Emergency department-initiated tobacco control: a randomised controlled trial in an inner-city university hospital

Short title: ED-initiated tobacco control: a RCT

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ABSTRACT

Objectives: Emergency department (ED) patients show high smoking rates. We investigated the effects of ED-initiated tobacco control (ETC) on the 7-days abstinence at 12 months.

Methods: Randomised-controlled intention-to-treat trial (Trials Registry no.: ISRCTN41527831) in 1,044 patients in an urban ED. ETC consisted of on-site counselling plus up to 4 telephone booster sessions. Controls received usual care. Analysis was by logistic regression.

Results: Overall 630 (60.7%) were males, the median age was 30 years, (range 18 – 81), and the median smoking intensity was 15 (range 1 – 60) cigarettes per day. Five hundred eighty study participants (55.6%) were unmotivated, 331 (31.7%) were ambivalent, and 133 (12.7%) were motivated smokers. ETC (median time 30 (range 1 – 99) minutes) was administered to 472 (91.7% out of 515) randomised study participants. At follow-up, 685 study participants (65.6% of 1,044) could be contacted. Overall, 73 out of 515 (14.2%) in the ETC group were abstinent, whereas 60 out of 529 (11.3%) controls were abstinent (Odds ratio (OR) adjusted for age and gender: OR = 1.31 (95%-confidence interval (0.91 – 1.89), p=0.15). Stratified for motivation to change behaviour, the adjusted ORs for ETC versus usual care were OR = 1.00 (95%-confidence interval (0.57 – 1.76)) in unmotivated smokers, respectively OR = 1.37 (95%-confidence interval (0.73 – 2.58)) in ambivalent smokers and OR = 2.19 (95%-confidence interval (0.98 – 4.89)) in motivated smokers, p for trend = 0.29.

Conclusions: ETC, in the form of on-site counselling with up to 4 telephone booster sessions, showed no overall effect on tobacco abstinence after 12 month. A non-significant trend for a better performance of ETC in more motivated smokers was observed.

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WHAT THIS PAPER ADDS:

Although there is evidence that the smoking prevalence of emergency department patients exceeds the smoking prevalence in the population and a joint statement of US Emergency Medicine Organizations encourages administrators to implement tobacco control services, the effectiveness of such services is still unclear.

In a randomised controlled trial in more than 1000 emergency department patients with a median smoking intensity of 15 cigarettes per day, emergency department-initiated tobacco control (ETC) showed a non-significant overall effect on 7-days-abstinence at 12 month. Unmotivated smokers do not seem to profit from ETC while, in ambivalent and motivated smokers, a non-significant clinical effect of ETC was observed.

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INTRODUCTION

Emergency department (ED) patients show a prevalence of smoking that exceeds the smoking prevalence in the general population (1). Furthermore, ED patient often have limited access to medical care, and especially to health promotion services (2). With respect to the role of EDs in delivering preventive services and improving public health (3), in October 2006, a joint statement of the American Emergency Medicine Organizations encouraged ED administrators to implement "ED-initiated tobacco control" (ETC) services, and researchers to conduct evaluations of such efforts (2). A systematic review from 2002 (4) on the diagnosis and management of smoking and smoking-related illness in the ED identified two ED-based studies: one RCT with 152 study participants found no difference in quit rates (at a three-month follow-up) in those receiving standardized, scripted counselling including referral to a smoking cessation program together with a Stop Smoking Pamphlet from the American Heart Association compared to controls who only received the pamphlet. None of the intervention group joined the smoking cessation program (5). The second study which was based in a military ED identified 42 out of 86 smokers who were interested in quitting, of whom 40 were randomised to receive either a formal smoking cessation program or a brief counselling from the ED physician. None of the study participants completed the smoking cessation programme and only one patient in the brief counselling-group stopped smoking at a six month follow-up (6).

Later investigations included a non-controlled feasibility study of health promotion in an ED setting. Of 411 smokers who accepted referral to a smoking cessation programme, 158 were contacted at follow-up. The quit-rate was 12%, and another 40% reported reduced smoking (7). Another feasibility study with 39 study participants in a tertiary-care ED found no difference in the 7-day point prevalence of smoking abstinence at 6 months in either the intervention (telephone counselling through a tobacco quitline) or control (self-help manual) conditions (8). In an RCT with seventy-four 14 to 19 year old adolescents in a university-affiliated hospital ED, no differences in quit-rates were found between on-site motivational interviewing plus stage-based take-home material compared with usual care (9;10). Bock et al. (11) randomised 543 adult smokers in an observation unit of a university-based ED to either on-site motivational interviewing in combination with two telephone booster sessions or a control condition receiving a printed referral sheet with information on local smoking cessation resources. In a per-protocol analysis at 1, 3, and 6 month the odds ratio for a 7-day point prevalence abstinence was 1.62 (95%-CI (1.05 – 2.50)) in the intervention group compared with the control group. Boudreaux et al. (12) in their pilot study with 90 adult smokers in an urban, academic level 1 trauma centre found 7-day point abstinence rates at a 3-month follow-up between 6% (standard referral group) and 14% (motivational interviewing per phone in combination with a posted tailored 'motivational tool' which contained (among others) a 'Personalized Feedback Form' and a 'Pro/Con Worksheet'). Thus, due to the relative heterogeneity of the type and duration of ETC tested in previous studies, the superiority of ETC over no treatment conditions remains unclear.

Therefore, the aim of this study was to evaluate the effectiveness of ETC, combining on-site counselling with telephone booster sessions in a large sample of ED patients.

MATERIALS AND METHODS

Sample

Study participants were recruited in the ED at the Charité – Universitaetsmedizin Berlin between 06 October 2005 and 21 December 2006. The inner-city ED in the very centre of Berlin treats approximately 40,000 patients annually. After Ethical Committee approval, all patients, 18 years of age or older, treated in the ED were screened for tobacco use. Those reporting a minimum of 1 cigarette smoked per day during the last 7 days were asked to participate in the randomised controlled intervention study. Excluded were (1) patients with no capacity to understand the study information and/or no capacity to give informed consent because of acute or chronic mental or physical conditions (intoxication, severe injuries or organic conditions which required immediate

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medical care, chronic mental illness, blindness, deafness, other handicaps), (2) those with no capacity to operate the computerised screening tool (see below), (3) patients in police custody, (4) homeless patients (or those not reachable for telephone follow-up for other reasons), (5) patients unable to read and understand the informed consent or the screening questions because of language barriers, (6) inpatients treated in the ED, (7) patients treated in the ED not for emergency reasons, as well as (8) staff members of the hospital. Recruiting times were 8am to 4pm in Week 1, 1pm to 9pm in Week 2. Additionally, one Saturday per month patients were recruited from 11am to 9pm.

Sample size

At the time of the study enrolment, limited evidence on ETC efficacy (see introduction) did not allow a calculation of effect sizes. Therefore, the sample size calculation was based on tobacco control findings in hospitalised patients: tobacco control showed superiority over usual care conditions only with a combination of an initial intervention during hospital stay followed by supportive contacts for at least one month after discharge (13). Assuming a rate of 20% abstinence in the control group (13) and an effect size of the intervention of 1.8 (95%-CI (1.5 – 2.2)) (13), with an alpha error of 5% and a power of 80%, nQuery Advisor®, release 3.0 (14) calculated without continuity correction a study size of N1 (intervention) = N2 (controls) = 244 study participants. With an expected loss to follow-up of 50% of smokers during 12 months (15), the overall study size was established at 976. We assumed additional losses of 5% (n = 49) due to inappropriate allocation or incomplete baseline screening and thus the target size for study inclusion was n = 1024 randomised participants.

Randomisation

After written informed consent, all consecutive patients were administered a computerised screening tool. Study participants were randomly assigned to either the intervention or the control group, stratified for age (3 age-groups 18 – 25 years, 26 – 40 years, 41 years and older), gender, and motivation to change smoking behaviour (unmotivated, ambivalent, and motivated smokers, see below) based on the first three questions of the computerised screening tool. Neither study participants nor staff members on-site knew about the allocation, but the two senior researchers responsible for the ETC (BN, EWG) were informed via short message service (SMS) about a positive allocation. Study participants received this information after he/she had completed the questionnaire.

Baseline screening

The computerised screening tool at baseline, using a mouse-only technique requiring no typing, consisted of a question on motivation to change smoking behaviour according to the transtheoretical model of behaviour change (16): ‘When do you wish to stop smoking?’ (those answering ‘Not within the next 6 months’ were considered unmotivated smokers, i.e., smokers in the Precontemplation Stage; those answering ’Within the next 6 months but not within the next 4 weeks’ were considered ambivalent smokers, i.e., smokers in the Contemplation Stage; and those answering ‘Within the next 4 weeks’ were considered to be motivated smokers, i.e., smokers in the Preparation Stage) (17). Study participants were additionally administered the validated German version (18) of the Fagerstroem Test for Nicotine Dependence (FTND) (19), a detailed smoking history which includes questions on smoking history (duration of smoking, age at onset, attempts to quit during the last 12 months, and partner’s smoking status) (20). Further questions focused on alcohol consumption [hazardous alcohol consumption defined as $\geq$ 5 points on the AUDIT-PC (21)], illicit drug consumption (15), and socioeconomic parameters according to the German Health Survey 1998 (22). Overall, a maximum of 80 questions were asked, which took approximately 20 minutes. The questioning took place in the ED during waiting times for treatment or diagnostic procedures. Routine medical treatment was given priority over study assessment procedures.

Intervention

Study participants in the intervention group received ETC in the form of an on-site counselling session and telephone booster follow-up sessions (TBS). The ETC was conducted according to recent guidelines on tobacco control from the Association of the Scientific Medical Societies in Germany (23), based on the meta-analytical findings of Fiore, Silagy, and West (24-26). ETC

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consisted of a smoking cessation intervention using motivational techniques and aimed at unmotivated or ambivalent smokers who were willing to undergo on-site counselling of more than 1 – 3 minutes. In motivated smokers, the focus of the intervention was on behavioural support. Overall, the principle of the 5 "A"s was applied ["ask", "advice", "assess", "assist", and "arrange" (24)] as shown in Figure 1. All patients were given strong advice to quit. In study participants willing to continue on-site counselling but unwilling to agree on a quitting day, motivational interviewing according to the 5 "R´s" ["relevance", "risks", "rewards", "roadblocks", "repetition"] was performed (24). Study participants willing to stop smoking or to reduce their smoking were offered behavioural support (26) including nicotine replacement therapy (gum, patch, sublingual tablets) according to recent guidelines (23). Nicotine replacement therapy was provided free of charge on site. The primary goal of ETC was to motivate participants to quit or to agree on a quit date. The aim of the TBSs was to either further motivate the study participant toward behavioural change ("repeat" / "assist"-components) and to "arrange" quit attempts or the maintenance of nicotine abstinence. The time frames and frequency of the TBSs were arranged with the study participants. Times for TBS were Monday to Saturday from 9am till 8pm. If the study participant was not reached at the agreed time, up to four attempts at one-week-intervals were conducted. Those still unavailable following five attempts were considered to have an incomplete intervention (meaning the on-site counselling alone or on-site counselling in combination with one to three TBSs). ETC was conducted by two senior researchers (BN, EWG) who were not involved in the routine treatment of the ED patients. Both researchers were trained in tobacco control interventions by an independent research and teaching institute on the therapy of addictive disorders. A fidelity check on the adherence with recent guidelines was performed for each study participant and the fidelity checks were analyzed within a 90 minute supervision session by a therapist every four weeks.

Follow-up

Primary study outcome was 7-days abstinence at the 12 month follow-up. Additionally the 7-days abstinence at 1, 3, and 6 month was evaluated independently of the study arm, by staff members who were blinded to the group assignment. Study participants were additionally asked for changes in address, telephone number, and E-Mail-address in order to minimize attrition due to inappropriate reachability. Telephone interviews were arranged at times that were convenient for study participants. Telephone interviews took place Monday to Friday from 10 AM to 9 PM and on Saturdays from 10 AM to 6 PM. At each time point, 3 attempts were made to reach participants by telephone before a brief questionnaire was posted. Those unreachable with these 4 attempts were categorized, at the specific time point, as "discontinued follow-up", but were contacted at the next time point with the same procedure. Follow-up telephone interviews were carried out between November 2005 and January 2008. To validate the self-reported smoking intensity at the 12 month follow-up, exhaled carbon monoxide concentration (CO) was measured in a subsample of 100 study participants living in the greater Berlin area. CO measures took place in participants' homes or in the ED between March and November 2007 if study participants were willing to again visit the ED. One staff member contacted 188 study participants before this number could be reached (28 declined to participate, in 34 no appointment for a CO measurement within one month was possible and 26 could not be contacted or did not attend the scheduled appointment). CO was measured using a NeoMed EC50 CO-Analyzer (Smokerlyser), Series Number 41693, NeoMed Medical Technology, Korschenbroich, Germany. The cut-off of was chosen as 6.5 ppm CO in the exhaled air as previous reported (27).

Statistical analysis

All binary and categorical variables are shown as frequencies. Metric variables are shown as medians (ranges). In study participants with complete baseline screening, smoking-related variables and socioeconomic parameters were compared across intervention and control groups using the Mann-Whitney-U-Test for metric variables and the chi-square-test for nominal respectively ordinal variables. The Jonckheere-Terpstra-Test was used to compare metric variables and the Mantel-Haenszel-Test-for-Trend was used to compare nominal respectively ordinal variables across the

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three stages of motivation to change behaviour. Intention-to-treat analysis of the primary study outcome was by binary logistic regression analysis, adjusted for age and gender (Proc Logistic in SAS with the Contrast-Statement to evaluate the effect of ETC stratified for motivation). Study participants not reached at follow-up were assumed to be continuous smokers. Subgroup analysis in the 1012 study participants with complete baseline screening regarding 7-days-abstinence at 12 month additionally included the degree of nicotine dependency, the latter mentioned as independent predictor of smoking cessation (28;29). A $p \leq 0.05$ (two-sided) was determined as being significant. All statistical analysis was done using SAS® software (SAS Institute Inc., Cary, NC, USA), release 9.1 (30).

RESULTS

In total, 11,218 consecutive patients were assessed for eligibility (Figure 2). Overall, 4,992 (44.5%) did not meet the inclusion criteria. Of 6,226 patients questioned about their smoking status, 4,498 (72.2%) were non-smokers. This left 1,728 potential study participants. Of these, 716 (41.4% of 1,728) refused study participation. Reasons for non-participation are given in Figure 2. Overall 1,044 were randomised (515 in the ETC and 529 in the control group). There was no difference between the ETC group and the control group concerning the proportion of male study participants (311/515, 60.4% vs. 319/529, 60.3%, p = 0.98), motivation to change smoking behaviour (286/515, 55.5% unmotivated, 165/515, 32.0% ambivalent, and 64/515, 12.4%[1] motivated smokers vs. 294/529, 55.6% unmotivated, 166/529, 31.4% ambivalent, and 69/529, 13.0% motivated smokers, Mantel-Haenszel-Test for Trend: p = 0.90) and the median age at baseline (29 (18 – 78) years vs. 30 (18 – 72) years, p = 0.35).

In the ETC group 10 study participants and in the control group 22 study participants discontinued baseline screening after the randomisation, leaving 1012 study participants with complete baseline screening. Another 33 patients in the ETC group (6.4% of 515) refused on-site counselling or immediately left the study site. Table 1 shows patients' baseline characteristics in the ETC group compared to the control group in those 1,012 study participants with complete baseline screening. Significant differences were found in the median number of cigarettes smoked per day (ETC group 15 (1 – 60) compared to 16 (1 – 50) in the control group, p = 0.04) and regarding size of household (p = 0.03). The majority of study participants (51.4%) had smoked for more than 10 years, and more than half had started smoking before age 17.

[1] Percentage does not sum up to 100% because of rounding error

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Table 1: Basic patients' characteristics and comparison between ETC and control group in patients with complete baseline screening, n = 1,012

Parameter	All patients n = 1,012 (100%)	ETC-group n = 505 (49.9%)	Controls n = 507 (50.1%)	p
Age in years [median (range)]	30 (18 – 78)	29 (18 – 78)	30 (18 – 72)	0.35
Gender [n, (%)]				
male	614 (60.7)	308 (61.0)	306 (60.4)	0.84
female	398 (39.3)	197 (39.0)	201 (39.6)	
Motivation to change smoking behaviour [n, (%)] #				
unmotivated smokers	557 (55.0)	280 (55.4)	277 (54.6)	
ambivalent smokers	327 (32.3)	163 (32.3)	164 (32.3)	0.73*
motivated smokers	128 (12.6)§	62 (12.3)	66 (13.0)§	
Number of cigarettes smoked per day during the last 7 days [median (range)]	15 (1 – 60)	15 (1 – 60)	16 (1 – 50)	**0.04**
Nicotine dependency [n, (%)] ‡				
low	424 (41.9)	222 (44.0)	202 (39.8)	
medium	241 (23.8)	112 (22.2)	129 (25.4)	0.36*
high	347 (34.3)	171 (33.9)§	176 (34.7)§	
Smoking duration [n, (%)]				
< 1 year	25 (2.5)	16 (3.2)	9 (1.8)	
1-3 years	81 (8.0)	41 (8.1)	40 (7.9)	0.39*
4-10 years	386 (38.1)	191 (37.8)	195 (38.5)	
> 10years	520 (51.4)	257 (50.9)	263 (51.9)§	
Age of smoking onset [n, (%)]				
< 14 years	151 (14.9)	80 (15.8)	71 (14.0)	
14-16 years	375 (37.1)	192 (38.0)	183 (36.1)	
17-18 years	227 (22.4)	105 (20.8)	122 (24.1)	0.36*
19-30 years	245 (24.2)	121 (24.0)	124 (24.5)	
> 30 years	14 (1.4)	7 (1.4)	7 (1.4)§	
Attempts to quit smoking during the last 12 month [n, (%)]				
none	584 (57.7)	275 (54.5)	309 (60.9)	
1	232 (22.9)	126 (25.0)	106 (20.9)	0.08*
2-5	159 (15.7)	84 (16.6)	75 (14.8)	
> 5	37 (3.7)	20 (4.0)§	17 (3.4)	
Partner smoking [n, (%)]				
no	280 (27.7)	134 (26.5)	146 (28.8)	
yes	434 (42.9)	217 (43.0)	217 (42.8)	0.66
no partnership	298 (29.4)	154 (30.5)	144 (28.4)	
Hazardous alcohol consumption †				

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[n, (%)] yes no	 349 (34.5) 663 (65.5)	 177 (35.0) 328 (65.0)	 172 (33.9) 335 (66.1)	 0.71
Illicit drug use (last 12 months) [n, (%)] none 1-3 times 4 times up to weekly several times per week till daily	 614 (60.7) 158 (15.6) 131 (12.9) 109 (10.8)	 299 (59.2) 83 (16.4) 70 (13.9) 53 (10.5)	 315 (62.1) 75 (14.8) 61 (12.0) 56 (11.0)§	 0.58*
Types of drugs in illicit drug users (n = 398) [n, (%)] Cannabis only Ecstasy/Designer drugs only Cocaine only all other combinations	 201 (50.5) 15 (3.8) 1 (0.3) 181 (45.5)§	 104 (50.5) 4 (1.9) 1 (0.5) 97 (47.1)	 97 (50.5) 11 (5.7) 0 (0.0) 84 (43.8)	 0.18
School Education [n, (%)] discontinued 10 years 11-13 years in school education	 13 (1.3) 484 (47.8) 501 (49.5) 14 (1.4)	 10 (2.0) 232 (45.9) 256 (50.7) 7 (1.4)	 3 (0.6) 252 (49.7) 245 (48.3) 7 (1.4)	 0.18
Current occupation [n, (%)] fulltime working unemployed all other	 495 (48.9) 96 (9.5) 421 (41.6)	 252 (49.9) 47 (9.3) 206 (40.8)	 243 (47.9) 49 (9.7) 215 (42.4)	 0.82
Marital status [n, (%)] married, living with the partner married, living separate widowed, divorced single	 153 (15.1) 34 (3.4) 82 (8.1) 743 (73.4)	 68 (13.5) 19 (3.8) 39 (7.7) 379 (75.0)	 85 (16.8) 15 (3.0) 43 (8.5) 364 (71.8)§	 0.42
Size of household [n, (%)] 1 person > 1 person	 388 (38.3) 624 (61.7)	 210 (41.6) 295 (58.4)	 178 (35.1) 329 (64.9)	 **0.03**
Net family income / month [n, (%)] below average ** above average ** no data	 473 (46.7) 298 (29.4) 241 (23.8)§	 239 (47.3) 141 (27.9 125 (24.8)	 234 (46.2) 157 (31.0) 116 (22.9)§	 0.54
Family doctor [n, (%)] yes no	 724 (71.5) 288 (28.5)	 359 (71.1) 146 (28.9)	 365 (72.0) 142 (28.0)	 0.75
Visits at the family doctor (last 12 month) in patients with a family doctor (n = 724) [n, (%)] none	 63 (8.7)	 28 (7.8)	 35 (9.6)	

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1 or 2	353 (48.8)	173 (48.2)	180 (49.3)	0.32*
3 or more	308 (42.5)	158 (44.0)	150 (41.1)	
Medical status [n, (%)]				
surgical	485 (47.9)	238 (47.1)	247 (48.7)	0.61
internal	527 (52.1)	267 (52.9)	260 (51.3)	

ETC = Emergency department-initiated tobacco control; # When do you wish to stop smoking?" [Not within the next 6 month = unmotivated smokers, within the next 6 month but not within the next 4 weeks = ambivalent smokers, and within the next 4 weeks = motivated smokers]; § does not sum up to 100% because of rounding error; * = Mantel-Haenszel-Test for Trend; ‡ measured with the Fagerstroem-test for nicotine dependency, low = 0-2 points, medium = 3-4 points, high = 5-10 points; † measured with the AUDIT-PC-questionnaire: no = 0 to 4 points, yes = 5 to 20 points; ** average = mean net household income per month in Berlin in 2004, i.e. 1,725€ (31).

Differences between motivation–to-change-smoking groups (see Table 2) in those 1,012 study participants with complete baseline screenings were found regarding time variables (longer smoking duration and earlier onset of smoking in less motivated smokers), and attempts to quit smoking (more attempts in higher motivated smokers).

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Table 2: Age, gender, and smoking related variables stratified according to the motivation to change behaviour in patients with complete baseline screening, n = 1,012

Parameter	Stratified according to the motivation to change smoking behaviour at baseline*			p
	Unmotivated smokers n = 557 (55.0%)	Ambivalent smokers n = 327 (32.3%)	Motivated smokers n =128 (12.6%)§	
Age in years [median (range)]	29 (18 – 72)	30 (18 – 73)	30.5 (19 – 78)	0.48†
Gender [n, (%)]				
male	339 (60.9)	192 (58.7)	83 (64.8)	0.70‡
female	218 (39.1)	135 (41.3)	45 (35.2)	
Number of cigarettes smoked per day during the last 7 days [median (range)]	15 (1 – 60)	16 (1 – 50)	10 (1 – 60)	0.12†
Nicotine dependency [n, (%)] #				
low	229 (41.1)	138 (42.2)	57 (44.5)	
medium	133 (23.9)	79 (24.2)	29 (22.7)	0.49‡
high	195 (35.0)	110 (33.6)	42 (32.8)	
Smoking duration [n, (%)]				
< 1 year	6 (1.1)	8 (2.4)	11 (8.6)	**0.003**‡
1-3 years	45 (8.1)	23 (7.0)	13 (10.2)	
4-10 years	212 (38.1)	128 (39.1)	46 (35.9)	
> 10 years	294 (52.8)§	168 (51.4)§	58 (45.3)	
Age of smoking onset [n, (%)]				
< 14 years	83 (14.9)	46 (14.1)	22 (17.2)	
14-16 years	224 (40.2)	112 (34.3)	39 (30.5)	**0.043**‡
17-18 years	122 (21.9)	78 (23.9)	27 (21.1)	
19-30 years	123 (22.1)	87 (26.6)	35 (27.3)	
> 30 years	5 (0.9)	4 (1.2)§	5 (3.9)	
Attempts to quit smoking during the last 12 month [n, (%)]				
none	411 (73.8)	143 (43.7)	30 (23.4)	< **0.001**‡
1	89 (16.0)	97 (29.7)	46 (35.9)	
2-5	44 (7.9)	80 (24.5)	35 (27.3)	
> 5	13 (2.3)	7 (2.1)	17 (13.3)	
Partner smoking [n, (%)]				
no	134 (24.1)	99 (30.3)	47 (36.7)	
yes	261 (46.9)	130 (39.8)	43 (33.6)	0.083
no partnership	162 (29.1)§	98 (30.0)§	38 (29.7)	

* When do you wish to stop smoking?" [Not within the next 6 month = unmotivated smokers, within the next 6 month but not within the next 4 weeks = ambivalent smokers, and within the next 4 weeks = motivated smokers]; § does not sum up to 100% because of rounding error; # measured with the Fagerstroem-test for nicotine dependency, low = 0-2 points, medium = 3-4 points, high = 5-10 points; † = Jonckheere-Terpstra-Test; ‡ = Mantel-Haenszel-Test for Trend.

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For study participants in the intervention group, Table 3 shows the characteristics of the ETC as well as differences in subgroups stratified for motivation to change smoking behaviour. The overall median time of ETC for the 472 study participants who received at least the on-site counselling was 30 minutes (range 1 – 99), with the on-site counselling taking a median duration of 13 (range 1 – 45) minutes. Less than half (230 out of 515, 44.7%) of the intervention group completed the ETC intervention. Approximately 15% of the 472 ETC participants who received at least the on-site counselling chose nicotine replacement therapy. Significant differences in different subgroups of motivation to change smoking behaviour were found regarding the time of the on-site counselling and the overall duration of ETC, the proportion of study participants who received NRT or agreed on a quitting day. Motivated smokers had the longest ETC times, and more motivated smokers, compared to ambivalent or unmotivated smokers, agreed on a quitting day and/or received NRT.

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Table 3: ED-initiated tobacco control in study participants with complete baseline screening, allocated to intervention, and stratified for the motivation to change smoking behaviour, n = 515

	All patients in the ETC-group n = 515 (100%)	Patients in the ETC group stratified according to the motivation to change smoking behaviour at baseline #			p
		Unmotivated smokers n = 286 (55.5%)	Ambivalent smokers n = 165 (32.0%)	Motivated smokers n = 64 (12.4%)§	
Number of contacts during ETC [n, (%)] 0 = no intervention 1 2 3 4 5 = complete intervention	 43 (8.3) 64 (12.4) 48 (9.3) 61 (11.8) 69 (13.4) 230 (44.7)§	 24 (8.4) 36 (12.6) 30 (10.5) 41 (14.3) 32 (11.2) 123 (43.0)	 16 (9.7) 19 (11.5) 11 (6.7) 15 (9.1) 27 (16.4) 77 (46.7)§	 3 (4.7) 9 (14.1) 7 (10.9) 5 (7.8) 10 (15.6) 30 (46.9)	0.31‡
Time of the on-site counselling in minutes [median (range)] in n = 472*	13 (1 – 45)	12 (1 – 45)	15 (1 – 35)	17 (1 – 35)	**0.002**†
Only on-site counselling of 1 – 3 minutes [n, (%)] in n = 472* yes	20 (4.2)	11 (4.2)	6 (4.0)	3 (4.9)	0.87‡
Overall time of ETC in minutes [median (range)] in n = 472*	30 (1 – 99)	27 (1 – 75)	34 (2 – 99)	35 (1 – 77)	< **0.001**†
Received nicotine replacement therapy [n, (%)] in n = 472* yes	70 (14.8)	28 (10.7)	28 (18.8)	14 (23.0)	**0.004**‡
Agreed on a quitting day during the on-site counselling [n, (%)] in n = 472* yes	83 (17.6)	39 (14.9)	28 (18.8)	16 (26.2)	**0.036**‡

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ETC = Emergency department-initiated tobacco control; * only those study participants who were allocated to intervention and received at least the on-site counselling; # When do you wish to stop smoking?" [Not within the next 6 month = unmotivated smokers, within the next 6 month but not within the next 4 weeks = ambivalent smokers, and within the next 4 weeks = motivated smokers]; § does not sum up to 100% because of rounding error; † = Jonckheere-Terpstra-Test; ‡ = Mantel-Haenszel-Test for Trend.

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At the 12 month follow-up 685 participants (65.6% of 1,044) could be reached. As shown in Figure 2, 177 out of 515 (34.4%) study participants in the ETC group were lost to follow-up (therein 10 study participants who discontinued the baseline questionnaire) and 182 out of 529 study participants (34.4%) in the control group were lost to follow-up (therein 22 study participants who discontinued the baseline questionnaire). Table 4 shows the results of the non-responder analysis. Responders were a median age of one year older, more often women, less nicotine dependent, less often characterized by additional substance use, more highly educated, and were more likely to have a family doctor.

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Table 4: Comparison between responder and non-responder at 12 month, n = 1,044

Parameter	Responder n = 685 (65.6%)	Non-responder n = 359 (34.4%)	p
Randomisation [n, (%)] ETC-group control-group	 338 (49.3) 347 (50.7)	 177 (49.3) 182 (50.7)	 0.990
Age in years [median (range)]	30 (18 – 81)	29 (18 – 78)	< **0.001**
Gender [n, (%)] male female	 396 (57.8) 289 (42.2)	 234 (65.2) 125 (34.8)	 **0.021**
Number of cigarettes smoked per day during the last 7 days [median (range)], n = 1012	15 (1 – 60)	15 (1 – 60)	0.124
Nicotine dependency [n, (%)], n = 1012 ‡ low medium high	 310 (45.3) 158 (23.1) 217 (31.7) §	 114 (34.9) 83 (25.4) 130 (39.8) §	 **0.002***
Motivation to change smoking behaviour [n, (%)] # unmotivated smokers ambivalent smokers motivated smokers	 375 (54.7) 227 (33.1) 83 (12.1) §	 205 (57.1) 104 (29.0) 50 (13.9)	 0.905*
Attempts to quit smoking during the last 12 month [n, (%)], n = 1012 none 1 2-5 > 5	 395 (57.7) 153 (22.3) 111 (16.2) 26 (3.8)	 189 (57.8) 79 (24.2) 48 (14.7) 11 (3.4) §	 0.667*
Hazardous alcohol consumption † [n, (%)], n = 1012 yes no	 221 (32.3) 464 (67.7)	 128 (39.1) 199 (60.9)	 **0.031**
Illicit drug use (last 12 months) [n, (%)], n = 1012 none 1-3 times 4 times up to weekly several times per week till daily	 430 (62.8) 109 (15.9) 84 (12.3) 62 (9.1)	 184 (56.3) 49 (15.0) 47 (14.4) 47 (14.4)	 **0.006***
School Education [n, (%)], n = 1012 discontinued 10 years 11-13 years in school education	 5 (0.7) 311 (45.4) 364 (53.1) 5 (0.7)	 8 (2.4) 173 (52.9) 137 (41.9) 9 (2.8)	 < **0.001**

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Family doctor [n, (%)], n = 1012 yes no	 507 (74.0) 178 (26.0)	 217 (66.4) 110 (33.6)	 **0.012**

ETC = Emergency department-initiated tobacco control; ‡ measured with the Fagerstroem-test for nicotine dependency, low = 0-2 points, medium = 3-4 points, high = 5-10 points; * = Mantel-Haenszel-Test for Trend; # When do you wish to stop smoking?" [Not within the next 6 month = unmotivated smokers, within the next 6 month but not within the next 4 weeks = ambivalent smokers, and within the next 4 weeks = motivated smokers]; § does not sum up to 100% because of rounding error; † measured with the AUDIT-PC-questionnaire: no = 0 to 4 points, yes = 5 to 20 points.

The results on 7-days-abstinence in the ETC group compared with the control group based on intention-to-treat were overall 73/515 (14.2%) vs. 60/529 (11.3%). In unmotivated smokers 26/282 (9.1%) in the ETC group and 27/294 (9.2%) in the control group were abstinent, whereas in ambivalent smokers 26/165 (15.8%) in the ETC group and 20/166 (12.0%) in the control were abstinent. In motivated smokers 21/64 (32.8%) in the ETC group and 13/69 (18.8%) in the control group were abstinent, respectively. This translates, after adjustment for age and gender, to an overall odds ratio of 1.31 (95%-CI (0.91 – 1.89), p = 0.15 for the ETC group vs. the control group (Model 1 in Figure 3). Additional adjustment for motivation to change smoking behaviour did not change the estimate of ETC vs. usual care. The estimate for motivation to change smoking behaviour was highly significant (p for trend < 0.001, Model 2a in Figure 3). The interaction between ETC and motivation (Model 2b in Figure 3) revealed no effect of ETC vs. usual care in unmotivated smokers, a non-significant positive effect of ETC vs. usual care in ambivalent smokers, and a more than twofold non-significant effect of ETC vs. usual care in motivated smokers. The test for trend for the interaction of ETC and motivation was not significant, p = 0.29.

A subgroup analysis in 1,012 study participants with complete baseline screening (Model 3 in Figure 3) revealed an independent negative effect of nicotine dependence on 7-day abstinence at 12 months while the effect of ETC vs. usual care in motivated smokers became significant. The interaction of ETC and motivation remained non-significant, p for trend = 0.14, respectively.

Of the 100 study participants with CO measured in the exhaled air at 12 month follow-up, one dataset could not be used because of technical failure of the CO-measurement. Of the remaining 99 study participants 18 reported 7-days abstinence (see Table 5). Sensitivity was 80.2% and specifity was 88.9%. The area under the receiver operated curve (ROC) equalled 0.880 (95% Confidence-Interval (0.776 – 0.984)).

Table 5: Carbo-monoxide in pars per million in the exhaled air at 12 month follow-up, n = 99

CO-concentration *	Self-reported smokers	Self-reported non-smokers**	n (%)
7 or more ppm	65 (80.2%)	2 (11.1%)	67 (67.7%)
0 – 6.5 ppm	16 (19.8%)	16 (88.9%)	32 (32.3%)
N (%)	81 (100%)	18 (100%)	99 (100%)

CO = carbo-monoxide; ppm = pars per million; * measured with a NeoMed EC50 CO-Analyzer; ** 7-days-abstinence.

DISCUSSION

These results confirm previous findings of no overall effect of ETC (5;6;8-10). Patients motivation to quit was a strong predictor of smoking cessation at follow-up as previously reported (11). Concerning unmotivated smokers, our approach does not seem to have any advantages over

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usual care. Thus, one consequence of our findings might be to limit ETC in unmotivated smokers to brief advice. Law & Tang (32) in their analysis of 188 trials found a smoking cessation rate of 2% (95%-CI (1 – 3%)) following personal advice and encouragement to stop smoking given by physicians during a single routine consultation. Silagy (25) in a meta-analysis of 16 trials of brief advice versus no advice (or usual care) revealed a small but significant increase in the cessation rate of about 2.5%. Taking the lower limit of the 95%-CI of a single routine consultation (32), these findings would translate into a number needed to treat (NNT) of 100 or an overall consultation time of 100 - 300 minutes for one additional smoking cessation (2). During on-site counselling in this investigation, several unmotivated smokers suggested intervals for the telephone booster follow-up sessions of 6 to 12 months (which could not be scheduled because of the study protocol). We interpreted this suggestion as a request for a long-term, low threshold tobacco control program. Therefore, another option might be to evaluate, in future studies, whether unmotivated smokers treated in EDs profit from a longer term supportive therapeutic regimen, initiated on-site and maintained thereafter e.g. by a general practitioner (around 72% of unmotivated smokers had a family doctor, of these 90% with a minimum one visit during the last 12 month).

In ambivalent smokers, our results showed a non-significant benefit of tobacco control over standard care with a 3.8% difference in 7-day-abstinence rates at 12 month in an intention-to-treat analysis. The overall study was not designed to demonstrate differences in subgroups. Assuming clinical but not statistical significance due to an inappropriate number of study participants in this subgroup, the results would translate into a NNT of around 26 and a treatment time of 884 minutes (the mean time for one ETC in ambivalent smokers in this investigation was 34 minutes) for one additional smoking cessation. Thus, for ambivalent smokers who account for one third of the ED patients, alternative treatment regimes must be developed.

In motivated smokers we observed a 14.0% difference in 7-day-abstinence rates at 12 months, with a NNT of around 7. This difference is based on a relatively small number of observations and should be interpreted cautiously. However, it would translate into an overall treatment time of 245 minutes (the mean time for one ETC in motivated smokers in this investigation was 35 minutes) to achieve one additional smoking cessation at 12 month. This finding would be consistent with the overall time for one additional smoking cessation after brief advice in unmotivated smokers (see above). In this investigation, being more highly motivated was associated with a shorter smoking duration and a higher age of smoking onset. Higher motivated smokers already had the most experience with quitting attempts within the last 12 month. When offered ETC, motivated smokers more intensively used the proposed consulting and were more often than unmotivated or ambivalent smokers willing to agree on a quitting day or to use NRT.

Study limitations: Although study participants were randomised, stratified for age, gender, and motivation to change behaviour, a statistical significant difference in the number of cigarettes per day between both study arms was observed. The median difference of one cigarette per day between groups, however, is probably of little clinical significance.

Because of the limited evidence on ETC at the time of study enrolment the sample size calculation was based on findings of inpatients showing an overall peto odds ratio of 1.82 (95%-CI (1.49 – 2.22)) in tobacco control interventions with supportive contacts for at least one month compared with control condition (13). An update of this meta-analysis in 2007 based on 17 trials found a weaker overall effect of tobacco control (peto odds ratio 1.65 (95%-CI (1.4 - 1.9))) (33). Thus, the study size calculation for this investigation was probably based on overestimated findings and led to incorrect sample sizes. ETC may be less effective than tobacco control in non-ED patients, due to a high prevalence of conjoint substance use and a cluster of further medical and social risks in ED patients. Another reason for the overall failure of ETC may be its initial application in an often hectic setting, one that hinders the establishment of a therapeutic relationship that is significant enough to assist the patient through the tobacco quitting process.

Findings from this study regarding baseline as well as follow-up enrolment must be seen as being impacted by potential selection bias during study participation assessment, incomplete allocation, and incomplete ETC interventions. Richman et al. reported complete allocation to

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intervention in their ED-based RCT in 152 out of 216 eligible patients (70.4%) and a three month follow-up of 103 (67.8%) study participants (5). Referral to a smoking cessation programme was accepted by less than half of 1095 smokers in the ED-based feasibility study by Cummings and colleagues (7). Schiebel and Ebbert found in their feasibility study that 152 out of 212 smokers who initially indicated interest in quitting decided not to participate in their study and of those 39 finally randomised, 19 (48.7%) could not be reached or refused the 6-month follow-up (8). In our investigation, selection bias of those finally agreeing to study participation (1044 out of 1728) may have led to a positive sampling of those being more susceptible to health promotion since more than half of those smokers who refused participation were not interested in a study on tobacco control. Recall biases during follow-up may have further impacted on the validity of the results. But we assume that selection biases through discontinuation of the follow-up – in this study strongly associated with the degree of nicotine dependency as well as additional substance use parameters but independent of the motivation for behavioural change – was adequately controlled through our statistical approach.

The validation of self-reported smoking intensity through CO-measurement in the exhaled air was conducted in the sub-sample of 100 out of 188 study participants leaving 99 data-sets for analysis. Although validity in the subsample was satisfactory, the overall validity of the self-reported results on smoking cessation still remains questionable. But, our finding on the proportion of smoking deceivers (self reported non-smokers chemically classified as smokers) was in the range of 4.0% and 13.0% smoking deceivers evaluated in previous studies on the validation of self-reported smoking (32;34;35).

Despite these limitations, – which might reflect the reality of future implementation into clinical routine – our study clearly showed the feasibility of ETC during routine activity in an urban ED. ETC, in the form tested in this investigation, appears to enhance the patient's self-motivation in ambivalent and motivated smokers. The negative impact of nicotine dependence probably reflects the limiting (physical) factors in patients´ baseline characteristics. Systematically evaluating the benefit of nicotine replacement therapy in ETC services might adequately address these limiting factors in the future. Nicotine replacement therapy may further reduce attrition rates with ETC-services since in this investigation higher nicotine dependency but not lower motivation to change smoking behaviour was associated with loss to follow-up.

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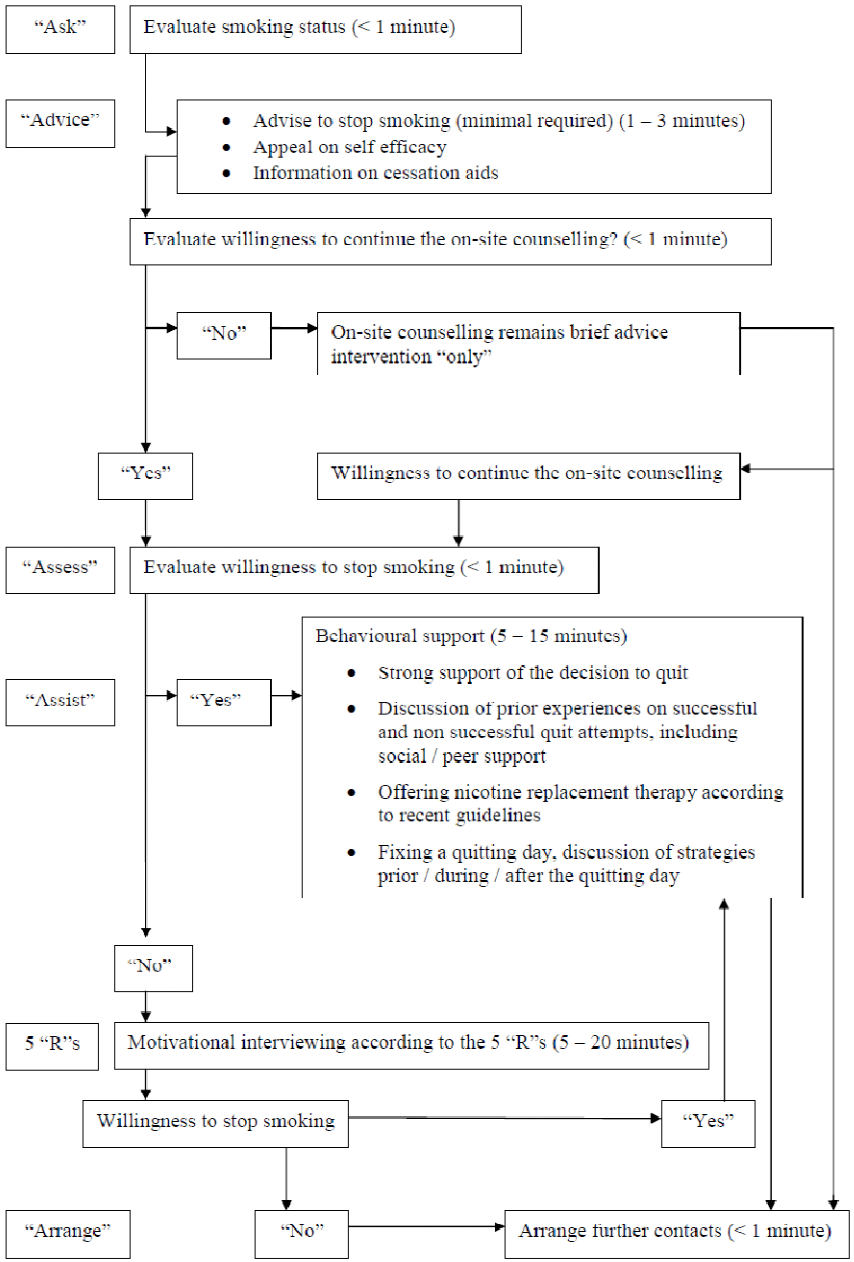

The 5 "R"s: "relevance", "risks", "rewards", "roadblocks", "repetition".

Figure 1: Stages of the on-site counselling in the emergency department

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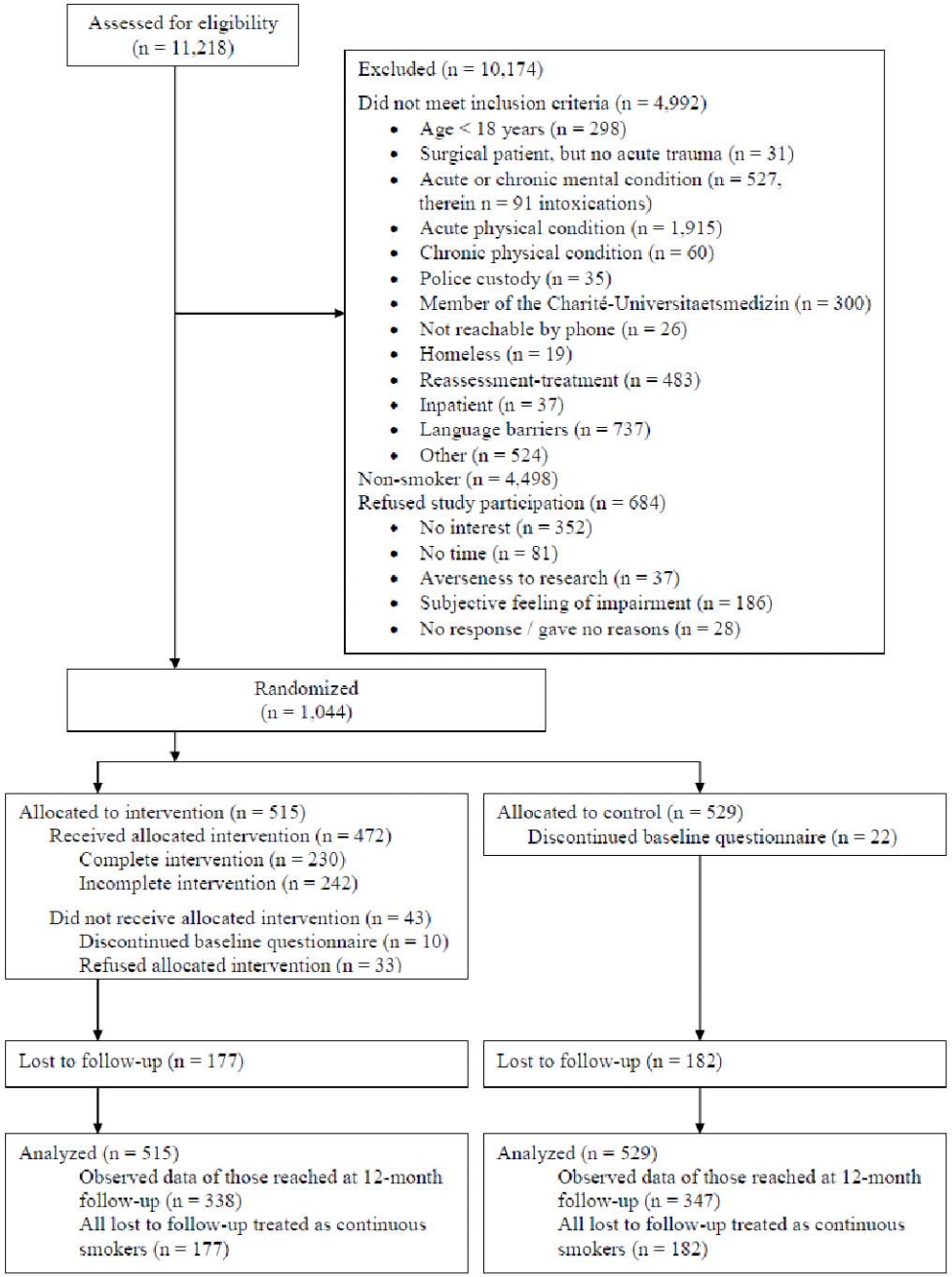

Figure 2: Flow-chart of all patients, baseline enrolment and follow-up

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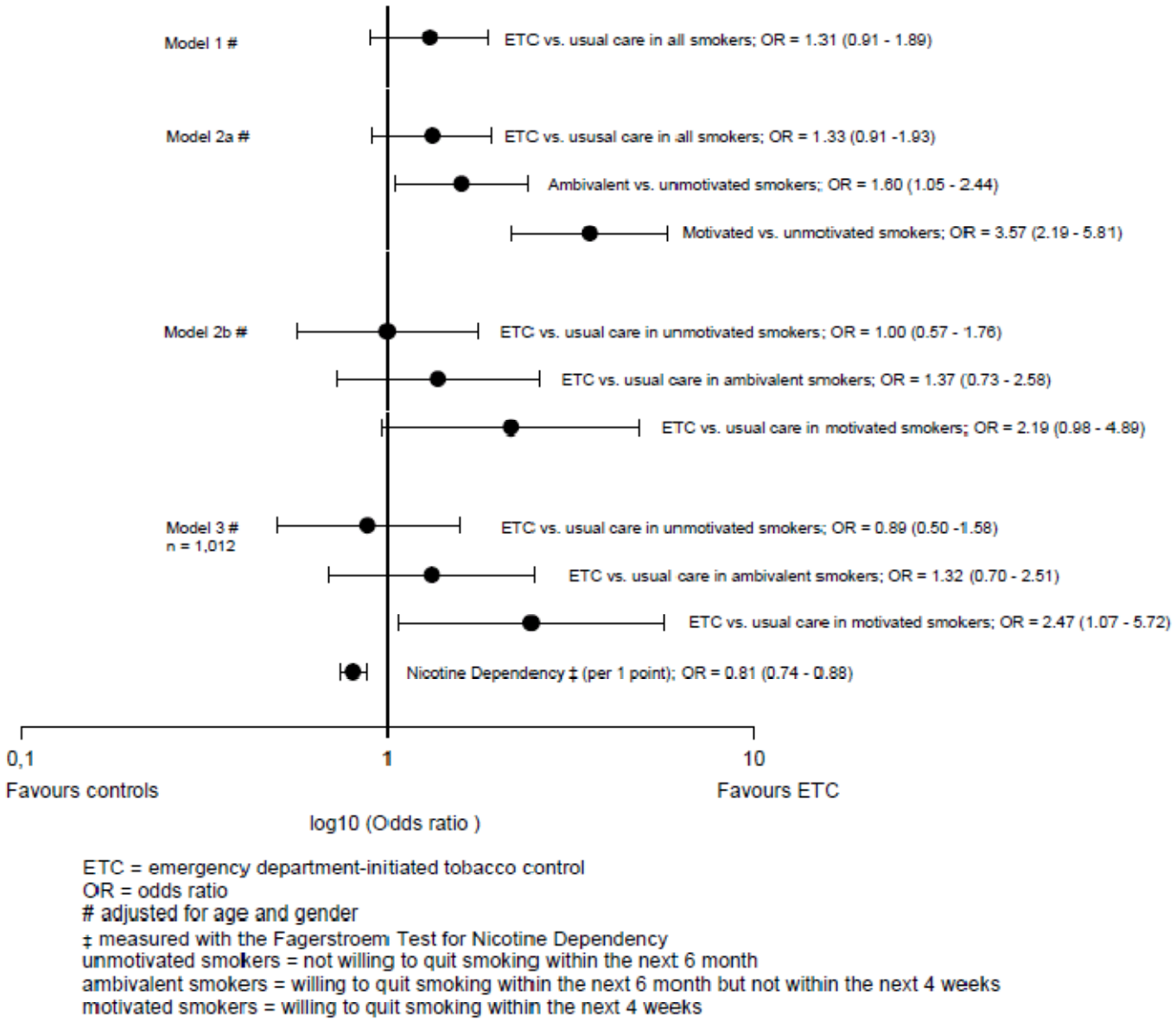

Figure 3: Odds ratios and their corresponding 95%-confidence intervals of the effect of Emergency Department-initiated tobacco control on 7-days-abstinence at 12-month follow-up adjusted for age and gender, n = 1,044 (models 1 and 2) and subgroup analysis in patients with complete baseline screening, n = 1012 (model 3)

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