

SUPPLEMENTARY MATERIALS

Appendix A: Selection Criteria

Table 1: Inclusion and exclusion criteria for article selection

Inclusion Criteria	Exclusion criteria
Randomized controlled trial	Secondary analysis or study protocol
Low socio-economic status*	Not homeless, low SES or low income
Tobacco dependence intervention – end point is quitting tobacco smoking	Not a tobacco dependence intervention, smoking cessation of participant is not end point
Adults, tobacco dependant	Not adults
Outpatients	No abstract or article available
Full-text	Non full-text
English language only	Non English language
Minimum six-month outcome	Less than a six-month outcome

* Low socio-economic status was defined as any of the following key words: homeless, vulnerable, marginalized, poverty, unemployment, low-income, low socioeconomic status, and food insecurity

Appendix B: Search Strategy

Summary of Key words used

- Smoking cessation, smoking cessation program Tobacco, smoking, cigarette, cessation, quit, dependence
- Vulnerable Populations, Homeless Persons, vulnerable or marginalized, social marginalization, low socio-economic, poverty, unemployment, low income, minority or minorities, underserved or disadvantaged, Food Supply, food insecure, Ethnic Groups
- Randomized controlled trial, clinical trial, random, placebo, adults, no animals, no adolescent

Medline

1. "tobacco use cessation"/ or smoking cessation/
2. "Tobacco Use Disorder"/dt, pc, th
3. exp "Tobacco Use"/dt, pc, th or "smoking"/pc, th, dt
4. ((smoking or tobacco or cigarette\$) adj3 (cessation or quit\$)).tw,kf.
5. exp "Tobacco Use Cessation Products"/
6. (("tobacco use" or tobacco dependence or smoking or cigarette\$) adj management).tw,kf.
7. or/1-6
8. Vulnerable Populations/
9. Homeless Persons/
10. (vulnerable or marginali\$).tw,kf.
11. (sensitive adj (population\$ or group\$)).tw,kf.
12. homeless\$.tw,kf.

13. minority groups/ or social marginalization/ or socioeconomic factors/ or poverty/ or poverty areas/ or Unemployment/
14. low income.tw,kf.
15. (minority or minorities).tw,kf.
16. poverty.tw,kf.
17. low socioeconomic.tw,kf.
18. (underserved or disadvantaged).tw,kf.
19. Food Supply/
20. food insecur*.tw,kw.
21. Raciali?ation.tw,kw.
22. exp Ethnic Groups/
23. (ethnic* or ethnocultural or ethno cultural).tw,kw.
24. ("at risk" adj2 (communit* or people or population* or person* or group*)).tw,kw.
25. or/8-24
26. 7 and 25
27. randomized controlled trial.pt.
28. controlled clinical trial.pt.
29. random*.tw.
30. placebo.ab.
31. clinical trials as topic.sh.
32. trial.ti.
33. or/27-32
34. animals/ not humans/
35. 33 not 34
36. 26 and 35
37. adolescent/ not exp adult/
38. 36 not 37

Appendix C: Summary of Included Articles

Table 2. Descriptive Summary of Included Articles

Author(s)	Country	Project site ^a	Number of study arms	Mean age (years)	Men n(%)	Race n(%)	Average Income/year (\$USD) ^d	Average # of cigarettes/day	Total # randomized	Intervention Component(s) ^b	Frequency/duration of Intervention	Control Component(s) ^b	Tobacco Smoking Outcome	Bio-chemical verification	Intervention Tobacco Smoking Quit rate (%)
Froelicher et al., 2010	USA	CB	Two	46.6	17(28.3%)	Black: 60(100%)	<\$15,000	11.3	60	1. Group counseling (in-person) 2. Individual counseling (telephone) 3. Social Capital (in-person) 4. Non-formal education (in-person) 5. Pharmacotherapy 6. Compensation (Honorarium)	Weekly for 5 weeks	1. Group counseling (in-person) 2. Individual counseling (telephone) 3. Non-formal education (in-person) 4. Pharmacotherapy 5. Compensation (Honorarium)	7-day point prevalence (6-and 12-months)	Yes	6M: 13.5 12M:15.7
Andrews et al., 2016	USA	CB	Two arm RCT	42.3	0	Black: 385(94%) Other: 60 (14.6%)	<\$20,000	12.7	409	1. Social Capital (in-person) 2. Group counseling (in-person) 3. Social support (peer) 4. Pharmacotherapy (in-person)F 5. Compensation (honorarium)	24 weeks	1. Non-formal education (in-person) 2. Compensation (Honorarium)	7-day point prevalence (6- and 12-months)	Yes	6M: 10 12M:12
Brooks et al., 2017	USA	CP	Two arm RCT	<40	66(26.4%)	Caucasian: 46(18.4%) Black: 150(60%) Hispanic: 54(21.6%)	Unclear	<10	250	1. Social support (peer) 2. Enhanced individual counseling (in-person, telephone) 3. Pharmacotherapy 4. Non-formal education (in-person, printed) 5. Compensation (honorarium)	9 sessions over 6 months	1. Individual counseling (in-person) 2. Pharmacotherapy 3. Non-formal education (in-person, printed)	7-day point prevalence (12-months)	Yes	16.5
McBride et al., 2002	USA	CP	Two arm RCT	44.5	223(40%)	Black: 557(100%)	Unclear	15.5	557	1. Biomarker feedback 2. Individual counseling (telephone) 3. Pharmacotherapy 4. Non-formal education (printed) 5. Compensation (contingency management)	10 weeks	1. Brief quit advice 2. Pharmacotherapy 3. Non-formal education (printed)	7-day point prevalence (6- and 12-months)	Yes	6M: 19 12M:14
Alaniz et al., 2020	USA	CP	Two arm RCT	28.5	0	Caucasian: 58(31.3%) Black: 101 (55%) Other: 26 (14.3%)	<\$10,000	Unclear	185	1. Social Capital (in-person) 2. Non-formal education (in-person) 3. Individual counseling (in-person, telephone) 4. Compensation (honorarium, contingency management)	4 sessions over 6 months	1. Individual counseling (in-person, telephone) 2. Compensation (honorarium)	Smoking abstinence at 6-months post-partum	Yes	36.6
Bonevski et al., 2018	Australia	CP	Two arm RCT	38	220(51%)	Indigenous: 74(17%) Other:357(83%)	<\$10,000	15	431	1. Brief quit advice 2. Individual counseling (in-person and telephone) 3. Pharmacotherapy 4. Branded quit gifts	5 sessions	1. Brief quit advice 2. Telephone quit hotline 3. Branded quit gifts	7-day point prevalence (6-months)	Yes	1
Brunette et al., 2017	USA	CP	Three arm RCT	45	236(36%)	Caucasian: 610 (93%) Other: 51(7%)	<\$16,000	17.3	661	1. Non-formal education (multi-media)	12 sessions	1. Brief quit advice 2. Pharmacotherapy	7-day point prevalence(Yes	6M: 16 ^e 12M: 12.5 ^e

										2. Individual counseling (telephone) 3. Pharmacotherapy 4. Compensation (honorarium)		3. Compensation (Honorarium)	6-and 12-month)		
Lasser et al., 2017	USA	I	Two arm RCT	50	161(46%)	Caucasian: 79(22%) Black: 197(56.2%) Hispanic: 40(11%) Other: 36(10%)	<\$20,000	15	352	1. Individual counseling (in-person, telephone) 2. Compensation (honorarium) 3. Non-formal education (printed) 4. Pharmacotherapy	4 hours over 6 months	1. Brief quit advice 2. Non-formal education (printed)	6-and 12-month smoking abstinence	Yes	6M:9.6 12:11.9
Okuyemi et al., 2013	USA	CP	Two arm RCT	44	321(74.7%)	Caucasian: 153(35.5%) Black: 242(56.2%) Hispanic: 10(2.3%) Indigenous: 10(2.3%) Other: 14(3.2%)	<\$10,000	19.3	430	1. Individual counseling (in-person) 2. Non-formal education (printed) 3. Pharmacotherapy 4. Compensation (honorarium)	6 sessions, 15-20 mins each	1. Brief quit advice 2. Non-formal education (printed) 3. Pharmacotherapy 4. Compensation (Honorarium)	7-day point prevalence (6-months)	Yes	9.3
Okuyemi et al., 2007	USA	CP	Two arm RCT	45.5	52(30.1%)	Caucasian: 18(10.4%) Black: 143 (93%) Hispanic: 5(2%) Other: 6(3%)	<\$10,000	17.5	173	1. Pharmacotherapy 2. Non-formal education (multimedia, printed) 3. Individual counseling (in-person, telephone) 4. Compensation (honorarium)	5 sessions over 20 weeks	1. Individual counseling (in-person, telephone) 2. Fruits & Vegetables education (multi-media) 3. Compensation (Honorarium)	7-day point prevalence (6-months)	Yes	7.6
Bock et al., 2014	USA	I	Two arm RCT	39.6	264(31.2%)	Caucasian:447(52%) Black:111(13.1%) Hispanic:198(23.4%) Other:90(10.6%)	Unclear	Unclear	846	1. Brief quit advice (in-person) 2. Individual Counseling (telephone) 3. Pharmacotherapy	3 sessions	1. Brief quit advice (in-person) 2. Pharmacotherapy	7-day point prevalence (6- and 12-months)	Yes	6M: 24 12M: 29
Bullock et al., 2009	USA	I	Four arm RCT	22	0	Caucasian: 630(91%) Black: 24(3.5%) Hispanic: 12(1.7%) Asian: 2(0.3%) Indigenous: 10(1.4%) Other: 17(2.5%)	Unclear	Unclear	695	1. Social support (telephone) 2. Non-formal education (printed) 3. Compensation (Honorarium)	Weekly for 8 months	1. Social support (telephone) 2. Or Non-formal education (printed) alone	Point prevalence (32 weeks gestation and 6-weeks post-delivery)	Yes	32 weeks: 17 Post delivery: 12.5
Coleman-Cowger et al.,2018	USA	I	Two arm RCT	26	9	Caucasian: 20(15.6%) Black: 103(80.6%) Other: 5(3.9%)	Unclear	8.6	128	1. Individual counseling (telephone) 2. Non-formal education (telephone, printed) 3. Compensation (honorarium)	10 calls over 6 months	1. Telephone quit hotline 2. Compensation (honorarium)	7-day point prevalence (6-months post-partum)	Yes	24
Curry et al., 2003	USA	I	Two arm RCT	34	0	Caucasian: 100(33%) Black: 190(62.7%) Hispanic: 13(4.3%)	<\$10,000	12.1	303	1. Individual counseling (in-person, telephone) 2. Non-formal education (printed) 3. Compensation (honorarium)	3 sessions	Unclear	7-day point prevalence (12-months)	Yes	14
Fraser et al. 2017	USA	I	Two arm RCT	45	760(40%)	Caucasian: 783(41.2%) Black: 973(51.2%) Hispanic: 76(4%) Asian: 4(0.02%) Indigenous: 34(1.8%) Other: 74(3.9%)	Unclear	17.2	1,900	1. Individual counseling (multi-media, telephone) 2. Non-formal education (telephone, printed) 3. Compensation (contingency management)	5 sessions	1. Individual counseling (multi-media, telephone) 2. Non-formal education (telephone, printed)	7-day point prevalence (6-months)	Yes	21.6
Fu et al., 2016	USA	Virtual	Two arm RCT	unclear	657(27.3%)	Caucasian:1885(78.4%) Black:256(10.6%) Hispanic: 42(1.8%) Indigenous: 167(6.9%)	<\$10,000	13.6	2406	1. Individual counseling (telephone) 2. Pharmacotherapy 3. Non-formal education (printed)	Unclear	Usual care	6-month smoking abstinence (12-months)	No	16.5

Gielen et al., 1997	USA	I	Two arm RCT	23.5	0	Black: 209(85%) Other: 37(15%)	Unclear	8.6	246	1. Individual counseling (in-person, telephone) 2. Non-formal education (printed, telephone) 3. Social support	1 session (15 mins)	Usual care	6-month post-partum smoking abstinence	Yes	6.2
Lepore et al., 2018	USA	I	Two arm RCT	33.3	53.9(16.5%)	Black: 271(83%)	Unclear	11.5	327	1. Individual counseling (telephone) 2. Pharmacotherapy 3. Non-formal education (in-person, printed)	5 sessions over 12 weeks	1. Non-formal education (in-person, printed) 2. Individual counseling (telephone, nutrition-focused)	7-day point prevalence (12-months)	Yes	15.2
Marks & Sykes et al., 2002	UK	I	Two arm RCT	Unclear	94(26.2%)	Unclear	Unclear	25	260	1. Group counseling (in-person, multi-media) 2. Non-formal education (multi-media, in-person) 3. Pharmacotherapy	10 sessions over 3 months	1. Brief quit advice 2. Non-formal education (multi-media, in-person)	7-day point prevalence (12-months)	Yes	17.2
McClure et al., 2018	USA	I	Two arm RCT	44.3	274(38.2%)	Caucasian: 419(58.4%) Black: 208.9 (29.1%) Other: 89.7(12.5%)	<\$20,000	19.1	718	1. Individual counseling (telephone, multi-media) 2. Non-formal education (multi-media, telephone, printed) 3. Pharmacotherapy	16 text messages, 5 counseling sessions	1. Non-formal education (multi-media, telephone, printed) 2. Pharmacotherapy	7-day point prevalence (6-months)	No	30.3
Okuyemi et al., 2006	USA	CB	Two arm RCT	43.8	28(60.8%)	Caucasian: 14(31.3%) Black: 29(62.1%) Other: 3(6.6%)	<\$10,000	15.3	46	1. Individual counseling (in-person) 2. Group counseling (in-person) 3. Pharmacotherapy 4. Compensation (honorarium)	5 sessions over 20 weeks	1. Individual counseling (in-person) 2. Group counseling (in-person) 3. Pharmacotherapy	7-day point prevalence (6-months)	Yes	17.4
Rash et al., 2018	USA	CP	Two arm RCT	45	52(74%)	Caucasian: 34(49%) Black: 25(36%) Hispanic: 15(21%) Other: 11(16%)	unclear	15.4	70	1. Individual counseling (in-person) 2. Pharmacotherapy 3. Compensation (contingency management)	4 sessions over 24 weeks	1. Individual counseling (in-person) 2. Pharmacotherapy	4-week smoking abstinence (6-months)	Yes	10
Resenicow et al., 1997	USA	CP	Two arm RCT	45	577(50%)	Black: 1244(100%)	<\$5,000	15.9	1244	1. Individual counseling (telephone, multi-media) 2. Non-formal education (multi-media, printed) 3. Non-medical cessation aids	6 months	1. Non-formal education (multi-media, printed)	6-month smoking abstinence	No	8.9
Solomon et al., 2000	USA	I	Two arm RCT	33	0	Caucasian: 193(90%) Other: 21(0.09%)	\$12,806	23	214	1. Individual counseling (telephone) 2. Pharmacotherapy 3. Compensation (Financial incentive)	Weekly to bi-weekly calls for 3 months	1. Pharmacotherapy	6-month smoking abstinence	Yes	20
Sykes et al., 2001	UK	I	Two arm RCT	Unclear	140(35%)	Unclear	Unclear	25	214	1. Group counseling (in-person, telephone) 2. Non-formal education (multimedia, printed) 3. Pharmacotherapy	3 months	1. Non-formal education (printed)	6-month smoking abstinence	Yes	17.2
Lipkus et al., 1999	USA	I	Three arm RCT	unclear	77(48%)	Black: 160(100%)	Unclear	<11	160	1. Individual counseling (telephone) 2. Non-formal education (telephone, printed)	1-2 calls for 1 year	1. Brief quit advice (in-person) 2. Non-formal education (telephone, written)	16-month smoking abstinence	No	13.2
Gritz et al., 2013	USA	CP	Two arm RCT	44.7	331(70%)	Caucasian: 59(12.4%) Black: 361(76.2%) Hispanic: 43(9.1%) Other: 11(2.3%)	Unclear	19.1	474	1. Individual counseling (telephone) 2. Non-formal education (printed)	Unclear	1. Non-formal education (printed)	7-day point prevalence (12-months)	Yes	20

Baker et al., 2018	USA	I	Two arm RCT	26	0	Caucasian: 466(46%) Black: 385 (38%) Hispanic: 51(5%) Asian: 5(0.05%) Indigenous: 15(1.5%) Other: 19(1.9%)	Unclear	<20	1014	1. Individual counseling (in-person, telephone) 2. Compensation (contingency management)	8 sessions over 6 months	1. Individual counseling (in-person)	7-day point prevalence (6-months)	Yes	14.65
Mayer et al., 1990	USA	I	Three arm RCT	22.7	0	Caucasian: 164(75%) Black: 46(20.8%) Other: 9(4.2%)	Unclear	19.9	219	1. Individual counseling (in-person) 2. Non-formal education (in-person, printed)	1 session (20 mins)	1. Individual counseling (in-person)	9-month post-partum smoking abstinence	Yes	7
Sarkar et al., 2017	India	CP	Two arm RCT	46.3	966(79.7%)	unclear	\$800	Unclear	1213	1. Individual counseling: Brief quit advice (in-person) 2. Yoga breathing exercises	1 session	1. Individual counseling: Brief quit advice (in-person)	6-month smoking abstinence (7-months)	Yes	2.6
Solomon et al., 2005	USA	I	Two arm RCT	34.3	0	Caucasian: 206(92.7%) Other: 24(7.3%)	Unclear	23.6	330	1. Individual counseling (telephone) 2. Pharmacotherapy	12 calls over 4 months	1. Pharmacotherapy	6-month smoking abstinence	No	38
Wagner et al., 2016	USA	CB	Two arm RCT	45	165(41.3%)	Caucasian: 106(26.5%) Black: 279 (69.7%) Other: 15(3.7%)	\$27,754	Unclear	400	1. Individual counseling (in-person) 2. Pharmacotherapy	12 sessions	1. Group counseling (in-person)	9-month smoking abstinence	Yes	8.9
Dornelas et al., 2006	USA	I	Two arm RCT	26.1	0	Caucasian: 18(17%) Black: 11(11%) Hispanic: 70(66%) Other: 6(6%)	<\$15,000	Less than 10	105	1. Individual counseling (in-person, telephone)	1 session (90 mins)	1. Non-formal education (printed)	7-day point prevalence (end of pregnancy and 6-months post-partum)	Yes	End of pregnancy: 28.3 Post partum: 9.4

^a Project site is categorized into either I (institution), CP (community placed), or CB (community-based)

^b Intervention and control components derived from the customized data collection sheet titled, "A Checklist for a Comprehensive Community-based Chronic Disease Management Program for Marginalized Populations: Example Tobacco Dependence"

^c Smoking quit rates estimated from figure in article

^d Average income values reported are from different years

Appendix D: Risk of Bias Analysis

Table 3. Risk of Bias Analysis

Study ID	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting	Other Bias	Overall Bias	Justification
Alaniz et al., 2020	Low	Unclear	Low	High	High	Low	Low	High	Blocked randomization occurred before baseline. Personnel not blinded to allocation at baseline/data collection but were during intervention. Only 50% completed the 6 month f/u, completed intent to treat analysis and missing (sig different). "It was not possible to conceal group assignment from field staff, as data collection took place during the same calls (baseline) and home visits during which intervention elements were provided."
Andrews et al., 2016	Unclear	Low	High	Low	High	Low	Low	Low	Reading the 2007 paper and another paper from 2012 the authors cite (doi: 10.1007/s10464-011-9482-6); they can only apply to the intervention design, not the study procedures. There's no discussion on how HD were randomized in the main text. Blinding: "Once blinded data collectors completed baseline data on participants for a matched pair of neighborhoods, the statistician notified the study intervention staff to which condition the neighborhood had been randomized" Of the 409 women recruited, 36 (8.8%) did not complete the study. There were no statistically significant differences in drop-out rates observed between intervention and control groups, (10% and 7.5% respectively) as shown in Fig. 1. Among non-African-American participants, >18% did not complete the study compared to 7% among African-American women (p = 0.005). There is no evidence presented to demonstrate there is no bias due to missingness. Even though article mentions the drop-out rates does not differ across the arms, it does not mean they had similar characteristics. A sensitivity analysis could have given a better idea how much the results were biased. More non-black participants left the study than the black one which can stem the bias.
Baker et al., 2018	Low	Low	Unclear	Unclear	High	Low	Low	Low	For the primary outcome, a total of 316 of 509 (37.9%) control condition participants had missing data; a total of 145 of 505 (28.7%) incentive condition participants had missing data. Participants with missing data for the primary outcome were counted as smoking. The participants with missing outcome data were considered as smokers and analysis was performed which might produce biased estimates. No information on blinding of participants and personnel
Bock et al., 2014	Low	Low	Unclear	Unclear	Low	Low	Low	Low	No info on blinding of participants/personnel. For outcome assessment participants completed surveys, but unsure if they knew group assignment when they filled survey or if anyone helped them; incomplete data, while it was a worry I think the authors reported their missing data and handling of the data adequately: "Participants were randomized to the ME (n = 406) or SC (n = 440) arms of the study. Dropout rates by last study visit attended are shown in Table 2 and in the Consort Diagram (Figure 1). It

									appears that 16% of subjects in each study arm (66 from SC and 71 from ME) dropped out immediately after their baseline visit. Cumulative dropout by month 12 reached 58.6% in SC (n = 238) and 52.7% in ME (n = 232). Results highlight the need to take both per-randomization and post-randomization attrition into account when modeling abstinence rates..'
Bonevski et al., 2018	Low	Low	Low	Low	Low	Low	Low	Low	Blinding of outcome assessment (unsure who was collecting data but person doing analysis was blinded to allocation) and incomplete data (sufficient information provided: Thus participants who are missing outcome data at six months, but are followed up at one month and are not abstainers at this time are by definition not continuous abstainers at six months and were classified as such in the analyses. All other participants with missing outcome data were excluded from the primary analysis. i.e. intention to treat...Sensitivity analyses (MI, worst case and PMM) showed similar results to the available case analysis for the majority of outcomes indicating the results were robust to the treatment of missing data.)
Brooks et al., 2017	Low	Low	Low	Unclear	Low	Low	Low	Low	Authors reported missing data and how they handled, including analysis results: Estimates based on multiple imputation were slightly attenuated (7-day a OR 2.22, 95% CI: 1.09–4.50; 30-day a OR: 2.59, 95% CI: 1.18–5.69). Estimates based on the assumption that all participants without outcome data were currently smoking were very similar (7-day a OR 2.09, 95% CI: 1.10–3.97; 30-day a OR: 2.24, 95% CI: 1.00–5.03). The intervention's impact on 7-day abstinence was similar among participants with one (a OR: 2.05, 95% CI: 0.93–4.51) or greater than one (a OR: 2.66, 95% CI: 1.71–4.16) TTA session. The same pattern was seen for 30-day abstinence)
Brunette et al., 2017	Low	Unclear	High	Unclear	Low	Low	Low	Low	Used equipoise randomization that allowed participants to opt out of one of the cessation treatment conditions or allowed randomization to any of the three options. This strategy is recommended for comparative effectiveness trials that include more than two treatments. No mention if coordinators who delivered the intervention and facilitation were blinded but assume not. High participation rate and moderate loss to follow up. Relatively large small size
Bullock et al., 2009	Low	Low	Low	High	High	Low	Low	High	"The nurses who collected samples when they conducted the follow-up interviews in late pregnancy and 6-weeks postdelivery were aware of the study group assignment. "There is conclusive evidence that the results were not biased by missing the saliva sample. But study oversampled as mentioned here: The total number of women recruited for the study was 695, more participants than planned because of a laboratory error that resulted in unusable cotinine values for 165 women (932 saliva samples).
Coleman-Cowger et al., 2018	Low	Low	Low	Unclear	High	Low	Low	Low	25% attrition observed: Sixteen participants (25%) withdrew from the Intervention only (n=13) or from the entire study (n=3). All participants lost to follow-up were considered to be smokers.
Curry et al., 2003	Low	Low	Unclear	Low	High	Low	Low	Low	Not conclusive evidence for blinding of participants/personnel is provided. For the pediatricians, they received training and for intervention a flow chart was clipped in front of folder. We can assume based on this information that doctors received information on what to talk to the patients but they might not know if it was part of intervention or control. There were missing observations which were then imputed as smokers. The complete case

									analysis in table-3 shows the directionality of the outcome at 12 months are still same. In fact, the abstinence rates are higher in table-3.
Dornelas et al., 2006	Unclear	Unclear	Unclear	Unclear	High	Low	Low	Unclear	No information on exact randomization process is provided in the article. But is safe to assume that participants did not know if they are assigned to the intervention given the nature of activities envisaged in both the arms. Smoking status was obtained for 100% of the sample at end of pregnancy. Used intent to treat but did not report numbers.
Fraser et al., 2017	Low	Low	High	Unclear	High	Low	Unclear	Low	“Randomization occurred via computer-generated lists with order stratified by county and race.” Counselors at the WTQL were not blinded. Also, the rate of completion of follow-up phone calls was modest, leading to considerable missing data. “Despite these limitations, significant treatment effects were consistently found among participants differing in recruitment route, type of biochemical test, and self-reported versus biochemical determination of abstinence.”
Froelicher et al., 2010	Low	Low	High	Low	High	Low	Low	Low	“Randomization was by random permuted blocks for groups of participants, each group having an equal chance of assignment to the CG or the IAM intervention group.” Because true blinding is not possible with a behavioral intervention, “all baseline data were collected before random allocation to blinded data collectors to subsequent group assignment.”
Fu et al., 2016	Low	Unclear	High	Low	Low	Unclear	Low	Low	“Randomised, with equal likelihood within each of the 12 age, gender and MHCP strata (Medicaid or MinnesotaCare), to receive either (1) proactive outreach intervention or (2) usual care.” Participants were not blinded. However, study staff who administered the questionnaires to collect primary outcome data were blinded to participant’s treatment allocation. The follow-up survey response rate was 74%. “While this is an excellent response rate considering the low socioeconomic characteristics of the population, there was differential response by intervention and usual care arms and potential for non-response bias. We conducted a series of selection model analyses to account for non-response and observed similar effects, suggesting that our findings are robust.”
Gielen et al., 1997	Low	Unclear	Unclear	Unclear	High	Low	High	High	“Smokers were randomly assigned at their first visit to receive either the prenatal and post-partum smoking cessation/relapse prevention intervention.” High loss to follow up rate but does not explain if statistical analysis included non-responses as well. There is no sufficient evidence to conclude that Author’s have purposefully selected one outcome over another. It is safe to assume they stick to their analytical plan and reported the outcomes with pre-decided measurement strategy.
Gritz et al., 2013	Low	Unclear	Unclear	Low	Low	Low	Low	Low	Participants were randomized to 1 of 2 treatment groups: usual care (UC) vs cell phone intervention (CPI). High follow up response rate (~70%) and non-responses counted in analysis. Paper did not mention if participants/personnel were blinded or not.
Lasser et al., 2017	Low	Low	High	High	Low	Low	Low	Low	“Through stratified randomization, participants were assigned to 1 of 2 groups.” Unblinded RCT study. Random number generator with allocation concealment to a research assistant using sealed envelopes. A research assistant, unblinded to study group assignment, attempted to contact all

									participants by telephone 6 and 12 months after enrollment, and asked whether they had stopped smoking. "Expected the majority of missing data to be due to moving or failure to remain in the study. We investigated whether missing data was associated with patient characteristics."
Lepore et al., 2018	Low	Low	Low	Low	Low	Low	Low	Low	"Participants were then randomized to a 12-week treatment. Randomization used a permuted block design of varying lengths with two strata (hospital clinic site and race). Sealed, opaque envelopes organized by strata were created by the project biostatistician to conceal assignment information from research staff until immediately prior to intervention assignment." Assessment staff were blind to treatment assignment. Samples were labeled with a numerical code so that the lab conducting the assays was blind to participants' identity and experimental condition. Low loss to follow up rate.
Lipkus et al., 1999	Low	Unclear	High	Unclear	High	Low	Low	Low	These smokers were randomly assigned to one of the three study groups. 1/3 participants loss to follow up. "...achieved an average 48% compliance rate by the study's end. It is uncertain to what extent the interventions would have been more effective if higher compliance rates had been observed."
Mayer et al., 1990	Low	Unclear	Unclear	Low	Low	Low	Low	Low	Following informed consent, participants were randomly assigned to one of three groups. No mention of blinding or allocation concealment in the paper.
Marks et al., 2002	Low	Low	Unclear	Unclear	High	Low	Low	Low	These sessions consisted of treatment or control in a random order. Twenty-nine participants left the trial before the 12-month data-point: one died, four moved house and 24 became non-contactable by telephone or mail. The study has high number of drop outs. The researchers simply excluded them from analysis rather performing any sensitivity analysis. Therefore, in my opinion, the study should be ranked "High" in this category. "Twenty-nine participants were unavailable for follow-up at 12 months, 12 (9%) from the CBT group and 17 (13%) from the control group. This difference was not statistically cant."
McBride et al., 2002	Low	Low	Unclear	Unclear	Low	Low	Low	Low	"Eligible smokers were randomized in a 1:2 ratio to EUC or BF." Samples were collected by mail using a method that has been validated previously. Follow up rate ~50%. Outcome analyses that excluded those with missing follow-up data were similar at each time point.
McClure et al., 2018	Low	Low	High	High	High	Low	Low	High	From protocol paper McClure et al(2017)-Oral Health 4 Life: Design and Methods of a Semi-pragmatic Randomized Trial to Promote Oral Health Care and Smoking Abstinence among Tobacco Quitline Callers: Due to the nature of this trial, neither participants nor AW counselors in the experimental group were blinded to treatment group. Counselors delivering the control intervention were aware that participants were enrolled in a research study, but they were not trained in or provided access to the oral health intervention materials. From protocol paper it intends to do both analysis by including and excluding 19 missing individuals but will be presenting results from the sample where 19 individuals are excluded: "Analytic findings based on this second analytic sample will be considered

									the primary study results, but we will present the results from both analyses if results for the primary outcomes differ between the two samples." From protocol paper: However, since missing data will be imputed as smokers and non-utilizers of dental care, and the 19 individuals not included in the primary analytic sample were equitably distributed across groups (9 vs. 10), we do not anticipate their exclusion will alter the primary findings.
Okuyemi et al., 2013	Low	Unclear	High	Unclear	Low	Low	Low	Low	Sequential randomization of 430 individuals at baseline appointment using pre-assigned randomization numbers prepared by study statistician. Assignment was not blinded to participants or personnel. 101 participants loss to follow-up (i.e. unable to locate) and 5 participants with unknown, illness, rehab treatment reasons for discontinuing intervention - however loss FU included with intention to treat analysis, and secondary analysis completed with loss to FU as missing.
Okuyemi et al., 2007	Low	Low	High	Unclear	Low	Low	Low	Low	Sequential randomization of housing developments in 2 strata of family vs non family developments. Study staff were blinded to randomization before/during recruitment (treatment unconcealed to staff after recruitment and randomization). 64 loss to follow up by 6 month, no reason provided, however completed analysis with Loss FU as missing and no change (intent to treat).
Okuyemi et al., 2006	Low	Low	High	Unclear	Low	Low	High	Low	46 participants were randomized using a block design (in blocks of four). Participants and personnel were not blinded to allocation. 18 Loss to f/u, 13 did not return, 5 withdrew at week 26, however all included with intent to treat (and comparing loss to f/u as missing).
Rash et al., 2018	Low	Low	High	Unclear	Low	Low	Low	Low	All participants randomized (stratified by pre-treatment reductions in smoking) after 2nd pre-quit counselling session using a computerized urn procedure. Allocation no concealed to either participant or personnel. Use intent to treat analysis with 6 loss to f/u and 1 missing CO verification (unclear if analysis conducted with/without missing vs unsuccessful)
Resenicow et al., 1997	Low	Unclear	Unclear	Unclear	High	Low	High	High	Used a cluster randomized design. No indication of blinding of staff or participants. Majority of participants did not complete the booster call due to no phone, those reached and not reached by phone did not differ with gender, marital status cig/day but did differ by age, education and state of change. Reported outcome for all subjects and separately for those reached by phone. 86 individuals were loss to f/u included in intention to treat analysis (no significant difference in results).
Sarkar et al., 2017	Low	High	High	Unclear	Low	Low	Low	Low	Cluster randomization using computer blocked generated sequence. Participant concealed to allocation, but not research team (before recruitment?). 55 loss to f/u (not contactable) including those who did not provide saliva samples (n=14) at 7 months but used intention to treat analysis (secondary analysis on missing vs ITT).
Solomon et al., 2005	Unclear	Unclear	High	Unclear	High	Low	Low	Unclear	Randomization and baseline interview (no details provided, including order). Staff other than the ones providing telephone support collected survey response, but not clear if they were blinded to allocation. 6 month f/u was

									87% in each condition so , but no reason given for 13% loss to f/u (intention to treat)
Solomon et al., 2000	Unclear	Low	High	High	High	Low	Low	High	Randomized after baseline but no details provided. RA collecting data aware of allocation. 30% in each condition at 6 month and unclear how missing were treated in analysis.
Sykes et al., 2001	Unclear	Low	High	Unclear	High	Low	Low	Low	No details on how randomization of sessions/groups occurred (as people called, would be assigned to be booked into session, which was randomly allocated to intervention). Person setting appointments was blinded (allocation concealed). RA not blinded. 20 loss to f/u (non-contactable) and unsure what was done during analysis.
Wagner et al., 2016	Unclear	Unclear	High	Low	High	Low	High	High	Participants given letter randomly with their group, but unsure who gave them and if they were aware of contents. Participants/Personnel were not blinded. 37 loss to f/u and use intention to treat analysis. Many did not even complete the intervention (1 in 2), so effect being measured is unclear and poor quality chart review.

Low risk of bias = met the criteria in the domain

High risk of bias = did not met the in the domain

Unclear = did not mention the domain, partially mentioned how the domain criteria was met or some concerns were present

Summary of Risk of Bias Findings

Majority of studies in the random sequence generator domain were judged to be at low risk of bias as the study described how the allocation sequence was generated. Six studies did not mention how random allocation sequence was generated and was judged to be unclear risk.

Similarly, twenty studies were classified as low risk of bias for describing allocation concealment.

The risk of bias from blinding participants and research personnel was judged to be high if participants, research personnel, and outcome assessors were not blinded. Ten studies did not mention if blinding participants and research personnel occurred and were classified as unclear. Comparably, nineteen studies did not mention if outcome assessors were blinded in the study.

If a study described the rates of attrition (e.g. with a visual flow chart) and how they commentated for high rates of attrition, it was judged to be low risk of bias for incomplete outcome data. Eighteen studies did not mention attrition rates and were classified as high rate of bias.

All studies reported outcomes that they have described in their method sections and were judged to be low risk of bias.

Overall, two of the included studies was classified as low risk of bias on all domains of the Cochrane Risk of Bias Tool.

Appendix E: Forest Plots

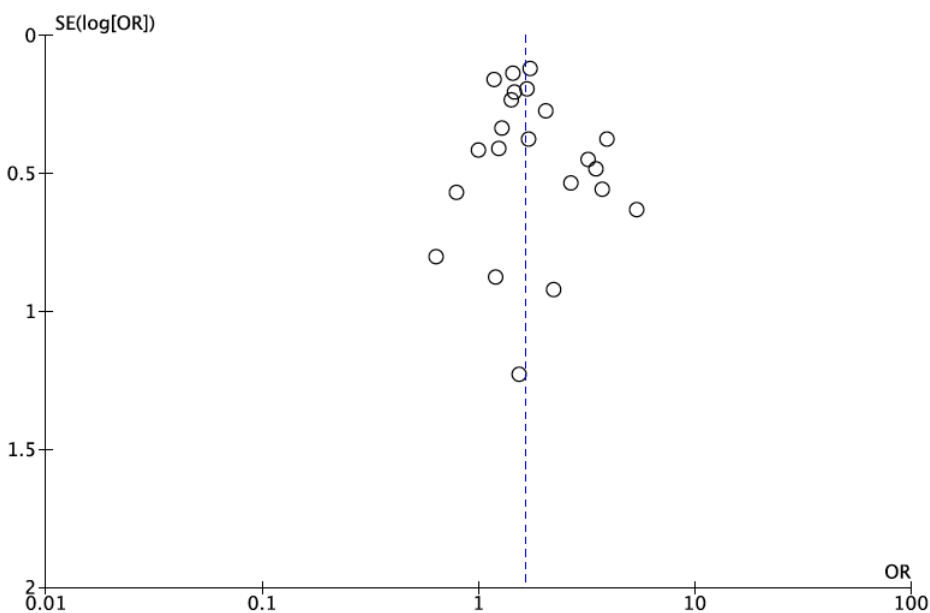


Figure 1. Funnel plots comparison for Smoking Abstinence Outcome at 6-months

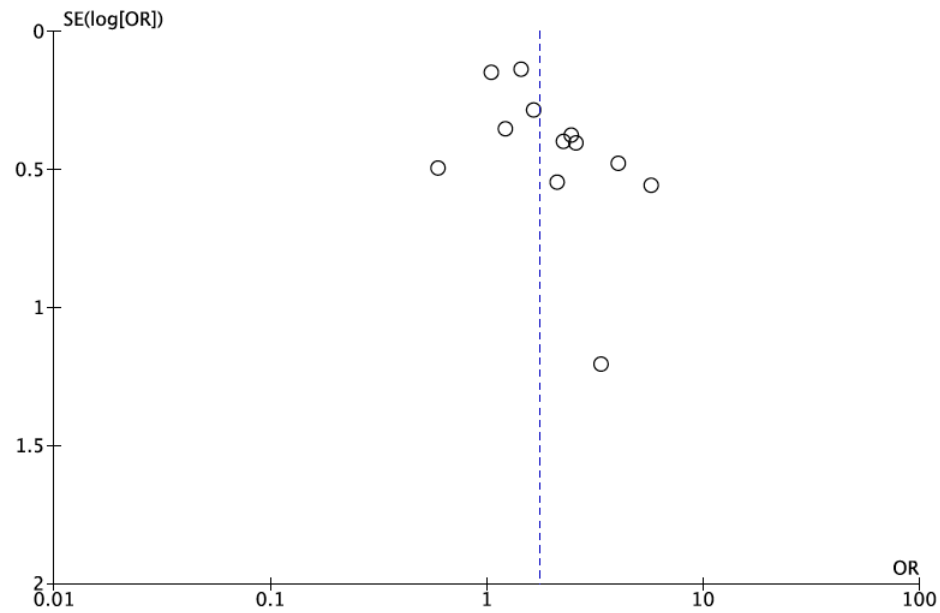


Figure 2. Funnel plots for comparison for Smoking Abstinence Outcome at 12-months

Following guidance from the Cochrane handbook for systematic reviews of interventions, the lowest point causing appearance of asymmetry is due to the effect estimates from smaller studies and is not a source of bias. [1]

Appendix F: A Checklist for a Comprehensive Community-based Chronic Disease Management Program for Marginalized Populations: Example Tobacco Dependence

Name of Study:

Author:

Section	Item #	Component	Conducted By	Location or Delivery Method	Frequency	Reported on Page #
Social Support	1A	<input type="checkbox"/> Peer support	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	_____/14
	1B	<input type="checkbox"/> Place of residence	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/14
	1C	<input type="checkbox"/> Sex/Gender identity and expression	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/14
	1D	<input type="checkbox"/> Social capital <input type="checkbox"/> Community connections <input type="checkbox"/> Cultural Identity (race/language/ethnicity) <input type="checkbox"/> Other: _____	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/17
	2A	<input type="checkbox"/> Formal Education	<input type="checkbox"/> Community Peer	<input type="checkbox"/> In-person	<input type="checkbox"/> Daily	

Social-economic Supports			<input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> Multimedia/Virtual <input type="checkbox"/> Printed material <input type="checkbox"/> Referral	<input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/15	
	2B	<input type="checkbox"/> Non-formal Education	<input type="checkbox"/> Patient centered (e.g. resume building, job training) <input type="checkbox"/> Tailored tobacco dependence education material <input type="checkbox"/> Other: _____	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> Telephone <input type="checkbox"/> In-person <input type="checkbox"/> Multimedia/Virtual <input type="checkbox"/> Printed material	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/18
	2C	<input type="checkbox"/> Social Service Support	<input type="checkbox"/> Legal aid <input type="checkbox"/> Digital literacy <input type="checkbox"/> Financial literacy <input type="checkbox"/> Social assistance <input type="checkbox"/> Housing <input type="checkbox"/> Harm Reduction supplies <input type="checkbox"/> Other: _____	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Telephone <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/21
	2D	<input type="checkbox"/> Occupation		<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/14
	2E	<input type="checkbox"/> Volunteering		<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/14
Counseling	2	<input type="checkbox"/> Group <input type="checkbox"/> Individual	<input type="checkbox"/> Patient centered (e.g. resume building, job training)	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff	<input type="checkbox"/> Telephone <input type="checkbox"/> In-person	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly	

			<input type="checkbox"/> Tailored tobacco dependence education material <input type="checkbox"/> Other: _____	<input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> Multimedia/Virtual	<input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/18
Follow-up	4	<input type="checkbox"/> Case report /clinical forms <input type="checkbox"/> Study/clinical measurements		<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> Telephone <input type="checkbox"/> In-person <input type="checkbox"/> Mail <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/16
Pharmacotherapy	5	<input type="checkbox"/> Nicotine Replacement Therapy <input type="checkbox"/> Varenicline <input type="checkbox"/> Bupropion <input type="checkbox"/> Other: _____	<input type="checkbox"/> Patient centered NRT (e.g. choice in NRT: patch, gum) <input type="checkbox"/> Tailored tobacco dependence material (off the label, combination/dosages catered) <input type="checkbox"/> Other: _____	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> In-person <input type="checkbox"/> Mail <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/20
Compensation	6	<input type="checkbox"/> Transportation <input type="checkbox"/> Food <input type="checkbox"/> Childcare <input type="checkbox"/> Honorarium <input type="checkbox"/> Other: _____	<input type="checkbox"/> Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Monetary <input type="checkbox"/> Non-monetary	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	If applicable (eg. Childcare): <input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/28

Study site and approach	7	<input type="checkbox"/> Institutional (clinic, hospital, university) <input type="checkbox"/> Community placed <input type="checkbox"/> Community-based approaches	<input type="checkbox"/> Community Peer <input type="checkbox"/> Healthcare professional <input type="checkbox"/> Research staff <input type="checkbox"/> Virtual Assistance	<input type="checkbox"/> On-site <input type="checkbox"/> Referral <input type="checkbox"/> Virtual	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Bi-annually <input type="checkbox"/> Other: _____	/16
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Total Score: ____/239

Social Support: The perceived or actual physical and emotional comfort provided by family, friends, community health professionals, and others for individuals to feel valued, cared for, and belonging to a particular network.

Social Economic Supports: Comprising of social and economic support to increase an individual's social economic status (SES), which is often measured using a combination of education, income, and occupation.

Non-formal Education: Education programs that take place outside the school system and do not have a structured curriculum.

Counseling: The process of an 'expert counsellor' assisting and guiding individuals to help resolve or understand personal, social, or psychological challenges in their day-to-day life. The definition of an 'expert counsellor' has been broadened to include informal counseling by active healthcare professionals, peers, and volunteers.

Follow-up: A procedure carried out as a part of the program (or intervention) to monitor progress or further develop on earlier work. Follow up procedures increase retention and engagement with participants in the program, overall increasing effectiveness of the program.

Pharmacotherapy: Treatment involving the use of medication or pharmaceutical drugs

Compensation: Monetary, non-monetary items or services provided to participants to acknowledge the time and effort they have provided in the program or intervention.

Community-placed: A organization that is located in the community it serves to help but the community members are not involved in the design, implementation or dissemination of research programs.

Community-based participatory action approaches: a joint partnership with communities they serve to help, who are equal partners and are involved in every step of the research project from study design to knowledge dissemination. [2]

Patient centered: Providing care that is responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions.

Tailored tobacco dependence materials: intervention material(s) are tailored towards the barriers and facilitators the target population faces. This includes tailoring the material based on cultural beliefs, literacy levels, and lived experiences.

References

- 1 Higgins JPT GS (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 | Cochrane Training. Cochrane Collab. 2011. www.handbook.cochrane.org.31 (accessed 1 Apr 2022).
- 2 Burns JC, Cooke DY, Schweidler C. A Short Guide to Community Based Participatory Action Research. *Adv Proj City* 2011;;1–18.