Nicotine and Tobacco Research, 2022, **XX**, 1–9
https://doi.org/10.1093/ntr/ntac159
Advance access publication 27 June 2022
Original Investigation

Comparison of Motivational Short Interventions to Improve Smokers' Health Behavior (The COSMOS Study): A Pragmatic Cluster-Randomized Two-Arm Trial in General Practice

Thomas Grischott MD, MSc[1], Oliver Senn MD, MPH[1], Anja Frei PhD, MSc[2], Thomas Rosemann MD, PhD[1], Stefan Neuner-Jehle MD, MPH[1]

[1]Institute of Primary Care, University Hospital Zurich, University of Zurich, Zurich, Switzerland
[2]Epidemiology, Biostatistics and Prevention Institute, University of Zurich, Zurich, Switzerland

Corresponding Author: Thomas Grischott, MD, MSc, Institute of Primary Care, University Hospital Zurich (USZ), University of Zurich (UZH), Pestalozzistrasse 24, CH-8091 Zurich, Switzerland. Telephone: +41 43 253 01 42; E-mail: thomas.grischott@usz.ch

Abstract

Introduction: Helping smokers to quit is an important task of general practitioners (GPs). However, achieving tobacco abstinence is difficult, and smokers who fail may still want to improve their health in other ways. Therefore, Swiss GPs developed a multithematic coaching concept that encourages health behavior changes beyond smoking cessation alone.

Aims and Methods: To compare the effectiveness of such coaching with state-of-the-art smoking cessation counseling, we conducted a pragmatic cluster-randomized two-arm trial with 56 GPs in German-speaking Switzerland and 149 of their cigarette smoking patients. GPs were instructed in either multithematic health coaching or smoking cessation counseling. After 12 months, we compared their patients' improvements in cigarette consumption, body weight, physical inactivity, alcohol consumption, stress, unhealthy diet, and a health behavior of their own choice, using hierarchical logistic regression models and Fisher's exact and *t* tests.

Results: Over 95% of all participants achieved clinically relevant improvements in at least one health behavior, with no difference between study arms (health coaching vs. smoking cessation counseling: aOR = 1.21, 95% CI = [0.03–50.76]; and aOR = 1.78, 95% CI = [0.51–6.25] after non-responder imputation). Rates of clinically relevant improvements in the individual health behaviors did not differ between study arms either (they were most frequent in physical activity, achieved by 3 out of 4 patients), nor did the extent of the improvements.

Conclusions: Multithematic health coaching and state-of-the art smoking cessation counseling were found to be comparable interventions, both in terms of smoking cessation success and, quite unexpectedly, their effects on other health behaviors.

Implications: The findings of our study suggest that in general practice, multithematic health coaching is an effective smoking cessation intervention, and conversely, monothematic smoking cessation counseling also achieves the beneficial effects of a multithematic health behavior intervention. This opens up the possibility for GPs to support their smoking patients in improving their health behavior in additional and more flexible ways.

Introduction

One in ten deaths around the world and one in seven in Switzerland are caused by tobacco use, making it one of the biggest single preventable causes of death both worldwide and in Switzerland.[1,2] In 2017, more than a quarter (27%) of the adult population in Switzerland (15 years or older) were current smokers.[3] This substantial proportion calls for effective efforts to reduce tobacco-related morbidity and mortality.

General practitioners (GPs) are key players in the promotion of smoking cessation,[4] not least because of their regular contact with a large segment of the population.[3] Long-term doctor-patient relationships allow the GPs to continually encourage their smoking patients to keep trying to quit, and to offer them individual support in a trusted environment. In the outpatient community setting, attempts to give up smoking have been shown to achieve success rates after 6 months of about 4% without physician involvement and 6%–24% with state-of-the-art smoking cessation interventions by GPs, depending on specifics and complexity of the interventions.[5]

In Switzerland, the division of public health of the *Swiss Medical Association*—the professional organization of Swiss doctors—coordinates the project *Free of Tobacco* (FoT), launched in 2002 to provide continuing education on state-of-the-art medical smoking cessation counseling in the form of 4-h seminars for primary health care providers.[6] The seminars are paid for by the *Tobacco Control Fund* of the *Federal Office of Public Health*. FoT seminars use active learning methods and standardized patients to teach the practical skills necessary to counsel smokers depending on their motivation and, if necessary, prescribe appropriate medication.[7] FoT has proven

Received: March 7, 2022. Revised: June 20, 2022. Accepted: June 27 2022.

its effectiveness, achieving superior quit rates after one year of 13% compared with 5% in the placebo group.[8]

Recognizing the potential for harm from unhealthy behaviors and the significance of health-related behavior change for public health, the *Swiss College of Primary Care Medicine*[9] advocates the multithematic and patient centered coaching concept *Health Coaching* (HC). This concept, developed by GPs for GPs in 2013, does not only focus on smoking cessation alone but aims to stimulate and support positive changes in several health behaviors.[10] Core elements of HC include shared decision-making and motivational interviewing as well as validated tools from existing health promotion programs on physical activity, alcohol consumption, and healthy eating.

The high number of failed attempts at tobacco abstinence prior to quitting successfully[11] demonstrates the difficulty of smoking cessation, even with the best medical advice and support. However, smokers who cannot overcome this difficulty or are unwilling to quit smoking for other reasons may still be willing, or even more so, to improve their health in other ways. They are therefore potential beneficiaries of a more general (multithematic) coaching concept like HC.

While FoT has been established as a standard in smoking cessation counseling in Switzerland for two decades, HC is a relatively new concept with innovative features. HC is based on plausible assumptions and accepted communication paradigms and has already shown subjective benefit from the patients' view.[12] However, objective benefits have yet to be substantiated. It is neither clear to what extent HC actually leads to improvements in various health behaviors, nor how effective it is in promoting tobacco abstinence.

Postulating that both interventions achieve beneficial effects on the health behaviors targeted, as well as unintended spillover effects on other health behaviors, we expected patients who were not ready to stop smoking but willing to improve another health behavior to profit from intended *and* spillover effects if they received HC, but from spillover effects *only* if subjected to FoT. Further assuming HC to be comparable to FoT in promoting tobacco abstinence, we expected patients ready to stop smoking to benefit to a similar extent from both interventions.

To test these assumptions, we investigated (1) whether improvements in overall health behavior resulting from multithematic HC outweighed those from monothematic state-of-the-art FoT smoking cessation counseling and (2) whether this potential overall superiority of HC was counterbalanced by an inferior effectiveness of HC as a smoke stop intervention.

Methods

Recruitment, Randomization, Patient Inclusion, Data Collection

The study was designed as a prospective, double-blind, cluster-randomized, two-arm parallel trial involving GPs in German-speaking Switzerland and their cigarette-smoking patients.[13] As recommended for smoking cessation studies,[14] follow-up lasted 12 months, and abstinence was biochemically verified. Ethics approval was granted by the Ethics Committee Zurich, Switzerland (BASEC No. 2017-02043). All participants gave written informed consent.

GP Recruitment

From January 2018 until September 2019, approximately 700 GPs were invited to participate in a study on "improving their smoking patients' health behaviour" via governing bodies of doctor networks. The study was also presented orally and/or in writing (with information leaflets) at several continuing medical education events. Finally, invitation letters were sent to all 2776 GPs in 10 Swiss cantons (administrative regions). GPs with previous training in HC were excluded from participation, and all GPs were offered a base compensation of CHF 600 plus an additional CHF 100 per included patient.

Cluster Allocation

From August 2018 to November 2019, we randomized 90 GPs in six batches of 10-24 GPs each, to either the HC or the FoT arm, using covariate-constrained randomization to ensure balance with respect to sex, practice size (single vs. pair vs. group practice) and employment status (employed vs. self-employed).[15] An additional constraint required that GPs from the same practice were assigned to the same study arm. This prevented contamination between study arms, but entailed a slight deviation from the targeted 1:1 allocation ratio.[13]

Intervention on the GP Level

The GPs were instructed in 10 training sessions (5 per arm) between July 2018 and December 2019 by unvarying members of the study team with extensive experience in HC or FoT. Training sessions lasted 4 h in both study arms and included identical instructions on patient recruitment and data collection. The study arm-specific content in the HC arm covered all key elements of the HC concept, that is, shared decision making and motivational interviewing, as well as the use of validated tools to foster health-promoting behaviors including smoking cessation. The GPs in the FoT arm were taught a slightly shortened version of the full FoT syllabus for medical smoking cessation counseling. All trainings involved role play with standardized patients and case vignettes.[13,16] To maintain blinding, GPs were not informed about the intervention in the other study arm.

Patient Inclusion

Patient recruitment took place consecutively between July 2018 and August 2020 among adult cigarette smokers who consulted their GPs for any reason. The study was presented not as a smoking cessation trial, but as a comparison of brief interventions to improve smokers' health behaviors. GPs were provided with wall posters for their waiting rooms and memory aids for their desks to support their recruitment efforts. In order to minimize selection bias, the GPs were instructed to offer study participation to all eligible patients during predefined recruitment windows (days or half days in which all patients whose smoking status was not known or evident from their medical records had to be asked about it), and to record the patients' decisions. Inclusion criteria were (1) current cigarette smoker at the time of inclusion, (2) male or female aged 18 years or older, (3) registered in the GP's patient database, (4) capable of judgment with regard to study participation, and (5) written informed consent. Patients were excluded in case of (1) severe general or psychiatric illness, (2) inability to follow study procedures (eg due to language barriers), or (3) foreseeable change of their GPs within one year.

Intervention on the Patient Level

Patients of GPs allocated to the HC arm received health coaching according to the HC concept. They were encouraged by their GPs to decide which unhealthy behaviors or risk factors they wanted to address (options were: cigarette smoking, body weight, physical inactivity, alcohol consumption, stress, unhealthy diet, or another health behavior of their own choice), and were then supported to achieve beneficial changes therein.[12] In the FoT arm, patients received smoking cessation counseling according to FoT.[7] The number and duration of consultations remained open in both study arms, and was jointly decided by patients and GPs (see Supplementary Appendix B).

Data Collection

GP and patient characteristics were collected together with written informed consent by the study team or the recruiting GPs, respectively. Immediately before their first consultations, the patients provided baseline data on their health behavior, and attitudes towards the intended behavior changes (motivation, confidence, planning). Current attitudes were reported again after each consultation, and data on health behavior at 1, 6, and 12 months after the first consultations. All data was collected on paper case report forms (CRFs) which had been mailed by a study nurse to the patients 4–7 days before the deadlines and were then returned by mail to the study center. Outstanding responses were reminded once by letter and then by repeated phone calls until an answer was explicitly refused. At the study center, the data from the paper CRFs were transferred into an OpenClinica database by the study nurse and student helpers not otherwise involved in the study and unaware of the patients' allocations. Accuracy and consistency of the database were verified by a second person on random subsets of records during data entry and by means of exploratory analyses during data analysis.

The study flowchart is shown in Figure 1. Throughout the study, 7 newsletters were sent to the GPs to address potential difficulties in recruiting or counseling, and to draw the GPs' attention to important aspects of the study.

Outcomes

The binary *primary outcome* was *any* (=at least one) clinically relevant improvement in cigarette smoking, body weight, physical inactivity, alcohol consumption, stress, unhealthy diet, or – in the HC arm only – another health behavior of the patients' own choice, 12 months after the first consultation. The relevance criteria reflect the smallest behavioral changes with evident health benefits, and are listed in Supplementary Appendix A, together with the measuring instruments (Supplementary Table S1). For a detailed justification of the specific choices, we refer the reader to the published study protocol.[13]

Secondary outcomes covered *any* (= at least one) clinically relevant improvement after 1 and 6 months, clinically relevant improvements in each separate behavior after 1, 6, and 12 months, and the *changes* in cigarette consumption, body weight, physical activity, alcohol consumption, stress score (PSS-10, German version[17]), and diet index (MedDietScore[18]) within 1, 6, and 12 months from their baselines at the first consultations. Additional secondary outcomes were the patients' degrees of motivation and confidence to achieve and maintain a beneficial change, and of their time, action, and coping (ie relapse management) planning.

Process outcomes according to the RE-AIM framework[19] were collected alongside primary and secondary outcomes.

Statistical Analysis

Characteristics of GPs and patients were tabulated as numbers and proportions or means with standard deviations and with (purely formal) p values as balance measures (Table 1).

The primary outcome – *any* clinically relevant improvement after 12 months – was summarized as crude counts and proportions with p values from Fisher's exact tests for study arm comparisons (Table 2c). It was further analyzed using logistic mixed models with adjustments for GP and patient sex and age and patient baselines (fixed effects) and for clustering by GPs (random effect).

For the primary analysis, all data were analyzed following an intention-to-treat approach after excluding patients without any baseline information (Figure 1). All missing values in the primary outcome and all baselines and covariates were multiply imputed in $m = 90$ datasets using R's mice package (version 3.14.0[20]) and 2l.binary and 2l.pmm from the miceadds package (version 3.11-6[21]) (Supplementary Table S3a). As a sensitivity analysis, we used non-responder imputation (NRI) for missing outcome values, and multiple imputation (MI) for baselines and covariates in $m = 40$ datasets (Supplementary Table S3b). Planned per-protocol analyses were moot as all GPs completed their instruction as planned and in the assigned study arm, and deviations from the protocol after their instructions were precluded by the pragmatic study design. (See Supplementary Appendix B for related implementation issues.)

Secondary outcomes were analyzed as follows: Counts and proportions of clinically relevant improvements in individual health behaviors as well as the compound outcomes after 1 and 6 months were again summarized in tabular form and with exact p values for each stage during follow-up (Table 2). Changes from the participants' individual baseline levels were compared between study arms using two-sided 2 sample t tests per follow-up stage and behavior, and were presented graphically as means with 95% Wald confidence intervals (Supplementary Figure S1). Trends in motivation, confidence, and levels of planning over the course of successive consultations were displayed analogously (Supplementary Figure S2). Significance refers to a level of $\alpha = 5\%$, and R version 4.1.2 was used for all analyses.[22]

Results

Of 90 randomized GPs, 56 (62.2%) received the study instruction and 45 (50.0%) actively included 149 (64.8%) of 230 eligible patients. Of the included patients, 104 (70.0%) patients provided both patient profile and outcome baselines. Figure 1 shows the study flowchart, without significant recruitment discrepancies between the study arms.

GPs and patients were similar in both study arms with respect to randomization covariates (GP sex, employment status, and practice type) as well as other covariates and outcome baselines (Table 1, Supplementary Table S2).

Primary Outcome

Success rates (to achieve *any* relevant improvement) after 12 months did not differ between HC and FoT arms (95.2% vs.

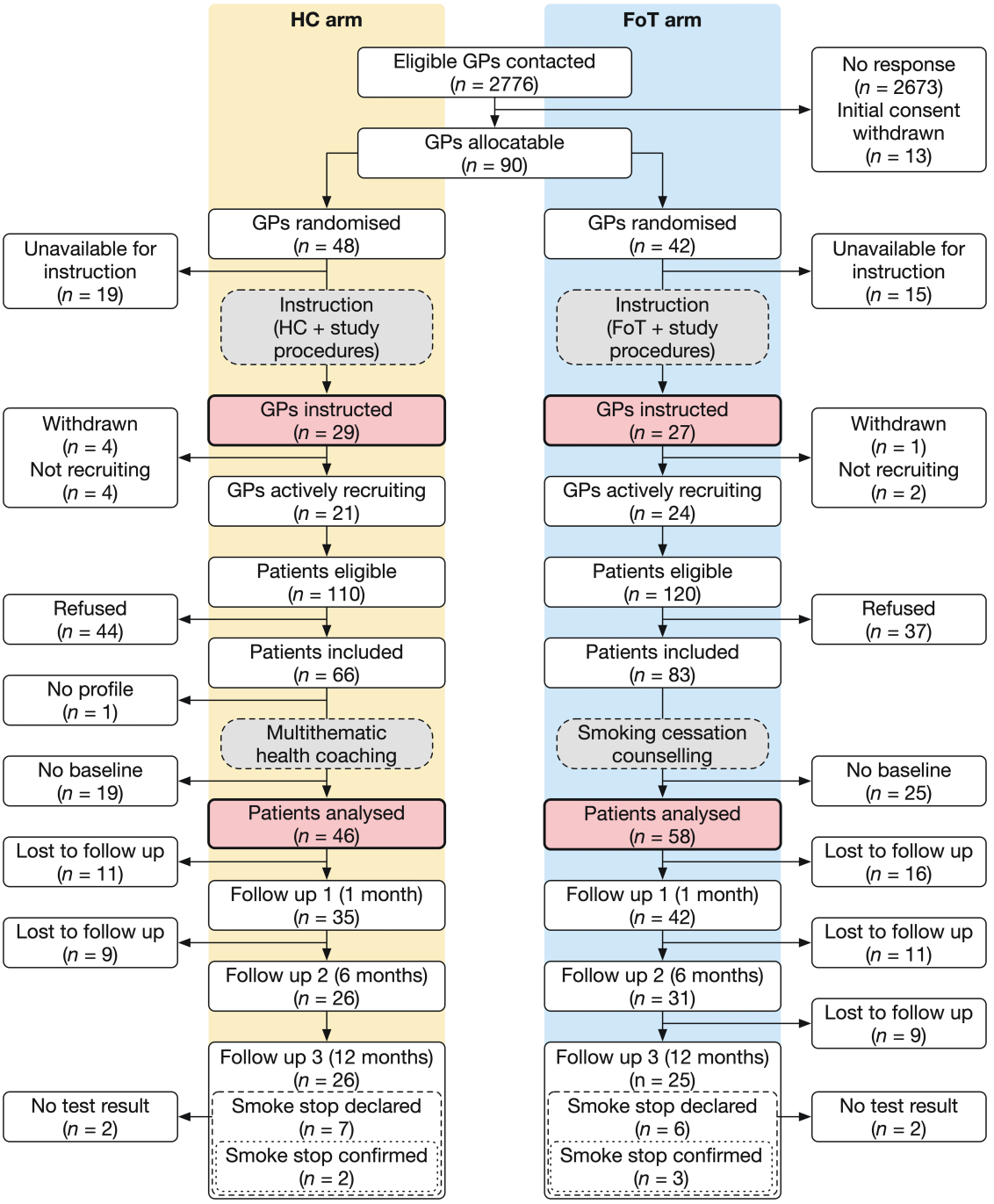

Figure 1. CONSORT diagram of study design and participant flow. In total, 27 of 48 randomized GPs in the HC arm versus 18 of 42 in the FoT arm recruited no patients (Fisher's exact $p = .29$), and 20 of 66 included patients in the HC arm versus 25 of 58 in the FoT arm provided no baseline information ($p = .19$). HC, health coaching; FoT, free of tobacco; GP, general practitioner.

100%, Fisher's exact $p = .49$, Table 2c). The logistic mixed models confirmed this result: Adjusted odds ratios (aOR) for HC versus FoT were aOR = 1.21 with 95% CI = [0.03–50.76] after MI of all missing values, and aOR = 1.78 with 95% CI = [0.51–6.25] in the sensitivity analysis with NRI for missing outcome values (Supplementary Table S3).

Secondary Outcomes

Table 2 presents numbers and fractions of patients who achieved *any* clinically relevant improvements after 1 and 6 months into follow-up, and of those who achieved clinically relevant improvements in individual health behaviors after 1, 6, and 12 months. There were no significant differences in any of these outcomes between the HC and FoT arms. Changes from the participants' baseline levels are shown for all six (except for the self-chosen) health behaviors and by follow-up stage in Supplementary Figure S1. Again, there were no significant differences between the two study arms.

Motivation, confidence, and planning outcomes are reported in Supplementary Appendix A (Supplementary Figure S2 and Table S5), and all results of the process evaluation are presented in Supplementary Appendix B.

Table 1. Selected GP and Patient Characteristics (With Formal *p* Values as Balance Measures).

	Unit	HC arm			FoT arm			*p*[1]
		n	# (%)	Mean (SD)	*n*	# (%)	Mean (SD)	
a. General practitioners		(*n* = 29)			(*n* = 27)			
Sex = male (vs. female)		29	16 (55.2)		27	16 (59.3)		(.79)
Age	y	29		47.9 (8.7)	27		51.0 (8.5)	.17
Work experience	y	29		10.1 (8.4)	26		14.4 (8.6)	.07
Status = self-employed (vs. employed)		29	17 (58.6)		27	15 (55.6)		(1.00)
Practice type:		29			27			(.32)
Single practice			3 (10.3)			5 (18.5)		
Pair practice			5 (17.2)			8 (29.6)		
Team practice			21 (72.4)			14 (51.9)		
Practice ownership:		25			22			.45
GP owned			21 (84.0)			17 (77.3)		
Owned by health insurer			1 (4.0)			0 (0.0)		
Other ownership			3 (12.0)			5 (22.7)		
Practice location:		28			25			.05
Urban			15 (53.6)			6 (24.0)		
Suburban			10 (35.7)			11 (44.0)		
Rural			3 (10.7)			8 (32.0)		
Patients per year[2]	#	26		3862.0 (6140.3)	25		3956.0 (4718.2)	.95
Consultations per year[2]	#	27		4199.7 (3425.6)	26		4169.6 (2404.2)	.97
Smokers, fraction of patients[2]	%	29		22.3 (8.1)	27		26.0 (10.5)	.14
Consultations regarding health promotion and prevention per week[2]	#	27		14.6 (12.4)	26		18.1 (12.7)	.32
Duration of such consultations[2]	min	28		9.1 (5.7)	26		14.4 (10.3)	.02
b. Patients		(*n* = 46)			(*n* = 58)			
Sex = male (vs. female)		46	21 (45.7)		58	31 (53.4)		.55
Age	y	46		50.0 (14.6)	58		51.9 (15.0)	.50
Education level:		45			58			.40
≤ Secondary I (ISCED[3] 2)			3 (6.7)			7 (12.1)		
Secondary II (ISCED 34 + 35)			21 (46.7)			31 (53.4)		
Tertiary (≥ ISCED 6)			21 (46.7)			20 (34.5)		
Civil status = with (vs. without) partner		46	24 (52.2)		58	38 (65.5)		.23
Living arrangement = with others (vs. alone)		46	29 (63.0)		52	39 (75.0)		.27
Pack-years	y	41		29.3 (17.4)	50		31.7 (18.9)	.53
≥ (vs. <) 15 cigarettes/day		46	32 (69.6)		58	39 (67.2)		.83
Body weight	kg	46		78.3 (18.0)	57		77.2 (18.0)	.75
BMI ≥ (vs. <) 25 kg/m^2		46	23 (50.0)		57	35 (61.4)		.32

[1]Fisher's exact and two-sided 2 sample *t* tests; (...) = variable used in randomization.
[2]GPs' guesses.
[3]International Standard Classification of Education 2011.

Discussion

In this study, we compared two strategies available to GPs to assist their smoking patients in achieving better health behavior, namely a. multithematic and patient-driven health coaching HC, with b. state-of-the-art monothematic smoking cessation counseling FoT. Our analysis found no differences between the two strategies neither in terms of smoking cessation rates nor in their potential to effect beneficial changes in other health behaviors.

Self-reported smoking cessation rates found in our trial (Supplementary Figure S1b and Table S4b) were similar to the 13% after 12 months reported in the FoT efficacy study[8] and to 4–14% in primary care after 6 months according to a very recent systematic review by Lindson et al.[5] As expected, HC could not outperform FoT in the latter's core discipline of smoking cessation promotion. On the other hand, smoking cessation success was no less frequent with HC than with FoT either, even though smoking cessation was only one

Table 2. Raw Numbers and Proportions of Patients With *Any* Clinically Relevant Health-Promoting Behavior Change, and With Relevant Improvements in Individual Health Behaviors, by Follow-up Stage.

	Unit	HC arm			FoT arm			p^1
		n	# (%)	Mean (SD)	*n*	# (%)	Mean (SD)	
a. After 1 month		(*n* = 46)			(*n* = 58)			
Any relevant[2] improvement		27	25 (92.6)		37	34 (91.9)		1.00
Relevant improvement in:								
Cigarette smoking		35	9 (25.7)		42	16 (38.1)		0.33
Body weight		33	2 (6.1)		42	4 (9.5)		0.69
Physical inactivity		32	18 (56.2)		39	27 (69.2)		0.32
Alcohol consumption		27	2 (7.4)		32	2 (6.2)		1.00
Stress		30	9 (30.0)		31	11 (35.5)		0.79
Unhealthy diet		26	0 (0.0)		30	1 (3.3)		1.00
Health behavior of patient's choice		12	7 (58.3)		–	– (–)		–
b. After 6 months		(*n* = 46)			(*n* = 58)			
Any relevant improvement		23	21 (91.3)		28	27 (96.4)		0.58
Relevant improvement in:								
Cigarette smoking		26	9 (34.6)		31	9 (29.0)		0.78
Body weight		26	2 (7.7)		30	2 (6.7)		1.00
Physical inactivity		23	14 (60.9)		26	19 (73.1)		0.54
Alcohol consumption		22	2 (9.1)		27	2 (7.4)		1.00
Stress		21	8 (38.1)		25	7 (28.0)		0.54
Unhealthy diet		19	2 (10.5)		21	1 (4.8)		0.60
Health behavior of patient's choice		14	9 (64.3)		–	– (–)		–
c. After 12 months		(*n* = 46)			(*n* = 58)			
Any relevant improvement (=primary outcome)		21	20 (95.2)		22	22 (100.0)		0.49
Relevant improvement in:								
Cigarette smoking		24	5 (20.8)		20	5 (25.0)		1.00
Body weight		25	2 (8.0)		25	2 (8.0)		1.00
Physical inactivity		24	18 (75.0)		21	16 (76.2)		1.00
Alcohol consumption		21	1 (4.8)		21	2 (9.5)		1.00
Stress		23	8 (34.8)		20	6 (30.0)		1.00
Unhealthy diet		19	2 (10.5)		19	2 (10.5)		1.00
Health behavior of patient's choice		11	3 (27.3)		–	– (–)		–

[1]Fisher's exact test.
[2]For relevance criteria, see Supplementary Table S1.

of several fields of action within HC and received considerably less attention in the training of GPs than in the FoT arm. This first remarkable finding of our study indicates that HC is likely similar to FoT in promoting smoking cessation.

Second, FoT's unintended but beneficial side effects on non-tobacco-associated health behaviors varied widely by behavior but were overall comparable to the effects achieved by the multi-behavioral health promotion program HC (Table 2). This is once again a remarkable finding; while multi-behavior interventions have received considerable theoretical and practical interest in the last 20 years[23–29] and, in particular, their impact on smoking cessation has been studied,[30–32] it is largely unknown whether, how, and to what extent monothematic smoking cessation interventions affect other health behaviors. We hypothesize that patients who are overwhelmed with smoking cessation may – consciously or unconsciously – seek alternative fields of activity, possibly to alleviate the cognitive dissonance between their understanding of the harmfulness of smoking and not being ready or able to stop.

Clinically relevant spillover effects were most frequently observed in physical activity and stress, whereas they were relatively rare in other health behaviors, where improvements may be more difficult to achieve or less prone to overestimation (Table 2). Physical activity seems to be a particularly popular and successfully implemented alternative. This could be due to the special focus put on weight gain within smoking cessation interventions which propose increased physical activity as an obvious countermeasure, or to GPs explicitly recommending exercise as a substitute for smoking or to distract from craving. Overall, much remains open for further research on spillover effects of smoking cessation interventions.

With FoT being comparable to HC in terms of its effects on non-tobacco-related health behavior changes, there seems to be no obvious reason to prefer HC over FoT. However, if shared decision making and patient empowerment are core goals in addition to clinically relevant health improvements then HC still has its merit, as it offers the GPs greater methodological freedom and allows them to advise their smoking

patients according to their – GPs' *and* patients' – own preferences and values.

In keeping with our main finding that neither strategy was superior in terms of smoking cessation success or other health behaviors, there was also no difference between study arms regarding the smokers' attitudes and self-efficacy (Supplementary Figure S2). This is consistent with an additional analysis that showed no association of the initial motivation to quit smoking with eventual success (Supplementary Figure S3). While this neither negates the fundamental role of motivation within the smoking cessation process nor the value of motivational interviewing in health behavior interventions, it can be seen as confirmation that motivation alone does not determine success,[33] and that quitting advice and encouragement should not be restricted to the motivated.[34]

As another notable finding of the study, we observed no decrease in cigarette use over time (Supplementary Figure S1c), suggesting that most successful quitters probably reduced their tobacco use abruptly instead of gradually. This reflects the fact that neither FoT nor HC promote reduction-to-quit, but rather abrupt quitting, as the former strategy has not shown to be more effective than the latter,[35] but further delays consumption. As an aside, this finding also fits with the somewhat surprising observation that more or longer consultations did not increase the probability of success: A multivariable logistic regression model showed no significant effects on smoking cessation success (with NRI) of neither the number (p = .37) nor the average duration (p = .49) of consultations. The same was true for the primary outcome (p = .88 and p = .30, respectively) (Supplementary Appendix B).

Finally, there were markedly fewer biochemically confirmed cessations than self-reported unconfirmed successes (n = 5 vs. 13; Figure 1). In one case, a smoker had initially used nicotine replacement products, which, in case of continued or renewed use, may have led to a false positive cotinine test result, and others might have missed to report such use. Even after accounting for possible false positive test results, there remains an impressive proportion of up to 8/13 = 61.5% unreported or concealed non-cessations. This proportion is, however, within the range of published verification failure rates of, for example, up to two in three in trials of hospital-initiated smoking cessation interventions.[36]

Strengths and Limitations

The authors are not aware of other studies examining the effects of smoking cessation interventions on multiple, non-tobacco-associated health behaviors. Our results suggest that such spillover effects occur to very different extents for different health behaviors. They therefore deserve greater attention, for which our study has paved the way.

Since little was known about the extent of spillover effects, the sample size of the study had been calculated for an alternative hypothesis which, in retrospect, proved to be too pessimistic. Given the unexpectedly frequent spillover effects, the sample size would have needed to be considerably higher than originally calculated to achieve the same statistical power. This imparts a certain pilot character to our results, even though the study was not planned as a pilot study. Moreover, some of the GPs recruited in late 2019 were unable to enroll the planned number of patients due to the Covid-19 situation in early to mid-2020 in Switzerland. This led to mild under-recruitment, in itself negligible in our opinion, as the sample size had been calculated for a high power and rounded up again generously after accounting for dropouts.

Virtually all GPs have experience or training in various forms of patient counseling, including, for example, certain sub-disciplines of HC and, in particular, smoking cessation counseling. We assume that such prior knowledge was balanced by randomization, so that residual effects on the study results, although not completely excluded, are likely to be small.

The ambitious study design required simultaneous collection of several complex outcomes, not all of which could be measured with the utmost precision and reliability. For feasibility reasons, we had to refrain from recording physical activity using exercise trackers or measuring food portion sizes. Due to the amount of data to be collected, a relatively high fraction of missing data as well as recall, desirability, and interpretation biases on the part of the participants could not be fully avoided. We addressed this as far as possible by imputation methods and sensitivity analyses.

Since the study was pragmatic in nature, we did not have complete control over its implementation in the GPs' offices. Even though we asked the GPs to offer participation to *all* eligible patients during specific recruitment periods, and although we maintained close contact with all GPs through personal communication as well as newsletters which allowed us to intervene quickly whenever we learned of irregularities, we cannot exclude any residual selection bias or minor deviation from the study plan.

Conclusion

HC and FoT were found to be comparable interventions, both in terms of their potential as smoking cessation interventions as well as their effects on other health behaviors. The beneficial side effects of FoT on non-tobacco related health behaviors varied by behavior, and merit targeted investigation using more sophisticated methods of assessment. HC offers GPs an additional tool to assist, in their preferred ways, their smoking patients in improving their health behavior.

Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at https://academic.oup.com/ntr.

Funding

S.N.J. received funding for this work from the Tobacco Control Fund (TCF) of the Swiss Federal Office of Public Health (FOPH), decision no. 17.003152.

Declaration of Interests

The authors have no competing interests or conflicts to declare.

Author Contributions

Thomas Grischott: Conceptualization, Data Curation, Formal analysis, Investigation, Methodology, Project administration, Software, Validation, Visualization, Writing - Original Draft, Writing - Review & Editing. Oliver Senn: Conceptualization,

Funding acquisition, Investigation, Supervision, Writing - Review & Editing. Anja Frei: Conceptualization, Funding acquisition, Investigation, Writing - Review & Editing. Thomas Rosemann: Conceptualization, Funding acquisition, Resources, Writing - Review & Editing. Stefan Neuner-Jehle: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing - Review & Editing.

Study Registration and Ethics Approval

Study registration: https://doi.org/10.1186/ISRCTN38129107. Ethics approval: Ethics Committee Zurich, Switzerland (BASEC no. 2017-02043)

Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Acknowledgments

We would like to thank all participating GPs and patients for contributing their time and personal data to our study.

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APPENDICES

The COaching of SMOkerS study

A. ADDITIONAL TABLES AND FIGURES

Additional table 1: Criteria for clinical relevance of health behaviour improvements

Behaviour	Relevance criterion *(Measuring method)*
Smoking	Abstinence, or reduction of daily number of cigarettes by ≥ 50% from a baseline of ≥ 15 cigarettes *(Self-declaration, confirmatory saliva cotinine test at 12 months for alleged quitters)*
Body weight	Reduction by ≥ 5% if baseline-BMI ≥ 25 kg/m2 *(Standardised home measurements)*
Physical activity	Increase of MVPA by ≥ 90 min per week or increase of LIPA by ≥ 200 min per week, compared to baseline *(Recollection-based self-declaration in questionnaire)*
Alcohol consumption	Reduction in number of standard drinks (10 g) per week by ≥ 7 drinks from a baseline of ≥ 14 drinks/week *(Recollection-based self-declaration in questionnaire)*
Stress level	Reduction in score of the "Perceived Stress Scale" (PSS-10, German version) by ≥ 5, compared to baseline *(Recollection-based self-declaration in validated questionnaire)*
Diet	Increase by ≥ 10 in score of adapted MedDietScore questionnaire, compared to baseline *(Recollection-based self-declaration in validated questionnaire)*
Participant's choice	Increase by ≥ 2 levels on a 5 level Likert-type scale (-/0/+/++/+++) *(Self-declaration in questionnaire)*

For rationales with references, see Grischott T, Senn O, Rosemann T, et al. Efficacy of motivating short interventions for smokers in primary care (COSMOS trial): study protocol for a cluster-RCT. *Trials*. January 25 2019;20(1):81.
BMI: Body mass index; LIPA: Light-intensity physical activity; MVPA: Moderate- to vigorous-intensity physical activity.

Additional table 2: Additional GP traits and patient characteristics

		HC arm			FoT arm			
	unit	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)	p^1
a. GPs' views on health promotion and prevention			(*n* = 29)			(*n* = 27)		
GPs addressing health promotion with:								
known patients			16 (55.2)			13 (48.1)		0.79
new patients			17 (58.6)			12 (44.4)		0.42
patients at risk for NCD		29	18 (62.1)		27	13 (48.1)		0.42
women			11 (37.9)			6 (22.2)		0.25
men			11 (37.9)			6 (22.2)		0.25
all			25 (86.2)			18 (66.7)		0.12
Follow-up after such counselling:								
always			12 (41.4)			11 (40.7)		
sometimes		29	14 (48.3)		27	15 (55.6)		0.77
rarely			3 (10.3)			1 (3.7)		
never			0 (0.0)			0 (0.0)		
GPs not addressing health promotion with:								
patients with severe chronic conditions			4 (13.8)			4 (15.4)		1.00
patients with psychic conditions			3 (10.3)			1 (3.8)		0.61
old patients		29	2 (6.9)		26	0 (0.0)		0.49
other patients			6 (20.7)			1 (3.8)		0.10
no such patient group			15 (51.7)			21 (80.8)		0.05
Reasons for such exemption:								
no time			4 (23.5)			3 (33.3)		0.66
counselling considered inappropriate			5 (29.4)			3 (33.3)		1.00
forgotten		17	1 (5.9)		9	2 (22.2)		0.27
no confidence in success			4 (23.5)			2 (22.2)		1.00
other reasons			6 (35.3)			2 (22.2)		0.67
b. Additional patient characteristics			(*n* = 46)			(*n* = 58)		
Body height	cm	46		171.6 (7.9)	58		170.4 (9.9)	0.52
Highest education level:								
compulsory education			3 (6.7)			7 (12.1)		
vocational training		45	18 (40.0)		58	25 (43.1)		0.25
specialised or vocational secondary school			3 (6.7)			2 (3.4)		

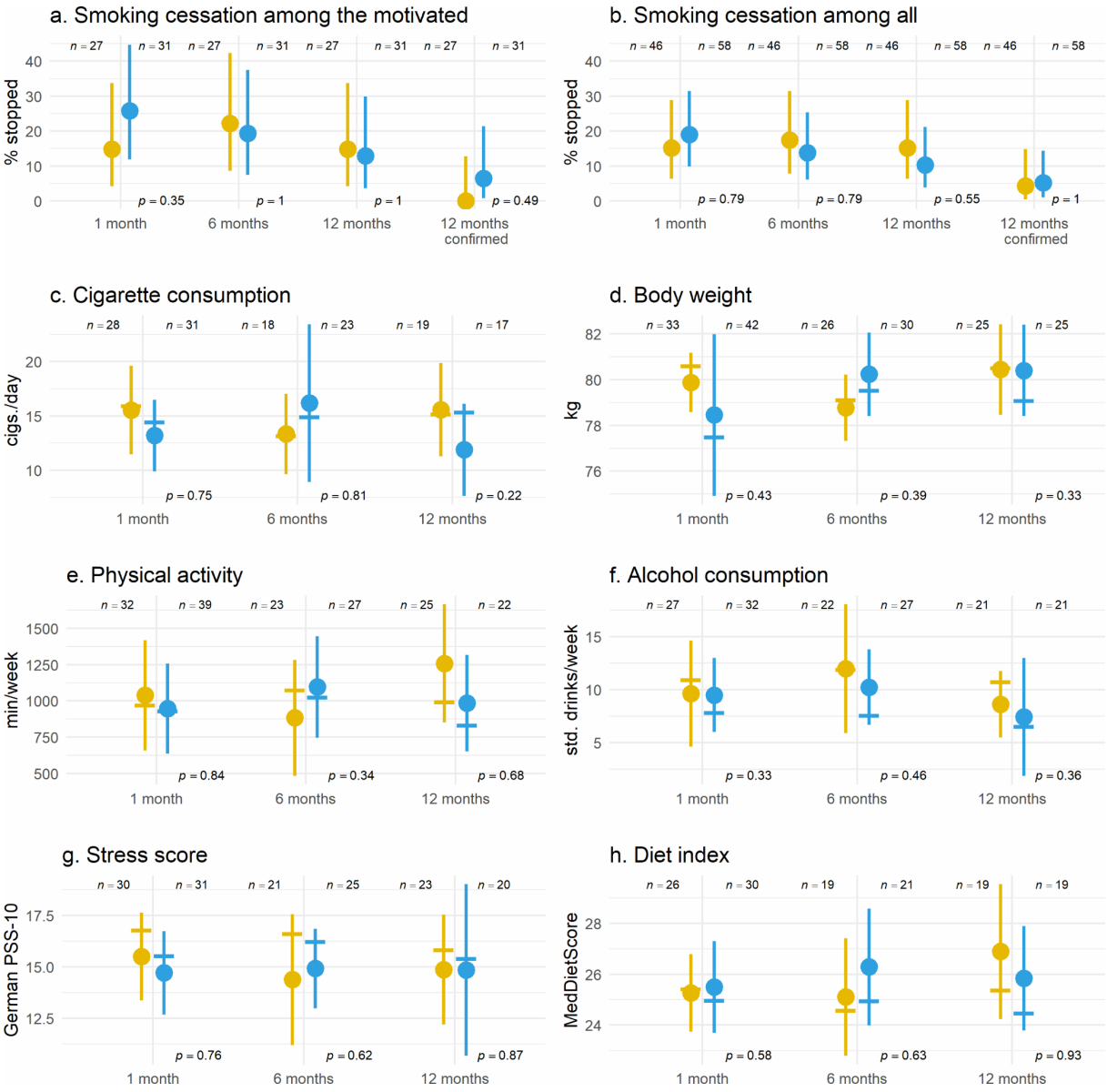
secondary/grammar school			0 (0.0)			4 (6.9)	
higher professional education			11 (24.4)			15 (25.9)	
university of applied sciences			4 (8.9)			1 (1.7)	
university			6 (13.3)			4 (6.9)	
Age at start of smoking	y	45	17.8 (3.3)		57	18.1 (5.1)	0.72
Duration of tobacco consumption	y	45	31.1 (14.7)		57	32.4 (14.5)	0.66
Cigarette consumption							
1-4 cigarettes/day			0 (0.0)			1 (1.7)	
5-10 cigarettes/day			7 (15.2)			13 (22.4)	
11-14 cigarettes/day		46	7 (15.2)		58	5 (8.6)	0.20
15-20 cigarettes/day			26 (56.5)			23 (39.7)	
21-30 cigarettes/day			4 (8.7)			13 (22.4)	
≥ 31 cigarettes/day			2 (4.3)			3 (5.2)	
Time to first cigarette after waking up:							
0-5 min			8 (17.4)			14 (24.6)	
6-30 min		46	22 (47.8)		57	27 (47.4)	0.79
31-60 min			10 (21.7)			9 (15.8)	
≥ 61 min			6 (13.0)			7 (12.3)	
Smoking pattern:							
regular smoker			35 (76.1)			42 (73.7)	
binge smoker[2]		46	10 (21.7)		57	11 (19.3)	0.62
occasional smoker			1 (2.2)			4 (7.0)	
Smoking cessation attempts:							
0			11 (23.9)			15 (26.3)	
1-5		46	30 (65.2)		57	34 (59.6)	0.88
≥ 6			5 (10.9)			8 (14.0)	
Tobacco associated diseases:							
respiratory disease			10 (52.6)			18 (47.1)	0.78
cardiovascular disease			9 (47.4)			12 (31.6)	0.26
cancer			1 (5.3)			1 (2.6)	1.00
metabolic disease, e.g. diabetes		19	1 (5.3)		38	4 (10.5)	0.66
depression or burnout			0 (0.0)			6 (15.8)	0.16
other mental or psychiatric condition			0 (0.0)			4 (10.5)	0.29
other addiction, incl. alcohol or drugs			4 (21.1)			1 (2.6)	0.04
others			3 (15.8)			5 (13.2)	1.00
Partner = smoker (vs. non-smoker)		24	14 (58.3)		38	15 (39.5)	0.19
Exposed to second-hand smoke at home or work		45	11 (24.4)		55	18 (32.7)	0.39

[1] Fisher's exact and two-sided 2 sample *t*-tests
[2] Intermittent excessive smoker

Additional table 3: **Imputed logistic mixed models for the primary outcome** (*any* clinically relevant health-promoting behavioural change), **a.** without and **b.** with non-responder imputation.

		a.			**b.**		
Variable	unit	aOR	95% Wald CI	*p*	aOR	95% Wald CI	*p*
Study arm = HC (vs. FoT)		**1.21**	[0.03-50.76]	0.92	**1.78**	[0.51-6.25]	0.36
Patient sex = male (vs. female)		0.69	[0.02-22.65]	0.83	0.72	[0.24-2.15]	0.55
Patient age	y	1.04	[0.81-1.33]	0.74	1.02	[0.98-1.06]	0.31
Cigarette consumption	cigarettes/day	0.98	[0.79-1.22]	0.85	0.96	[0.89-1.02]	0.17
Body weight	kg	1.01	[0.79-1.28]	0.94	1.02	[0.99-1.05]	0.28
Physical activity	hours/day	0.99	[0.79-1.24]	0.91	1.00	[0.96-1.03]	0.90
Alcohol consumption	standard drinks/week	1.01	[0.88-1.15]	0.93	1.00	[0.95-1.04]	0.88
Stress score (German PSS-10)	0-40	1.00	[0.76-1.33]	0.98	1.00	[0.92-1.09]	0.92
Diet index (MedDietScore)	0-55	0.99	[0.62-1.57]	0.95	0.97	[0.86-1.09]	0.58
GP sex = male (vs. female)		2.04	[0.06-64.74]	0.68	2.68	[0.69-10.43]	0.15
GP age	y	0.99	[0.70- 1.40]	0.96	0.95	[0.87- 1.03]	0.20

a. With MI (*m* = 90) of missing outcome, covariate, and baseline values
b. With NRI of missing outcome values, and MI (*m* = 40) of missing covariate and baseline values
Abbreviations: aOR: odds ratio adjusted for GP and patient sex and age, for outcome baselines (fixed effects), and for clustering by GPs (random effect); CI: confidence interval.



Additional figure 1: **Health behaviour changes from individual baseline values.** Dots are follow-up means, short horizontal bars are baseline means (of the *n* participants with available follow-up values at the respective study stage), and long vertical bars are 95% Wald confidence intervals for the changes; each by HC arm in yellow (left) and FoT arm in blue (right).

a. and **b**. With NRI; all baselines = 0. Patients were considered motivated if they had chosen smoking cessation among their target behaviours (HC arm) or indicated a motivation level of at least 8 on an integer scale of 1-10 (FoT arm).

g. German PSS-10: 10-item Perceived Stress Scale; integer scale of 0-40.

h. MedDietScore: Integer scale of 0-55.

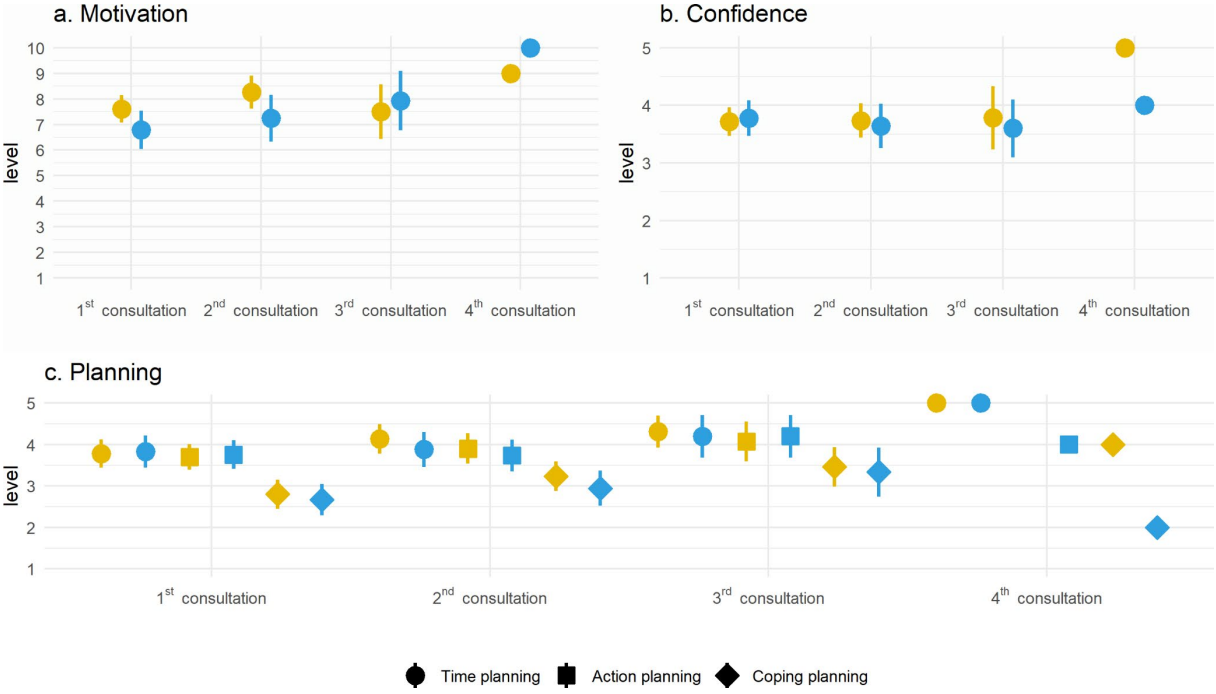
For the underlying data including overall baselines, see the following Additional table 4.

Additional table 4: Clinically relevant improvements in individual health behaviours (**a**. and **b**. with NRI)

		HC arm			FoT arm			
	unit	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)	*p*[1]
a. Smoking cessation among the motivated			(*n* = 27)			(*n* = 31)		
After 1 month, self-declared		27	4 (14.8)		31	8 (25.8)		0.35
After 6 months, self-declared		27	6 (22.2)		31	6 (19.4)		1.00
After 12 months, self-declared		27	4 (14.8)		31	4 (12.9)		1.00
After 12 months, confirmed by cotinine test		27	0 (0.0)		31	2 (6.5)		0.49
b. Smoking cessation among all			(*n* = 46)			(*n* = 58)		
After 1 month, self-declared		46	7 (15.2)		58	11 (19.0)		0.79
After 6 months, self-declared		46	8 (17.4)		58	8 (13.8)		0.79
After 12 months, self-declared		46	7 (15.2)		58	6 (10.3)		0.55
After 12 months, confirmed by cotinine test		46	2 (4.3)		58	3 (5.2)		1.00
c. Reduction in cigarette consumption			(*n* = 46)			(*n* = 58)		
Baseline	cigarettes/d	46		15.6 (7.3)	58		15.8 (9.1)	0.93
After 1 month	cigarettes/d	28		0.4 (11.0)	31		1.3 (9.3)	0.75
After 6 months	cigarettes/d	18		-0.2 (8.0)	23		-1.3 (17.8)	0.81
After 12 months	cigarettes/d	19		-0.4 (9.6)	17		3.5 (8.9)	0.22
d. Body weight loss			(*n* = 46)			(*n* = 58)		
Baseline	kg	46		78.1 (17.9)	58		76.7 (18.1)	0.70
After 1 month	kg	33		0.7 (3.8)	42		-1.0 (11.7)	0.43
After 6 months	kg	26		0.3 (3.8)	30		-0.7 (5.1)	0.39
After 12 months	kg	25		0.1 (5.0)	25		-1.3 (5.1)	0.33
e. Increase in physical activity			(*n* = 46)			(*n* = 58)		
Baseline	min/w	45		1025.7 (948.3)	54		926.7 (932.0)	0.60
After 1 month	min/w	32		67.7 (1098.0)	39		16.5 (991.1)	0.84
After 6 months	min/w	23		-191.4 (978.2)	27		69.9 (931.8)	0.34
After 12 months	min/w	25		267.1 (1041.5)	22		154.0 (795.3)	0.68
f. Reduction in alcohol consumption			(*n* = 46)			(*n* = 58)		
Baseline	std. drinks/w	35		11.4 (15.2)	41		8.3 (12.6)	0.33
After 1 month	std. drinks/w	27		1.3 (13.2)	32		-1.7 (10.0)	0.33
After 6 months	std. drinks/w	22		-0.1 (14.5)	27		-2.7 (9.4)	0.46
After 12 months	std. drinks/w	21		2.1 (7.3)	21		-0.9 (13.0)	0.36
g. Reduction in stress score (German PSS-10)			(*n* = 46)			(*n* = 58)		
Baseline	0-40	41		17.2 (6.4)	49		15.7 (7.3)	0.30
After 1 month	0-40	30		1.3 (6.0)	31		0.8 (5.8)	0.76
After 6 months	0-40	21		2.2 (7.5)	25		1.3 (4.9)	0.62
After 12 months	0-40	23		1.0 (6.6)	20		0.6 (9.5)	0.87
h. Increase in diet index (MedDietScore)			(*n* = 46)			(*n* = 58)		
Baseline	0-55	36		25.6 (4.4)	50		25.1 (5.3)	0.66
After 1 month	0-55	26		-0.2 (4.0)	30		0.5 (5.1)	0.58
After 6 months	0-55	19		0.5 (5.1)	21		1.3 (5.4)	0.63
After 12 months	0-55	19		1.5 (5.9)	19		1.4 (4.6)	0.93

[1] Fisher's exact and two-sided 2 sample *t*-tests

Additional figure 2 shows the progress of the participants' self-assessed attitudes in terms of self-efficacy and planning over the course of the ongoing consultations. No significant differences between the study arms were found:



Additional figure 2: **Trends in the participants' a. motivation and b. confidence to achieve and maintain a beneficial change in behaviour, and c. of the availability of plans on when (dots) and how (squares) to take action and how to deal with relapses (diamonds)**.
Symbols are means, and vertical bars are 95% Wald confidence intervals, each by HC arm in yellow (left) and FoT arm in blue (right). Only one patient per study arm provided (incomplete) data on a 4th consultation. All *p* values were > 0.09 and therefore omitted.
a. Integer scale of 1-10, with 1-3 = *not motivated*, 4-7 = *ambivalent* and 8-10 = *motivated*.
b. and **c**. Integer scales of 1-5 from 1 = *not confident at all/no plan available whatsoever* to 5 = *very confident/already started or clear ideas available*.
For the underlying data including *n* and *p*, see the following Additional table 5.

Additional table 5: Motivation, confidence, and planning

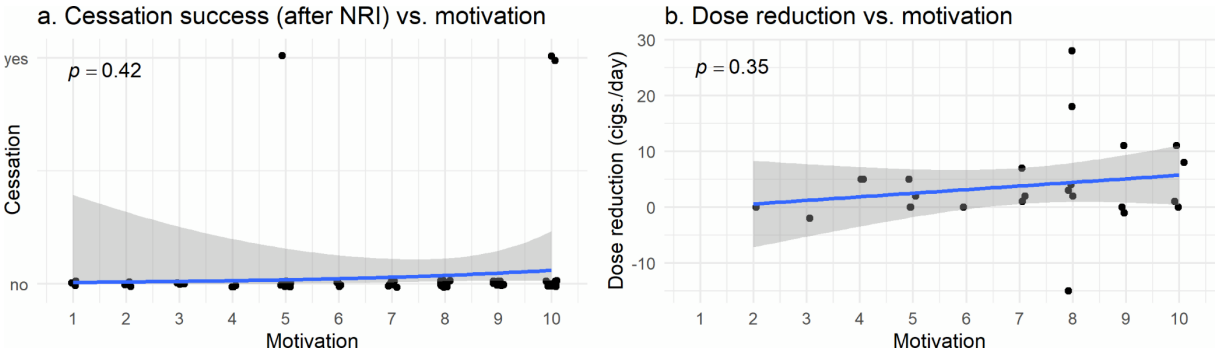
		HC arm			FoT arm			
	unit	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)	*p*[1]
a. Motivation to achieve and maintain change			(*n* = 46)			(*n* = 58)		
1st consultation	1-10	46		7.6 (1.9)	57		6.8 (2.9)	0.10
2nd consultation	1-10	30		8.3 (1.8)	36		7.2 (2.8)	0.09
3rd consultation	1-10	14		7.5 (2.0)	15		7.9 (2.3)	0.59
4th consultation	1-10	1		9.0 (-)	1		10.0 (-)	-
b. Confidence to achieve and maintain change			(*n* = 46)			(*n* = 58)		
1st consultation	1-5	46		3.7 (0.9)	45		3.8 (1.1)	0.77
2nd consultation	1-5	30		3.7 (0.8)	36		3.6 (1.2)	0.71
3rd consultation	1-5	14		3.8 (1.1)	15		3.6 (1.0)	0.63
4th consultation	1-5	1		5.0 (-)	1		4.0 (-)	-
c1. Availability of plan *when* to start			(*n* = 46)			(*n* = 58)		
1st consultation	1-5	46		3.8 (1.2)	46		3.8 (1.3)	0.87
2nd consultation	1-5	30		4.1 (1.0)	33		3.9 (1.2)	0.38
3rd consultation	1-5	23		4.3 (0.9)	15		4.2 (1.0)	0.77
4th consultation	1-5	1		5.0 (-)	1		5.0 (-)	-

c2. Availability of plan *how* to start			(*n* = 46)		(*n* = 58)	
1st consultation	1-5	46	3.7 (1.1)	45	3.8 (1.2)	0.80
2nd consultation	1-5	30	3.9 (1.0)	34	3.7 (1.1)	0.55
3rd consultation	1-5	14	4.1 (0.9)	15	4.2 (1.0)	0.72
4th consultation	1-5	0	- (-)	1	4.0 (-)	-

c3. Existence of relapse/coping plan			(*n* = 46)		(*n* = 58)	
1st consultation	1-5	45	2.8 (1.2)	45	2.7 (1.3)	0.61
2nd consultation	1-5	30	3.2 (1.0)	35	2.9 (1.3)	0.32
3rd consultation	1-5	13	3.5 (0.9)	15	3.3 (1.2)	0.75
4th consultation	1-5	1	4.0 (-)	1	2.0 (-)	-

[1] Two-sided 2 sample *t*-tests

Additional figure 3 illustrates the absence of an association between initial motivation to quit smoking and eventual success. The figure shows all patients in the FoT arm and those in the HC arm who chose smoking among their target behaviours.



Additional figure 3: **Association of a. (confirmed) cessation success and b. dose reduction after 12 months with initial motivation to quit smoking**. (*p* values are from standard two-sided *z* and *t*-tests.)

B. PROCESS EVALUATION

The process evaluation follows the RE-AIM framework[1] which we found well suited for our study with its focus on individual behaviour change.

R = Reach

Key question: Did the intervention reach the individuals who needed it?

The 56 instructed GPs from German-speaking Switzerland estimated a mean fraction of 24.1% of smokers among their patients. They screened a total of 377 smoking patients and found 230 (= 61.0%) eligible for participation. All 230 eligible patients were invited to participate. 149 patients (= 64.8% of those invited) gave informed consent, and the remaining 35.2% refused to participate, most often because of lack of motivation, will, or interest to stop (often when partner was unwilling to stop), language difficulties, lack of time for consultations, unwillingness to participate in a study, desire to succeed without help, lack of confidence in success, only low tobacco use, or more pressing issues (demanding caregiving tasks, death of spouse or relative, relocation).

		Study sample[1]			**Reference population**[2]	
	unit	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
Patients			(*n* = 101)			(*N* = 6199405)	
Sex = male (vs. female)		101	51 (50.5)			(49.1)	
Age:							
25-44			35 (34.7)			(37.6)	
45-64	y	101	46 (45.5)			(38.3)	
≥ 65			20 (19.8)			(24.1)	
Education:							
≤ secondary I			10 (10.0)			(19.5)	
secondary II		100	50 (50.0)			(46.0)	
tertiary			40 (40.0)			(34.5)	

[1] Excluding 3 participants < 25 years for appropriate comparison.
[2] Permanent resident population ≥ 25 years of Switzerland in 2018, according to: Federal Statistical Office (Bundesamt für Statistik). Highest level of education completed. Available from: https://www.bfs.admin.ch/bfs/en/home/statistics/education-science/level-education.assetdetail.11627129.html (accessed January 20, 2022).

Dropout rates (before completion of counselling) were 20/66 = 30.3% in the HC arm and 25/83 = 30.1% in the FoT arm (Fisher's exact $p = 1.00$). Most dropouts failed to report their patient profiles or baseline data without giving reasons. Loss-to-follow-up rates (after completion of counselling) were 20/46 = 43.5% in the HC arm and 36/58 = 62.1% in the FoT arm (Fisher's exact $p = 0.08$). The most frequently mentioned reasons for withdrawing during follow-up were death of a close relative, medical problems, stress caused by study participation, difficult-to-complete study forms, change of GP, and relocation of the participant. Also, several patients stated they simply no longer felt like participating in the study.

For further description of the participating patients see Table 1b and Additional table 2b.

[1] https://re-aim.org, and: Glasgow RE, Harden SM, Gaglio B, et al. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. *Front Public Health*. 2019;7:64.

In brief: Our intervention reached smokers of both sexes and of all ages and educational levels, provided they were interested and initially motivated.

E = Effectiveness

Key question: Did the intervention work under study conditions?

Primary and secondary outcome measures (behaviour change rates and changes in self-efficacy and planning) are presented in the main text body and in Additional tables 3 and 4.

Both over time and in comparison between study arms, the participants were consistently and equally satisfied with the course of the consultations. Therefore, it seems unlikely that the implementation of the intervention was affected by varying or different degrees of satisfaction.

		HC arm			FoT arm		
	unit[1]	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
Satisfaction with counselling			(*n* = 46)			(*n* = 58)	
1st consultation	1-5	45		4.2 (0.9)	56		4.3 (0.8)
2nd consultation	1-5	30		4.5 (0.6)	35		4.2 (0.9)
3rd consultation	1-5	13		4.7 (0.5)	15		4.3 (0.8)
4th consultation	1-5	1		5.0 (-)	1		5.0 (-)

[1] Integer scale of 1-5 from 1 = *not satisfied at all* to 5 = *very satisfied*.

In brief: Under study conditions, HC was as efficacious as FoT in terms of smoking cessation, while FoT had similar effects as HC on health behaviour beyond cigarette smoking.

A = Adoption

Key question: Was the intervention adopted in the targeted setting?

All 2776 GPs in 10 northern, eastern and central cantons of Switzerland were contacted. 103 GPs (= 3.7% of those contacted) agreed to participate with the predominant reason for participation being the opportunity to brush up on smoking cessation counselling. Two GPs politely refused to participate due to impending retirement. All other GPs did not react to the invitation. 13 GPs withdrew their initial consent, mostly for reasons of high workload, but also due to practice shutdown, unsuitable patient population, accident, maternity leave or erroneous consent, and in one case without reason. Of the 48 GPs randomized into the HC arm, 19 were unavailable for the study instruction, as were 15 of the 42 GPs allocated into the FoT arm (Fisher's exact $p = 0.83$).

		Study sample			Reference population[1]		
	unit	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
GPs			(*n* = 56)			(*N* = 8308)	
Sex = male (vs. female)		56	32 (57.1)			(58.7)	
Age	y	56		49.4 (8.7)			51.6 (11.6)
Practice structure:							
single		56	8 (14.3)			(27.8)	
group			48 (85.7)			(34.8[2])	

Practice location:			
urban		21 (39.6)	(76.1)
suburban	53	21 (39.6)	(15.7)
rural		11 (20.8)	(8.2)

[1] General internist members of the Swiss Medical Association in 2018, according to: Swiss Medical Association (Foederatio Medicorum Helveticorum). Physicians' Statistics. Available from: https://www.fmh.ch/themen/aerztestatistik/fmh-aerztestatistik.cfm#i131905 (accessed January 20, 2022).
[2] Plus 37.3% not specified, as working in hospitals.

For further description of the participating GPs see Table 1a and Additional table 2a.

After being instructed, 4 (HC arm) + 1 (FoT arm) = 5 GPs dropped out for similar reasons as mentioned above, and 4 + 2 = 6 GPs could not find patients willing to participate in the study and therefore did not deliver the intervention.

Although the study plan allowed GPs to delegate consultations to medical practice assistants (MPAs), provided they had attended the training along with their GPs, this option was very rarely used. Of all 37 MPAs meeting this condition, only 3 were ultimately involved in consultations with a total of 4 patients, and in only one case (in the FoT arm) was the initial consultation led by an MPA. The reasons for the low MPA participation are unclear and should be further investigated.

The 56 instructed GPs' views on the HC and FoT counselling concepts and their respective trainings, as declared immediately after the training sessions, are summarised in the following table.

		HC arm			FoT arm		
	unit[1]	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
a. Prior knowledge and self-perception			(*n* = 29)			(*n* = 27)	
I consider myself experienced in coaching and communication/smoking cessation counselling.		29	29 (100.0)		27	25 (92.6)	
I have already been trained in coaching and communication/smoking cessation counselling.		29	11 (37.9)		27	9 (33.3)	
Prevention and health promotion have a high priority in my work.	1-5	29		3.9 (1.1)	27		4.5 (0.6)
I uphold a modern participatory rather than paternalistic understanding of my professional role.	1-5	29		4.3 (0.7)	27		4.4 (0.6)
b. Knowledge gain			(*n* = 29)			(*n* = 27)	
The training has improved my communication/smoking cessation counselling skills.	1-5	29		3.8 (0.8)	27		3.7 (0.9)
I would rate my skills and knowledge in communication and coaching/smoking cessation counselling as:	1-10	29		7.2 (1.0)	27		7.4 (0.7)
c. Understanding and assessment of concepts			(*n* = 29)			(*n* = 27)	
I am familiar with the core elements of the coaching/counselling concept.	1-5	29		4.2 (0.6)	27		4.2 (0.6)
I am aware of the different roles in coaching patients.	1-5	29		4.3 (0.8)	-		- (-)
I know how to implement my role as a coach into my consultations.	1-5	29		4.3 (0.6)	-		- (-)
The coaching/counselling will reinforce the patients' proactive health behaviour.	1-5	29		4.3 (0.7)	27		4.2 (0.5)
The setting of GP consultations is appropriate for health coaching/smoking cessation counselling.	1-5	29		4.2 (0.8)	27		4.7 (0.6)
d. Evaluation of training structure and course design			(*n* = 29)			(*n* = 27)	
The training objectives were clear.	1-5	29		4.4 (0.8)	27		4.3 (0.7)
Training structure and didactics were good.	1-5	28		4.7 (0.7)	27		4.4 (0.6)
The duration of the training was adequate.	1-5	28		4.3 (1.1)	26		4.3 (0.9)

The documentation provided was useful.	1-5	27	4.4 (0.7)	27	4.5 (0.6)
The content was tailored to daily practice work.	1-5	28	4.4 (0.7)	27	4.3 (0.6)
Sharing experiences with peers was helpful.	1-5	28	4.7 (0.5)	27	4.6 (0.5)
The training was worth the time invested.	1-5	28	4.6 (0.8)	27	4.2 (0.8)
e. Recommendation to peers		(*n* = 29)		(*n* = 27)	
I will tell interested colleagues about this course.	1-5	28	4.4 (0.8)	27	4.3 (0.7)
I will recommend further training in health coaching/smoking cessation counselling to my colleagues.	1-5	28	4.5 (0.7)	27	4.3 (0.7)

[1] Integer scales of 1-5 from 1 = *not at all* to 5 = *very much so*, and 1-10 from 1 = *very poor* to 10 = *very good*.

Among additional comments on the training, several positive mentions of the role play with the standardised patients stood out, with one participant even calling it too short while another thought it unnecessary. Two GPs in the HC arm expressed some confusion about the scope of the training and the study as a whole; because the latter had been advertised as "study with smoking patients in primary care", they had expected training in smoking cessation counselling rather than in the broader field of multithematic health coaching.

On average, the GPs in the HC arm coached 2.56 patients (SD = 1.62) in a mean total of 5.78 (SD = 5.82) consultations per GP, and the corresponding numbers in the FoT arm were 2.90 patients (SD = 2.07) and 7.55 (SD = 5.9) consultations. The following table shows the average time spent on each consultation. The multithematic health coaching concept appears to be somewhat more time-consuming at first; thereafter, the time requirements decrease with each additional consultation, and converge.

		HC arm			**FoT arm**		
	unit	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
Duration of consultations			(*n* = open[1])			(*n* = open[1])	
1st consultation	min	37		22.9 (10.9)	57		16.8 (10.0)
2nd consultation	min	28		18.8 (9.2)	42		14.6 (8.4)
3rd consultation	min	20		18.0 (8.8)	29		13.6 (6.8)
4th consultation	min	10		10.5 (5.5)	13		13.5 (7.2)
5th consultation	min	6		9.2 (6.6)	6		13.0 (5.8)
6th consultation	min	2		2.5 (3.5)	3		10.0 (0.0)

[1] The numbers of coaching/counselling sessions were not pre-specified, but were mutually agreed on by both patients and GPs.

When asked to rate the tools provided for coaching and counselling, the GPs provided the following opinions. The health coaching tools were considered easier to use, but the tools provided to facilitate smoking cessation counselling were rated more useful.

		HC arm			**FoT arm**		
	unit[1]	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
Usefulness and manageability of tools			(*n* = 29)			(*n* = 27)	
The tools used in health coaching/smoking cessation counselling have proven useful.	1-5	15		3.2 (1.1)	20		3.9 (0.7)
The coaching/counselling effort is easy to manage in everyday work.	1-5	15		3.9 (1.1)	20		3.7 (0.9)

[1] Integer scale of 1-5 from 1 = *not at all* to 5 = *very much so*.

From the GPs' perspective, the most essential factors for implementing successful coaching or counselling concepts were sufficient time and the possibility to involve medical practice assistants. In addition, the importance of good training was mentioned, as well as stable and trusting relationships with the patients. One GP suggested to expand the coaching concept to include patient recall, and one hypothesized that cost coverage of a limited number of

consultations by health insurers would probably boost the smokers' readiness to question and adjust their health behaviour. Lack of time and the need for a designated room were also mentioned as barriers to successful coaching/counselling, and so were temporary adverse circumstances such as practice relocations or vacation absence. According to the GPs, some patients would also refuse to make coaching appointments or not want to participate in studies.

In brief: The study was conducted mainly in urban areas, and GPs with busy schedules and high workloads tended to not participate. The intentions and goals of the interventions were well received, and training and study materials rated favourably.

I = Implementation

Key question: Was the intervention delivered properly?

Smokers with consultations as part of the study averaged 2.81 (SD = 1.49) consultations in the HC arm, similar to 2.65 (SD = 1.40) consultations in the FoT arm. It should be noted, though, that in the HC arm, 9 of the 46 participants sought no consultation at all, whereas in the FoT arm, this was the case for only 1 of 58 smokers (Fisher's exact $p < 0.01$). This might indicate that smokers perceive their tobacco use as a more pressing problem than other unhealthy behaviours.

Attitudes and competencies of the GPs – which may have influenced the implementation of the study activities – are summarised in the next table:

		HC arm			**FoT arm**		
	unit[1]	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
a. Attitudes			(*n* = 29)			(*n* = 27)	
Prevention and health promotion have a high priority in my work.	1-5	15		4.3 (1.0)	20		4.6 (0.6)
Multithematic and patient centred health coaching/structured smoking cessation counselling is indispensable and should be offered by GPs.	1-5	15		4.6 (0.5)	20		4.3 (0.7)
b. Competencies			(*n* = 29)			(*n* = 27)	
I am good at making patients aware of their health behaviours.	1-5	15		4.4 (0.5)	19		4.3 (0.7)
I am successful in working with patients to explore the potential for better health behaviour and to develop ideas for action.	1-5	15		3.7 (0.6)	20		4.0 (0.8)
I can help my patients with setting their health goals and developing binding steps to reach them.	1-5	14		4.1 (0.7)	20		4.1 (0.8)
I am proficient in important elements of conversation management, such as questioning techniques, active listening, nonverbal communication, etc.	1-5	15		3.9 (0.8)	20		4.0 (0.7)
My professional knowledge is sufficient to counsel my patients on healthier behaviours in various areas.	1-5	15		4.3 (0.7)	19		4.2 (0.7)
I consider myself sufficiently competent to support my patients in a multithematic and participatory coaching/in a smoking cessation attempt.	1-5	15		4.1 (0.7)	20		4.4 (0.7)

[1] Integer scales of 1-5 from 1 = *not at all* to 5 = *very much so*.

In retrospect, the following factors were critical to the successful implementation of both health coaching and smoking cessation support from the GPs' perspective: A long-standing and trusting doctor-patient relationship, the GP's ability to communicate, his professional competence, a GP's personal history as ex-smoker, creativity and flexibility to search for and follow individual approaches, the patient's motivation, comorbidities and advanced age, a role model function of the patient (e.g. for young athletes in a sports club), and the externalisation and documentation of progress (e.g. in logs or diaries). On the other hand, although many GPs did not encounter any barriers to coaching/counselling, some mentioned the following hurdles: High GP workload, coupled with little hope for success, and – on the part of the patients – lack of motivation, fear and shame in case of relapse, the time required for the consultations, a saturation effect and resignation on the topics of health and smoking, the will to "make it" without help, denial of the need for change, and fear of weight gain. Two GPs found the study setting to be a barrier; the study was perceived to be too long in duration and making the patients feel like guinea pigs.

Most GPs were able to carry out all study activities according to the protocol. One GP chose not to use the study tools for his consultations due to lack of time, another forgot that his consultations were part of the study and did therefore not document them in the study log, and a third GP scheduled all consultations in evening hours (not actually a breach of protocol).

The assessment of implementation fidelity is complicated by incomplete data due to the less than overwhelming response rates for some CRFs (see columns *n* in all tables). Also, data integrity is partially compromised by the retrospective reporting of alcohol consumption, physical activity and diet in rather difficult-to-fill questionnaires.

> *In brief: Most GPs encountered few barriers to delivering the intervention, and the study was carried out without any major violations of the protocol. Patient data integrity was not fully warranted in some cases.*

M = Maintenance

> *Key question: Was the intervention delivered over the long term?*

The following data on continuation of the HC intervention beyond the end of the study were collected in December 2021, i.e. between 1 and 3 years after a GP's last consultation with a study participant.

		HC arm			FoT arm		
	unit	*n*	# (%)	mean (SD)	*n*	# (%)	mean (SD)
Maintenance			(*n* = 29)			(*n* = 27)	
I have continued health coaching according to HC after the study was completed.		14	10 (71.4)		-	- (-)	
When counselling smokers, I offer them to choose which health behaviour to address and improve?		14	8 (57.1)		-	- (-)	
When counselling smokers, I make use of the HC tools.		14	9 (64.3)		-	- (-)	

Upkeep of beneficial changes by the patients, further trainings of additional GPs in health coaching HC, expert and media response as well as maintenance costs have not been systematically evaluated.

> *In brief: A remarkable proportion of GPs continued to offer HC to their patients after the end of the study.*

Conclusion

The analysis of the effectiveness outcomes has already shown that HC is not inferior to FoT in its potential to promote smoking cessation. The process evaluation shows now that its implementation in everyday practice is also unlikely to be less successful than FoT.