking patients, GPs’ participation in an 3.5h-training on the provision of brief stop-smoking advice according to the ABC or 5A method, including role-plays with professional actors and moderated by a senior researcher together with an experienced GP peer-trainer, was highly effective at increasing the rates of patient-reported receipt of such advice and recommendations of evidence-based smoking cessation treatment (behavioural, pharmacological, combination of both) delivered by GPs. Regarding the difference in the effectiveness of ABC and 5A, the increase of patient-reported delivery of brief stop-smoking advice from prior to following the training seemed to be higher in GPs trained in the ABC method compared to those trained in 5A. According to the data, no advantage for one of the training methods was found regarding the patient-reported recommendation or prescription rates of evidence-based cessation treatment delivered by GPs. However, the overall recommendation rates of such treatment were very low, resulting in large confidence intervals and inconclusive results.

**Strengths and limitations of study**

Our data are strengthened by the pragmatic “real-life” study setting, the face-to-face collection method with low rates of missing data, and by the consistency of age, sex, educational level, and smoking behaviour between pre-training and post-training data collection period as well as between treatment arms. Moreover, the data has been assessed by means of patient reports, which has been shown to be more precise than self-reports of the physicians when measuring the efficacy of physician-delivered counselling on health behaviour changes.38

A detailed study protocol including results and lessons-learned from the pilot study has been published and all statistical analyses were planned a priori. The statistical analyses code was written on a dataset blinded for the primary and secondary exposure variables and published prior to the final data analyses, and thus aimed to yield a maximum transparency and validity of all conducted analyses. The number of GP practices included was slightly higher than originally intended, resulting in adequately powered statistical analyses for the primary outcome.

The recruitment rate of patients within these practices was marginally lower than expected since some patients recurrently visited their GP within both periods of data collection but could only participate
once. For all comparisons of the effectiveness of the ABC vs. the 5A training, the statistical analyses thus seemed to be slightly underpowered, which might be the reason that the difference between ABC and 5A on the delivery rates of stop-smoking advice failed to be statistically significant.

Trial GP practices represented practices Rhine-Ruhr Metropolitan Region of the of the German federal state of North Rhine-Westphalia (NRW) and can thus not be regarded as representative for all GP practices across Germany. However, NRW is the most populous state in Germany, with a broad socioeconomic variability and trial practices were located in urban as well as in rural areas. Data from a recent representative population survey in smokers in Germany found rates (~14%) of GP delivered brief stop-smoking advice during the last visit of their GP strongly corresponding with the trial rates (~13%) prior to the training intervention, suggesting sound representativeness of the present data.

We chose patient-reported delivery of brief stop-smoking advice as primary outcome instead of using biochemically validated abstinence of smokers for example, since abstinence strongly depends on various factors such as the choice and use of methods to assist a quit attempt and can thus neither reflect the direct effectiveness of our training on GPs’ stop-smoking counselling performance nor the effectiveness of both training methods in comparison on the same outcome. Moreover, only short-term effects of the intervention were analysed, which can be seen as a major limitation of the present study. Thus, whether or not long-term effects occur and whether or not smoking patients might benefit from this in terms of quit rates and success, needs to be determined.

Another important limitation of the present study is that only a minority of the GPs who were invited to participate could be enrolled because a large proportion did not answer the invitation or could not be reached. It may be that the participating GPs were a selected group, indicated by the fact that they were already highly motivated prior to the training and saw themselves in charge to provide cessation counselling to their smoking patients. However, data indicate that this high level of motivation is not related to an exceptional high level of activity regarding the delivery of advice to quit smoking or the recommendation of evidence-based smoking cessation treatment (<2% recommendation rates).

Data on primary and secondary outcomes was patient-reported and may thus not reflect the actual performance of GPs. Moreover, we can only indirectly compare the effectiveness of ABC vs. 5A, since in this pragmatic setting it could not be verified that GPs have effectively implemented the corresponding method. The most optimal method of data collection would have been video observation during the consultation, a procedure which would not have been feasible in this study. Collecting the data by means of face-to-face interviews and immediately following the consultation with the GP was the next best realisable alternative, also minimising recall bias and difficulties in terms of understanding the interview questions. The presence of a researcher of the study team itself might have influenced the GPs’ performance leading to higher delivery rates of brief-stop-smoking advice. However, as described above, these rates strongly match with the rates of a recent population-
based study and substantial changes between the pre- to post-training data collection period were observed although a member of the study team was present in the practice during both periods.

As described in the study protocol and due to the pragmatic nature of this study, it was not possible to fully blind the researchers who conducted the data collection. We therefore applied several strategies to reduce contamination. Researchers were, for example, required to avoid comments on the intervention (training and training method) while talking to GPs or patients, they were not actively involved in the trainings, and were randomly or assigned in relation to the distance of their personal residence to the GP practices for data collection.

Although otherwise intended, patients were not only recruited by the researcher of the study team. In several practices the GPs took the initiative and directly referred smoking patients to the “study room”. In terms of recruitment, this procedure was more successful than recruitment by the study researcher, but we cannot estimate the influence on the measured outcomes. However, GPs acting accordingly did not change this behaviour between pre- and post-training period of data collection.

Comparison with other studies

Until to date, only few studies assessed the effectiveness of training GPs on the rates of delivery of evidence-based advice or counselling on smoking cessation. Verbiest et al. found that a one-hour group training aimed at decreasing personal and organizational barriers to provide brief advice to quit according to the 5A methods, increased the patient-reported frequency in which they asked their patients about their smoking status, and the GP-reported frequency in which the GPs advised them to quit smoking. No effect was observed regarding the provision of evidence-based pharmacotherapy or regarding the arrangement of a follow-up contact (GP- and patient-reported).

While our training was developed based on the COM-B theory on behaviour change, only the study of Girvalaki et al. used a theory (Theory of Planned Behaviour) to guide the intervention design. Their quasi-experimental pilot study found that full-day group training with two 3-hour refresher trainings was highly effective in increasing the patient- and GP-reported rates of provided smoking cessation counselling according to the 5A method, including the discussion and prescription of stop-smoking medications. Odds ratios in this study seem to be even higher than in the present study, although the analyses were not adjusted for patient characteristics. The training duration was four times longer compared to our training.

The study of Unrod et al., in contrast, showed that a 40min individual training session on the 5A method might be even effective in substantially improving physicians’ implementation of all steps of the 5As in primary care. However, this study as well as the study of McRobbie et al., which assessed the effectiveness of a group training with the same duration, did not particularly analyse prescription or recommendation rates of behavioural and pharmacological smoking cessation treatment but...
discussions with the patients on smoking cessation medication\textsuperscript{21} and referral rates to cessation services.\textsuperscript{19,21}

In the German healthcare context, clinics providing behavioural group therapy are rare, particularly in more rural areas, and specialist stop smoking services as in the United Kingdom\textsuperscript{39} do not exist. The GP therefore play a central role in not only providing brief advice to quit smoking but also in initiating evidence-based treatment including behavioural and pharmacological approaches. Our training therefore aimed at increasing the prescription and recommendation rates for such evidence-based therapies.

Although studies show that the implementation of the 5A’s in primary care settings is usually inadequate, and the level of performance for the most effective steps of the 5A (assist, arrange) is usually lowest,\textsuperscript{29,30} no studies comparing the effectiveness of the 5A approach vs. much briefer methods (3A, ABC) on the advice performance of GPs yet exist. A very early randomized controlled trial of Butler et al.\textsuperscript{40} compared the effectiveness on cessation of motivational consulting, which is also part of the 5A approach, versus brief advice for smokers in general practice, but this advice did not include any further evidence-based steps such as cessation support. Our study is therefore the first comparing two different methods of brief counselling – ABC and 5A.

Comparable to a study of Bobak et al.\textsuperscript{20}, who conducted a 3.5h-training for GP trainees, our training substantially increased the GP-reported capability and perceived opportunity to provide evidence-based brief stop-smoking advice during routine consultations, whereas motivation was high throughout. Although in our study only short-term effects were measured, in the study of Bobak et al., this GP-reported effect remained stable even at three-month follow-up. No patient-reports on the counselling activity of their GPs were assessed by Bobak and colleagues.\textsuperscript{20}

The present study further revealed that GPs with more years of working experience in clinical practice seem to benefit more from the training intervention with regard to their post-training delivery rates of brief stop-smoking advice. It can be assumed that more experienced GPs are more confident in their daily routine care and thus may have more time to apply new techniques.

**Conclusions and policy implications**

Our theory-based, 3.5h-training offers a highly effective and low-threshold strategy to improve the delivery of evidence-based smoking cessation advice in general practice. When comparing methods to provide such advice during routine GP consultations against each other (ABC vs. 5A), our data indicate that the ABC method might be more feasible to apply for GPs and thus might have a greater impact on the overall delivery of brief stop-smoking advice and recommendations for behavioural counselling to quit smoking (individual, group; in own practice or elsewhere) to decrease the national smoking prevalence. A corresponding recommendation regarding the ABC method will be proposed for the German clinical guideline\textsuperscript{7} for treating tobacco addiction.
|   | Abbreviations                                                                 | Description                                                                 |
|---|-------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 2 | BCT                                                                          | Behaviour Change Techniques                                                 |
| 3 | BMG                                                                          | "Bundesministerium für Gesundheit" (German Federal Ministry of Health)       |
| 4 | CONSORT                                                                      | Consolidated Standards of Reporting Trials                                  |
| 5 | cRCT                                                                         | Cluster randomised controlled trial                                         |
| 6 | GPs                                                                          | General Practitioner                                                         |
| 7 | HHU                                                                          | Heinrich-Heine University                                                    |
| 8 | MTSS                                                                         | Motivation to Stop Scale                                                    |
| 9 | NRT                                                                          | Nicotine replacement therapy                                                 |
| 10| SD                                                                           | Standard deviation                                                           |
| 11| SP                                                                           | Standardised patient                                                         |
| 12| SUTS                                                                         | Strength of Urges to Smoke Scale                                            |
DECLARATIONS

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Contributors

DK had the original idea and acquired funding for the current study together with SK and VL, and co-wrote this manuscript. SK, VL, and DK developed and conducted the GP trainings. SK coordinated all study processes of the main trial including scheduling and organisation of the trainings, and developed and wrote this manuscript. WV, an independent statistician, conducted a simulation study for the sample size calculation of the study and prepared the randomisation sequence for block randomisation. He also prepared the statistical analysis code, and advised on statistical analysis plans together with DK and SK who finally conducted all statistical analyses and interpreted the data. JH, DL, SKH, and CF were mainly involved in all study processes regarding GP and patient recruitment and data collection (including data entry, data cleaning, and preparation of the trainings and of the study material). As a GP and peer trainer, OR was mainly involved in the final evaluation of the training manual and the didactic methods, and supported the trainings as a peer trainer. SW, RW, TR, and HM gave valuable feedback at the time of designing the trial, and commented on and added to the present manuscript.

All named authors contributed substantially to the manuscript and agreed on its final version. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests
All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: support from the Federal Ministry of Health Germany for the submitted work. DK received an unrestricted grant from Pfizer for an investigator-initiated trial on the effectiveness of practice nurse counselling and varenicline for smoking cessation in primary care in 2009 (Dutch Trial Register NTR3067). HM has received honoraria for speaking at smoking cessation meetings and attending advisory board meetings that have been organised by Pfizer and Johnson & Johnson, TR has received honoraria from Pfizer, Novartis, Glaxo Smith Kline, Astra Zeneca and Roche as a speaker in activities related to continuing medical education and financial support for investigator-initiated trials from Pfizer and Johnson & Johnson, RW has undertaken research and consultancy for companies that develop and manufacture smoking cessation medications (Pfizer, Johnsons & Johnson, and Glaxo Smith Kline) and is an advisor to the UK’s National Centre for Smoking Cessation and Training; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

**Ethical approval**

The study protocol was approved by the local ethics committee of the Medical Faculty of the Heinrich-Heine-University Düsseldorf, Germany (5999R). Prior to the data collection and after full oral and written information on study processes, purposes, and on data protection, each participating general practitioner and each patient included in the study gave written informed consent for participation and publication.

**Transparency statement**

The corresponding author affirms that the manuscript is an honest, accurate, and transparent account of the present study; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned and registered have been explained.

**Data sharing**

The data underlying this study are third-party data (de-identified participant data, syntax of statistical analyses) and are available to researchers on reasonable request from the corresponding author (sabrina.kastaun@med.uni-duesseldorf.de). The study protocol has been published. All proposals requesting data access will need to specify how it is planned to use the data, and all proposals will need approval of the trial co-investigator team before data release.
Supplemental files

Supplementary table 1
Changes in capability, opportunity and motivation to provide brief stop smoking advice to smoking patients from prior to following the training reported by 69 general practitioners (GPs) of 52 GP practices.

Supplementary table 2
Self-reported assessment of general practitioners (GPs) following the training regarding the relevance of the training content and their learning curve (N=69 GPs from 52 GP practices).

Supplementary material 1:
Original German version of the Baseline questionnaire for patients (BaselineSurvey_ABCII_German.pdf) can be downloaded here: osf.io/7pmr5/.

Supplementary material 2:
Translated version of the Baseline questionnaire for patients into English (BaselineSurvey_ABCII_Engl.pdf) can be downloaded here: osf.io/f2p7b/.
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**Table 1** Baseline characteristics of general practitioners (GP), stratified by training method
(N=69 GPs from 52 practices).

|                      | ABC Training (n = 32) | 5A Training (n = 37) | Total sample (N = 69) |
|----------------------|-----------------------|----------------------|-----------------------|
| **Age, years (mean ± SD)** | 51.5 ± 7.5            | 52.8 ± 8.0           | 52.2 ± 7.7            |
| **Sex**              |                       |                      |                       |
| Female               | 56.3% (18)            | 48.7% (18)           | 52.2% (36)            |
| Male                 | 43.8% (14)            | 51.4% (19)           | 47.8% (33)            |
| **Years since becoming physician (mean ± SD)** | 22.6 ± 8.0            | 23.7 ± 9.0           | 26.1 ± 24.2           |
| **Years since established in practice (mean ± SD)** | 11.4 ± 8.6            | 13.5 ± 9.2           | 12.5 ± 8.9            |
| **Type of GP practice** |                       |                      |                       |
| Single practice      | 37.5% (12)            | 21.6% (8)            | 29.0% (20)            |
| Any type of group practice | 62.5% (20)          | 78.4% (29)           | 31.0% (49)            |
| **Area where GP practice is located** |                       |                      |                       |
| Rural area (<20,000 inhabitants) | 3.1% (1)              | 5.4% (2)             | 4.4% (3)              |
| Small city (>20,000 inhabitants) | 3.1% (1)              | 5.4% (2)             | 4.4% (3)              |
| City (<100,000 inhabitants) | 31.3% (10)            | 13.5% (5)            | 21.7% (15)            |
| Large city (>100,000 inhabitants) | 62.5% (20)          | 75.7% (28)           | 69.6% (48)            |
| **Ever participated in training on providing smoking cessation before = Yes** |                       |                      |                       |
| Daily smoker          | 3.1% (1)              | 0.0% (0)             | 1.5% (1)              |
| Occasional smoker     | 15.6% (5)             | 5.4% (2)             | 10.1% (7)             |
| Ex-smoker             | 21.9% (7)             | 32.4% (12)           | 27.5% (19)            |
| Never smoker          | 59.4% (19)            | 62.2% (23)           | 60.9% (42)            |

Data are presented as mean± standard deviation (SD) or percentages (number, N); GP = general practitioner.
|                          | Pre-training (n = 1,039) | Post-training (n = 898) | ABC Training (n = 986) | 5A Training (n = 951) | Total sample (N = 1,937) |
|--------------------------|--------------------------|-------------------------|-----------------------|----------------------|--------------------------|
| Age, years (mean ± SD)   | 46.1 ± 16.1              | 46.0 ± 15.7             | 46.2 ± 16.0           | 45.9 ± 15.8          | 46.1 ± 15.9              |
| Sex                      |                          |                         |                       |                      |                          |
| Female                   | 52.4% (544)              | 52.1% (468)             | 56.0% (552)           | 48.4% (460)          | 52.3% (1,012)            |
| Male                     | 47.5% (493)              | 47.7% (428)             | 44.0% (434)           | 51.2% (487)          | 47.6% (921)              |
| Level of education†      |                          |                         |                       |                      |                          |
| High school equiv.       | 21.6% (224)              | 22.8% (205)             | 22.4% (221)           | 21.9% (208)          | 22.2% (429)              |
| Adv. techn. college equiv.| 14.9% (155)             | 13.2% (118)             | 16.2% (160)           | 11.9% (113)          | 14.1% (273)              |
| Secondary school equiv.  | 29.7% (309)              | 28.1% (252)             | 29.3% (289)           | 28.6% (272)          | 29.0% (561)              |
| Junior high school equiv.| 30.5% (317)              | 32.3% (290)             | 29.1% (287)           | 33.7% (320)          | 31.3% (607)              |
| No qualification         | 3.2% (33)                | 3.6% (32)               | 2.7% (27)             | 4.0% (38)            | 3.4% (65)                |
| Cigarettes/day (mean ± SD)| 14.0 ± 9.3              | 13.6 ± 9.4              | 13.2 ± 9.2            | 14.5 ± 9.4           | 13.8 ± 9.3              |
| Time spend with urges to smoke§ (mean ± SD) | 2.9 ± 1.5 | 3.0 ± 1.5 | 3.0 ± 1.5 | 2.9 ± 1.6 | 2.9 ± 1.5 |
| Strength of urge to smoke§ (mean ± SD) | 2.0 ± 0.9 | 2.1 ± 1.0 | 2.0 ± 0.9 | 2.1 ± 0.9 | 2.0 ± 0.9 |
| Motivation to stop smoking (MRS)¥ (mean ± SD) | 3.3 ± 1.8 | 3.3 ± 1.9 | 3.4 ± 1.8 | 3.1 ± 1.8 | 3.3 ± 1.8 |
| Satisfaction with conversation on smoking with GP (if so)# | 2.0 ± 0.9 | 2.0 ± 0.9 | 2.0 ± 0.9 | 2.0 ± 0.9 | 2.0 ± 0.9 |

Data are presented as mean ± standard deviation (SD) or percentages (number, N). †German equivalents to education levels listed in table from highest to lowest: high school equivalent (“Allgemeine Hochschulreife”), advanced technical college equivalent (“Fachhochschulreife”), secondary school equivalent (“Realschulabschluss”), junior high school equivalent (“Hauptschulabschluss”), or no qualification; §VRS (“Verlangen zum Rauchen Skala”) = German version of the Strength of Urges to Smoke Scale (SUTS)§; SUTS§ is only posed to respondents who did not answer SUTS§ with “not at all”; ¥MRS (“Motivation zum Rauchstopp Skala”) = German version of the Motivation To Stop Scale (MTSS)§; #asked only to smoking patients who had a conversation on smoking with their GP (n=542) independently whether the patient reported the receipt of one of the outcomes, satisfaction was operationalised by ratings on a 6-point Likert scale ranging from 1 = “very satisfied” to 6 = “very dissatisfied; differences when calculating the total percentage can be explained by missing data on the respective variables.
Table 3 Patient-reported receipt of brief stop-smoking advice (primary outcome) and of recommendations/prescriptions of evidence-based treatment to quit smoking (secondary outcomes) delivered by their general practitioner (GP), stratified by pre-post data collection period and by training method of the GP they had consulted; and associations of these outcomes with training (pre vs. post) and with the interaction of training by training method (ABC/5A x pre/post) (N=1,937 smoking patients)

| Outcome (patient-reported) | Pre-training | Post-training | aOR imputed Post vs. Pre (95%CI)† | aOR imputed ABC vs. 5A† x Post vs. Pre (95%CI) |
|----------------------------|--------------|---------------|-----------------------------------|-----------------------------------------------|
|                            | PreABC (n = 527) | Pre5A (n = 512) | Pretotal (n = 1,039) | PostABC (n = 459) | Post5A (n = 439) | Posttotal (n = 898) |                                |                                |
| Brief stop-smoking advice  | 11.8% (62)    | 14.5% (74)     | 13.1% (136)                | 35.7% (164)       | 30.3% (133)       | 33.1% (297)          | 3.25 (2.34-4.51)***          | 1.71 (0.94-3.12)               |
| Behavioural counselling    | 1.5% (8)      | 1.6% (8)       | 1.5% (16)                  | 13.3% (61)        | 3.9% (17)         | 8.7% (78)            | 7.15 (4.02-12.74)***         | 4.59 (1.40-14.98)              |
| Behavioural counselling    | 0.6% (3)      | 0.4% (2)       | 0.5% (5)                   | 3.3% (15)         | 7.1% (31)         | 5.12% (46)           | 15.45 (5.67-42.10)***        | 0.21 (0.03-1.55)               |
| Nicotine replacement therapy | 0% (0)       | 1.4% (7)       | 0.7% (7)                   | 3.1% (14)         | 1.6% (7)          | 2.3% (21)            | 3.10 (1.27-7.53)***          | #                               |
| Varenicline or bupropion   | 0% (0)        | 1.8% (9)       | 1.2% (12)                  | 6.3% (29)         | 8.7% (38)         | 7.5% (67)            | 7.99 (4.11-15.52)***         | 1.81 (0.42-7.78)               |
| Any pharmacotherapy        | 1.9% (10)     | 1.8% (9)       | 1.8% (19)                  | 7.6% (35)         | 5.2% (23)         | 6.5% (58)            | 4.36 (2.46-7.73)***          | 1.42 (0.45-4.44)               |

Data are presented as adjusted Odds Ratios (aOR) and 95% confidence interval (95%CI) around aOR. *p<0.05; ***p<0.001; †Logistic regression models with a fixed effect for time (pre- vs. post training) and random effects for the practices and the time effect, for the ABC vs. 5A comparison: the group variable (5A or ABC training) and its interaction with time were be added to the models as fixed effects; both models were adjusted for patients’ sex, age, level of education, time spent with urges to smoke, and strength of urges to smoke (SUTS34); # model could not be fitted due to perfect separation.
Figure 1. CONSORT chart showing trial flow of general practices and participating smoking patients by pre-training and post-training data collection period and study arm (ABC vs. 5A training)
Figure 2. Scatter plot showing the relationship between the percentages of patients who reported the receipt of a stop-smoking advice delivered by their GP prior to the training (x-axis) and following the training (y-axis) by training group allocation of the GP.