

PMD	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question		
142546	Botvin GJ	Smoking prevention among urban minority youth: assessing effects on outcomes and mediating variables	1992	RCT	None	Q13 (RF10)	USA	Community (schools)	None/NR	NR	4 mo	Test the effectiveness of a social resistance/competence enhancement approach to smoking prevention among predominantly Hispanic 7th graders in New York City	3,153 (47 schools)	Pediatric/ Young Adults	7th grade Inner city schools in New York	Mean Age: 12 yr 10 mo Males: 49% Black: 18.7% White: 14.2% Hispanic: 55.6% Other race/ethnicity: 11.6% Schools with students from families with average income at or below 150% of the federal poverty level: 83% (39 schools) Parental education (college): Father: 17.0% Mother: 15.8% 2-parent family: 57.9% Language use mostly English: With parents: 41.6% With friends: 80.5%	1,795 (NR) 25 schools (NR)	Behavioral	Arm 1: 15-session smoking prevention program (INT) 5 major components: a cognitive component designed to provide information concerning the short-term consequences of smoking, prevalence rates, the current social acceptability of smoking, and the addictive nature of smoking; a decision-making component designed to facilitate critical thinking and independent decision making; a component to develop skills for coping effectively with anxiety; a component designed to teach social skills and assertiveness skills; a self-directed behavior change component designed to facilitate self-improvement and a sense of personal control	1,358 (NR) 22 schools (NR)	Control Arm: No prevention program (CON)	Primary: Mean proportion of students reporting cigarette smoking during the past mo [% (SD)] Smoking onset rate (%) Secondary: Mean smoking prevalence knowledge score (SD) Mean immediate consequences of smoking knowledge score (SD) Mean social acceptability knowledge score (SD) Mean anti-smoking attitudes score (SD) Mean normative expectations (peers)(SD) Mean normative expectations (adults)(SD)	Primary: INT: 4.6(3.78) to 5.1(94.35) CON: 5.0(3.44) to 7.15(3.57) Data not given but analysis showed significantly fewer new smokers in INT vs CON. Secondary: INT: 0.86(0.20) vs CON:0.57(0.19) INT: 4.32(0.48) vs CON: 3.94(0.38) INT: 1.17(0.17) vs CON: 0.91(0.21) INT: 37.71(1.42) vs CON: 38.32(2.18) INT:3.42(0.28) vs CON: 3.74(0.32) INT:4.28(0.37) vs CON:4.81(0.20)	S S** S* S** NS S** S**	None	No long term results available.	A social resistance/competence enhancement intervention in 7th graders significantly reduced smoking and increased knowledge at 4 month FU.	Q13. A social resistance/competence enhancement intervention in 7th graders significantly reduced smoking rates in those who were regular smokers at baseline with no effect in any other group.		
361276	Biglan A	Do smoking prevention programs really work? Attrition and the internal and external validity of an evaluation of a refusal skills training program	1987	RCT	None	Q10,Q13 (RF10)	USA	Community (schools)	None/NR	Approx. 2.5 wk	1 yr	Investigate the effects of a smoking prevention program that emphasizes refusal skills training	1,730 3 high schools 6 middle schools	Pediatric/ Young Adults	Students taking health or science classes designed for 7th, 9th, and 10th grade	Boys: 880 7th graders: 873 9th graders: 538 10th graders: 262 Students in other grades or did not report grade: 57 Predominately White	NR (NR)	Behavioral	Arm 1: Smoking prevention program that emphasized refusal skills training and included a brief review of the long and short-term health consequences of smoking and solicitation of a public commitment not to smoke; a follow-up booster session was given 2 wk later Refusal skills training component consisted of role-playing and excerpts from a film entitled "Resisting Pressure to Smoke," which depicted effective refusal	NR (NR)	Control Arm: No intervention	Primary: Proportion of subjects in each smoking category(%) Smoking index Secondary: Mean expired air carbon monoxide levels	Primary: No significant difference for any group. 6m: No intervention effect; males reported smoking less than females. 1y: Decreased in regular smokers; males reported smoking less than females Secondary: CO levels higher among CON vs INT in 9th grade subjects	NS NS for INT: S between sexes S for regular smokers: S between sexes S	None	High attrition rate in both groups with more high-rate smokers dropping out of treatment. Drop-outs were also more likely to be from high risk smoking situations.	A 1987 school-based study based on emphasizing refusal skills showed reduced smoking rates in those who were regular smokers at baseline with no effect in any other group.	Q10,13. A 1987 school-based study based on emphasizing refusal skills showed reduced smoking rates in those who were regular smokers at baseline with no effect in any other group.		
7673547	Dent CW	Two-year behavior outcomes of Project Towards No Tobacco Use	1995	RCT	None	Q11 (RF10) Q13 (RF10)	USA	Community (schools)	None/NR	1 yr	2 yr	Establish whether the preventive effects of "Project Towards No Tobacco Use" (Project TNT), a school based intervention to prevent adolescent use of tobacco, endured after students made their transition from junior high to high school	6,716 (48 schools)	Pediatric/ Young Adults	7th grade	Males: 50% White: 60% Hispanic: 27% Black: 7% Asian or other ethnicity: 6%	NR (NR)	Behavioral	Arm 1: Normative social influence curriculum of Project TNT Consisted of activities that counteract normative social influence (yielding to peer pressure to achieve acceptance; e.g., refusal assertion skills training) Arm 2: Informational social influence curriculum of Project TNT Consisted of activities that counteract informational social influence (social image misperceptions of tobacco; e.g., correction of tobacco use prevalence overestimation)	NR (NR)	Control Arm: Usual care	Primary: Change in prevalence of trial cigarette use [%] Change in prevalence of weekly cigarette use [%] Change in prevalence of trial smokeless tobacco use [%] Change in prevalence of weekly smokeless tobacco use [%] Secondary: Prevalence of cigarette use in urban vs rural schools [%]	Primary: Combined: 16%; Arm 1: 15%; Arm 2: 17%; Arm 3: 13%; CON: 23% Combined: 4%; Arm 1: 12%; Arm 2: 9%; Arm 3: 8%; CON: 9% Combined: 7%; Arm 1: 4%; Arm 2: 4%; Arm 3: 0%; CON: 7% Combined: -0.1; Arm 1: 2%; Arm 2: 2%; Arm 3: -1%; CON: 1% Secondary: 52% vs 60%	Primary: S between Combined INT and CON; NS between subgroups. S between Combined INT & CON; NS between subgroups; S for Arm 3 vs all other groups; NS for Combined INT and CON. S for Arm 3 vs all other groups; marginal effect for Combined INT group and CON.	None	More male than female students used smokeless tobacco. Weekly smoking overall was 14% at ninth grade. Change in prevalence of trial of cigarettes between 7th & 9th grades was 17%. Change in prevalence of weekly cigarette smoking between 7th & 9th grades was 8% overall. Neither change varied by gender or region.	Q10,13. A school-based tobacco use prevention program in junior high students showed that a physical consequences curriculum was successful at attenuating smokeless tobacco use and that a comprehensive program with all 3 approaches was necessary to significantly decrease both smoking and smokeless tobacco use at 2 yr FU in high school.	Q10,13. A school-based tobacco use prevention program in junior high students showed that a physical consequences curriculum was successful at attenuating smokeless tobacco use and that a comprehensive program with all 3 approaches was necessary to significantly decrease both smoking and smokeless tobacco use at 2 yr FU in high school.		
7673547	Dent CW	Two-year behavior outcomes of Project Towards No Tobacco Use	1995																											
9003134	Hovell MF	An adolescent tobacco-use prevention trial in orthodontic offices	1996	RCT	None	Q13 (RF10)	USA	Clinical	None/NR	NR	2 yr	Examine the effect of an orthodontist-delivered tobacco-use prevention program for adolescents	16,915 (154 orthodontic offices)	Pediatric/ Young Adults	11-18 yr	Mean age (SD): 14.4 yr (1.8) Males: 46% Caucasian: 73% Hispanic: 12% Black: 3% Asian: 9% Unreported race/ethnicity: 3% A parent graduated from college: 70%	NR (7,149) 77 offices (NR)	Behavioral	Arm 1: Clinician delivered tobacco use prevention trial (INT) Offices received 1.5 hours of tobacco prevention training based on National Cancer Institute tobacco cessation workshops for clinicians Instructions for anti-tobacco counseling and delivery of anti-tobacco "prescriptions" were provided Clinicians and staff were to write the patient's name, sign and give the prescription to the patient, briefly discuss the tobacco related topic printed on the prescriptions, and request that the patient not start smoking	NR (6,626) 77 offices (NR)	Control Arm: Usual care (CON)	Primary: 30-d tobacco use 2 y incidence rates [%] Lifetime use of tobacco > 100 times [%] Secondary: 30-d tobacco use by demographic and behavioral characteristics [%] 30-d tobacco use incidence associated with number of anti-tobacco prescriptions received [%]	Primary: INT: 12.0% vs CON: 12.6%; OR=0.94(0.82,1.08) INT: 6.8% vs CON: 7.6% Secondary: Blacks and Asians had significantly lower initiation rates than whites; females had a lower initiation rate than males; and tobacco use increased with age but intervention effects did not vary between groups. Pts who received the lowest # of prescriptions = 14.3% vs pts who had received the highest # of prescriptions = 10.0%	NS NS NS S	None	Although not significant, trends were in the right direction; effort by providers may have an effect.	A smoking prevention trial in adolescents based in orthodontists' offices showed no difference in tobacco use between experimental and control groups. With MVA, there was a significant dose response with pts who received more prescriptions having significantly lower incidence rates.	Q13. A smoking prevention trial in adolescents based in orthodontists' offices showed no difference in tobacco use between experimental and control groups. With MVA, there was a significant dose response with pts who received more prescriptions having significantly lower incidence rates.		
9772850	Kellam SG	Targeting early antecedents to prevent tobacco smoking: findings from an epidemiologically based randomized field trial	1998	RCT	None	Q10(RF10) Q13 (RF10)	USA	Community (schools)	None/NR	2 yr	Till students are 14 yr	Examine whether interventions aimed at aggressive/disruptive classroom behavior and poor academic achievement would reduce the incidence of initiation of smoking	2,311 (19 schools)	Pediatric/ Young Adults	Urban areas Socioeconomic levels ranging from very poor to middle class 1st grade students	Age range: 6-7 yr Males: 808 Birth year: 1978: 145 1979: 741 1980: 718	Arm 1: NR (352) Arm 2: NR (348)	Behavioral	Arm 1: "Good Behavior Game" intervention The Good Behavior Game, a behavior management strategy designed to improve aggressive/disruptive classroom behavior, was led by the teacher during regular class periods. In the beginning games were played for 10 min 3 times/wk with increased frequency and length in 1st and 2nd grades. After baseline assessments of target behaviors, teachers assigned all students to 1 of 3 teams, balancing sex and levels of aggressive behavior. Teams were rewarded when no member exhibits undesirable behaviors such as fighting, shouting and teasing	NR (904)	Control Arm: Customary school programs	Primary: Initiation of tobacco smoking through 14 yr of age [RR (95% CI)]	Arm 1: ~45% vs CON~60% Cohort 1 & 2: Males: RR=0.62(CI:0.40,0.97) Females: 0.9(CI:0.57,1.42) Arm 2: ~50% vs CON~60% Cohort 2: Males: RR=0.48(CI:0.24,0.87) Females: No difference between cohorts (specific results not given) Cohort 1: No difference between cohorts (specific results not given)	S NS S NS NS	None	Of 1604 children who had not tried smoking at 11, 502 had tried smoking by 14 yr of age.	A preventive trial based on behavior management or enriched reading in 1st and 2nd grade students significantly reduced smoking initiation in boys assessed by interview at 14 yrs of age. There was no measurable effect on girls.	Q10,13.A preventive trial based on behavior management or enriched reading in 1st and 2nd grade students significantly reduced smoking initiation in boys assessed by interview at 14 yrs of age. There was no measurable effect on girls.		
9772850	Kellam SG	Targeting early antecedents to prevent tobacco smoking: findings from an epidemiologically based randomized field trial	1998	RCT																										

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10181020	Josendal O	Effects of a school-based smoking prevention program among subgroups of adolescents	1998	RCT	None	Q13 (RF10)	Norway	Community (schools)	None/NR	6 mo	6 mo	Study the effects of a school-based intervention aimed at preventing smoking among pupils in Norwegian secondary schools	4,441 (99 schools)	Parental/ Family/ Caregiver	Born in 1981 7th grade students	Males: 50.6%	Arm 1: 1,126 (1,060) Arm 2: 946 (791) Arm 3: 969 (878)	Behavioral	Arm 1: Classroom smoking prevention program + parent involvement + teacher training Arm 2: Classroom smoking prevention program + parent involvement Arm 3: Classroom smoking prevention program + teacher training In the classroom program, students were involved in 8 sessions throughout the school yr. Main themes of the classroom smoking prevention were personal freedom, freedom to choose, freedom from addiction, to make own decisions, training social skills to resist smoking pressure and short-term consequences of smoking	1,088 (1,091)	Control Arm: No intervention	Primary: Prevalence of non-smokers (%) Secondary; Subgroup analyses: Prevalence of non-smokers (%)	Primary: CON: 92.6% to 94.5% MaxINT: 93.2% to 91.3% No teacher INT: 91.8% to 87.4% No parent INT: 89.8% to 83.5% Secondary; Subgroup analyses: CON vs Max INT: Among low sensation seekers, those with low outcome expectancies & no parental smoking there was no difference between groups. CON vs Max INT: For high sensation seekers, those with >= 1 parent who smokes, the increase in smoking prevalence was significantly lower in the MaxINT group. With MIA using a sum score of the high risk attitudes, there was a significant difference between the MaxINT & CON groups.	S* between CON & MaxINT. NS, NS; NS S; S*; S S	None	Short follow-up and modest differences between groups.	A school-based smoking prevention intervention that combined teacher courses, classroom programs and parental involvement was successful in decreasing the proportion of adolescents who began smoking over a 6 month period. The program was most successful in students defined as high risk to begin smoking.	Q13. A school-based smoking prevention intervention that combined teacher courses, classroom programs and parental involvement was successful in decreasing the proportion of adolescents who began smoking over a 6 month period. The program was most successful in students defined as high risk to begin smoking.	
10181020	Josendal O	Effects of a school-based smoking prevention program among subgroups of adolescents	1998																										
10482213	Williams GC	Presenting the facts about smoking to adolescents: effects of an autonomy-supportive style	1999	RCT	None	Q13 (RF10)	USA	Community (schools)	None/NR	2 d	4 mo	Test the self-determination model of health-related behavior by examining the degree to which adolescents experience an autonomy-supportive appeal as it relates to reduced smoking or smoking cessation	300	Pediatric/ Young adults	9-12 grade students Suburban high schools	Males: Arm 1: 42.2% Arm 2: 43.9% Minority: Arm 1: 15.2% Arm 2: 15.3% Father's educational level (SD): Arm 1: 4.4 (1.0) Arm 2: 4.6 (0.7)	Arm 1: NR (NR) Arm 2: NR (NR)	Behavioral	Arm 1: "It's Your Choice" presentation Presentation contained a theme emphasizing the seductive nature of the tobacco industry's advertising and the addictive nature of nicotine, both of which can function to subjugate adolescents' choice to not smoke Arm 2: "Fear and Demand" presentation Presentation emphasized the theme of disease and death caused by smoking and was intended to illustrate graphically the grave consequences of smoking	N/A	N/A	Primary: Change in autonomous motivation to not smoke (β) Change in smoking behavior (β)	Primary: All results are presented as multiple regression analyses with no basic data reported. From the MRA: (1) Neither intervention significantly increased autonomous motivation for not smoking, either 1 week or 4 months after the presentations. (2) The 2 interventions were not differentially related to change in smoking behavior. (3) Perception of autonomy support did predict a reduction in smoking. (4) Increased autonomous motivation for not smoking when present, did predict a reduction in smoking at 1 week and 4 months.	NS NS between interventions S S*at time 1, S** at time 2	None	None	A school-based intervention for adolescents compared an autonomy supportive message to a fear-based message. Neither intervention changed autonomous motivation for not smoking or was differentially related to smoking behavior. However, if autonomous motivation for not smoking was increased, it was associated with reduced smoking.	Q13. A school-based intervention for adolescents compared an autonomy supportive message to a fear-based message. Neither intervention changed autonomous motivation for not smoking or was differentially related to smoking behavior. However, if autonomous motivation for not smoking was increased, it was associated with reduced smoking.	
11121460	Peterson AV, Jr.	Hutchinson Smoking Prevention Project: long-term randomized trial in school-based tobacco use prevention—results on smoking	2000	RCT	None	Q6 (RF2, RF10) Q11 (RF10) Q13 (RF10)	USA	Community (schools)	None/NR	10 yr	12 yr	Determine the long-term impact of The Hutchinson Smoking Prevention Project, a long-term, theory-based, social-influences intervention program for smoking prevention among school age youth	8,388 (40 school districts)	Pediatric/ Young adults	3rd grade students	Single parent household: Arm 1: 23.3% Control Arm: 22.3%	4,177 (3,919)	Behavioral	Arm 1: Hutchinson Smoking Prevention Project (HSPPP) intervention The HSPPP intervention is a teacher-led, grade 9–10 tobacco use prevention curriculum together with unit-specific teacher training. There are a total of 85 classroom lessons in the HSPPP curriculum for all grade levels combined. The length of the classroom lessons varies with the lesson and the grade, ranging from 30 to 50 min. The curriculum is supplemented by 2 additional high school components: 1) self-help tobacco use cessation materials to help motivate smokers in grades 9–12 to think about quitting, and 2) biannual newsletters informing high school teachers about tobacco education resources and tobacco current events as well as about ways to incorporate these resources into various course subjects in high school	4,211 (3,946)	Control Arm: No intervention No restrictions were placed on the health promotion or tobacco use prevention activities of the control school districts, thus enabling the schools to continue whatever health curricula were normally offered	Primary: Difference in average daily smoking prevalence at grade 12 (%) Difference in average daily smoking prevalence at grade 12 + 2 (%) Secondary: Cigarettes/d [% (95% CI)] Any smoking [% (95% CI)] At least monthly smoking [% (95% CI)] At least weekly smoking [% (95% CI)] At least daily smoking [% (95% CI)] Average smoking acquisition stage [% (95% CI)] Cigarettes/d [% (95% CI)] Change in smoked > 100 cigarettes in lifetime [% (95% CI)] Difference in slopes of linear regression of self-reported level of tobacco use versus cotinine value (95% CI)	Primary: Girls: INT: 24.66% vs CON: 24.41% Boys: INT: 26.65% vs CON: 26.32% Girls: INT: 27.0% vs CON: 25.6% Boys: INT: 29.9% vs CON: 32.5% Secondary: Girls + Boys: INT: 9.6 vs CON:10.4(0.03,1.4) No significant difference in any measure below.	NS NS NS S NS	None	Significant increase in smoking prevalence in both groups in the 2 yrs after grade 12.	A theory-based social influences intervention conducted from grades 3 to 12 achieved high implementation fidelity and 94% follow-up. Despite this, there were no significant differences in smoking prevalence or any smoking behavior between students in the control and experimental schools at grade 12 or grade 12 + 2 yrs.	Q13. A theory-based social influences intervention conducted from grades 3 to 12 achieved high implementation fidelity and 94% follow-up. Despite this, there were no significant differences in smoking prevalence or any smoking behavior between students in the control and experimental schools at grade 12 or grade 12 + 2 yrs.	
11436934	Sussman S	Project EX: outcomes of a teen smoking cessation program	2001	RCT	None	Q10 (RF10)	USA	Community (schools)	None/NR	6 wk	NR	Evaluate the effectiveness of Project EX, an 8-session teen school-based clinic tobacco use cessation program that involves the inclusion of enjoyable, motivating activities to try to enhance quit rates among youth	335 (18 schools)	Pediatric/ Young adults	Had smoked in past 30 d	Patient characteristics for Arm 1 and Arm 2 Mean age (SD): 16.8 yr (0.8) Male: 64% Latino: 47% White: 27% Asian: 8% African American: 6% Other race/ethnicity: 12%	Arm 1: 139 (NR) Arm 2: 120 (NR)	Behavioral	Arm 1: Project EX clinic The clinic consisted of 8 sessions. In the first 4 sessions students are not asked or required to quit immediately, but rather are prepared to strengthen their attempt to quit between sessions 4 and 6. The second 4 sessions are focused on maintenance of their quit attempt Arm 2: Project EX clinic + school as community (SAC) The clinic consisted of 8 sessions. In the first 4 sessions students are not asked or required to quit immediately, but rather are prepared to strengthen their attempt to quit between sessions 4 and 6. The second 4 sessions are focused on maintenance of their quit attempt	76 (44)	Control Arm: Standard tobacco education Standard tobacco education was provided in regular health education class curricula	Primary: Smoking cessation per protocol [OR] Smoking cessation for ITT [OR] Smoking cessation for ITT + LTF [OR] Smoking cessation for ITT + LTF + CO agreement [OR] Secondary: Smoking cessation for students not addicted [OR] Smoking cessation for students with moderate addiction level [OR] Smoking cessation for students with heavy addiction level [OR]	Primary: INT: 30% vs CON: 16% OR=2.21 INT:30% vs CON: 16% OR=2.20 INT: 19% vs CON: 10% OR= 2.37 INT: 17% vs CON: 8% OR=2.36 Secondary: INT: 42% vs CON: 16% OR=3.80 INT: 13% vs CON: 8% OR=2.36 INT:7% vs CON:3% OR=1.96	None	Randomized by school but individual students volunteered to participate in the intervention and controls were students who did not volunteer. This therefore is not a randomized study.	In late adolescent smokers who volunteered for a cessation clinic, an 8-session intervention showed a significant difference in smoking rates at 3 m F/U by self report alone, compared with smokers who did not volunteer.	Q10.13. In late adolescent smokers who volunteered for a cessation clinic, an 8-session intervention showed a significant difference in smoking rates at 3 m F/U by self report alone, compared with smokers who did not volunteer.		
11436934	Sussman S	Project EX: outcomes of a teen smoking cessation program	2001																										

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11518093	Killen JD	Do adolescent smokers experience withdrawal effects when deprived of nicotine?	2001	RCT	None	Q10 (RF10)	USA	Clinical	Double	8 hr	2 d	Examine the extent to which adolescent smokers would manifest signs and symptoms of nicotine withdrawal when deprived of nicotine and whether brief treatment with nicotine replacement therapy could alleviate symptoms	105	Pediatric/ Young Adults	13-18 yr Smoke ≥ 10 cigarettes/d Expired-air carbon monoxide level ≥ 5 ppm	Mean age (SD): Arm 1: 17.1 yr (1.3) Control Arm: 16.8 yr (1.2) Boys: 51 Patient characteristics pertain to 92 patients included in follow-up analysis	NR (43)	Pharmacologic	Arm 1: Nicotine patch 15 mg/16 hr (NP) Participants not permitted to use any tobacco products (or alcohol or illicit drugs) for 8 hr and were required to wear a placebo patch	NR (46)	Control Arm: Placebo (Plac) Participants not permitted to use any tobacco products (or alcohol or illicit drugs) for 8 hr and were required to wear a placebo patch	Primary: Mean HR [bpm (SD)] Mean SBP (mmHg (SD)) Mean DBP (mmHg (SD)) Mean craving [1-10 scale of symptom severity (SD)] Secondary: Mean CO levels (ppm (SD))	Primary: Plac: BIL 86.61 to 80.41 NP: BIL 86.82 to 84.42 Plac vs NP: 80.41 vs 84.42 Plac: BIL 117.70 to 115.78 NP: BIL 114.39 to 118.47 Plac vs NP: 115.78 vs 118.47 Plac: BIL 60.54 to 60.44 NP: BIL 60.98 to 64.28 Plac vs NP: 60.44 vs 64.28 Plac: BIL 4.44 to 6.37 NP: BIL 4.33 to 6.20 Plac vs NP: 6.37 vs 6.20 Secondary: CON: BIL 15.7 vs Plac: 3.5 INT: BIL 15.5 vs NP: 3.3 Plac vs NP: 3.5 vs 3.3 * Multiple additional measures of potential withdrawal showed no difference between the NP and plac groups.	S** NS S NS S S S** S NS S** S** NS	Itching with active patch		A comparison of nicotine withdrawal with a nicotine patch to a placebo patch showed that the placebo patch was associated with lower HR but no decrease in SBP or DBP. Psychological symptoms of withdrawal were similar between groups.	Q10. A comparison of nicotine withdrawal with a nicotine patch to a placebo patch showed that the placebo patch was associated with lower HR but no decrease in SBP or DBP. Psychological symptoms of withdrawal were similar between groups.	
12456128	O'Nofrio CN	Curtailling tobacco use among youth: evaluation of project 4-health	2002	RCT	None	Q10.13 (RF10)	USA	Community (other)	None/NR	5 mo	2 yr 5 mo	Report the development and evaluation of Project 4-Health, a theory-driven, research-based program to prevent tobacco use among youth enrolled in 4-H clubs throughout California	1,967	Pediatric/ Young Adults	10-14 yr Enrolled in a California 4H club	Mean age (SD): 12.11 yr (1.32) Boys: 42.5% White non-Hispanic: 89.4% Latino: 6.5% Asian/Pacific Islander: 1.1% Native American: 0.6% African American: 0.3% Missing race/ethnicity: 2.1%	990 (938)	Behavioral	Arm 1: Project 4-Health smoking intervention The program aimed to enable youth to develop personal policies about tobacco use and to participate with others in developing and implementing sound tobacco policies and programs within the home, the 4-H club, the school, and the community through a core set of 5 experience-based sessions conducted during monthly club meetings	977 (915)	Control Arm: Regular 4-H club meetings	Primary: 24 outcome variables were assessed, 4 related to knowledge, 6 to attitudes, 6 to social influences, 2 to behavioral intentions and 6 to tobacco use. Secondary: At 4 mos after program delivery, 7 measures of knowledge and attitude were significantly increased but there was no change in behavior. At 2 y FU, there were no differences in any outcome measure.	NS	None	A community intervention for adolescents addressing knowledge, attitudes and behavior about smokeless tobacco and cigarette smoking had no significant effect on behavior at short or long term FU.	Q10.13. A community intervention for adolescents addressing knowledge, attitudes and behavior about smokeless tobacco and cigarette smoking had no significant effect on behavior at short or long term FU.			
12612363	Jackson C	Can parents who smoke socialise their children against smoking? Results from the Smoke-free Kids intervention trial	2003	RCT	None	Q11 (RF10) Q13 (RF10)	USA	Home	Single	10 wk	2 yr	Evaluate Smoke-free Kids, a new home based program to assist parents who smoke in socializing their children against smoking	887	Parental/ Family/ Caregiver	Parents or guardians who had a child enrolled in 3rd grade (ages 7-8) Parents or guardians who reported current smoking Children who had never smoked	Male children: 47% White parents: 78% African American parents: 16% Hispanic parents: < 1% Native American parents: 2% Other/multi race/ethnicity parents: 2% Parent with ≤ 8th grade education: 2% Parent with some high school: 6% Parent with high school degree or equivalent: 28% Parent with vocational or 2 yr college: 48% Parent with bachelor degree or higher: 16%	441 (327)	Behavioral	Arm 1: Smoke-Free Kids intervention Participants received 1 module every 2 wk for a total of 5 modules. The modules gradually increased parents' skills and comfort level in communicating with their children about their personal smoking history, addiction and expectations regarding abstinence. The intervention included a telephone call from a health educator, a toll-free number that parents were encouraged to use, parent newsletters, and newsletters for children	446 (344)	Control Arm: Fact based program Parents received 1 fact sheet every 2 wk. The fact sheets provided knowledge about youth smoking and focused parents' attention on macro-level variables relevant to youth smoking but not targeted by the treatment version of the program	Primary: Effectiveness evaluation: Child attributes that reduce susceptibility to smoking (% OR(95%CI)): -Believes parent likes to talk about smoking -Affirms having social contact with parent -Believes parent would detect smoking -Expects parent will reward abstinence Child attributes that raise susceptibility (% OR(95%CI)): -Intends to smoke in adolescence -Has a best friend who has smoked	INT: 59.2% vs CON: 41.6%; OR=1.52(1.10,2.10) INT: 77.3% vs CON: 85.2%; OR=1.30(0.82,1.85) INT: 88.3% vs CON: 80.5%; OR=1.30(0.89,2.04) INT: 38.6% vs CON: 28.2%; OR=1.55(1.06,2.25) INT: 8.5% vs CON: 16.1%; OR=0.60(0.37,0.95) INT: 19.2% vs CON: 30.8%; OR=0.73(0.52,1.03)	S* NS NS S NS(p=0.07)	None	Exposure to more than 3 of 5 modules predicted significantly higher levels of attributes that reduce susceptibility to smoking and lower levels of attributes that raise susceptibility.	Q13. An anti-smoking socialization program designed specifically for smoking parents of 3rd grade children found that anti-smoking socialization by parents reduced children's susceptibility to smoking over a 2 yr period.		
12612363	Jackson C	Can parents who smoke socialise their children against smoking? Results from the Smoke-free Kids intervention trial	2003												Parent employed full time: 61.5% Parent employed part time: 20% Parent not employed for pay: 18.5%														
12063728	Tyc-VL	Intervention to reduce intentions to use tobacco among pediatric cancer survivors	2003	RCT	None	Q13 (RF 10)	USA	Clinical	None/NR	NR	12 mo	Determine whether a risk counseling intervention would increase knowledge and perceived vulnerability to tobacco-related health risks and decrease future intentions to use tobacco among preadolescents and adolescents previously treated for cancer	103	Pediatric/ Young adults	Preadolescents and adolescents Previously treated for cancer	Median age: 15 yr Male: 51 White: 83 African-American: 22 High SES: 20.4% Middle SES: 67.0% Low SES: 12.6%	53 (42)	Behavioral	Arm 1: Intensive late effect risk counseling 1 session The intervention was administered in a single session with periodic reinforcement of tobacco goals by telephone. The content was designed to be relevant to both nonsmokers and smokers with the goal of tobacco abstinence. Patients received intensive late effects risk counseling in addition to an educational video, goal setting, written physician feedback, smoking literature, and follow-up telephone counseling The intervention was delivered using a scripted protocol that was tailored to the patients' individual responses to the questions posed during the intervention	50 (39)	Control Arm: Standard care Patients were asked about tobacco use and briefly advised about the health risks associated with tobacco use. All tobacco users were advised to stop and nonsmokers were encouraged to continue to resist tobacco	Primary: Mean score of patients' knowledge regarding adverse consequences associated with tobacco use (SD) Mean score of patients' perceptions of their perceived vulnerability to tobacco-related health risks (SD) Mean score of patients' intentions to use tobacco (SD) Mean score of patients' perceived positive effects that accompany tobacco use (SD)	Primary: BIL 6m 12m INT: 22.3(2.2) 23.6(1.5) 24.0(1.4) CON: 21.9(2.2) 23.4(1.4) 22.7(2.4) INT: 32.8(4.0) 35.3(4.0) 35.9(4.6) CON: 31.6(4.6) 33.8(4.9) 32.5(5.7) INT: 8.6(9.0) 9.0(4.1) 7.8(4.0) CON: 9.9(4.5) 9.3(4.4) 10.0(3.9) INT: 0.8(1.6) 0.5(1.3) 0.8(1.8) CON: 1.0(1.6) 0.9(1.8) 1.0(1.9)	S from BIL; S between groups at 12 m S from BIL; S between groups at 12 m NS from BIL S from BIL; S between groups at 12 m NS from BIL NS from BIL; NS between groups NS from BIL	None	Education of cancer survivors regarding tobacco use is important as 47.2% had attempted tobacco and 32.5% currently smoke.	A risk counseling intervention among adolescent childhood cancer survivors was effective in increasing knowledge, perceived vulnerability and decreasing intention to smoke.	Q13. A risk counseling intervention among adolescent childhood cancer survivors was effective in increasing knowledge, perceived vulnerability and decreasing intention to smoke.	
12933772	Crone MR	Prevention of smoking in adolescents with lower education: a school based intervention study	2003	RCT	None	Q13 (RF10)	Netherlands	Community (schools)	None/NR	5 mo	1 yr 5 mo	Assess the effect of an antismoking intervention focusing on adolescents in lower education	2,562 (26 schools)	Pediatric/ Young adults	First grade level of lower secondary schools	Mean age: 13 yr Male: Arm 1: 713 Control Arm: 677 Dutch: Arm 1: 1,252 Control Arm: 907 Non-Dutch: Arm 1: 150 control Arm: 154 Unknown ethnicity: Arm 1: 42 Control Arm: 57	1,444 (537)	Behavioral	Arm 1: Peer pressure-based program (NT) Participants received 3 lessons on knowledge, attitudes, and social influence, followed by class pact to not smoke for next 5 mo. Two extra videos were available and optional to view for students during the 5 mo period. This intervention was in addition to the school's already existing and operational drug prevention program	1,118 (404)	Control Arm: Standard program (CON) Participants received the drug prevention program the school normally provided	Primary: Smoking initiation(OR (95% CI)) Secondary: Smokes at least once a wk [%] Smokes less than once a wk [%] Experiments with smoking [%] Has smoked but quit [%] Has experimented with smoking, but does not smoke anymore [%] Has never smoked [%] Regular smoking (%)	Primary: OR=0.62 (0.43,0.90) at first follow-up; no difference at 1 y FU; (INT:15% to 17% to 25% vs CON: 15% to 23% to 29%) Secondary: BIL 6m 8m INT 9.3 12.4 CON: 9.7 15.3 INT 1.8 1.0 CON: 1.0 2.2 INT 6.1 6.4 CON: 5.6 6.6 INT 2.8 3.0 CON: 3.4 3.4 INT 27.4 34.6 CON: 32.5 34.4 INT 52.5 43.6 CON: 47.9 38.1 INT: BIL 15% to 17% at 5m & 25% at 1 y CON: BIL: 15% to 23% at 5 m to 25% at 1 y.	S,NS NS for all comparisons. NS at BIL; S at 5m; NS at 1 y.	None	None	A school-based intervention for young adolescents reduced uptake smoking at short term FU but there was no difference at 1 yr.	Q10.13. A school-based intervention for young adolescents reduced uptake smoking at short term FU but there was no difference at 1 yr.	
14636795	Curry SJ	A randomized trial of a family-based smoking prevention intervention in managed care	2003	RCT	None	Q13 (RF10)	USA	Home	None/NR	NR	20 mo	Evaluate a smoking prevention intervention package for parents and children (aged 10-12) provided through their managed care organization	4,026 (parents and children)	Parental/ Family/ Caregiver	Families with a dependent child aged 10-12	Mean age of children: 11 yr Male children: 48% Full time or part time employment: Arm 1: 81% Control Arm: 79% Household income ≥ \$45,000/yr: Arm 1: 58% Control Arm: 68% Single parent household: Arm 1: 10% Control Arm 1: 10%	Regular follow-up: 1,775 (NR) Assessment cohort: 245 (NR)	Behavioral	Arm 1: Family-based smoking prevention intervention Participants in regular follow-up and assessment cohort received a mailed packet that included materials for parents and child. 3 to 6 wk after, the parents received an outreach counseling call from a telephone counselor. Fourteen mo after enrollment in the study, parents received a newsletter followed by a second outreach call and were provided access to a Steering Clear website	Regular follow-up: 1,747 (NR) Assessment cohort: 259 (NR)	Control: Usual care	Primary: Susceptibility to smoking [%] Experimentation with smoking [%] Smoked in past 30 d [%]	Primary: INT: 20.2% vs CON: 19.9% Adjusted OR=1.01 INT: 13.6% vs CON: 12.1% Adjusted OR= 1.13 INT: 2.4% vs CON: 2.3% Adjusted OR= 1.08	NS NS NS	None	Parent-child discussions about tobacco were significantly more frequent in the INT group.	In young adolescents, a well-designed and executed office-based plus mailed intervention in a managed care organization showed no significant results in smoking prevention at 20 m FU.	Q10.13. In young adolescents, a well-designed and executed office-based plus mailed intervention in a managed care organization showed no significant results in smoking prevention at 20 m FU.	

PMD	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CJ	Significance	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question	
1485401	Schofield MJ	Evaluation of a Health Promoting Schools program to reduce smoking in Australian secondary schools	2003	RCT	None	Q10,13 (RF10)	Australia	Community (schools)	None/NR	2 yr	2 yr	Evaluate the effectiveness of a multicomponent Health Promoting Schools (HPS) intervention in improving self-reported smoking outcomes among a cohort of adolescents	4,841 (24 schools)	Pediatric/Young adults	Yr 7 and 8 students	Male: 45% Occupational status of fathers: Low: 61% Middle: 35% High: 7%	2,573 (NR) students 12 schools (12 schools)	Behavioral	Arm 1: Health Promoting Schools intervention (N1) Intervention schools were encouraged to adopt and own their Health Promoting Schools program and commit to implementing health promoting strategies to address health risk behaviors. Key interventions included development of a minimum set of health promotion actions for schools which targeted knowledge and skills, availability of products, environment, and role models	2,268 (NR) students 12 schools (10 schools)	Control Arm: No intervention (CON) Schools were not offered any of the resources or actions to reduce smoking; however, if they requested assistance, then the project team offered support for other health-related issues and promoted smoking-specific support at the completion of the study period	Primary: Smoking status in last week [%;OR(CJ)] Secondary: Maximum knowledge score about smoking [%] Perceived positives of smoking Perceived negatives of smoking Smoked cigarettes in the last 7 d [OR (95% CI)]	Primary: INT: BIL: 7.8% to POST: 17.5% CON: BIL: 10.5 to POST: 20.5% OR= 0.82(0.65,1.04) Secondary: INT: + 12% vs CON: + 7% No significant difference in any other measure.	NS between groups S** NS NS NS	None		A school-based intervention for adolescents had no significant effect on smoking behavior despite an increase in knowledge.	Q10,13. A school-based intervention for adolescents had no significant effect on smoking behavior despite an increase in knowledge.	
15301658	Killen JD	Randomized clinical trial of the efficacy of bupropion combined with nicotine patch in the treatment of adolescent smokers	2004	RCT	None	Q10 (RF10) Q11 (RF10)	USA	Clinical	Double	8 wk	26 wk	Examine the efficacy of bupropion combined with nicotine patch in smoking reduction and reduction maintenance among adolescent smokers	211	Pediatric/Young adults	Adolescents Currently smoked at least 10 cigarettes per d Had smoke for at least 6 mo Had made one or more failed attempts to quit smoking Score ≥ 10 on a modified version of the Fagerstrom Tolerance Questionnaire	Mean age (SD): Arm 1: 17.32 yr (0.73) Control Arm: 17.32 yr (0.80) Male: Arm 1: 69 Control Arm: 69 White: Arm 1: 45.63% Control Arm: 54.63% African-American: Arm 1: 1.94% Control Arm: 2.78% Hispanic/Latino: Arm 1: 13.59% Control Arm: 11.11% Native American: Arm 1: 1.94% Control Arm: 0%	103 (64)	Pharmacologic	Arm 1: Bupropion + nicotine patch Participants received 150 mg/d of bupropion sustained release and a nicotine patch. Participants who smoked > 15 cigarettes/d received a 21 mg patch during wk 1-4, 14 mg patch for wk 5-6; and 7 mg patch for wk 7-8. Participants who smoked between 10-15 cigarettes/d received a 14 mg patch for wk 1-6 and 7 mg patch for wk 7-8 Participants met weekly in groups for 45 min counseling session	108 (70)	Control Arm: Nicotine patch + placebo Participants received a placebo pill and a nicotine patch. Participants who smoked > 15 cigarettes/d received a 21 mg patch during wk 1-4, 14 mg patch for wk 5-6; and 7 mg patch for wk 7-8. Participants who smoked between 10-15 cigarettes/d received a 14 mg patch for wk 1-6 and 7 mg patch for wk 7-8 Participants met weekly in groups for 45 min counseling session	Primary: % Abstinent at wks 10 & 26 [%] Secondary: Cigarette consumption/d [g]	Primary: Wk 10: NP + Bup: 23% vs NP+Plac: 28% Wk 26: NP + Bup: 8% vs NP+Plac: 7% Secondary: With a random regression model, average cigarette consumption/d decreased significantly over the treatment interval but no main or interaction effects were detected.	NS NS S* for all subjects - no difference between groups	No difference between groups for AE reporting	There were no differences between groups for craving or depression on F.U.	An adolescent smoking cessation trial that compared nicotine patch + bupropion to nicotine patch + placebo showed no difference between groups. With a random regression model, average cigarette consumption/d decreased significantly over the treatment interval for all study participants with no intervention specific effects.	Q10,13. An adolescent smoking cessation trial that compared nicotine patch + bupropion to nicotine patch + placebo showed no difference between groups. However, with a random regression model, average cigarette consumption/d decreased significantly over the treatment interval for all study participants with no intervention specific effects.	
15301658	Killen JD	Randomized clinical trial of the efficacy of bupropion combined with nicotine patch in the treatment of adolescent smokers	2004																										
15805342	Moolchan ET	Safety and efficacy of the nicotine patch and gum for the treatment of adolescent tobacco addiction	2005	RCT	None	Q10,13(RF10)	USA	Clinical	Double	3 mo	6 mo	Determine the safety and efficacy of the nicotine patch and gum for adolescents who want to quit smoking	120	Pediatric/Young adults	13-17 yr Smoke ≥ 10 cigarettes per d (CPD) for ≥ 6 mo Score ≥ 5 on the Fagerstrom Test of Nicotine Dependence Motivated to quit smoking (≥ 5 on a 10-point integer scale) Exclusions: Use of other tobacco products Current use (within past 30 d) of medication for smoking cessation (e.g., NRT or bupropion)	Mean age (SD): 15.2 yr (1.33) Arm 1: 34 (18) Arm 2: 46 (19) Male: 30% White: 72.5% Pacific Islander/Filipino: Arm 1: 8.74% Control Arm: 3.7% Asian: Arm 1: 6.80% Control Arm: 7.41% Multi-ethnicities: Arm 1: 21.36% Control Arm: 17.59% Unknown race/ethnicity: Arm 1: 0% Control Arm: 2.78%	40 (16)	Pharmacologic	Arm 1: Nicotine replacement patch + placebo gum (GUM) Participants received an active 21-mg or 14-mg nicotine patch. Participants weighing < 100 lbs (45 kg) and smoking < 20 CPD at baseline received the 14-mg patch Arm 2: Nicotine replacement gum + placebo patch (PATCH) Participants were told to use the gum as needed, with the approximate goal of using 1 half their baseline reported CPD values in numbers of pieces of gum. Participants smoking ≤ 24 CPD used 2 mg gum and those smoking > 24 CPD used 4 mg gum. Participants in Arm 1 and Arm 2 attended a 45-min cognitive behavioral group therapy session at the end of each treatment visit	Control Arm: Placebo (CON) Participants received a placebo patch and placebo gum Participants attended a 45-min cognitive behavioral group therapy session at the end of each treatment visit	Primary: CO-confirmed prolonged abstinence at 3 mo [%] Prolonged CO-confirmed abstinence [OR (95% CI)] Self-reported change in cigarettes/d [%] Secondary: Change in CO level [%] Change in saliva thiocyanate level [%]	Primary: PATCH: 18% vs GUM: 6.5% vs CON: 2.5% PATCH: 17.7% vs GUM: 6.5% vs CON: 2.5% PATCH: OR= 6.84(0.89,20.1) GUM: OR=2.72(0.27,27.3) PATCH: -80.4(7.52); GUM: -85.1(5.13); CON: -89.6(4.98) Secondary: No change No change	PATCH vs CON: S; GUM vs CON: NS PATCH vs CON: S; GUM vs CON: NS p=0.055 NS S from BIL for all 3 groups; no difference by treatment grp. NS NS	No biological safety measurements. No major AEs reported.	Compliance for the patch was much higher than for the gum.	A smoking cessation intervention showed that the nicotine patch was significantly more effective than placebo in assisting dependent adolescent smokers receiving cognitive-behavioral therapy to quit smoking. However, neither biomarker of cigarette smoking declined during the trial. Nicotine gum was not beneficial in smoking cessation.	Q10,13. A smoking cessation intervention showed that the nicotine patch was significantly more effective than placebo in assisting dependent adolescent smokers receiving cognitive-behavioral therapy to quit smoking. However, neither biomarker of cigarette smoking declined during the trial. Nicotine gum was not beneficial in smoking cessation.		
15805374	Hollis JF	Teen reach: outcomes from a randomized, controlled trial of a tobacco reduction program for teens seen in primary medical care	2005	RCT	None	Q11 (RF10) Q13 (RF10)	USA	Clinical	None/NR	Arm 1: 35.5 min Control Arm: 5 min	2 yr	Test the long-term efficacy of brief counseling plus a computer-based tobacco intervention for teens being seen for routine medical care	2,526	Pediatric/Young adults	14-17 yr 14 yr: 674 15 yr: 650 16 yr: 637 17 yr: 565 Male: 1,028 Black: 118 Asian/Pacific Islander: 93 Hispanic/Latino: 118 Native American/Alaskan Native: 53 White: 1,962 Other: 164	1254 (1074)	Behavioral	Arm 1: Teen Reach intervention (N1) Intervention consisted of a 30-60 sec message from primary care clinicians to encourage teens to quit smoking or not to start, a 10-12-min session using the Pathways to Change (PTC) interactive computer program, and 3-5 min post PTC motivational counseling. Participants also received 2 10-min booster sessions with PTC and counseling during the next 11 mo	1272 (1143)	Control Arm: Diet intervention (CON) Health counselors provided 3-5 min of motivational counseling to promote increased consumption of fruits and vegetables	Primary: Smoke-free at 1 & 2 y FU [%;OR, 95% CI] Secondary: Nonsmokers at baseline who remained smoke-free [OR (95% CI)] Experimenters at baseline who were smoke-free [OR (95% CI)] Smokers at baseline who were smoke-free [OR (95% CI)]	Primary: Y1: INT: 77.2% vs CON: 72.8% OR: 1.27(1.08,1.51) Y2: INT: 72.8% vs CON: 68.6% OR: 1.23(1.03,1.47) Secondary: Y1: INT: 90.8% vs CON: 87.9% OR: 1.37(1.01,1.85) Y2: INT: 88.8% vs CON: 83.1% OR: 1.25(0.97,1.61) Y1: INT: 46.4% vs CON: 50.0% OR: 0.80(0.40-1.60) Y2: INT: 49.7% vs CON: 48.7% OR: 0.95(0.97-1.61) Y1: INT: 28.4% vs CON: 13.8% OR: 2.45(1.43-4.20) Y2: INT: 23.9% vs CON: 11.4% OR: 2.42(1.40-4.16)	S S S NS NS S S	None	Among smokers, the tobacco intervention was statistically more effective than placebo in assisting dependent adolescent smokers receiving cognitive-behavioral therapy to quit smoking. Results are all self-reported with no biological measure of smoking status.	A smoking cessation intervention based on brief provider counseling plus a computer-based program in teens in primary care practice achieved significantly higher self-reported smoking abstinence rates after 1 and 2 yrs. Treatment effects were strong among BIL smokers but not among non-smokers or self-described experimenters.	Q10,13.13. A smoking cessation intervention based on brief provider counseling plus a computer-based program in teens in primary care practice achieved significantly higher self-reported smoking abstinence rates after 1 and 2 yrs. Treatment effects were strong among BIL smokers but not among non-smokers or self-described experimenters.		
15847627	Hamilton G	A school-based harm minimization smoking intervention trial: outcome results	2005	RCT	None	Q10,13 (RF10)	Australia	Community (schools)	None/NR	2 yr	2 yr	Determine the impact of a school-based harm minimization smoking intervention compared to traditional abstinence-based approaches	4,636 (30 schools)	Pediatric/Young adults	9th grade students 13-14 yr	Mean age: 13.6 yr Male: 2,167	2035 (NR) 14 schools (14 schools)	Behavioral	Arm 1: The Smoking Cessation for Youth Project (N1) Intervention schools were provided with classroom, school nurse and parental harm minimization intervention materials and training in accordance with the Health Promoting Schools Model. Intervention consisted of a total of 8 1-hr interactive activities, brief counseling strategies based on motivational interviewing by school nurses, and school policy development to address smoking as a health issue	2,601 (NR) 16 schools (16 schools)	Control Arm: Standard "usual" intervention (CON) Participants received standard "usual" intervention available to all Western Australian schools that included abstinence-based, smoking education program provided by the government funded drug education project. Activities included 7 1-hr activities addressing cigarette smoking based on social influences approach	Primary: Regular smoking [%;OR(CJ)] Smoking in the previous 30 d [%;OR(CJ)]	Primary: INT: 3.0% to 5.0% vs CON: 4.4% to 10.9% OR=0.51(0.35,0.71) INT: 20.4% to 13.9% vs CON: 25.3% to 21.2%. OR=0.69(0.53,0.91)	S S		There is evidence of a dose-response relationship with students who received more of the harm minimization intervention less likely to smoke regularly.	A school-based harm minimization intervention for adolescents lasting 2 yrs was effective at assessment immediately after completion of the program in decreasing self-reported regular smoking and smoking in the last 30 days. There were no biologic measure of smoking status.	Q10,13. A school-based harm minimization intervention for adolescents lasting 2 yrs was effective at assessment immediately after completion of the program in decreasing self-reported regular smoking and smoking in the last 30 days. There were no biologic measure of smoking status.	
15893085	Coby SM	Brief motivational intervention for adolescent smokers in medical settings	2005	RCT	None	Q10 (RF10)	USA	Clinical	Single	NR	6 mo	Evaluate the efficacy of using a brief motivational intervention to reduce smoking among adolescent patients treated in a hospital outpatient clinic or Emergency Department	85	Pediatric/Young adults	12-19 yr Reported daily smoking for the prior 30 d	Mean age (SD): 16.3 yr (1.5) Male: 25 White: 55% Hispanic: 22% Black/African American: 12%	Arm 1: 43 (NR)	Behavioral	Arm 1: Motivational Interviewing (MI) (N1) MI protocol included 6 sections: establishing rapport, exploring pros and cons, personalized feedback, imagining the future, setting goals, and increasing self-efficacy. One wk after the intervention, participants received a booster call from interventionists for a 16-20 min follow-up where they reinforced the MI. Participants received a pamphlet and list of local treatment referrals and were also given the feedback sheet, goal sheet, and information about strategies for quitting and coping with withdrawal	Control: 42 (NR)	Control: Brief advice (CON) The brief advice condition included interventionists stating to the participants that "quitting smoking is the most important thing you can do to protect your current and future health. We recommend that you quit smoking as soon as possible" and being provided a pamphlet and list of local treatment referrals. Participants received a call to remind them of their 1-mo interview	Primary: Self-reported 7-d abstinence rates [% (Chi square)] Mean cigarettes per d [g (SD)] Biochemically confirmed 7-d abstinence [% (Chi square)] Mean change in cotinine levels [ng/ml (SD)]	Primary: INT: 1m 5% CON: 0% 3m 5% CON: 0% 6m 23% CON: 3% Both groups decreased from BIL from 9.9(6.8) to 7.9(5.9) at 1m, 7.1(5.1) at 3m and 6.1(4.3) at 6 m. INT: 1m 2% CON: 0% 3m 5% CON: 0% 6m 9% CON: 2% For both groups combined, cotinine decreased from BIL: 222.0(181.8) to 215.7(174.9) at 1m and 185.2(155.7) at 6m. 3m: INT: 243.3(253.1) to 179.8(152.7) CON: 209(148) to 221.3(140.6)	NS NS NS S** at each time period NS NS NS NS at both time periods. S NS	None	Motivation to quit from pre- to post intervention showed a trend for a group by time effect (p=0.06)	In older adolescent smokers, a motivational intervention works better than brief advice in achieving smoking cessation but differences between groups with self-reporting were not confirmed biochemically. However, cotinine levels were down in both grps at 6 m FU.	Q10,13. In older adolescent smokers, a motivational intervention works better than brief advice in achieving smoking cessation but differences between groups with self-reporting were not confirmed biochemically. However, cotinine levels were down in both grps at 6 m FU.	

PMD	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question	
15025127	Huang M	Stages of smoking acquisition versus susceptibility as predictors of smoking initiation in adolescents in primary care	2005	RCT	None	Q13 (RF10)	USA	Clinical	None/NR	16 min	2 yr	Evaluate whether susceptibility, the stages of smoking acquisition, and socio-environmental factors can identify adolescents who will become smokers	1,955	Pediatric/ Young adults	14-17 yr Nonsmokers Receiving routine medical care Exclusions: Smokers	Age: 14 yr: 607 15 yr: 524 16 yr: 443 17 yr: 381 Male: 845 White: 1536 Nonwhite: 419	971 (NR)	Behavioral	Arm 1: Tobacco Intervention Participants received brief physician advice to not smoke (< 1 min), 10-min session with interactive computer program that delivered tobacco interventions individually tailored to teen's stage of smoking initiation/cessation, and a 5-min session with a health counselor. Two booster computer and counseling sessions were offered during the 11-mo after the visit	984 (NR)	Control Arm: 5 min nutrition session After the physician visit, participants saw a health counselor for 5-min motivational interview focused on nutrition	Primary: Susceptibility as a predictor of smoking according to integrated measure model [OR (95% CI)] Susceptibility as a predictor of smoking according to susceptibility and stages of acquisition model [OR (95% CI)] Contemplative stage as a predictor of smoking according to stages of acquisition model [OR (95% CI)] Contemplative stage as a predictor of smoking according to susceptibility and stages of acquisition model [OR (95% CI)] Preparation stage as a predictor of smoking according to stages of acquisition model [OR (95% CI)] Preparation stage as a predictor of smoking according to susceptibility and stages of acquisition model [OR (95% CI)]	Primary: OR=3.27(2.46,4.36) OR=2.16(1.56,3.00) OR=4.88(3.03,7.85) OR=3.13(1.88,5.22) OR=7.78(4.46,13.58) OR=4.86(2.69,8.76)	S S S S S	None	The intervention which combined a brief office counseling with computer-based follow-up showed no difference in smoking status between groups. This study analyzed the EIL demographic and susceptibility factors associated with subsequent initiation of smoking. A model assessing susceptibility has c statistic of 0.74 with increasing susceptibility making tobacco use more likely; usual predictors (education, peers, race and family) all significant but did not improve c statistic.	Analysis of psychological characteristics associated with smoking initiation identifies susceptibility and stages of behavior acquisition as significant predictors. This is important information for design of subsequent interventions.	Q13. Analysis of psychological characteristics associated with smoking initiation identifies susceptibility and stages of behavior acquisition as significant predictors. This is important information for design of subsequent interventions.	
15025127	Huang M	Stages of smoking acquisition versus susceptibility as predictors of smoking initiation in adolescents in primary care	2005	RCT																									
16389212	Jackson C	Enabling parents who smoke to prevent their children from initiating smoking: a 3 year intervention evaluation.	2006	RCT	None	Q13(RF10)	USA	Home	None	3y	3y	Evaluate the effects of a home-based anti-smoking socialization program on the initiation of smoking among children whose parents smoke	873	Pediatric/ Young Adults	Parents or guardians who had a child enrolled in 3rd grade (ages 7-8) Parents or guardians who reported current smoking Children who had never smoked	Male children: 47% White parents: 78% African American parents: 16% Hispanic parents: < 1% Native American parents: 2% Other/multi race/ethnicity parents: 2% Parent with < 8th grade education: 2% Parent with some high school: 6% Parent with high school degree or equivalent: 28% Parent with vocational or 2 yr college: 49% Parent with bachelor degree or higher: 16%	371	Behavioral	Arm 1: Smoke Free Kids Participants received 1 module every 2 wk for a total of 5 modules. The modules gradually increased parents' skills and comfort level in communicating with their children about their personal smoking history, addiction and expectations regarding abstinence. The intervention included a telephone call from a health educator, a toll-free number that parents were encouraged to use, parent newsletters, and newsletters for children	405	Control Arm: Fact based program Parents received 1 fact sheet every 2 wk. The fact sheets provided knowledge about youth smoking and focused parents' attention on macro-level variables relevant to youth smoking but not targeted by the treatment version of the program	Primary: Initiation of smoking [%adjusted OR(95%CI)] Primary: INT: 12% vs CON: 19% Adjusted OR: 2.16(1.39,3.37)	S**	None	In bivariate analysis, the smoking status of the child's friends had the strongest association with initiation of smoking (12% for children with no best friends who had tried smoking vs 29% for children who had 1 or more best friends who had tried smoking.	A parental education, support and behavior change program significantly reduced the likelihood that children of parents who smoke would initiate smoking by the 6th grade.	Q13. A parental education, support and behavior change program significantly reduced the likelihood that children of parents who smoke would initiate smoking by the 6th grade.		
16616449	Patten CA	Randomized clinical trial of an Internet-based versus brief office intervention for adolescent smoking cessation	2006	RCT	None	Q10 (RF10)	USA	Multi settings	None	4-24 wk (depending on treatment group assignment)	36 wk	Compare the efficacy of an office-based smoking cessation intervention and a home-based, internet-delivered smoking cessation intervention	139	Pediatric/ Young Adults	Smoked ≥ 10 cigarettes in the last 30 d Use cigarettes as primary tobacco product	Mean age (SD): 15.7 yr (1.3) Male: 70 Caucasian: 88% American Indian: 4% Hispanic: 3%	Arm 1: 69 (42%) Arm 2: 70 (53%)	Behavioral	Arm 1: Clinic-based smoking cessation intervention (BOI) 4 weekly, individual motivational interviewing sessions intended to enhance self-efficacy or expectations for success First session was 30-40 min in duration and each of the remaining 3 sessions were 10-20 min each in duration Weekly homework assignments and support towards establishing a personal stop date and self-rewards Arm 2: Home-based, Internet-delivered smoking cessation intervention (SOS) Given access to the Stomp Out Smokes (SOS) program and the Internet for 24 wk without significant in-person contact with research staff	N/A	N/A	Primary: Mean smoking abstinence rate [% (95% CI)] Secondary: Mean reduction in # of cigarettes smoked/d [SD] Mean reduction in number of smoking days [% (SD)]	Primary: WEEK 24: BOI - 12% (CI: 5, 22%) vs SOS - 6% (CI: 2, 14%) Secondary: WEEK 24: BOI - 26.8 +/- 43.6 vs SOS - 33.8 +/- 46.6 WEEK 24: BOI - 14.6 +/- 34.4 vs SOS - 19.6 +/- 36.0	NS NS NS	None reported	Among smokers, SOS participants significantly reduced their smoking days vs BOI.	A home-based Internet-delivered smoking cessation intervention was ineffective for adolescent smoking cessation with abstinence rates slightly higher among participants receiving the office-based counseling intervention.	Q10. A home-based Internet-delivered smoking cessation intervention was ineffective for adolescent smoking cessation with abstinence rates slightly higher among participants receiving an office-based counseling intervention.	
16616449	Patten CA	Randomized clinical trial of an Internet-based versus brief office intervention for adolescent smoking cessation	2006																										
1682858	Pbert L	A school nurse-delivered adolescent smoking cessation intervention: a randomized controlled trial	2006	RCT	None	Q10 (RF10)	USA	Community (schools)	None	1 mo	3 mo	Evaluate the efficacy of a school nurse-delivered smoking cessation intervention to improve abstinence rates among adolescents interested in quitting	71 schools	Pediatric/ Young Adults	Adolescents in participating high schools who reported using tobacco, including cigarettes, cigars, bidies and smokeless tobacco, on at least 1 d in the past 30 d and were interested in quitting in the next 2 wk	Mean age (SD): Arm 1: 16.8 yr (1.1) Control Arm: 16.9 yr (1.1) Male: Arm 1: 39% Control Arm: 36% White: Arm 1: 30% Control Arm: 86% Black: Arm 1: 2% Control Arm: 2% Hispanic: Arm 1: 6% Control Arm: 10%	571 (NR) 37 schools (NR)	Behavioral	Arm 1: One-on-one smoking cessation program 4 counseling sessions delivered by a school nurse based on the 5A (ask, advice, assess, assist, arrange) intervention model and individualized to the thoughts, behaviors and preferences of the participant The intervention allowed for additional sessions at the nurse's discretion	577 (NR) 34 schools (NR)	Control Arm: Usual smoking cessation care	Students reporting quitting [% (95% CI)] Students smoking ≤ 10 cigarettes/d [% (95% CI)] Mean days smoked in the last 30 days [n (SD)]	INT 18% CON 2% 6 wks: OR=6.4(CI:3.7,20.6) 3 m: OR=6.4(CI:3.4,11.4) INT 79% CON 63% 6 wks: OR=2.6(CI:1.9,3.6) 3 m: OR=3.5(CI:2.5,5.1) INT 15.2(12.2) CON 23.8(9.1)	S** at 6 wks & 3 mos. S** at 6 wks & 3 mos. S** at 6 wks & 3 mos.	None reported	In adolescent smokers who report wanting to quit within 2 wks, a school nurse-delivered 4 session cessation intervention was highly effective. Results are compromised by self-reported smoking status.	Q10. In adolescent smokers who report wanting to quit within 2 wks, a school nurse-delivered 4 session cessation intervention was highly effective. Results are compromised by self-reported smoking status.		

PMD	First Author	Title	Year	Study Type	CVD	RF by CQ	Country	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N	Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baseline (n at Follow-up)	Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CJ	Significance	Safety and Adverse Events	Additional Findings	Summary	Main Reported Findings by Critical Question
16920183	Kelly AB	The HYP program-targeted motivational interviewing for adolescent violators of school tobacco policy	2006	RCT	None	Q10 (RF10)	Australia	Community (schools)	None	1 h	6 mo	Evaluate the efficacy of a short-term tobacco-focused intervention for high school students referred by school administrators because of tobacco use	56 (3 schools)	Pediatric/ Young Adults	14-16 yr Detected smoking tobacco by school administrators or teachers	Mean age (SD): 15 yr (1.0) Male: 66% Mean 7-point Likert scale for SES (SD): SES of father: 2.1 (1.6) SES of mother: 1.6 (1.5)	Arm 1: 30 (24) Arm 2: 26 (18)	Behavioral	Arm 1: Motivational interview (MI) Focused on ambivalence and indifference, the personal meaning of smoking in participants' lives, the positives and negatives of smoking/quitting, the impact of smoking on self-concept, health goals, and identification of obstacles to goal attainment Reading materials were provided but were not reviewed during the session Arm 2: Standard care (SC) Session was based on a psychoeducation model Reviewed published reading materials to educate participants on the broad effects of smoking regardless of personal experience Participants were given a smoking "quit kit"	N/A	N/A	Mean smoking days [IQR] (SD) Mean cigarettes smoked [cigarettes/wk] (SD) Mean smoking refusal self-efficacy (SD) Rate of abstinence [%]	BL: 1mo 3mo 6mo M: 6.6(1.4) 4.8(3.0) 4.7(3.0) 4.6(3.1) SC: 5.7(2.3) 5.5(2.7) 5.2(2.8) 5.8(2.3) M: 52(40) 28(34) 42(47) 42(45) SC: 48(43) 57(52) 51(46) 57(46) M: 89(24) 99(29) 108(32) 109(37) SC: 94(36) 99(36) 89(40) 91(40) M: - 20% 20% 23% SC: - 15% 15% 12%	By group: NS. By time: S*. GroupXTime: S By group: NS. By time: NS. GroupXTime: S By group: NS. By time: S*. GroupXTime: S NS at any time	N/A	All results are self-reported. 25% of subjects dropped out of the study before completion.	In adolescents, a motivational interviewing approach resulted in modest short term gains in self-reported smoking and improved cigarette refusal self-efficacy relative to standard care.	Q10. In adolescents, a motivational interviewing approach resulted in modest short term gains in self-reported smoking and improved cigarette refusal self-efficacy relative to standard care.
16998171	Roddy E	Use of nicotine replacement therapy in socioeconomically deprived young smokers: a community-based pilot randomized controlled trial	2006	RCT	None	Q10 (RF10)	UK	Community (other)	Double	6 wk	13 wk	Determine whether nicotine replacement therapy (NRT) when combined with counseling is effective in young smokers in a deprived inner city area of Nottingham, UK	98	Pediatric/ Young Adults	14-20 yr and able to consent 12-14 yr and parental consent > 1 cigarette per d (cpd) < 1 cpd but past or anticipated withdrawal Carbon monoxide validation > 5 ppm Exclusions: Age < 12 or > 20 yr Self-reported non-smoker	Mean age: Arm 1: 14.9 yr Control Arm: 14.7 yr Male: Arm 1: 36% Control Arm: 44%	49 (3)	Pharmacologic	Arm 1: Nicotine Replacement Therapy (NT) Participants received NRT of 15 mg at wk 0-2, 10 mg at wk 3-4, and 5 mg at wk 5-6. All subjects also received 10-15 min one-on-one or small friendship group counseling on a weekly basis	49 (5)	Control Arm: Placebo (CON) All subjects also received 10-15 min one-on-one or small friendship group counseling on a weekly basis CO validated point abstinence at 4 wk CO validated point abstinence at 13 wk	Primary: Median exhaled CO [ppm] CO validated point abstinence at 4 wk CO validated point abstinence at 13 wk Primary: INT: 12.9 vs CON: 11.8 INT: 5.49 vs CON: 4.49 INT: 0.49 vs CON: 0.49	NS NS NS	None	High dropout rate with median duration in the trial of only 1 week; 63/98 participants never returned for any FU. However, self reported use rates fell in the community and youth were interested in quitting and in health advice but could not comply with treatment.	A smoking cessation trial comparing nicotine replacement therapy to placebo in socially deprived adolescents with a baseline smoking rate of 49% was unsuccessful with very high drop-out rates and no smoking abstinence at 13 wk FU.	Q13. A smoking cessation trial comparing nicotine replacement therapy to placebo in socially deprived adolescents with a baseline smoking rate of 49% was unsuccessful with very high drop-out rates and no smoking abstinence at 13 wk FU.	
18381502	Pbert L	Effect of a pediatric practice-based smoking prevention and cessation intervention for adolescents: a randomized, controlled trial	2008	RCT	None	Q10.11 (RF10)	USA	Clinical	NR	21 wk	12 mo	Determine whether a pediatric practice-based smoking prevention and cessation intervention increases abstinence rates among adolescents.	2,711	Pediatric/ Young Adults	Adolescents aged 13 - 17 y	UC: 52.9% F 91.2% W 2.0% B 69.5% Never smoked 10.6% Smoke now 15.9% Dad smokes 15.4% Mom smokes 7% Sibling smokes 41.3% No smoking friends INT: 55.4% F 91.6% W 4.0% Hispanic 1.5% B 71.4% Never smoked 8.7% Smoke now 15.4% Dad smokes 17.0% Mom smokes 6.2% Sibling smokes 39.5% No smoking friends	1,346 (1,344)	Behavioral	Provider- and peer-delivered smoking intervention Trained providers asked about smoking, advised cessation or continued abstinence, and referred the patient to a peer counselor for tailored cessation strategy. 15- to 30-minute meeting with trained peer counselors immediately following the provider session, followed by 15-minute follow-up phone calls after 2, 6, 12, and 21 wk.	1,365 (1,365)	Usual care; providers received no training and no materials to provide to patients.	Smoking status: Smoking abstinence Prevention: (Non-smokers at BL): INT vs CON: 6 m FU (OR 2.15 [CI: 1.12-4.15]); 12 m FU (OR 1.64 [CI: 1.01, 2.67]) Cessation: (Smokers at BL): INT vs CON: 6 m FU (OR 1.59 [1.06-2.40]); 12 m FU No difference between ggps Abstinence was predicted by INT exposure & more physician visits, decreased by older age and having more friends who smoked at baseline.	S** S** S* NS	None	98.2% reported that the intervention was helpful & 93.8% found it interesting.	A smoking prevention and cessation intervention can be feasibly delivered in pediatric practices and can prevent initiation of smoking for > 1 y and improve abstinence rates among smokers for > 6 m.	Q 10.11. A smoking prevention and cessation intervention can be feasibly delivered in pediatric practices and can prevent initiation of smoking for > 1 y and improve abstinence rates among smokers for > 6 m.	