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RESEARCH PAPER

Acceptance and practicability of a visual communication tool in smoking cessation counselling: a randomised controlled trial

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Abstract

Background: Smoking cessation advice is important for reducing the worldwide burden of disease resulting from tobacco smoking. Appropriate risk communication formats improve the success of counselling interventions in primary care.

Aims: To test the feasibility and acceptance of a smoking cessation counselling tool with different cardiovascular risk communication formats including graphs, in comparison with the International Primary Care Respiratory Group (IPCRG) 'quit smoking assistance' tool.

Methods: GPs were randomised into an intervention group (using our communication tool in addition to the IPCRG sheet) and a control group (using the IPCRG sheet only). We asked participants for socioeconomic data, smoking patterns, understanding of information, motivation, acceptance and feasibility, and measured the duration and frequency of counselling sessions.

Results: Twenty-five GPs performed 2.8 counselling sessions per month in the intervention group and 1.7 in the control group (p=0.3) with 114 patients. The median duration of a session was 10 mins (control group 11 mins, p=0.09 for difference). Median patients' motivation for smoking cessation was 7 on a 10-point visual analogue scale with no significant difference before and after the intervention (p=0.2) or between groups (p=0.73 before and p=0.15 after the intervention). Median patients' ratings of motivation, self-confidence, understanding of information, and satisfaction with the counselling were 3–5 on a 5-point Likert scale, similar to GPs' ratings of acceptance and feasibility, with no significant difference between groups.

Conclusions: Among Swiss GPs and patients, both our innovative communication tool and the IPCRG tool were well accepted and both merit further dissemination and application in research.

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See linked editorial by Lewis on pg 387

The full version of this paper, with online appendices, is available online at www.thepcrj.org

Introduction

Tobacco smoking is a significant public health problem. About half of all persistent cigarette smokers are killed by their habit – a quarter while still in middle age – with an estimated mortality worldwide of 5,000,000 per year.[1-4] According to the World Health Organization, smoking is the leading preventable cause of death worldwide.[3] Compared with non-smokers, the relative risk of a smoker developing cardiovascular disease (CVD) is 1.6–3.0, of suffering a stroke is 1.8–4.8, and of developing lung or oropharyngeal cancer is 17.8–22.3, dependent on age and gender.[1] However, the incidence (absolute risk) of malignant disease due to smoking is considerably lower than that of CVD as a potential long-term consequence of smoking.

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In a recent survey in Switzerland the proportion of smokers in the population was 27%, similar to the last decade.[5] Half of the smokers who consider quitting are either in a contemplation state or in a preparation state according to the transtheoretical model (TTM) of changing behaviour.[5,6] In this process of reconsidering, motivation and self-efficacy are independent predictors of success.[7] As the majority of Swiss smokers (84%) discussed smoking cessation issues with their general practitioners (GPs),[5] GPs are important key players in the effort to reduce the proportion of smokers in a population. A short smoking cessation intervention from the GP based on the individual smoker's motivational state helps patients to quit[8] and is therefore an important and relevant method of reducing the hazards associated with smoking.

In patient counselling, communication tools (particularly visual aids) and motivational interviewing techniques improve the success of interventions aimed at behaviour change.[9-12] We therefore developed a smoking cessation counselling tool which integrates visual aids and facilitates motivational interviewing techniques. Based on the International Primary Care Respiratory Group (IPCRG) 'quit smoking assistance' tool and the counselling process,[13] we added some relevant risk information about smoking. To translate CVD risks, we used a combination of communication formats (verbal, numerical, visual) and focused on the benefits to the patient (risk reduction) of smoking cessation. The IPCRG tool was used as the reference standard and we hypothesised that our tool is not inferior to the IPCRG tool with regard to feasibility and acceptance.

Methods

Development of the tool: choice of outcome (risk) to communicate

We chose CVD morbidity as the main risk communication issue for our tool in order to achieve maximal motivation. We calculated the absolute 10-year risk for cardiovascular events for smokers aged 35–65 years versus non-smokers of the same age using the risk calculator of the Swiss Task Force on Lipids and Atherosclerosis (www.agla.ch),[14] which uses the database of the PROCAM cohort.[15] Risk calculation by this tool requires age, gender, menopausal state, total serum cholesterol, serum HDL, serum triglycerides, diabetes, and family history. Our intention was to perform the counselling tool as a short intervention and as time-sparingly as possible. On the other hand, we wanted to perform individualised counselling based on the individual risk situation of each patient. Therefore, in order to avoid time-consuming data sampling from patients, we assumed gender-specific average values for most of the required cardiovascular risk factors based on the representative population-based Swiss cohort study SAPALDIA.[16] Thus, GPs only had to define gender, age, and smoking state of the patients to assess the individualised cardiovascular risk, which was possible to do within a few seconds (see Appendix 1, available online at www.thepcrj.org).

In our tool, risks are shown numerically with absolute percentages, relative percentages and natural frequencies, and visually with colour-coded bar charts (see Appendix 2, available online at www.thepcrj.org). Additionally, the age-related cardiovascular risk of a smoker is communicated in relation to the age of a non-smoker with the equivalent risk (organ age risk communication format, analogous to the lung age concept[12]). In order to standardise the 'usual' counselling interventions for tobacco smoking cessation, all participating GPs used the recommended Opinion Sheet for smoking cessation of the IPCRG[13] (see Appendix 3, available online at www.thepcrj.org) which is using motivational interviewing techniques.

Study protocol

The 27 participating GPs were randomised into an intervention group using our communication tool in addition to the IPCRG sheet, and a control group using the IPCRG sheet only. All study GPs underwent a group instruction. After a run-in period of two months to assess the frequency of usual counselling activity, the study period was six months. In each practice the GPs included up to 10 consecutive smokers aged 20–80 years. Exclusion criteria were a short life expectancy (<10 years), cognitive impairment, or any acute disease.

Table 1. Baseline characteristics

Characteristic	Median	IQR	Number	% of cases
Physician characteristics (n=27*)				
Age, years	48	43-55		
Experience as a GP, years	10	4-19		
Workload, percentage (100%=5 days working/week)	100	60-100		
Sex, males			14	52.9
Practice type, solo			9	33.3
No. of patients counselled per GP	4	2-7		
Patient characteristics (n=114)				
Age, years	47	33-57		
Sex, male			60	50.9
Education level, primary			12	10.2
secondary			67	56.8
high school			11	9.3
academic			28	23.7
Age at the begin of smoking, years	17	15-20		
Duration of smoking, years	29	15-38		
Cigarettes per day 1-5			4	3.4
6-10			23	19.5
11-15			18	15.3
16-20			39	33.1
21-25			18	15.3
>25			16	13.6
No attempts to quit			74	64.4
Partner smoking (n with partner=67)			31	46.3

*Two GPs did not perform any counselling session.

Measurements

Patient data on socioeconomics, smoking history, smoking patterns, comprehensiveness of the information, satisfaction, self-confidence, acceptance, and feasibility were collected by a questionnaire using a 5-point Likert scale. Patients rated their motivation before and after the intervention on a 10-point numerical visual analogue scale (VAS). GPs measured counselling duration and frequency as a proxy for acceptance and were asked about their estimates of acceptance and practicability of the tool by a short questionnaire.

Statistics

We defined a difference in counselling frequency between the intervention and control groups of ≤20% as suggesting non-inferiority of the tool compared with usual care. Data are presented as median (IQR) and frequencies. Patient and counselling characteristics were compared between the intervention and control groups using Wilcoxon tests. In addition, a modified Wilcoxon rank sum test[17] was applied to account for the potential cluster dependence at the GP level. A two-sided alpha level of 0.05 was assumed to indicate significance. The analyses were performed using Stata® Version 12.1 (Stata Corporation, College Station, Texas, USA; www.stata.com).

All patients gave written informed consent and the study was approved by the local ethics committee of Zurich.

Results

The characteristics of the GPs and patients are shown in Table 1. On average (medians), GPs had 10 years' practice experience; two-thirds of them were working in group practices. The average patient had been a smoker since the age of 17 and for almost 30 years. One-third of patients had not tried to quit smoking before and half of the patients had partners who smoked. The prevalence of comorbidities in our study population was equal to the average Swiss practice population (data not shown).

Detailed group comparisons of counselling and tool characteristics are shown in Table 2. During the 6-month study period, 25 GPs performed 2.8 (IQR 1.7–4.2) counselling sessions per month in the intervention group and 1.7 (IQR 1.3–3.3) in the control group (p=0.3), with a total of 114 patients. Compared with the run-in period, fewer counselling sessions were performed in both groups (43.1% fewer in the intervention group and 40.0% fewer in the control group), resulting in a median (IQR) difference in change between the groups of –1.6% (–39.7% to 40.0%), p=1.0; Table 2). The median duration of a counselling session was similar in both groups (10 mins in the intervention group and 11 mins in the control group, p=0.09); 51% of counselling sessions took less than 10 mins. GPs' ratings on practicability and usefulness were high for both tools (median of 4 on a 5-point Likert scale in the intervention group and 3 in the control group, p=0.13 and p=0.55, respectively). Patients' motivation for smoking cessation was already high before the intervention (median 7 on a 10-point VAS) with no significant difference after the intervention (p=0.20) or between groups (p=0.73 and p=0.15 before and after the intervention, respectively). Patients' ratings of the increase in motivation, self-confidence, comprehensiveness of the information, and satisfaction with the

Table 2. Comparisons of counselling and tool characteristics between groups. Results are based on 25 GPs (15 controls) and 114 counselling sessions (67 controls)

Counselling and tool characteristics	Intervention Median (IQR)	Control Median (IQR)	p Value
Number of counselling sessions, per month	2.8 (1.7-4.2)	1.7 (1.3-3.3)	0.30
Number of counselling sessions in the run-in study period, per month	5.5 (2.3-6.0)	4.0 (2.5-6.0)	0.72
Change in number of counselling sessions from the run-in period to study period, per month	–1.9 (?3.2;0.3)	–1.3 (–2.7;0.5)	0.74
Change in number of counselling sessions from the run-in period to study period, %	–43.1 (–55.6;17.4)	–40.0 (–62.5;20.4)	1.00
Duration of counseling sessions, min	10 (7-12)	11 (8-17)	0.09
*Practicability, rated by GP	4 (3-4)	3 (2-4)	0.13
*Usefulness, rated by GP	4 (3-4)	3 (2-4)	0.55
†Patients' motivation for smoking cessation, rated by patients:			
Before intervention	7 (5-8)	7 (5-8)	0.73
After intervention	7 (5-8)	7 (5-9)	0.15
Difference before and after intervention	0 (0-0)	0 (0-1)	0.20
*Patients' increase in motivation, rated by patients	4 (3-4)	4 (3-5)	0.26
*Self-confidence, rated by patients	3 (3-4)	4 (3-4)	0.42
*Understanding of information	5 (4-5)	5 (5-5)	0.35
*Satisfaction with counselling	5 (4-5)	5 (5-5)	0.57
*Understanding of the tool	4 (4-5)	-	
*Patients' increase in motivation by the tool, rated by patients	4 (3-4)	-	

*Five-point Likert scale from 1 (denied) to 5 (highly approved).

†VAS from 1 ("I don't want to quit smoking at all") to 10 ("I want to quit smoking by all means").

counselling were generally high (medians 3–5 on a 5-point Likert scale). In clustered data group comparisons using Wilcoxon rank sum tests, counselling time and patient ratings remained unchanged between groups (data not shown). With regard to the visual intervention tool, comprehensiveness and increase in motivation for smoking cessation due to the tool were both rated highly (medians of 4 on a 5-point Likert scale).

Discussion

Main findings

Our main finding is that adding a visual tool with a pictorial risk message as proposed by our group is not inferior to the usual smoking cessation IPCRG tool in terms of acceptance and feasibility. In fact, the majority of GPs rated both counselling tools as equally practicable and useful. No significant differences were seen between the intervention and control groups with regard to the patients' estimates of increased motivation, self-confidence, comprehensiveness of the information, and satisfaction.

Most of the counselling activities with the pictorial intervention tool were performed within 10 mins, with no significant difference in the duration of counselling compared with the control group. This underlines the feasibility of the tool, fulfilling the criteria of a short-term intervention.

The motivation level for smoking cessation was surprisingly high (median 7 points on a 10-point VAS), which could partially be due to selection bias at the patient level. The increase in motivation resulting from the counselling was not consistent: the item about self-estimated increase of motivation was mostly answered positively whereas the VAS measurement before and after counselling did not show a significant difference. A possible explanation is the short time between the two measurements: change of motivation as a basis for change of behaviour is often an iterative process over a long period. It is important to note that neither of the two communication tools decreased motivation in patients.

The decrease in counselling frequency during the study period compared with the run-in period is difficult to explain. Feedback from the study GPs suggests two main reasons: (1) a recall effect (the longer time since the instruction was given, the less alert were GPs about recruiting patients); and (2) many study GPs claimed a higher work load and lack of time during the study period in comparison with the run-in period. However, the decrease in counselling frequency was not significantly different between the intervention and control groups, so our tool was not the cause for less counselling activity.

Because a sharpened awareness of developing CVD can function as a strong motivator for behaviour change,[18] the concept of how to communicate individualised risks for smokers versus non-smokers is highly relevant for fostering smoking cessation. We chose to communicate cardiovascular risks visually rather than respiratory risks because the absolute CVD risks (incidence) are higher than the respiratory risks, reflecting an even higher impact of the total burden of smoking-associated diseases on a patient as well as at the population level. Furthermore, the systemic effects of smoking do not only affect the respiratory system, but also the cardiovascular and other symptoms. The epidemiological evidence linking chronic obstructive pulmonary disease (COPD), for example, and cardiovascular morbidity and mortality is strong: patients with COPD have a 2–3-fold increase in the risk of cardiovascular events including death.[19] In individuals with severe airways obstruction (forced expiratory volume in one second (FEV_1) <50% of predicted), the leading causes of death are cardiovascular in nature.[20] For every 10% decrease in FEV_1, cardiovascular mortality increases by about 28% and non-fatal coronary events increase by about 20% in patients with mild to moderate COPD.[21]

In our tool we emphasise the communication of relative risks (known to enhance the motivation to avoid risk[11]) and present it numerically and visually. To minimise the risk of manipulation of patients with the risk format, we combined information about relative risk with data on the absolute risk of a smoker. In order to facilitate decisions, we offer a comparison with a healthy (non-smoking) reference subject. The communication of the organ (heart) age of a current smoker versus a non-smoker is another way of creating motivation by comparison of two options.[12] Thus, using risk communication at the state of the art level[9-12] results in positive effects in smoking cessation.

While calculating the relative risks of smokers versus non-smokers in the age group 35–65 years based on the data of a middle European cohort (PROCAM),[15] we found an identical relative risk of 2 (or nearly 2) as reported from other calculators based on the Framingham cohort. Recently, the SCORE risk charts[22] – which are also based on the Framingham cohort – started to communicate this relative risk of smokers versus non-smokers in addition to information on the absolute 10-year risk of a lethal cardiovascular event in the charts.

Strengths and limitations of this study

To our knowledge, this is the first randomised controlled trial (RCT) using the IPCRG smoking cessation tool as a 'usual care' standard. Moreover, the tool we developed is innovative and integrative in putting modern and evidence-based risk communication recommendations into daily practice.[9-12]

Our study took place in one single region of Switzerland and with a relatively small number of GPs, so the results are not generalisable without restrictions. Most of our outcomes were self-estimates and not clinical outcomes, as we had neither the intention nor the means to do a RCT of the clinical effects of the intervention but, rather, wanted to test our approach and its acceptance and feasibility. As the focus of the current study was the feasibility and acceptability of the novel counselling tool, a proper *a priori* sample size calculation was not possible due to the lack of reliable *a priori* assumptions. However, based on the 114 counselling sessions in our study, there was 80% power to detect a minimal one-sided difference of 23% (alpha level=0.05), which almost meets the *a priori* non-inferiority level postulated to be clinically relevant (difference of ≥20%).

We cannot exclude a selection bias due to the recruitment procedure of GPs and patients. GPs with a higher motivation for counselling activities in the field of smoking cessation might have been more prone to agree to participate and patients willing to participate might have been more motivated to start counselling than

those who declined to participate. The high ratings of motivation (preparation stage of the TTM model) for a change at baseline might be an indicator of a possible bias. However, there was no significant difference between the intervention and control groups. We think the possible selection bias has only a small – if any – impact on our acceptance and feasibility results.

Interpretation of findings in relation to previously published work

Our findings encourage the use of both instruments in smoking cessation counselling. The IPCRG tool seems to be a well-accepted and feasible tool for short-term intervention smoking cessation counselling in Swiss primary care and merits further dissemination. Our additional tool fostering visual risk communication in order to increase motivation of smokers to quit is equally well accepted and feasible and might be an important add-on to the IPCRG tool.

The high level of acceptance of our tool may be due to the mixed communication formats we used – especially the focus on relative risks and visual elements – both of which were preferred by general practice patients.[11] With regard to efficacy, the additional use of information about organ age (in our tool, heart age) is a promising way to encourage smoking cessation. Parkes *et al.* demonstrated an absolute difference in quit rate of 7.2% (13.6% in the intervention group versus 6.4% in the control group) using a similar lung age communication tool.[12]

Implications for future research, policy and practice

Considering the immense impact of smoking cessation on patients' health and healthcare resources, it is of utmost importance to support and optimise smoking cessation counselling in primary care. Based on our results, we plan to carry out a RCT to test whether our visual risk communication tool has an additional effect on smoking cessation rates compared with the usual short intervention counselling, and whether the combination of our pictorial tool with the IPCRG tool is superior to the IPCRG tool alone.

Conclusions

In Swiss primary care, the feasibility and acceptability of both our visual smoking cessation communication tool and the IPCRG tool were equally high. Both merit further dissemination and clinical use as well as application in research.

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Conflicts of interest The authors declare that they have no conflicts of interest in relation to this article.

Contributorship SN-J had the idea for this study. SN-J, CS-S and OS designed the study. SN-J and MIK carried out data collection. OS performed the statistical analysis. SN-J drafted the manuscript. All authors contributed to the writing of the manuscript and all authors read and approved the final manuscript.

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Appendix 1. Communication aid for GPs: Calculation of absolute risks and organ age in smokers versus non-smokers

What does your patient win by quitting smoking?

The risk of the patient to suffer a heart attack or stroke in the next 10 years time is:

as a women

age	10-y-risk as a smoker	10-y-risk as a non-smoker
≥65	10.6	5.7
64	9.6	5.2
63	8.7	4.7
62	7.9	4.2
61	7.2	3.8
60	6.5	3.5
59	5.9	3.1
58	5.4	2.8
57	4.9	2.6
56	4.4	2.3
55	4	2.1
54	3.6	1.9
53	3.3	1.7
52	2.9	1.5
51	2.7	1.4
50	2.4	1.3
49	0.5	0.3
48	0.5	0.3
47	0.4	0.2
46	0.4	0.2
45	0.4	0.2
44	0.3	0.2
43	0.3	0.2
42	0.3	0.1
41	0.2	0.1
40	0.2	0.1
39	0.2	0.1
38	0.2	0.1
37	0.2	0.1
36	0.1	0.1 *
≤35	0.1	0.1 *

as a man

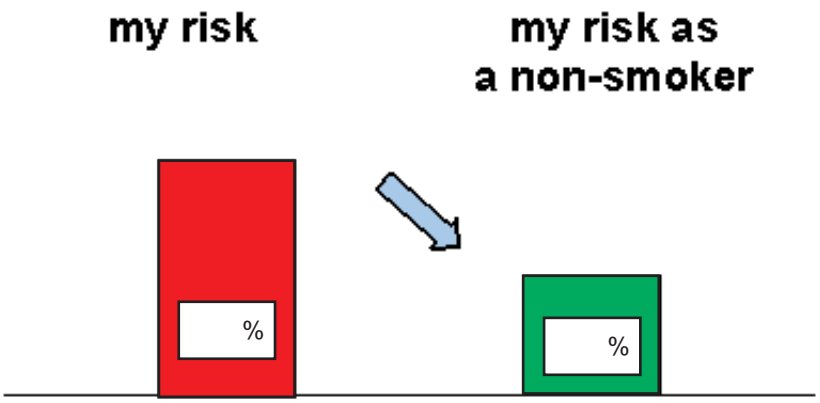
age	10-y-risk as a smoker	10-y-risk as a non-smoker
≥65	21.6	12.2
64	19.8	11.1
63	18.1	10.1
62	16.6	9.2
61	15.2	8.3
60	13.8	7.5
59	12.6	6.8
58	11.5	6.2
57	10.5	5.6
56	9.5	5.1
55	8.6	4.6
54	7.8	4.2
53	7.1	3.8
52	6.5	3.4
51	5.8	3.1
50	5.3	2.8
49	4.8	2.5
48	4.3	2.3
47	3.9	2.1
46	3.6	1.9
45	3.2	1.7
44	2.9	1.5
43	2.6	1.4
42	2.4	1.2
41	2.1	1.1
40	1.9	1.0
39	1.8	0.9
38	1.6	0.8
37	1.4	0.7
36	1.3	0.7
≤35	1.2	0.6

Comments:
Blood pressure and lipids (total cholesterol, triglycerides, HDL, LDL) refer to the average values of the Swiss SAPALDIA population. Family history of early cardiovascular events was assumed to be negative for the calculation (as this is the more frequent situation compared to a positive family history). Women up to the age of 49 years were classified as premenopausal, over the age of 50 years as postmenopausal. These assumed data were entered to the AGLA online cardiovascular risk calculator (www.agla.ch/p10-1.html) adding the co-variates gender, age and smoker or non-smoker.

*The relative risk of smokers versus non-smokers is almost 2 in all age groups. Only in women below 30 years of age the risks of smokers and non-smokers are equal (equally low). This should be communicated in counseling, for example „The risk is not staying so low all the time; yet from the age of 37, you can lower your risk by 50 % with stop smoking."

Appendix 2. Visually supported risk communication tool (intervention tool)

What do I win by quitting smoking?



If I continue to smoke, my risk to get a heart attack or stroke within the next 10 years is % (1 out of).

With quitting smoking right now, I lower my risk by almost 50 % (from % to %) compared with going on with smoking.

In my age, the risk to get a heart attack or stroke within the next 10 years is equal to the risk of a years old non-smoker!

If I have elevated blood pressure, lipid (cholesterol) or blood sugar values, the risks ar higher than the above mentioned values. By quitting smoking, the risk will be half in comparison to going on with smoking as well. I also lower further risks substantially, such as lung cancer or chronic bronchitis with quitting smoking.

Appendix 3. IPCRG Opinion sheet for stop smoking (in english)

OPINION

IPCRG OPINION 3

Helping patients quit smoking: brief interventions for healthcare professionals

How to help smokers quit: flowchart

Ask about tobacco use (smoking and smokeless tobacco) for all patients and reassess users at every clinic call/at least once a year.
This alone doubles the rate of success. Document smoking status/stage of motivation/tobacco burden.

ASK Have you used tobacco in the last 12 months?

No – never: Congratulate. Reinforce non-use. Patients who have smoked in the past should be asked about smoking for some years after quitting. Relapse is unlikely after 5 years abstinence.

Yes – Quit in the last 12 months: Congratulate. Ask if they need help to remain smoke free. Advise them to contact you or to seek other counselling if they have any difficulty (quit line, smoking cessation clinic, other ...)

Yes – Current smoker: Take brief smoking history including number of cigarettes smoked a day, year started smoking, presence of smoking-related disease, previous quit attempts and what happened?
Use non-judgmental questions such as "How do you feel about your smoking at the moment?
Express concern/interest and not criticism.

ASSESS: Motivation to stop:
On a scale from 1-10 how interested are you in trying to quit?

1	2	3	4	5	6	7	8	9	10

Are you planning to QUIT in the next 6 months?

Not planning to QUIT	Planning to QUIT within the next 6 months	Planning to QUIT within a month
NO **NOT READY** **(PRECONTEMPLATION)**	**YES, but not yet...** **UNSURE (CONTEMPLATION)**	**YES** **READY TO QUIT**

NO – NOT READY (PRECONTEMPLATION)

- Focus on motivation.
- Advise the patient on the benefits of quitting without criticism/confrontation.
- Respect the patient's decision.
- Ask if you may tell the patient about the dangers of smoking.

ADVISE
- Ask, *"Is there anything that might help you consider quitting?" or "Can you imagine any benefits of quitting?"*
- Offer help if the patient should change his/her mind.

ARRANGE
- Follow up – ask patient if you should discuss smoking again at next consultation.

YES, but not yet... UNSURE (CONTEMPLATION)

ADVISE
- Focus on their ambivalence, help them motivate themselves.
- Offer help by asking:
  "What are the things you like and don't like about your smoking?"
  "Have you tried to quit before?"
  "How did you get on when you last quit?"
  "What would have to happen for your motivation score to increase?"
  "How can I help you increase your confidence in quitting?"

ASSIST
- Explore barriers to cessation.
- Offer help quitting.
- Refer to quit line or other counseling, refer to smoking cessation unit if patient prefers.
- Hand out written material/contact numbers.
- Follow up consultation or telephone contact within 6 months OR remember to ask when you next see the patient.

YES – READY TO QUIT

ASSIST
- Provide assistance in developing a quit plan.
- Help patient to set a quit date. Discuss abstinence and suggest coping strategies. Encourage social support.
- Assist in dealing with barriers such as fear of failure, stress coping, weight gain, social pressure.
- Give nutritional advice: sleep well, avoid caffeine and alcohol.
  Physical activity may help.
- Assist in giving advice on pharmacotherapy for smoking cessation: NRT (adequate dosage during sufficient time, help through the first 4-7 weeks). Withdrawal symptoms occur mostly during the first 2 weeks and are fading after 4-7 weeks.
- Assist with a prescription for varenicline or bupropion when indicated.

ARRANGE
- Follow-up consultations/phone calls - ideally weekly first weeks, then monthly.

5 As of smoking cessation: ASK, ASSESS, ADVISE, ASSIST, ARRANGE[1]

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VISTO pilot study - CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1,2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	not applicable
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	2
	6b	Any changes to trial outcomes after the trial commenced, with reasons	not applicable
Sample size	7a	How sample size was determined	2
	7b	When applicable, explanation of any interim analyses and stopping guidelines	not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	2
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	not applicable
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	not applicable

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3
	13b	For each group, losses and exclusions after randomisation, together with reasons	no exclusions or losses
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	3
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	data not shown
Harms	19	All important harms or unintended effects in each group *(for specific guidance see CONSORT for harms)*	not applicable as no harms
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	4
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	4
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	4
Other information			
Registration	23	Registration number and name of trial registry	as a pilot trial, not registrated
Protocol	24	Where the full trial protocol can be accessed, if available	available for editors
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4