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Tobacco cessation in low- to middle-income countries: A scoping review of randomized controlled trials

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HIGHLIGHTS

- We conducted a review to identify LMIC tobacco cessation RCTs.
- RCTs tended to be psychosocial, limited behavioral and pharmacological variants.
- We suggest continued tobacco control research within LMICs.

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ABSTRACT

Objective: The growing prevalence of tobacco use in low "to middle" income countries (LMICs) and the hurdles of conducting tobacco cessation in that context necessitates a focus on the scope of randomized controlled trials (RCTs) in LMICs to guide tobacco cessation in this environment. We conducted a scoping review to identify LMIC tobacco cessation RCTs.

Methods: Consistent with PRISMA-ScR guidelines and without language restrictions, we systematically searched peer-reviewed databases (MEDLINE, Embase, PsycINFO, articles published since inception, latest searches in March 2020) and gray literature (clinical trials registries, searches between September and December 2019). We searched for data on RCT type, outcome significance and intervention description. Inclusion: research conducted in LMICs; tobacco cessation; RCT. Exclusion: research conducted in high income countries; non-RCT; studies involving only those aged <18. Data was extracted from published reports. We generated narrative summaries of each LMIC's tobacco cessation RCT research environment.

Results: Of 8404 articles screened, we identified 92 studies. Tobacco cessation RCTs were recorded in 16 of 138 countries/territories in LMICs. Evidence was weak in quality and severely limited. Most RCTs were psychosocial, with limited behavioral and pharmacological variants.

Conclusions: Tobacco control within LMICs is essential to reduce the tobacco mortality burden. Researchers should be cognizant that tobacco cessation in LMICs is still not an environment where best practice has been established. We suggest that developing solutions specific for LMICs is key to effective tobacco control in LMICs.

1. Introduction

Tobacco consumption is the leading cause of preventable death globally (Ghebreyesus, 2019). Most of the global mortality burden of tobacco use lies predominantly in low "to middle" income countries (LMICs) (Sinha et al., 2018). LMICs are experiencing a growing epidemic of tobacco use (Sreeramareddy, Harper, & Ernstsen, 2018). Tobacco control is key to any nation's public health strategy (Goodchild & Zheng, 2018). Tobacco control, such as cessation interventions, should thus be a priority for policymakers in LMICs to mitigate effects of tobacco-related morbidity and mortality (Ghebreyesus, 2019). There are stark differences between LMICs and high-income countries regarding smoking prevalence (Reitsma et al., 2017), making evident the necessity of tobacco cessation research in this environment. For example, Australia has witnessed an annualized rate of change in male smoking prevalence of −2.2% from 1990–2015 (Reitsma et al., 2017). LMIC smoking rates still persist (Hughes, Arora, & Grills, 2016), with Bangladesh seeing an annualized rate of change in male smoking

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prevalence of +0.3% from 1990–2015 (Reitsma et al., 2017). Given the high tobacco use prevalence, LMICs are harnessing techniques from high-income countries to conduct tobacco cessation interventions (Ward, 2016; Asfar, Ward, Al-Ali, & Maziak, 2016). However, the effectiveness of these studies is not clear, given the highly varied cultures and infrastructure in LMICs (Asfar et al., 2016). The growing prevalence of tobacco use in LMICs and the hurdles of conducting tobacco cessation in this context necessitates a focus on the scope of randomized controlled trials (RCTs) in LMICs to guide tobacco cessation in this environment. There are several reasons for the difficulties in implementing smoking cessation RCTs in LMICs, such as, smoking initiation as a favored practice, lack of public awareness of smoking hazards, limited government support, poor enforcement of smoke-free policies, and resistance from the tobacco industry (Zhang, Ou, & Bai, 2011; Kaur et al., 2011; Radwan, Loffredo, Aziz, Abdel-Aziz, & Labib, 2012; Katanoda et al., 2014).

Previous reviews explored tobacco control in LMICs (Brathwaite, Addo, Smeeth, & Lock, 2015; Gadhave & A, 2017; Alzahrane et al., 2019; Akanbi et al., 2019). However, past work was limited as they did not include studies across all LMICs, were not centered on RCTs or detailed only tobacco smoking. For example, one review detailed the efficacy of smoking cessation interventions in LMICs (Akanbi et al., 2019), but did not explore other forms of tobacco use. Another review evaluated tobacco cessation interventions in Arab populations (Alzahrane et al., 2019), but did not detail studies in other LMICs. Exploring a broader arc of tobacco use is essential as smokeless tobacco is common in LMICs (Sinha et al., 2017). Examples of smokeless tobacco in LMICs are chewing tobacco, moist snuff, mawa (areca nut with tobacco and slaked lime), gutka (areca nut, slaked lime, catechu, condiments and powdered tobacco), and betel quid (betel leaf, areca nut and slaked lime) with tobacco (Gupta & Ray, 2003; Mejia & Ling, 2010). Smokeless tobacco has great health and economic implications (Sinha et al., 2018), such as an increased risk for cardiovascular deaths and stillbirth (Mehrotra et al., 2019). Globally, one in ten males and one in 20 females used smokeless tobacco (Sinha et al., 2018). Most smokeless tobacco users (91%) resided in LMICs, often with a greater burden in rural and lower-income communities. The popularity of such forms of smokeless tobacco, especially in LMICs, may be due to the product being deeply integrated into sociocultural life for centuries (Gupta & Ray, 2003). There are multiple observational and quasi-experimental studies on tobacco cessation in LMICs. However, tobacco cessation RCTs are minimal in this context. We acknowledge the issues inherent with RCTs (Bothwell, Greene, Podolsky, & Jones, 2016), such as overgeneralization of results, small sample sizes (Rosner, 2003), validity and reliability (Morrison, 2001). However, other study designs are not an adequate replacement for RCTs in establishing efficacy (Gerstein, McMurray, & Holman, 2019), key to tobacco cessation (Zhu, Lee, Zhuang, Gamst, & Wolfson, 2012). RCTs are considered the most valid assessment of an intervention (Spilker, 1992) and tobacco cessation RCTs seem to be the most efficacious of tobacco control activities (Hughes, 2007). To effectively design RCTs that mitigate tobacco-related harms in LMICs, further understanding of RCTs in this environment is key. Greater understanding around tobacco cessation RCTs may also aid the evidence base to enhance tobacco cessation scholarship, policy and implementation globally, perhaps mitigating the tobacco epidemic (Berg et al., 2018).

We conducted a scoping review to locate and review all published literature relating to tobacco cessation RCTs in LMICs, detailing gaps in literature. For example, we detailed if there were LMICs where comparatively fewer RCTs had been conducted. We chose to conduct a scoping review due to the broad research question, suited for mapping an area of research (Arksey & O'Malley, 2005). We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews guidelines (PRISMA-ScR), used standard tools to assess study quality (McGowan et al., 2020) and proposed a reproducible strategy to query the literature about the scope of tobacco cessation RCTs in LMICs. To reduce publication bias, we also included a broad range of studies, such as gray literature (Mitchell, Wilson, & MacKenzie, 2012). We reviewed articles by thematically, dividing them by country and RCT type.

2. Methods/design

2.1. Search strategy

The search strategy was elaborated and implemented prior to study selection, with the PRISMA-ScR checklist as guidance (McGowan et al., 2020). We published a study protocol (Kumar et al., 2020) and preregistered the protocol on PROSPERO (CRD42020136161) to enhance methodological transparency and to improve reproducibility of results and evidence synthesis. We used the following guiding question to ensure a scoping literature search: 'What is the scope of tobacco cessation RCTs in LMICs?'. While scoping reviews normally include all evidence, not just RCTs (Pham et al., 2014), we sought to focus on RCTs for two reasons. Firstly, previous reviews had centered on other study designs, such as quasi experimental studies. Secondly, to effectively design RCTs that mitigate tobacco-related harms in LMICs, further understanding of RCTs in this environment will be helpful.

Studies were reviewed across six databases, including MEDLINE, Embase, PsycINFO, Global Health, Web of Science and Sociological Abstracts. To account for contemporary studies, a literature search was conducted from inception until March 2020. No language restrictions were imposed. Reference lists of the articles were used to identify more studies. We conducted a gray literature search using Google Scholar, clinical trials registries and governmental websites. We spoke with leading tobacco control experts to identify any relevant studies. EndNote, a bibliographic software, was used to store, organize and manage all references (Clarivate Analytics, 2017). Covidence was used to manage the title/abstract and full-text screening phases (Veritas Health Innovation, 2017). We used the search strategy indicated in Appendix A. We manually excluded non-RCTs to avoid bias.

2.2. Study selection criteria

Studies were excluded if they were conducted in high-income countries. LMICs and high-income countries were defined based on the World Bank's per capita gross national income metric (see Appendix B) (World Bank, 2019). Two independent reviewers screened each title and abstract as per inclusion/exclusion criteria (see Fig. 1). Only studies involving adults (⩾18 years) were included. However, we included studies focusing on both youth and young adult populations, wherever possible reporting data for the adult population only. The adult population was the focus as the bulk of tobacco use is with adults globally, along with the highest prevalence by age group (Ng et al., 2014). We did not exclude studies in non-English languages. The key outcome was tobacco cessation in adults.

Inclusion criteria

- Research was conducted in low- to middle-income countries
- Research investigating tobacco cessation in adults
- Randomized controlled trials (RCTs)

Exclusion criteria

- Any commentaries, editorials, or opinion pieces
- Research conducted in high-income countries
- Qualitative studies
- Non-RCT studies
- Studies involving only children or adolescents

Fig. 1. Inclusion and exclusion criteria.

2.3. Study selection

Reviewers were trained in calibration and utilized standardized screening forms. Reviewers worked in teams of two and independently screened all titles and abstracts that we identified by the literature search strategy. We obtained full-text articles of all eligible studies and evaluated article eligibility. Reviewers resolved disagreement around eligibility by discussion or, if necessary, with a third reviewer. We included conference abstracts as they are more likely to contain positive results and are often published sooner (Scherer & Saldanha, 2019), key to a scoping review on RCTs. We contacted authors where necessary if abstracts did not provide sufficient information (Scherer & Saldanha, 2019).

2.4. Outcome measure

The primary outcome of interest was tobacco cessation, defined broadly. Examples of outcomes were: smoking cessation; quit rates; point prevalence smoking abstinence rates for any time period; urine test for cotinine. We used a broad range of outcomes to account for the large range of tobacco cessation RCTs in LMICs.

2.5. Data extraction

Four pairs of reviewers underwent practice exercises and then worked in pairs to independently extract data from studies. Reviewers resolved disagreement through discussion. When differences were unable to be resolved, a third reviewer made the final decision. Reviewers abstracted the data using a pretested data extraction template, which included: study design; participants; interventions; comparators; outcomes.

2.6. Risk of bias assessment

While it is not common to assess risk of bias in scoping reviews (Munn et al., 2018), we only included RCTs and thus the review was amenable for study quality assessment. Reviewers worked in pairs to independently assess the risk of bias for included RCTs. Disagreements were resolved by a third reviewer. We used the Cochrane Collaboration's instrument (Higgins et al., 2011) which included nine domains: adequacy of sequence generation; allocation sequence concealment; participant blinding; data collectors blinding; outcome assessment blinding; data analyst blinding; incomplete outcome data; selective outcome reporting and potential sources of bias (Guyatt & Busse, 2015). The risk of bias was summarized as a narrative statement, supported by a risk of bias table and harvest plot (Crowther, Avenell, MacLennan, & Mowatt, 2011).

2.7. Descriptive analysis

A narrative synthesis of selected studies was detailed by country. We included information such as: RCT type; Significance of outcome; Intervention description; Impact of bias.

2.8. Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

3. Results

3.1. Included studies

Through title and abstract screening, we assessed 736 full texts and included 92 publications (see Fig. 2). Studies excluded from the review did not include tobacco cessation as an outcome, did not include adults as the study population, were opinion pieces, among other criteria. Table 1 indicated study location, number of participants, inclusion criteria, among other characteristics. Tobacco cessation RCTs were recorded in 16 of 138 countries/territories within LMICs. Twenty-six RCTs (28%) were in India, 17 (18%) in China, 9 (10%) in Thailand, followed by other nations. Fifty-two (57%) RCTs were psychosocial, 20 (21%) were psychosocial/behavioral, 9 (10%) were pharmacological/behavioral, 8 (9%) were pharmacological, and 3 (3%) RCTs were behavioral. Psychosocial RCTs were defined as those involving counseling and psychotherapy treatments such as cognitive behavioral therapy, motivational interviewing, behavioral support sessions, SMS text messages providing smoking cessation advice/support. Studies where SMS text messaging and telephone calls were used to provide psychosocial therapies were categorized as psychosocial RCTs. Behavioral RCTs were those involving techniques to effect behavior change in some form, but not utilizing psychosocial methods. Examples of such studies were RCTs involving yoga, contingency management, and banning tobacco advertisements. Pharmacological RCTs were defined as studies involving pharmacological therapies such as bupropion and varenicline. The first tobacco cessation RCT in LMICs was conducted in 1988, with a steady rise in studies over the years (see Fig. 3). Table 2 indicated study characteristics related to population, intervention, or exposure groups, comparator, and assessed outcomes. Most interventions (65%) targeted generic smokers. Generic smokers referred to broad smoking populations i.e. there was no subgroup within smokers that was of interest. Commonly measured outcomes included continuous abstinence and point prevalence abstinence. We noticed a range of tobacco products detailed in the included articles, such as cigarettes, waterpipe tobacco, bidis, and smokeless tobacco. Cigarettes were the most common tobacco product examined in included studies (61%).

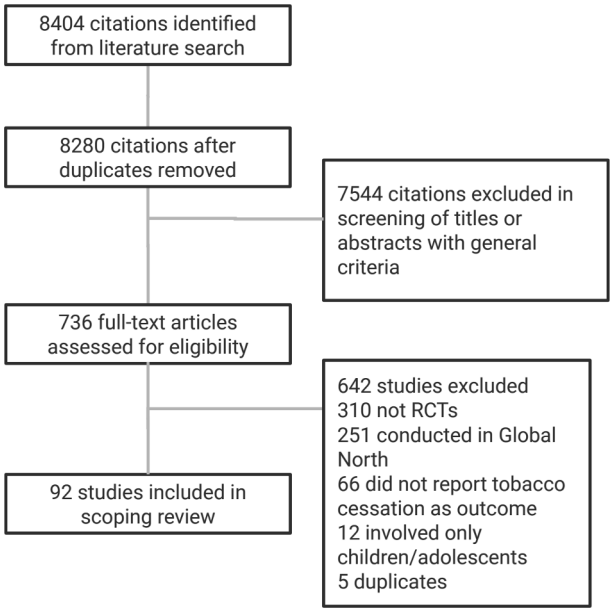

Fig. 2. Data extraction methodology for tobacco cessation RCTs in LMICs.

3.2. Quality of evidence

We indicated relevant evidence for the five categories of RCTs in a harvest plot (see Fig. 4) (Crowther et al., 2011; Ogilvie et al., 2008). Stronger designs tended to be used for psychosocial RCTs conducted in China, India, Brazil, Malaysia, and Thailand. Other RCTs with stronger designs were conducted across combined categories in China, India, Iran, Kyrgyzstan, Pakistan, South Africa, Syria, and Thailand. Thirteen

Table 1
Study characteristics related to design of study, setting, number of participants, mean age, gender, inclusion and exclusion criteria, and follow-up.

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Aggarwal 2017	India, Gurgaon	124 (NA)	Expressed self-intent to quit	NA	12 week
Ahmadi 2003	Iran, Shiraz	171 (100)	Meet DSM-IV criteria for nicotine dependence; Daily use of 10 cigarettes or more for at least one year; Between 17 and 64 years old; Had good health.	Using any medications that were a contraindication for the use of nicotine gum, naltrexone, or clonidine; Substance dependence other than tobacco/nicotine	24 weeks
AidaMaziha 2018	Malaysia	50 (NA)	Smoking 10 cigarettes per day; Over 18 years old; Muslims able to recite the Quran; Intending to quit smoking.	Difficulty attending interventions; Were participating in other interventions; Using pharmacotherapy to quit smoking	12 weeks
Areechon 1988	Thailand	200 (94.5)	Only healthy persons under age 60 years who smoked at least 15 cigarettes daily were selected.	NA	6 months
Aryanpur 2016	Iran, Tehran	210 (78.6)	Newly-diagnosed pulmonary TB patients according to a positive sputum smear based on treatment guideline of WHO; Patients classified as Category I (newly-diagnosed TB patients); Aged 18 years or older; Persian speaking patients.	Extra-pulmonary TB (brain, pericardium, adrenal glands, etc.); Multi drug resistance; Co-infection with HIV/AIDS; Opium addiction; Patients classified as Category II (recurrence, treatment failure or treatment errors); Patients classified as Category III (chronic TB); Contraindications for treatment with bupropion; Not willing to participate; Unable to communicate and comprehend the written consent form	25 weeks
Asfar 2014	Syria, Aleppo	50 (94.0)	Adults who were 18 years of age; Smoked waterpipe 3 times per week in the last year; Did not smoke cigarettes; Interested in quitting waterpipe; Recruited by flyers, ads, and word of mouth.	Inability to understand the study and consent procedures	3 months
Augustson 2017	China, Zhejiang, Heilongjiang, and Shaanxi provinces	8000 (NA)	Among first 276,000 Life Tools users to opt in and self-identifying as adult smokers interest in joining study/receiving free smoking cessation messages.	Not smoking at the beginning of the study	6 months
Aung 2013	Thailand, Lampang province	328 (NA)	Current smokers with diabetes;Current smokers with hypertension;Current smokers with both diabetes and hypertension; Smokers who have never succeeded in giving up smoking;Male or female;Aged 35–80 years.	Any female patients who are pregnant or planning to become pregnant;Patients aged younger than 35 years;Patients with documented type I diabetes;Patients with cancer;Patients with severe chronic pulmonary diseases using home oxygen therapy;Patients with a known diagnosis of a previous cardiovascular disease (CVD) event	1 year
Aung 2019	Thailand, Lampang province	319 (71.2)	Current smoker with diabetes;Current smoker with hypertension;Current smoker with both diabetes and hypertension; A smoker that has never succeeded in giving up smoking;Male or female;Age range from 35 to 80 years.	Any female patient who is pregnant or planning to become pregnant;Patient aged younger than 35 years;Patient with documented type I diabetes;Patient with cancer;Patient with severe chronic pulmonary diseases using home oxygen therapy;Patient with known diagnosis of a previous cardiovascular disease (CVD) event.	12 months
Blebil 2013	Malaysia, Penang	231 (96.1)	NA	NA	6 months
Blebil 2014	Malaysia, Penang	231 (96.1)	New registered smokers who attend the Quit Smoking Clinic (either walk-in, referred from the outpatient clinics from the same hospital, or referred from outside primary clinics);Male or female aged 18 years old;Willing to stop smoking.	Any inpatient referred to the Quit Smoking Clinics;Recent (three months or below) history of serious cardiac arrhythmia, angina pectoris, myocardial infarction, or other medical conditions that from researchers' view participants might not be commitment with the study;Currently using NRT or other smoking cessation treatments (bupropion or varenicline) within the last 12 months before study enrollment;Use tobacco products other than cigarettes;Pregnant, lactation or intend to be pregnant;Use of Psychoactive drugs;Suspected drug or alcohol abuse;Patients who continue to buy nicotine gum after the first 2 weeks of treatment.	6 months
Campos 2014	Brazil, Niterói	90 (61.1)	Subjects had to be current cigarette smokers; Between 18 and 80 years of age; Motivated to remain abstinent from smoking after hospital discharge.	Were receiving end-of-life care;Were clinically unstable;Had cognitive or memory deficits;Had a psychiatric disorder;Were pregnant	6 months
Campos 2018	Brazil, Niterói	90 (61.1)	Current cigarette smokers; Between 18 and 80 years of age; Motivated to remain abstinent from smoking after hospital discharge.	Receiving end-of-life care;Clinically unstable;Cognitive or memory deficits;Psychiatric disorder;Pregnant	6 months

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Table 1 (*continued*)

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Cruvinel 2018	Brazil	66 (51.5)	Patients aged 18 years admitted to the hospital who had smoked cigarettes within the past 30 days;Have their own mobile phone;Received at least one text message in the past year; Able to provide informed consent.	Admitted to an intensive care unit;In isolation;Physically or cognitively unable to participate;Currently incarcerated.	3 months
Davoudi 2017	Iran, Kashan	70 (100)	Age of 18–40 years;An educational degree of at least primary diploma;Presence of nicotine dependence criteria according to the Diagnostic and Statistical Manual of Mental Disorders-4th Edition (DSM-IV);No comorbid psychiatric disorders except for depression and anxiety;No history of drug abuse and psychotic disorders;No history of receiving psychotherapies during the past six months;Depression and an anxiety score of greater than 13 and 8, respectively.	Participants whose depression and anxiety were due to major life events (such as loss, marital conflicts, or divorce);Participants who were longer willing to participate in ACT sessions;Participants who had two or more absences from the sessions;Participants who received other medication or psychological therapies for cessation during the study	6 weeks
deAzevedo 2010	Brazil, Campinas	353 (NA)	Patient report of a smoking habit of at least one cigarette smoked daily immediately prior to hospital admission; Aged 18 years or older;Consecutively admitted to the hospital wards (except intensive care and psychiatric units).	Patients who presented with smoking comorbidity together with alcohol abuse or dependence	6 months
Dogar 2014	Pakistan, Jhang and Sargodha districts	1955 (88.3)	18 years or older;Suspected pulmonary TB (cough for >3 weeks without any other cause); Regular tobacco smokers (>1 cigarette/ hookah session a day).	Patients requiring hospitalization or urgent medical attention	6 months
Dogar 2018 (#1)	Pakistan, Punjab	510 (84.1)	Adults (18 years of age and above);Smoked waterpipe on a daily basis (25 days in a month) for at least 6 months; Motivated to quit all forms of smoking.	Had used any smoking cessation medications in the last 30 days; Were pregnant, lactating or planning to become pregnant; Required hospitalization; Had an allergic reaction to varenicline in the past; Had unstable angina, untreated cardiac arrhythmia, myocardial infarction, cardiac procedure (in last three months), uncontrolled hypertension, stroke, chronic kidney disease, epilepsy or severe mental illnesses; Chewed smokeless tobacco;Substances (including alcohol) misuse.	25 weeks
Dogar 2018 (#2)	Pakistan	510 (84)	NA	NA	25 weeks
Faustino da Silva 2018 (#1)	Brasil, Porto Alegre	600 (NA)	Smokers 18 years and older;Participate in group smoking treatment.	Missing more than two sessions of the smoking group.	30 days
Faustino da Silva 2018 (#2)	Argentina, Buenos Aires	120 (NA)	Aged 24 to 65 years;Minimum consumption of 5 cigarettes per day;Score of 4–9 on the Contemplation Scale (CL);Residents in the City of Buenos Aires;Own an Android mobile phone with gyroscope;Have data plan or Wi-Fi access;Expressed an interest in using VR as a method to quit smoking.	Diagnosed with a current psychiatric disorder.	90 days
Ghanem 2014	Egypt	255 (100)	NA	NA	6 months
Ghoreishi 2019	Iran, Kashan	76 (95.6)	Age of 19 to 65; Daily use of 10 or more cigarettes over a year or more; No history of admission due to psychiatric illness; No history of drug abuse; No use of any interfering or contraindicating medication with Gemfibrozil.	Drug abuse during the intervention and follow-up periods;Pregnancy during the study;Reluctance to continue treatment.	7 weeks
Goel 2017	India, Chandigarh	156 (96.7)	Sputum smear-positive pulmonary TB patients;Males and females;Aged 15 years and above;Registered for treatment under Revised National TB Control Program (RNTCP) in two-quarters (January till June 2013) in various DMCs of Chandigarh; Consenting current and occasional smokers.	Smokeless tobacco users	6 months
Haggstram 2006	Brazil, Porto Alegre	156 (33.9)	Cigarette smoker of at least 10 pack years;At least 18 years of age;Being motivated to quit smoking;Having a Fagerström score of at least 4.	Serious or unstable clinical or psychiatric disorders (including history of severe depression); Pregnancy or lactation; Alcohol or any other drug abuse; Current use of other smoking cessation treatments;Regular use of any other tobacco product;Contraindications to either of the drugs used, as history of seizures, recent myocardial infarct or use of monoaminooxidase inhibitors.	26 weeks
Han 2014	Malaysia, Selangor	163 (100)	NA	Illiteracy;Already quit smoking.	3 months
Heydari 2012	Iran, Tehran	272 (58.8)	NA	NA	1 year

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Table 1 (*continued*)

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Heydari 2014	Iran, Tehran	424 (100)	History of drug abuse, including the use of opiates such as opium and heroin, hashish, recreational drugs or others narcotics, for at least 1 year prior to referral to the drug treatment center;Inclusion was conditional upon at least 1 year of habitual tobacco consumption, in the form of cigarettes or hookah.	If they exhibited mental or physical illness that could have affected outcomes	6 months
Hofmeyr 2018	South Africa, Cape Town	105 (77.9)	At least 18 years old; Had smoked at least 100 cigarettes in his/her life; Had smoked in the last 10 h; Smoked at least five cigarettes a day; Reported an interest in quitting smoking and taking part in a smoking cessation program;Had a carbon monoxide (CO) in expired air reading of at least 8 ppm (ppm).	NA	6 months
Iyapparaja 2018	India, Chennai	100 (NA)	NA	NA	3 months
Jain 2014	New Delhi, India	237 (97.0)	Use of smokeless tobacco each day for the past year (confirmed with urinary cotinine assessment; 50 ng/ml); Age over 18;Residing within 60 miles of New Delhi.	Current cigarette use (confirmed with breath carbon monoxide [CO] >10 ppm); Current or planned use of tobacco cessation treatment; Current use of cocaine, marijuana, or opioids or current consumption of 25 alcoholic drinks/week; Current or recent use of psychiatric, pain, or asthma medications; Current pregnancy or lactation; History or current diagnosis of psychosis, schizophrenia, bipolar disorder, or suicidality; Current diagnosis of depression; Diagnosis of cancer, heart disease, or HIV/AIDS in past 6 months; History of epilepsy/seizures; History or diagnosis within the last 6 months of abnormal heart rhythms and/or tachycardia (>100 beats/min); History or current diagnosis of chronic obstructive pulmonary disease, cardiovascular disease, heart attack in the last 6 months, and uncontrolled hypertension (systolic blood pressure > 150 or diastolic blood pressure > 90); History of kidney or liver failure.	12 weeks
Jhanjee 2017	India, East Delhi	100 (0)	Women reporting current tobacco use;Coming in moderate risk scores as classified by ASSIST;Willing to participate.	Women reporting the current use of any other drug of abuse besides tobacco	3 months
Josephson 2019	India, Dalkhola and Jabalpur	560 (NA)	Adults; Between the ages of 18 and 70 years; Smoke cigarettes or bidis daily; Individuals able and willing to give informed consent.	Individuals who are bed-bound because of acute illness or have a chronic condition that makes them bed-bound;Individuals who refuse consent;Individuals who do not reside in the community and are only visiting, therefore being unlikely to be available for continuous follow up;Individuals who have stayed less than 6 months in the study area, or whose name is not on the voter list of the area will be excluded;Individuals who are not able to participate in the intervention due to significant disabilities, such as blindness, deafness or the intellectually disabled.	1 year
Khetan 2019	India, Dalkhola and Jabalpur	560 (NA)	Adults aged 18 to 70 years;Live in either of the two study sites and smoke daily; Those who smoke cigarettes or bidis daily (self-reported);Access to a mobile phone will be recruited into the study.	Bed-bound because of an acute illness or a chronic condition; Participants who have significant disabilities that would prevent them from participating in the study in a meaningful way such as being blind, deaf or intellectually disabled.	1 year
Koegelenberg 2014	South Africa	446 (85.5)	NA	NA	24 weeks
Kumar 2010	India, Tamilnadu	400 (100)	Adult men between 20 to 40;Resident of the village;Current user of any form of tobacco;Willing to participate in the study; Willing to provide a written informed consent.	Bedridden patients with debilitating illness;people who were planning for migration in the next three months.	2 months
Kumar 2012	South India, Tamil Nadu	400 (100)	Men;Aged 20–40 years;Resident of the village;Current user of any form of tobacco;Willing to participate in the study and provide informed consent.	Planning to migrate in the next 3 months; Older than 40 years.	2 months
Kumar 2017	India, Madurai	160 (100)	Patients aged > 18 years;Either TB or HIV and with a history of current smoking (at least one cigarette in the past 1 week) referred to the NIRT clinic, Madurai;Patients with HIV and TB co-infection were included in the HIV group.	NA	1 month

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Table 1 (*continued*)

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Liao 2016	China	2000 (NA)	Daily Chinese cigarette smokers;18 years of age and older living;Being able to read and write in Chinese;Owning a text-capable cell phone and knowing how to text;Willing to make an attempt to quit smoking in the next month;Willing to provide informed consent to participate in the study.	Nonsmokers; Below 18 years old; Unable to read and write in Chinese.	24 weeks
Liao 2018	China, 30 cities	1369 (94.6)	Daily smokers 18 years of age and older living in China; Being able to read and write in Chinese;Owning a text-capable cell phone and knowing how to text; Willing to make an attempt to quit smoking in the next month;Agreeing to smoking cessation status verification by a significant other (e.g., family member, friend);Being willing to provide informed consent to participate in the study.	NA	24 weeks
Lin 2013	China, Guangzhou	126 (100)	Male patients who answered 'yes' to the question, 'Do you smoke cigarettes?'	Patients who asked about smoking cessation before randomization; Patients who had diseases necessitating urgent advice to quit smoking.	12 months
Lou 2013	China, Xuzhou	3562 (47.9)	COPD diagnosed by the standards set forth by the Global Initiative for Chronic Obstructive Lung Disease (GOLD);Aged 35 years or older;Smoked 1 cigarette or more per day for the previous year;Had not stopped smoking for more than 3 months during that year.	Serious or unstable medical disorders such as psychiatric that might affect lung function;Current diagnosis of major depression.	48 months
Louwagie 2014	South Africa, Soshanguve	409 (90.0)	All adult patients initiating TB treatment at the six clinics.	Under 18;Too ill to participate;Unable to understand one of the two languages in which the questionnaire was administered;Not currently smoking;Had already been on TB treatment for more than 1 month.	6 months
Luo 2018	China, Beijing	320 (94.3)	Aged between 18 and 80 years; Currently being a smoker (had smoked 1 cigarette daily and lasted for 6 months before enrollment);Documented ACS; A mobile handset and residents in Yuetan Community of Beijing; Not ready to quit at the time of enrollment;Agreed to participate in the study after the initial counseling lasting 10–15 min by the first doctor in charge.	Had a tumor or multiple organ failure;Enrolled in another formal smoking cessation study;Had a life expectancy less than 1 year;Unable to complete follow-up.	6 months
Naik 2014	India, Bangalore	600 (100)	Current adult smokers who smoked any tobacco product either daily or occasionally at the time of the study;Convicted male prisoners with at least 1 year left to serve;Prisoners giving informed consent to quit smoking.	Inmates with acute mental illness (current suicidal ideation/actively psychotic);Inmates with mental retardation such that they could not provide informed consent;Medically compromised inmates (like those with respiratory disorders).	6 months
Nair 2015	India, Kerala	928 (100)	Males;Age group of 18–60 years;Had reported using at least one cigarette/bidi daily during the study period.	Females; Subjects who could not speak;Mentally disabled;Terminally ill patients.	12 months
Nichter 2016	Indonesia, Yogykarta province	87 (100)	Patients who were in the intensive phase of TB treatment (week 1–10 of DOTS treatment); Smokers at the time of TB diagnosis or were currently smoking at any level;Had a family member willing to be a DOTS supporter.	Patients who would possibly move away from the study area within the next one year	12 months
Nurul Asyikin 2018	Malaysia, Selangor	400 (99.2)	Smokers who attended Ministry of Health Dental Clinics in Selangor and smoked at least one cigarette in 30 days; Malaysian citizens; Adults aged between 15 and 70 years (this age range was adapted from the Malaysian Global Adult Tobacco Survey (GATS) in 2011 (Institute for Public Health 2012), a nationally representative household survey of noninstitutionalized men and women aged 15 years or older); Those who are contactable via a mobile phone or a landline; Those who are not currently undergoing smoking cessation treatment with other health clinics.	NA	6 months
Onyechi 2017	Nigeria	20 (100)	Participants with higher scores on the CDS-12; Participants more eligible if reported smoking cigarette regularly in the past 30 days; Participants also needed to be able to attend the counseling sessions held in the prison hall.	NA	6 months

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Table 1 (*continued*)

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Otero 2006	Brazil, Rio de Janeiro	1199 (37.5)	Being currently smoking; Wish to stop smoking; Reside in the city of Rio de Janeiro, Brazil; Be aged between 19 and 59 years.	Smoking five or less cigarettes per day; Having a diagnosis of untreated chronic hypertension, cancer, mental disorders in life, dermatological diseases that prevented the use of the patch, unstable cardiovascular diseases, severe respiratory diseases and other tobacco-associated diseases in the last five years; Make current use of drugs to stop smoking, such as bupropion (Zyban®), nicotine and gum replacement adhesive; Being dependent on alcohol and other drugs; Be pregnant or lactating; Have hearing or visual impairment.	12 months
Peng 2007	China, Beijing	240 (NA)	Aged 18 to 65 years old;At least one–year smoking history;Smoking 10 or more cigarettes per day;At least one quit attempt failure; All knew and agreed to participate in the experiment;Participants with positive urinary cotinine excretion.	NA	8 weeks
Pengpid 2015	Thailand, Nakhon Patthom province	620 (97.7)	Age between 18 and 60 years; Able to participate in a 3- and 6-month follow-up post-intervention; Able to give contact details for at least two to three other people (for follow-up); Having a fixed address; Not pending incarceration within the next 3 months; Absence of cognitive impairment or severe behavior problems; Not intoxicated or going through withdrawal from alcohol or other drugs; Not currently in drug or alcohol or nicotine treatment; Scored between 4 and 26 (moderate risk) for tobacco and between 11–26 for alcohol (moderate risk).	Participants who scored between 0 and 26 on the ASSIST for cannabis, cocaine, ATS and opioids, hallucinogens, sedatives, and inhalants;Participants who score low between 0–3 for tobacco and 0–10 for alcohol;Participants who scored in the high risk category (27 or higher for any of the substances);Participants who had frequently injected drugs in the last three months (more than 4 times per month on average),	6 months
Pimple 2016	India, Mumbai	400 (NA)	Subjects who are willing to participate; All workers employed in each of the listed zari units; Who are willing to give informed consent.	Who are NOT willing to give informed consent.	12 months
Rajanandh 2012	India, Kanchipuram	80 (100)	Men from 18 to 65 years of age;Participant with FEV1 value from (50–80)%.	Women;Participants with chronic illness; Mentally challenged.	3 months
Rungruang-hiranya 2008	Thailand, Nonthaburi	43 (97.7)	18 years of age or older;Had smoked an average of 10 cigarettes or more per day for the past year;Interested in quitting smoking within the next 30 days.	Pregnancy;Previous use of other smoking cessation aids in the past month;A history or current diagnosis of coronary artery disease;Stomach ulcers; Uncontrolled hypertension;Diabetes mellitus;Use of illicit drugs;Nonadherence to treatment.	3 months
Rungruang-hiranya 2012	Thailand, Nondhaburi	100 (89.9)	Older than 18 years old;Smoked regularly at least one year prior to study;Desired to quit smoking;Signed informed consent.	Current dental problems;Active peptic ulcer disease;Psychiatric disorders;Citrus allergy;Pregnancy;Use of illicit drugs;Participation in another clinical trial;Using any first-line smoking cessation aids within 30 days.	24 weeks
Sarkar 2013	India, Delhi	992 (NA)	Adult of age 23 years or above;Current self–reported daily user of any tobacco product;Residing in the study community.	Pregnancy in women.	7 months
Sarkar 2014	India, Delhi	992 (NA)	Age 23 years or above;A current self–reported daily user of any tobacco product;Residing in the study community.	Pregnancy in women.	7 months
Sarkar 2017	India, Delhi	1213 (79.7)	Current, daily, adult tobacco user;Aged 23 years or above;Living in selected low-income communities;Provided consent to participate.	Adults aged 22 or younger.	7 months
Savant 2013	India, Maharashtra	150 (NA)	Above 18 years;Wanting to quit tobacco.	Individuals who had frank lesions of oral cancer; Individuals who were uncooperative and unwilling to participate.	6 months
Scarinci 2019	Brazil, Parana	338 (NA)	Woman; Current tobacco user; 18 years of age; Living in the randomized neighborhood.	NA	7 months
Schuurmans 2004	South Africa, Cape metropolis	200 (55.0)	Age of subject 18 years;Daily cigarette consumption 15 for >3 years; Exhaled carbon monoxide (CO) >10 ppm (p.p.m); 1 quit attempt(s) in the last 12 months.	Current NRT;Use of non-cigarette tobacco products;Pregnancy or intended pregnancy;Use of psychoactive drugs; Drug or alcohol abuse;Any unstable medical condition;Myocardial infarction in the last 6 months.	26 weeks
Selvamary 2016	India, Chennai	170 (NA)	All tobacco users (both smoking and smokeless form) reporting at the Department of Public Health Dentistry, Tamil Nadu Government Dental College and Hospital, Chennai	Patients who are deaf and dumb;Patients who are mentally challenged or under treatment for psychiatric disorders.	6 months
Sharifirad 2012	Iran, Gorgan	110 (98.2)	Having readiness to quit; Age range were between 12 and 80-years-old; Not being pregnant; Not suffering from MI or CVA (Myocardial Infarction or Cerebra Vascular Accident) in the last 3 weeks.	NA	6 months

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Table 1 (*continued*)

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Sharma 2018	India, New Delhi and Tirupati	800 (99.8)	All adult patients (>18 years);Newly diagnosed sputum-positive pulmonary tuberculosis with self-reported history of current cigarette/rolled tendu or temburni leaf (bidi) smoking (more than 10 per day, every day for at least two months);Providing written informed consent were recruited by invitation.	Monoresistant TB, multidrug-resistant TB, extensively drug-resistant TB cases21;Patients who had received ATT for more than 1-week; Patients with known contraindications to the use of NRT; Patients with asthma, depression, on immunosuppressive therapy; HIV-TB co-infected patients.	24 weeks
Shelley 2020	Vietnam, Hanoi	100 (NA)	Smoke 10 cigarettes per day;Capability to read and communicate;Plan to quit in the next 30 days;Has a mobile phone; Has experience using mobile phone text messaging during the past 6 months.	Under smoking cessation treatment;Participating in other tobacco cessation intervention Pregnant or breastfeeding.	3 months
Siddiqi 2010	Pakistan	Proposed two focus groups of 6–8 participants for each category (NA)	NA	NA	6 months
Siddiqi 2013	Pakistan, Jhang and Sargodha districts	1955 (95.3)	Consenting patients aged 18 years or older with suspected pulmonary tuberculosis (cough for 3 weeks without any other cause);Regular tobacco smokers (1 cigarette/d) were enrolled in the trial between June 2010 and February 2011.	Those requiring hospitalization or urgent medical attention	6 months
Singh 2010	India, Delhi	30 (96.7)	Age 18 years;Smokers 10 cigs/bidi per day for past one year;Subjects motivated to quit smoking.	History of stroke or brain tumor; Presence of an unstable cardiac or renal condition; Pregnancy; Lactation; Current alcohol abuse (>2 "yes" on CAGE questionnaire); Current use of a chewable tobacco containing product which the patient refuses to give up;Current episode of major depression (Beck's depression inventory score of >9);History of a current drug abuse.	16 weeks
Sorensen 2013	India, Bihar	947 (69.5)	Eligible schools had at least 8 teachers. School districts located in flood zones;Teachers who started work at the study schools after the beginning of the intervention school year from secondary analyses	9 months	
Sorensen 2013	India, Bihar	947 (69.5)	Government schools with grades 8 to 10 from 10 school districts in Bihar with at least 8 teachers.	School districts located in flood zones	9 months
Sorensen 2017	India, Mumbai	7,633 (94.1)	Employ at least 200 production workers (this definition was expanded to include at least 60% of the workforce to be comprised of production workers); Be located in the Greater Mumbai area, including the Mumbai, Thane, or Raigad districts; Be involved in some type of manufacturing;Be willing to provide a current employee roster as part of survey planning; all workers eligible.	NA	18 months
Tang 2018	China, 30 cities	1369 (94.6)	Daily smokers 18 years of age and older;Living in China; Being able to read and write in Chinese;Owning a text-capable cell phone and knowing how to text;Willing to make an attempt to quit smoking in the next month;Agreeing to smoking cessation status verification by a significant other (e.g., family member, friend);Willing to provide informed consent to participate in the study.	NA	24 weeks
Thankappan 2014	India, Kerala	224 (100)	Adult male diabetic patients;Aged 18 years and older;Smoked in the previous month from two diabetes clinics of Kerala.	NA	1 year
Tundulaw-essa 2010	Thailand, Lopburi	24 (100)	18 years of age or older;Average of 10 cigarettes or more per day for the past year smoking;Interested in quitting smoking within the next 30 days.	Pregnancy;Previous use of other smoking cessation aids in the past month;A history or current diagnosis of coronary artery disease;Stomach ulcers; Uncontrolled hypertension.	4 weeks
Urdapilleta-Herrera 2013	Mexico	94 (NA)	NA	NA	12 months

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Table 1 (*continued*)

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Vinnikov 2008	Kyrgyzstan	171 (97)	20 years old and older;Smoked at least 15 cigarettes a day during the year prior to inclusion into the trial;Claimed high motivation to quit smoking and readiness to do so immediately and had not had any experience of cytisine use before; Recruited all our patients from the staff of the mining company in Kyrgyzstan, mainly men, who either had taken part in group cessation programs at the workplace before, but unsuccessfully, or were invited into this trial as the first attempt to stop smoking.	Having serious or unstable disorders;Being contraindicated for cytisine use (ischemic heart disease, severe arrhythmia, severe atherosclerosis, schizophrenia, tumors, pregnancy, breastfeeding).	6 months
Wang 2018	China	300 (93.3)	Voluntarily participated in this trial; Daily smokers and were motivated to quit;Aged 18 to 70 years; Smoked for > 1 year; Smoked an average of at least 10 cigarettes per day during the previous year; Signed the informed consent; and had positive results of a urine nicotine test at screening.	Had mental diseases;Had serious cardiovascular diseases;Had apoplexy or nervous system diseases;Had disturbances of blood coagulation;Were pregnant;Had use of acupuncture, auricular point pressing, or NRT within the last 30 days	24 weeks
Ward 2013	Syria, Aleppo	269 (78.5)	18–65 years of age;Smoked at least 5 cigarettes/day for at least 1 year.	A diagnosis of generalized dermatology disease, liver failure, hyperthyroidism or pheochromocytoma; Current use of psychotropic drugs; Past year history of drug or alcohol abuse;Current unstable cardiovascular or psychiatric illness, or any other debilitating disease based on their physician's assessment; Currently pregnant, lactating or intending to become pregnant during the next three months	12 months
Wee 2018	Malaysia	502 (NA)	NA	NA	6 months
Wei 2013	China, Zhejiang province	31708 (NA)	Participants will be identified from existing health records;Adults aged 50 to 74 years;Calculated 10-year CVD risk of 20% or higher, or diabetes;Township hospitals that have electronic health records of their residents for the last two years; Situated within the three selected counties of Zhejiang; Have agreed to participate in the trial.	Patients with mental health problems or other disabilities which mean they cannot communicate with family doctors well or regularly; Patients who have had any severe CVD event, including acute coronary events, acute myocardial infarction, and any ischemic or hemorrhagic cerebrovascular events;Patients with other severe diseases, for example, late stage cancer; Patients who are hospitalized; Patients who have had serious adverse effects to the drugs used in the trial; Patients who have diastolic blood pressure lower than 60 mmHg as they are contraindicated to hypertensive drugs; Patients who are at high risk of CVD but do not have hypertension (more than 140/90 mmHg) or diabetes;Individuals who decline to participate in the trial.	24 months
White 2013	Thailand, Nakhon Nayok province	201 (87.2)	Current smokers aged 20 and older;Resided in a study community.	NA	14 months
White 2018	Bangkok, Thailand	4241 (NA)	NA	NA	12 months
Wu 2017	China, Beijing	369 (100)	Aged 18 years or above;Smoked 10 cigarettes or more daily in the past month; Had no intention to quit smoking; Agreed to participate in the follow-up and provided a telephone number; Signed an informed consent form, which included information of the study aims, assessments and data collection.	Had smoked fewer than 10 cigarettes per day in the past month; Had a disease that made the physician decide that it was unethical to advise the patient to quit smoking quickly; Had severe deafness or were unable to understand and complete the questionnaire; Were pregnant or lactating.	12 months
Xavier 2016	India	806 (83.0)	Discharged after an acute coronary syndrome event who consented to adhere to the procedures of the trial for 1 year.	Patients living more than 120 km (75 miles) from hospital; Patients unlikely to survive the study duration because of serious illness.	12 months

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Table 1 (*continued*)

Author, year	Location (Country, City)	No. of Participants (No. Male %)	Inclusion Criteria	Exclusion criteria	Study Duration
Xiao 2016	China, multiple cities	483 (96.3)	Chinese adult smokers (at least 18 years old who smoked daily for at least 1 year before study enrollment);Had a strong motivation to quit smoking as assessed by an affirmative response to the question "Are you motivated to quit smoking within the next 30 days using NRT or placebo lozenges?" and the investigator's clinical opinion.	Used tobacco other than cigarettes (eg, pipes, cigars, snuff) or nicotine delivery systems other than lozenge (eg, nicotine gum, nicotine patch, nicotine inhaler, or nasal spray); Smoked illicit substances (eg, cannabis, cocaine, heroin, ice drug); used smoking cessation aids within 30 days before study entry; Had a history of alcohol or drug use; Were currently involved in any other clinical trial or previous participation in this study; Were pregnant, breastfeeding, or of childbearing potential but refused use of medical contraception; had unstable or uncontrolled systemic medical conditions, hyperthyroidism, or used insulin for diabetes mellitus; Recent myocardial infarction or cerebral vascular accidents; Allergy to aspartame or phenylpyruvic acid; Diagnosis of phenylketonuria; Medical history endangering subject safety or study result validity.	12 months
Yu 2006	China	60 (NA)	NA	NA	12 weeks
Yu 2017	China, Changchun	342 (NA)	Nonsmoking mothers and their newborns were currently exposed to SHS in the home; Fathers currently smoked cigarettes in the home; The parents both owned a mobile phone that could receive text messages; The family was able to provide informed consent.	NA	12 months
Yuan 2015	China, Qianjiang	1008 (94.4)	Over 40 years of age; Confirmed COPD or at high risk for COPD	Incomplete information such as census data or moving to another area after the study began; If they had diseases such as asthma, bronchiectasis, interstitial lung disease, active tuberculosis, chronic heart failure, cancer, or other diseases that could potentially affect the spirometry test; If they could not communicate well with the respiratory specialist;Unwilling to participate in the study.	18 years
Yuhongxia 2011	China	220 (NA)	Smoking over 10 years;Over 10 cigarettes each day; Age 18 to 70 years; Have strong motivation to quit smoking; Be suitable and willing to receive Varenicline treatment; Be able to receive SM and willing to receive relevant information; Sign the Informed Consent Form.	Serious abnormality of liver and kidney functions; Have serious skin allergy or mental diseases history, or any other disease not suitable for using Varenicline;Alcohol abuse or other drug abuse; Any concomitant illness or mental condition that could interfere with the study; Any conditions indicating study subjects uncooperative; Unable to receive or read SM;Any subject that Investigators think not to be suitable for enrollment	24 weeks
Zahid 2017	Pakistan, Punjab	510 (NA)	Adults who smoke a waterpipe on a daily basis for at least 6 months, with or without concomitant cigarette, bidi or other tobacco smoking;Who wish to quit smoking.	Have used any pharmacotherapy for tobacco dependence (including nicotine replacement therapy and electronic cigarettes) in the last 30 days; Are pregnant, lactating or planning to become pregnant;Have a medical condition requiring hospitalization;Have previously used varenicline and had an allergic reaction;Have a history of heart disease, including unstable angina, untreated cardiac arrhythmia, myocardial infarction, or have undergone a cardiac procedure (in the last 3 months);Have uncontrolled hypertension or a history of stroke;Have a history of chronic kidney disease;Have a history of epilepsy; Have suicidal ideation or a history of self-harm;Have a history of schizophrenia, psychosis or bipolar disorder;Have current moderate or severe depression;Currently use smokeless tobacco;Actively use substances (including alcohol misuse) other than tobacco.	25 weeks
Zheng 2007	China, Shanghai and Changqiao	225 (93.4)	Being 18 years or older; Smoked more than 100 cigarettes in life time and still smoking when they were recruited; Willing to attend a five-session course and to be followed up for at least 6 months.	NA	1 year

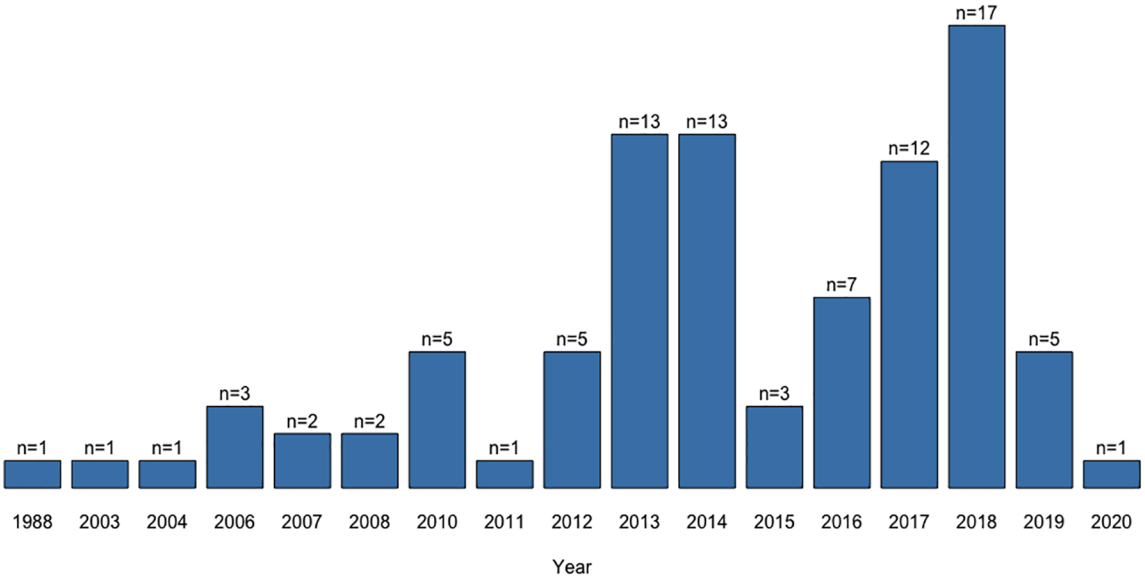

Fig. 3. Tobacco cessation RCTs in LMICs by year.

studies met all five criteria. Another thirteen studies met four criteria. Studies on psychosocial RCTs were most likely to fulfil the criteria for quality of execution, with eight studies meeting all five criteria. One behavioral study, two psychosocial/behavioral RCTs, and two psychosocial/pharmacological RCTs met five criteria. Studies on psychosocial RCTs and psychosocial/pharmacological RCTs were most likely to fulfil four criteria, with four studies in each category meeting four criteria. The remaining studies in this review met between zero and three of the criteria.

Table 3 indicated the risk of bias assessment for the RCTs. The major issue regarding risk of bias was sequence generation. RCTs had additional problems of small sample sizes, and use of tobacco cessation self-report.

4. Overview of research by countries

In this section we provided an overview of tobacco cessation RCTs by country. For each country, we first detailed the number of RCTs, followed by a breakdown by RCT type and then provided an example of an RCT of each type, where available, which had a large and significant difference in treatment and control groups. For brevity, we did not provide significant detail for every RCT.

4.1. India

Twenty-six studies were conducted in India. Most (70%) were psychosocial RCTs, followed by psychosocial/behavioral (19%) and psychosocial/pharmacological (8%). There was a single pharmacological RCT, using bupropion, that had a significant difference in seven-day point prevalence abstinence rate at the end of week 2 (P = 0.04) (Singh & Kumar, 2010). Most psychosocial studies involved counseling, using techniques such as 30 min individual counseling and group counseling. Other variants of psychosocial RCTs included physician-led health education, site-based health education, and patient discussions with community health workers. A psychosocial RCT with a large effect size was one targeting adult smokers with pulmonary tuberculosis through brief counseling and cessation support (Goel, Kathiresan, Singh, & Singh, 2017). The study reported higher smoking cessation in the intervention group (80.2%) relative to the control (57.5%) (adjusted incidence risk ratio = 1.56; 95% CI = 1.24–1.93; P < 0.0001). Within psychosocial/behavioral RCTs, there were several culturally specific variants incorporating counseling and yoga. One of these studies found that participants in the yoga group had higher odds of abstinence compared to participants who only experienced behavioral counseling (OR = 2.9, 95%CI = 1.2, 6.7) (Aggarwal & Kumar, 2017). Other variants of psychosocial/behavioral RCTs included health education combined with banning tobacco advertising at a school. Both psychosocial/pharmacological RCTs combined a pharmacological therapy with counseling. For example, one RCT used varenicline for smokeless tobacco users receiving behavioral counseling (Sharma et al., 2018). Self-reported abstinence was significantly greater for varenicline (43%) versus placebo (31%; adjusted odds ratio = 2.6, 95% CI = 1.2–4.2, P = .009).

4.2. China

Seventeen studies were conducted in China. Most (71%) were psychosocial RCTs, followed by pharmacological (12%) and psychosocial/pharmacological (12%). There was a single behavioral RCT, which was culturally specific, investigating the efficacy of acupuncture, auricular point pressing, and nicotine replacement therapy on tobacco cessation (Wang et al., 2018). There were two pharmacological RCTs, one used nicotine lozenges and the other provided nicotine sublingual tablets. This second RCT used nicotine tablets and indicated a statistically significant difference in exhaled carbon monoxide concentration over the control (Peng & Wang, 2007). Most psychosocial RCTs used counseling, with techniques such as brief smoking cessation advice and healthy lifestyle counseling. The remaining psychosocial RCTs used text messaging or phone calls, such as regular text messages providing smoking cessation advice or weekly health education messages. Within the psychosocial RCTs, we noted a study with large differences in control vs treatment groups, where smokers with chronic obstructive pulmonary disorder reported differences in continuous smoking abstinence rates between the 24th and 48th months of the intervention [44.3% (intervention) vs 5.1% (control), P < 0.001] (Lou et al., 2013). There were two psychosocial/pharmacological RCTs, which combined pharmacological therapies with either counseling or text messaging. One psychosocial/pharmacological RCT used nicotine replacement therapy and a psychosocial intervention, and reported statistically significant differences in the relapse rate between groups [8.33% (nicotine replacement therapy and psychosocial intervention) vs 33.33% (nicotine replacement therapy)] (Yu, Zang, & Lin, 2006).

Table 2
Study characteristics related to population, intervention or exposure groups, comparator, and assessed outcomes.

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
Aggarwal 2017	Adults in urban low-income communities	Only behavioral counseling: 62Yoga group: 62	behavioral counseling and bi-weekly yoga classes.	behavioral counseling at 0, 2, 4, 8 and 12 weeks.	7-day point prevalence smoking abstinence rates at 4-week follow-up.	NA	Participants in the yoga group exhibited higher odds of being abstinent at the end of 8 weeks [Odds Ratio: 3.1, 95% CI: 1.2 – 6.4] and 12 weeks [Odds Ratio: 2.9, 95% CI: 1.2– 6.7]
Ahmadi 2003	Chronic smokers	Nicotine gum: 57Clonidine: 57Naltrexone: 57	Nicotine gum (2 mg pieces), oral naltrexone (50 mg), or oral clonidine (0.4 mg) for up to 24 weeks.	NA	Quitting success rate.	NA	Abstinence rates at 24 weeks were 36.8% for the nicotine gum group, 19.3% for the clonidine group and 5.3% for the naltrexone group (x^2 = 17.53, DF = 2, p =.000).
AidaMaziha 2018	Chronic smokers	Al-Quran recitation: 25Counseling: 25	Counseling using Al-Quran recitation.	Counseling using the 12'M' method	Primary: Smoking cessation rate at the 1-year follow-up.Secondary: Smoking cessation rate at the 6-month follow-up, CVD risk, blood pressure and heart rate at 12 month follow-up.	NA	The reduction in the number of cigarettes smoked was 7 cigarettes in the counseling group and 9 cigarettes in Al-Quran recitation group by end of treatment.
Areechon 1988	Chronic tobacco users	Intervention group: 99Placebo: 101	Chewing gum containing 2 mg of alkaline-buffered nicotine and 1 mg of unbuffered nicotine.	Placebo gum without nicotine.	Smoking status (claims of abstinence from smoking was assessed after six months).	NA	At six months, 56 members of the active gum group and 37 members of the placebo group were not smoking (P < 0.01).
Aryanpur 2016	Families with fathers who smoke	Control: 70Brief advice: 70Combined intervention: 70	Smoking cessation counseling with bupropion over a short course of Directly Observed Treatment (DOTS).	DOTS regimen.	Cost-effectiveness of a multi-faceted intervention to control tobacco dependence.	Nonsmokers: patients with an exhaled CO level of less than 7 ppm.Smokers: subjects with a CO level of higher than 7 ppm.	Abstinence rate at the end of six months was higher in the combined intervention group (71.7%) than the brief advice group (33.9%) and control group (9.8%).
Asfar 2014	Female tobacco users	Intensive Intervention: 27Brief Intervention: 23	Three 45-min, individual, in-person sessions and five brief phone calls.	One 45-min, individual, in person educational/ counseling session and three brief (approximately 10 min) phone calls.	Number of days without smoking and number of cigarettes smoked per day.	Prolonged abstinence: complete abstinence after a two-week grace period following the quit day at three months post-cessation.Seven day point prevalence abstinence: no waterpipe use during the seven days preceding the follow up interview, based on self-report and a CO level of <10 ppm.Continuous abstinence: complete abstinence since the quit day, based on self-report and a CO of 10 ppm	30.4% of brief intervention participants and 44.4% of intensive intervention participants had prolonged abstinence at 3 months.
Augustson 2017	Female tobacco users	High frequency text contact: 4000Low frequency text contact: 4000	High-frequency text contact (HFTC) group: 1–3 messages daily with smoking cessation advice and	Low frequency text contact (LFTC) group: 1 weekly health education message.	Smoking status at 0, 1, 3, and 6 months after intervention.	NA	Quit rates were high in both the HFTC and LFTC groups in all months with no

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
			health education information.				significant difference between groups.
Aung 2013	Generic smokers	Intervention: 164Control: 164	Individual counseling from nurses and nicotine replacement chewing gum for nicotine cravings.	Individual counseling from nurses.	Primary: self–reported 6–month sustained abstinence (biochemically verified).Secondary: sustained 3– month abstinence, 7–day point–prevalence abstinence at 1, 3 and 6 months after the intervention.	Smoking cessation: self-reported quitting confirmed by breath analysis of the level of carbon monoxide (CO) in expired air.	NA
Aung 2019	Generic smokers	Intervention: 160Control: 159	Regular patient motivation over 3 months, assistance from a family member using a smoking cessation diary and optional nicotine replacement chewing gum therapy.	Routine service: brief counseling and casual follow up.	Smoking cessation for six months at the end of the one year follow-up.	Smoking cessation: self-reporting of smoking cessation over the previous 24 h, self-reporting of smoking cessation over the previous seven days, and a confirmatory measurement of carbon monoxide in parts per million (ppmCO) using a piCo + Smokerlyzer.	At 6 months, the smoking cessation rate was significantly higher in the intervention group (25.62%) than to the control group (11.32%).
Blebil 2013	Generic smokers	NA	Control care plus extra counseling sessions through phone calls during the first month of quit attempt.	A combination of nicotine gum for the first 2 weeks and cognitive behavior therapy.	Absorption rate of nicotine in volunteer blood.	NA	At 6 months, the abstinence rate differed between the standard care and combination of standard care and extra phone calls (48.6% vs. 71.7%, respectively: < 0.001).
Blebil 2014	Generic smokers	Intervention group: 120 Control group: 111	Control care plus extra clinic visits and proactive phone calls for counseling.	Usual care: 20–30 min individual counseling session, self-help materials, weekly smoking clinic visits and phone calls.	Self-reported continuous smoking abstinence, point prevalence of abstinence (7 days), cigarettes smoked per day.	Smoker: cut-off point CO level o f7 part per million (ppm)	6 months after the quit date, self-reported 4-week point prevalence was significantly higher in the intervention group compared than the control group (74.2% vs. 51.4%, respectively: P<0.001).
Campos 2014	Generic smokers	Brief intervention (BI): 45Intensive intervention (II): 45	Intensive cognitive behavioral therapy comprising a 10-min oral intervention and a 30-min educational video presentation.	Counseling of the dangers of smoking and benefits of quitting in an ordinary session lasting 10 min Abstinence prevalence at 3 and 6 months after quit date.	NA	After 6 months follow-up, 40.7% patients continued abstinent (BI = 9	II = 24) and 59.3% had relapsed (BI = 31 and II = 17).
Campos 2018	Generic smokers	Intervention group: 45Brief intervention group: 45	Intensive cognitive behavioral therapy comprising a 10-min oral intervention and a 30-min educational video presentation.	10-min counseling session.	Self-reported abstinence in the 6-months preceding the 7-month follow-up, with confirmation by saliva cotinine.	NA	At 6 months of follow-up, the estimated overall abstinence rate was 40.7% in the BrInter and InInterV groups.
Cruvinel 2018	Generic smokers	Intervention: 44Control 22	A single telephone call from study staff during the first week following discharge, plus multiple text messages post-discharge.	Educational materials, brief intervention (BI) and access to NRT (adhesive patch and gum) for eligible patients.	Primary: incidence of severe CVD events over 24 months of follow-up.Secondary: blood pressure, blood glucose, serum total cholesterol (TC), and adherence to appointments, and	Verified abstinence: carbon monoxide of 10 ppm.	There was a higher prevalence of abstinence in the TXT compared to the control group at 3-month follow-up (31.8% vs. 9.1%).

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
					drugs and lifestyle changes.		
Davoudi 2017	Generic smokers	Intervention: 34Control: 33	Acceptance and commitment therapy (ACT) in eight 90-min one-to-one sessions.	Routine counseling services	Addiction level as measured by the 6 items scale of Fagerstrom Test for Nicotine Dependence	NA	Post-test, the number of patients in the intervention group who quit smoking was significantly greater than the number in the control group (22 vs. 12, Pearson chi-square = 5.38, P < 0.050).
deAzevedo 2010	Generic smokers	Low intensity intervention: 132High intensity intervention: 141Control: 80	Low intensity intervention: 15 min individual counseling session; High intensity intervention: 30 min individual counseling session (motivational interview).	Usual care: no specialist counseling for smoking cessation	Smoking cessation as determined by self reported 7 day point prevalence abstinence.	NA	The smoking-cessation rates were 44.9%, 41.7% and 26.3% for the HII, LII and UC groups, respectively (P =.03).
Dogar 2014	Generic smokers	Hookah smokers: BSS+: 27, BSS: 118, Control: 70; Cigarette: BSS+: 465, BSS: 371, Control: 419; Mixed: BSS+: 167, BSS: 151, Control: 167	BSS: behavioral support sessions; BSS+: behavioral support sessions + 7 weeks bupropion therapy	Usual care	Compliance of Varenicline usage and the smoking abstinence rate.	Continuous abstinence: expired CO measurement of 9 ppm.	Compared to the control, both interventions appeared to be effective among hookah smokers (RR = 2.5; 95% CI = 1.3–4.7 and RR = 2.2; 95% CI = 1.3–3.8, respectively) but less effective among cigarette smokers (RR = 6.6; 95% CI = 4.6–9.6 and RR = 5.8; 95% CI = 4.0–8.5), respectively.
Dogar 2018 (#1)	Generic smokers	Intervention: 253 Control: 257	behavioral support sessions and 0.5 mg varenicline tables for 1 week, and 1 mg for remaining weeks.	behavioral support and placebo.	Primary: 24-h point abstinence rate (<10 ppm), 24 weeks after quit day.Secondary: adverse events, continuous abstinence rate, Fagerstrom Nicotine Dependence Test (FTND) and Minnesota Nicotine Withdrawal Scale (MNWS) scores.	Self–reported point abstinence: not even a puff/chew/session in the previous 7 days. Verified by CO cut–off < 10 ppm.	NA
Dogar 2018 (#2)	Generic smokers	Intervention: 253Control: 257	behavioral support sessions and 0.5 mg varenicline tables for 1 week, and 1 mg for remaining weeks.	behavioral support and placebo	25 weeks continuous abstinence.	Abstinence: Biochemically verified by a carbon monoxide level of < 10 ppm.	NA
Faustino da Silva 2018 (#1)	Generic smokers	NA	Combination of cognitive interventions to develop behavioral skills.	Combination of cognitive interventions to develop behavioral skills.	Smoking cessation rate.	NA	NA
Faustino da Silva 2018 (#2)	Generic smokers	Intervention: 60Control: 60	Combination of cognitive interventions to develop behavioral skills.	Received a quit smoking manual.	Self-administered questionnaires, with validation conducted using expired air carbon monoxide measurement.	Sustained abstinence: self reported abstinence at 90 days after the end of the program.	NA
Ghanem 2014	Generic smokers	Intervention: 125Control: 130	Intensive anti-smoking counseling program with three follow up visits for	Standard clinical practice and short (1 to 3 min) sporadic sessions of	Self-reported smoking withdrawal rate and relapse rate.	NA	The rate of continuous abstinence at 6 months was 22.8%

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
			reinforcement of abstinence.	unstructured medical anti-smoking advice.			for the intervention versus 6.7% for the control group (p<0.000).
Ghoreishi 2019	Generic smokers	Intervention: 37Control: 38	300 mg Gemfibrozil at the same amount twice a day for 7 weeks.	300 mg placebo at the same amount twice a day for 7 weeks.	Long-term abstinence.	NA	There was no significant difference between frequency of quit success at the end of follow-up period between groups [treatment (43.2%), placebo (28.9%), P = 234].
Goel 2017	Generic smokers	Intervention: 78Control: 74	ABC intervention: ask about smoking habits, give brief advice on smoking cessation and provide cessation support.	Standard care.	Smoking cessation.	Smoking cessation: patient had not smoked at all in the last 2 weeks.Quit attempt: patient who tried to quit and succeeded for at least 24 h.	The intervention group reported 83.6% successful outcomes compared to the control group (88.2%).
Haggstram 2006	Generic smokers	Nortriptyline group: 52 Bupropion group: 53 Placebo group: 51	Cognitive behavior therapy, supportive phone call, pamphlet and bupropion or nortriptyline.	Cognitive behavior therapy, supportive phone call, pamphlet and placebo.	Primary: continuous smoking abstinence at 24 weeks.Secondary: self-reported 7-day point prevalence of abstinence, continuous abstinence and average number of cigarettes smoked per day.	Continuous abstinence: subject was not smoking since the target-quitting day (self-report) and had an expired carbon monoxide concentration of 10 ppm or less.	At 6 months, only the bupropion group had a significantly higher rate of abstinence (41.5%) than the placebo group (21.6%, p = 0.05).
Han 2014	Generic smokers	Intervention group: 83Control group: 80	Ten-minute physician counseling session to quit smoking with measurements of smoking behavior via questionnaire at baseline at intervals.	Received a list of quit smoking clinics addresses and contact numbers.	Biochemically assessed 7-day smoking abstinence.	NA	Statistically significant change in smoking behavior at one-month post intervention (p = 0.024, intention to treat analysis; OR = 2.525; CI = 1.109–5.747). Self-reported quit rate at three months in the control (8.8%) and intervention (10.8%) groups were not statistically significant.
Heydari 2012	Generic smokers	Brief counseling: 90 Nicotine patch: 92 Varenicline: 89	Brief counseling session and nicotine patches 15 mg/daily for 8 weeks or one 0.5 mg varenicline pill daily dosed up over 8 weeks.	NA	Quit rate and harm reduction (reduction of smoking more than 50% of baseline use).	NA	Follow up at a year showed 6.6% of the first group, 25% of the second group and 32.6% in the third group remained smoke free.
Heydari 2014	Generic smokers	Intervention group: 212Control group: 212	6-month methadone treatment and smoking cessation behavior therapy with concurrent nicotine replacement.	6-month methadone treatment and smoking cessation behavior therapy.	Self reported and test verified abstinence rates recorded weekly for 24 weeks.	Reduction in smoking: greater than 50% reduction in cigarettes smoked per day when compared with the initial severity of the habit.	After 6 months, 0.5% of the control group and 7.1% of the intervention group had quit smoking (P<0.0001).
Hofmeyr 2018	Generic smokers	Intervention: 52Control: 53	Aid-to-quit document and quit attempt monitoring and opportunity to earn abstinence-contingent incentives	Aid-to-quit document and quit attempt monitoring.	7-day point-prevalence abstinence 0 at the end of 8 weeks and 12 weeks.Abstinence: CO reading 6 ppm.	CM had no long-term effect on abstinence at 6 months but had a marked and statistically significant effect on the likelihood of abstinence by the end of the intervention period (p<0.001).	
Iyapparaja 2018	Generic smokers	NA	SMS text messages and regular tobacco cessation counseling.	Regular tobacco cessation counseling.	Abstinence, relapse rate (use of cigarettes for seven consecutive days	NA	Number of abstinent participants in the intervention arm

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
					or seven consecutive weekends).		went from 32 at baseline to 14, versus 29 to 5 in the control arm at the third month.
Jain 2014	Generic smokers	Intervention: 119Control: 118	Varenicline 1 mg twice per day, behavioral counseling every other week.	Placebo 1 mg twice per day, behavioral counseling every other week.	Self-reported abstinence, validated by measuring exhaled carbon monoxide.	Self-reported abstinence: urinary cotinine cutoff 50 ng/ml, breath CO <10 ppm.	Biochemically confirmed EOT abstinence was greater for varenicline versus placebo but not significant (25.2% vs. 19.5%, P = 0.15).
Jhanjee 2017	Generic smokers	Intervention: 50Control: 50	A single 30-min counseling session and patient education brochure.	Simple advice was given using a patient education brochure focusing on risk and consequences of tobacco use.	Primary: rate of continuous abstinence at 3 and 6 months of follow-up.Secondary: withdrawal symptoms, adverse events.	NA	The relative risk of stopping tobacco use among subjects in the BI was 2.24 (95% confidence interval [CI]: 0.96–5.20, P = 0.06).
Josephson 2019	Generic smokers	NA	Motivational interviewing delivered by a community health worker and weekly support provided through regular mobile text messages.	Brief verbal advice about the hazards of smoking and the benefits of smoking cessation; encouraged to seek physician help.	Proportion of quitting, the 6-month abstinence rate.	Quit rate: Self-reported abstinence, biochemically verified, for the past 14 days at the end of 1 year from the start of the intervention.	NA
Khetan 2019	Generic smokers	280 in each arm (8 clusters with 35 participants in each cluster)	Health education and motivational interviewing through community health workers with low frequency text messaging, focused on health education and the benefits of quitting.	Brief smoking cessation advice only, at the start of the trial.	Primary: 7-day repeated point prevalence abstinence from all forms of tobacco. Secondary: Point abstinence at weeks 5, 12, or 25.	Quitting: breath CO level < 10 ppm.	NA
Koegelen-berg 2014	Generic smokers	Intervention: 222Control: 224	Varenicline and 15 mg nicotine patch for 12 weeks.	Varenicline and placebo patch for 12 weeks.	Smoking status confirmed by exhaled CO measurements.	NA	Combination treatment was associated with a significantly superior abstinence rate than varenicline plus placebo at 6 months post TQD (39.2% vs. 24.6%, p = 0.001).
Kumar 2010	Generic smokers	Intervention: 200Control: 200	counseling and a self-help booklet.	Self-help material.	7-day point prevalence abstinence, reduction of tobacco use.	Self reported point prevalence abstinence: No tobacco use in the past seven days.	Use of smokeless (42%) tobacco higher than NFHS3 data (18.8%).
Kumar 2012	Generic smokers	Intervention: 200Control: 200	A physician offered two sessions of health education 5 weeks apart along with self-help material on tobacco cessation to the intervention group.	Self-help material.	7-day point prevalence abstinence, reduction of tobacco use.	Point prevalence abstinence: no tobacco use in the past 7 days.Quit attempts: any attempt to quit tobacco, which lasts more than 24 h.Harm reduction: reduction of tobacco use more than 50% of baseline.	Significant difference in the self-reported point prevalence abstinence from tobacco use at 2 months in the intervention and control groups (13.8% and 6.5%, respectively).
Kumar 2017	Generic smokers	Intervention: 80Control: 80	Physician advice using a modified version of the 5As strategy for smoking cessation plus a brochure containing smoking cessation information, and	Brochures and counseling.	Self-reported abstinence 1 day after the end of the program.	Abstinence at first monthly visit: self reported, confirmed by carbon monoxide monitor reading (<10 ppm).Cessation: not currently smoking and a carbon monoxide concentration of	Quit rate among the intervention group vs. the comparator group was 35% vs. 30% (P = 0.500).

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
			counseling from a counselor.			<10 ppm at first monthly visit.	
Liao 2016	Generic smokers	1000 in each group	Regular, personalized text messages providing smoking cessation advice, support and distraction.	One text message every week, thanking them for being in the study and providing study centre contact details.	Self-reported and biochemically verified abstinence at end of treatment, lapse and recovery events, medication adherence.	Self-reported continuous smoking abstinence: five cigarettes smoked in the past week at 4 weeks follow-up and since the start of the abstinence period at 6 months of follow-up. Point prevalence of abstinence: not even a puff of smoke, for the last 7 days, at 4, 8, 12, 16, 20 and 24 weeks. Cigarettes smoked per day: number of cigarettes smoked per day within the past 4 weeks.	NA
Liao 2018	Generic smokers	High frequency SMS: 674Low frequency SMS: 284Control: 411	High frequency: 3–5 messages per day for 12 weeks and 3–5 messages per week for 12 weeks; low frequency: 3–5 messages per week for 12 weeks and 1–2 messages per week for 12 weeks.	Text messages unrelated to quitting.	Primary: continuous abstinence rate through week 9 to week 12.Secondary: abstinence rate at 24 weeks.	Continuous abstinence: smoking not more than 5 cigarettes from the quit day to 24 weeks, with urine cotinine cut off point 200 ng/ml.	Biochemically verified continuous smoking abstinence at 24 weeks was significantly higher in both the HFM (6.5% versus 1.9%, $p < 0.001$) and LFM (6.0% versus 1.9%, $p = 0.002$) groups than the control.
Lin 2013	Generic smokers	Intervention group: 74Control group: 52	Physicians give patients a standardized warning message while taking smoking history, advice to quit and refer patients to smoking cessation clinics.	No message, usual care.	Primary: self-reported smoking status among the fathers and SHS exposure at home among the mothers. Secondary: fathers' self-reported intent to quit, and smoke-free home policy enforcement.	7-day quitting point prevalence: no smoking at all in the previous 7 days at 6-month follow-up.	At 12 months, sustained abstinence prevalence rates were 14.9% versus 3.8% ($P = 0.035$, 0.046, 0.074).
Lou 2013	Generic smokers	Intervention: 1814 Control: 1748	Brief smoking cessation advice after the baseline interview and a plan to quit smoking.	Usual care.	Primary: change in the ASSIST alcohol use scores and ASSIST tobacco use scores from baseline to follow-up.Secondary: point prevalence tobacco use outcomes and drinking outcomes.	Continuous abstinence: participant report of zero cigarettes per day for at least 6 months, exhaled carbon monoxide values of 10 ppm.	At the 48 months, more participants receiving behavioral intervention remained abstinent than those receiving usual care (44.3% vs 5.1%, $p<0.001$).
Louwagie 2014	Generic smokers	Intervention: 205Control: 204	Brief motivational interviewing by lay health–care workers.	Brief smoking cessation advice from a TB nurse.	Primary: self-reported continuous abstinence for at least 6 months.Secondary: point abstinence, early lapse, late lapse, early relapse and late relapse.	Sustained abstinence: no smoking at all after the initial window period.	Quit attempts: not smoking for 24 h or more with the intention to quit.Self–reported 6–month sustained abstinence was 21.5% for the intervention group versus 9.3% for the control group [relative risk (RR) = 2.29, 95% confidence interval (CI) = 1.34, 3.92].
Luo 2018	Generic smokers	Intervention: 160Control: 160	5As and 5Rs (IPANR) intervention: Participants received three counseling during hospitalization	5Rs intervention: Participants received three counseling during hospitalization conducted by	Primary: continuous abstinence from smoking for 2 years.Secondary: continuous abstinence	Continuous abstinence rate: self-reported, confirmed based on exhaled carbon monoxide levels 10 ppm.	At 24 weeks, participants in the IPANR group reported significantly greater abstinence compared with

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
			conducted by cardiologists with extensive experience in smoking cessation.	cardiologists with extensive experience in smoking cessation.	during months 24–36 and 24–48.		participants in the 5Rs, 23.8% versus 15.0%, RR:1.583, 95% CI = 0.998–2.512 (χ^2 = 3.921; p = 0.048).
Naik 2014	Generic smokers	Intervention: 300Control: 300	Motivational interviewing.	NA	Expiratory CO concentration.	NA	After smoking cessation intervention, 17% showed no change in smoking, 21.66% reduced smoking, 16% stopped smoking, and 45.33% relapsed (P < 0.0001) at the end of 6-month follow-up.
Nair 2015	Generic smokers	Intervention: 474Comparator: 454	Group-counseling session cum medical examination.	Two wards chosen randomly; given tobacco health pamphlets.	Quit and relapse rates at the end of 1 year.	Abstinence: self reported without biochemical verification during the last seven days or more.	Prevalence in smoking abstinence at 12 months after the baseline survey was 14.7% in the intervention and 6.8% in the control.
Nichter 2016	Generic smokers	Doctors' message and proactive support group: 51Doctors' message group: 50	TB-specific quit smoking messages delivered by doctor and a TB and smoking educational booklet and quit smoking guide.	Doctors' cessation messages, the educational booklet, and proactive support by a trained family member.	Primary: change in TB score at 24-weeks and culture conversion at 8-weeks.Secondary: time to sputum smear conversion, weight gain at 24 weeks, quit rate, mortality by 24th week.	NA	By the end of treatment (month 6), 72% remained quit, 10% maintained smoking, and 18% resumed smoking following a period of smoking abstinence.
Nurul Asyikin 2018	Generic smokers	5A group: 193Brief advice group: 207	Motivation counseling using the 5A's and 5R's and self-help pamphlets.	A brief advice message to quit smoking (1–5 min).	Prolonged abstinence from cigarettes at end of treatment and 6 and 12 months post-cessation.	NA	Statistically significant difference between the smoking cessation interventions and abstinence of participants at 6-months of follow-up (p<0.001).
Onyechi 2017	Generic smokers	Intervention: 10Control: 10	Group-focused cognitive behavioral health education program.	10 weeks' conventional counseling.	Change in stage of smoking behavior at 1 and 3 months. Self reported quit rates at three months.	NA	After the intervention, the treatment group had a post-test mean score of 24.30±1.06, while the control group had a post-test mean score of 80.20±2.62.
Otero 2006	Generic smokers	NA	Three intensive cognitive behavioral therapy sessions with or without trans-dermal nicotine patches.	Brief intervention session (20 min) and an intensive one (60 min).	Abstinence, degree of nicotine dependence, degree of craving.	Abstinence: absence of cigarette use (not even a puff) for at least seven consecutive days, before the maintenance visit.Relapse: cigarette use for seven consecutive days or seven consecutive weekends.Lapse: consisted of sporadic use of tobacco, without establishing a smoking pattern.	In groups without adhesive, abstinence proportions were: 20% (GB), 17% (G1-G2) and 23% (G3-G4). In the groups with adhesive, approximately 30% (GBA), 34% (G1A-G2A) and 33% (G3A-G4A).
Peng 2007	Generic smokers	Intervention: 120Control: 120	Zero to twenty nicotine sublingual tablets per day with	Starch–prepared placebo orally.	Successful rate of smoking cessation, decreasing rate of smoking and exhaled	NA	Successful rate and effective rate of smoking cessation in the

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
			doses decreasing progressively.		carbon monoxide concentration.		placebo–controlled group (19.1%, 57.4%) were lower than the nicotine sublingual tablet group (52.2%, 85.2%) at the end of treatment.
Pengpid 2015	Generic smokers	Intervention: 215Tobacco only control: 199Alcohol only control: 205	Alcohol and tobacco use control: Three sessions of brief counseling for alcohol use reduction and tobacco use cessation.	Tobacco use control: Three sessions of brief counseling on tobacco use cessation.	Primary: biochemically-verified 7-day abstinence at 6 months.Secondary: biochemically verified abstinence, self-reported abstinence, and the incremental cost per quitter of the intervention.	NA	Statistically significant differences between the three study groups over the 6-month follow-up in past week tobacco use abstinence (Wald χ^2 = 7.34, P = 0.007).
Pimple 2016	Generic smokers	NA	Medium Intervention: Tobacco cessation counseling in the form of 3 contact sessions, Low intensity Intervention: Only a single contact session of tobacco cessation counseling.	Tobacco awareness pamphlets and no active intervention.	Tobacco quit rate.	Quitting: Abstinence for 12 months or more.	NA
Rajanandh 2012	Generic smokers	Intervention: 40Comparator: 40	Motivational interviewing and counseling about beneficial outcomes of smoking cessation.	Usual care.	Minnesota Deprivation Measurement Scale, Fagerstrom Scale, smoking cessation (CO level).	NA	Intervention: 23 (60%) of them are less frequent level of smokers; 14 (36.7%) of them are more frequent level of smokers and 3 (3.3 %) smoker is most frequent level of smokers.Usual: 29 (80 %) of them are less frequent level of smokers; 7 (16.7%) of them are more frequent level of smokers and 4 (3.3%) is most frequent level of smoker.
Rungruang-hiranya 2008	Generic smokers	Intervention: 20Control: 23	Behavioral support (personalized message from physician, self help material, individual counseling) and nicotine polyestex gum.	Behavioral support and placebo.	Primary: smoking intensity (reduction in the number of cigarettes smoked per day). Secondary: changes in withdrawal symptoms and changes in CO levels from week 1 to week 4.	NA	Treatment with nicotine polyestex gum resulted in significantly greater abstinence rate at 3 months (50% vs. 9%; p = 0.003).
Rungruang-hiranya 2012	Generic smokers	Fresh lime: 47Nicotine gum: 53	Individual counseling and self-report card for the use of gum or fresh lime.	Nicotine gum with dosage based on FTND scores.	Primary: complete abstinence at six months after treatment.Secondary: smoking at low-moderate levels and quit attempts.	Continuous abstinence rate: proportion of participants who self-reported having refrained from smoking any tobacco products and confirmed by CO of 10 ppm. Point prevalence abstinence rate: percentage able to abstain from smoking during preceding week.	7-day point prevalence abstinence at week 4 of the fresh lime users was statistically significantly lower than those using nicotine gum (38.3% vs. 58.5%; p = 0.04).
Sarkar 2013	Generic smokers		Single session of quit advice and training	Very brief advice.	Self-reported abstinence and carbon monoxide	NA	Self-reported abstinence rate was

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
		32 clusters Intervention: 16 Control: 16	in craving control using simple yogic breathing exercises.		monitor reading at 1 month.		significantly higher in the intervention than the control arm (14.1% versus 7.2%, $p<0.001$, $\chi^2=14.2$).
Sarkar 2014	Generic smokers	Intervention: 496 Control: 496	Single session of face-to-face tobacco quit advice including training in yogic breathing exercises to control cravings.	Very brief advice.	Self-reported abstinence in the 6-months preceding the 7-month follow-up, with confirmation by saliva cotinine.	Abstinence: self-report of a maximum of five cigarettes/bidis or five occasions of use of tobacco in the 6 months preceding the follow-up, validated by salivary cotinine concentration of <20 ng/ml.	NA
Sarkar 2017	Generic smokers	Intervention: 611 Comparator: 602	Single session quit advice (15 min) plus a single training session in yogic breathing exercises.	Very brief quit advice.	6-month sustained abstinence, assessed 7 months post intervention delivery, biochemically verified with salivary cotinine.	Abstinence: self-report of a maximum of five cigarettes/bidis or five occasions of use of tobacco in the 6 months preceding the follow-up, validated by salivary cotinine concentration of <20 ng/ml. 7-day point prevalence: no use of tobacco in the past 7 days.	The smoking cessation rate was higher in the intervention group (2.6%) than in the control group (0.5%) (relative risk = 5.32, 95% CI 1.43 to 19.74, p = 0.013).
Savant 2013	Generic smokers	Individual counseling: 50 Group counseling: 53 Control: 47	Individual and group counseling over 6 months.	Brief quit advice for 10–15 min.	Beck Depression Inventory score, Beck Anxiety Inventory score, smoking status.	NA	Significant difference in the quit rates of participants in the individual counseling group (6%) and group counseling group (7.5%) when compared at 6 months with the control counseling group (CCG).
Scarinci 2019	Generic smokers	NA	12-home visits by the Community Health Worker and referring to an appointment for the participant to attend the tobacco cessation program.	One home visit by the Community Health Worker for tobacco cessation program scheduling.	Tobacco cessation (Time Frame: 7 months).	Cessation: not smoking any tobacco products for 7 months after recruitment.	NA
Schuurmans 2004	Generic smokers	Intervention: 100 Control: 100	counseling and a daily nicotine patch for 12 weeks.	Screening visit: counseling and pre-treatment with daily placebo patch. Quit date (week 0) onward: active nicotine patches for 12 weeks and counseling	Primary: total abstinence rate determined by self-report with CO verification. Secondary: change of QOL after smoking cessation.	Success: complete sustained abstinence self-reported from the quit date to 6 months and verified by expired CO 10 p.p.m. at each visit.	Overall sustained abstinence was documented in 17% of subjects at 6 months; 22% and 12% for AP and PP, respectively (P = 0.03).
Selvamary 2020	Generic smokers	NA	Health education with cognitive behavior therapy in tobacco cessation.	Health education alone.	Self reported drug abuse and smoking reductions and abstinence at 1 and 6 months.	Self reported quit attempt: 24 h abstinence from tobacco usage. Point prevalence abstinence: 7 days abstinence from tobacco usage. Continuous abstinence: complete abstinence from tobacco usage.	NA
Sharifirad 2012	Generic smokers	Intervention: 50 Control: 60	5 personal counseling sessions and used free nicotine chewing gum for 2 months	Recommendations for cessation.	Self-reported tobacco use and cessation.	Quit rate: not one puff of smoke during the past 7 days. Continuous abstinence: not one puff of smoke	At 6–month follow–up, the point prevalence for the control group was 3.3% and 52% for

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
			with a phone line follow–up.			during the past 6 months.	treatment group (χ^2 = 33.881, P<0.001).
Sharma 2018	Generic smokers	Intervention: 400 Control: 400	Nicotine replacement therapy and behavior change counseling.	Counseling.	Primary: biochemically verified abstinence for the past 14 days at 1 year. Secondary: uptake rates of text messaging.	Quit rate: self reported rate and biochemical quitting rate.	The self-reported quit rates (69.3% vs 38.7%, P<0.001) at 24 weeks were higher in the intervention arm than control arm.
Shelley 2020	Generic smokers	Intervention: 100 Comparator: 100	Text messages for smoking cessation.	2 weekly text questions asking the number of smoking days in the past week and the average number of cigarettes smoked per day.	7-day point prevalence.	NA	NA
Siddiqi 2010	Generic smokers	6–8 in each of the three categories	Systematic, standardized approach to deliver 'five steps to quit' to make it effective and equitable.	Usual care and informational leaflet.	Continuous smoking abstinence at the 1- and 6-month follow-up visits.	Point abstinence at 4 weeks: The proportion of trial participants who have completely given up all forms of nicotine use at four weeks after completion of intervention. Continuous abstinence up to 6 months: Proportion of trial participants who remained abstinent from 4 weeks onward up to six months.	NA
Siddiqi 2013	Hospital patients	BSS+: 659 BSS: 640 Control: 656	behavioral support sessions and a free 7-week course of bupropion.	Usual care and the self-help leaflet on smoking cessation.	Continuous 6-month smoking abstinence determined by carbon monoxide levels.	Continuous smoking abstinence: an expired carbon monoxide (CO) measurement of 9 ppm.	In the BSS + group, 45.4% [CI, 41.4% to 49.4%] of participants achieved continuous abstinence compared with the BSS group (41.0% [CI, 37.1% to 45.0%]) and the usual care group (8.5% [CI, 6.4% to 10.9%]).
Singh 2010	Hospital patients	Intervention: 15 Placebo: 15	Bupropion SR 300 mg/day for seven weeks.	Placebo for seven weeks.	Self–reported "point prevalence abstinence" in 3–and 6 months follow–ups from baseline and continuous 6-month abstinence.	Abstinence: not even a single puff.	The seven-day point prevalence abstinence rate at the end of week 16 in the drug group was 53.33 % and 20% in the placebo group (P = 0.05).
Sorensen 2013	Hospital patients	Intervention: 36 schools, 498 employees Control: 35 schools, 449 employees	Implementation of tobacco control policy and 6 health education events.	Delayed-intervention.	0-day tobacco quit rate, 6-month continuous abstinence at the 9-month post intervention survey. Cessation: stopping use of any tobacco product by self-report.	At the 9-month post-intervention survey, the adjusted 6-month quit rate was 19% in the intervention and 7% in the control group (P = .06).	
Sorensen 2013	Hospital patients	Intervention: 387 Control: 369	Implementation of tobacco control policy and 6 health education events.	NA	30-day tobacco quit rate, 6-month continuous abstinence at the 9-month post-intervention survey.	Quitting: participants who had quit using tobacco after the beginning of the intervention and had not used in the past 30 days.	Adjusted 6-month quit rates were approximately 19% and 7% in the intervention and control groups, respectively (P = .06).
Sorensen 2017	Hospital patients	Intervention: 10 work sites, 3,551	Implementation of tobacco control	Delayed intervention and	Self-reported tobacco abstinence at 6 months.		The intervention resulted in a doubling

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
		workers Control group: 10 work sites, 3,329 workers randomized	policy and 6 health education events.	one HIV or tobacco-related health event.		Cessation: stopping use of any tobacco product by self-report.	of the 6-month cessation rates among workers in the intervention work sites compared to the control.
Tang 2018	Individuals at risk of cardiovascular disease or diabetes	High-frequency messaging (HFM): 674 Low-frequency messaging (LFM): 284 Control: 411	High frequency messages (HFM): 5 messages sent per day for 12 weeks. Low frequency messages (LFM): 3 to 5 messages sent per week for 12 weeks.	Text messages unrelated to quitting.	Primary: Continuous abstinence since the smoking discontinuation. Secondary: exhaled CO and change in health-related QL.	NA	At 24 weeks, biochemically verified continuous smoking abstinence was 6.5% in the high-frequency messages group, 6.0% in the low-frequency messages group and 1.9% in the control group.
Thankappan 2014	Individuals with confirmed chronic obstructive pulmonary disorder (COPD) or at high risk for COPD	Intervention-1: 112 Intervention-2: 112	Smoking cessation counseling sessions administered by doctors using the five "As" (Ask, Assess, Advise, Assist, Arrange) and the five "Rs" (Relevance, Risks, Rewards, Roadblocks, Repetition).	NA	Quit attempts measured 6 months after baseline, counseling participation rates, quit outcomes 12 months after baseline.	Quit rate: abstinence of smoking for at least 7 days. Harm reduction: reduction of smoking more than 50% of baseline use.	Odds of quitting or harm reduction in the intervention-2 group were higher compared with the intervention-1 group (AOR 2.21; 95% CI 1.24–3.93).
Tundulawessa 2010	Industrial workers in India	Intervention: 12 Control: 12	Nicotine polyestex gum. Highly dependent smokers were assigned to the 4-mg dose, and the others to the 2-mg dose.	12 subjects: two 2 mg pieces of Nicomild-2 Sugar Free Gum 12 subjects: two 2 mg pieces of Nicorette Sugar Free (bio-equivalent assay)	7-day point-prevalence abstinence at 6 months end of the intervention period.	NA	Treatment with nicotine polyestex gum were reported 65.3% (130/199) at 4 weeks compared with failure 30.15% (60/199) [65.3% vs 30.15%; P = 0.005].
Urdapilleta-Herrera 2013	Inmates	Intervention: 46 Comparator: 48	Cognitive behavioral therapy combined with bupropion.	Cognitive-conductual therapy combined with placebo.	Incidence of COPD, decline in lung function, and mortality of COPD.	Continuous abstinence up to 6 months: proportion of trial participants who remained abstinent from 4 weeks onward up to six months.	A higher proportion of subjects remained abstinent after 6 months in the intervention group [53% vs 47% ($p > 0.05$)].
Vinnikov 2008	Law enforcement personnel	Intervention: 85 Placebo: 86	Cysteine tables according to manufacturer's instructions.	Placebo tables in the same regimen as the control group.	Primary: continuous abstinence rate (CAR) from week 9–12 with CO confirmation. Secondary: CAR from week 9–24 was a secondary efficacy variable; point prevalence abstinence rate (PAR) week 4, 8, 12 and 24.	Continuous abstinence: no cigarettes at all and verified with exhaled CO level (<9 ppm)	In the cytisine group, CO reduced from 26.7 ± 8.7 to 19.3 ± 11.0 ppm ($p < .001$), but there was no significant change in the placebo group.
Wang 2018	Male smokers	Acupuncture: 100 Auricular point: 100 Nicotine replacement therapy: 100	Acupuncture twice per week for 8 weeks.	One nicotine reduction therapy path per day.	Primary: prolonged abstinence. Secondary: 7-day point prevalence abstinence, continuous abstinence.	Abstinence: carbon monoxide-confirmed 24-h point abstinence rate (<10 ppm).	The CO-confirmed 24-h point abstinence rate was 43.00% at 24 weeks in the acupuncture group, 44.00% in the NRT group (P>.05), and 30.00% in the auricular point group (P < .05).
Ward 2013	Newly diagnosed tuberculosis (TB) smokers	Intervention: 134 Control: 135	Patients received a six-week supply of Nicotinell™ patches, 24-h dose, using a step-down algorithm.	Placebo patches using a step-down algorithm, three individual, in-person sessions (approximately 30 min each) and 5	Primary: withdrawal symptoms after the quit date assessed by the Wisconsin questionnaire. Secondary: sustained abstinence at 26 weeks.	Prolonged abstinence: complete abstinence after a two–week grace period following the quit day 11. Seven day point prevalence abstinence: no	The crude proportions of patients in the nicotine and placebo groups with prolonged abstinence

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
				brief (approximately 10-min) phone call.		cigarette use during the past seven days at each follow–up, based on self–report and carbon monoxide levels of <10 p.p.m.	were 12.7% and 11.9% at 12 months.
Wee 2018	Patients with acute coronary syndrome	Intervention: 330 Control: 172	NHS Centre for Smoking Cessation and Training behavior modification administered by health staff.	Usual care.	Self reported quit attempt (24 h abstinence), 7-day point prevalence abstinence, continuous abstinence and relapse rates.	NA	No significant difference between the intervention and control group.
Wei 2013	Smokeless tobacco users	450 participants per cluster 32 clusters per arm	Healthy lifestyle counseling, prescription of a combination of drugs (antihypertensives, aspirin, and statin), and adherence support for drug compliance.	Usual care for hypertension and diabetes management.	Primary: Continuous smoking abstinence at 24 weeks Secondary: self-reported 7-day point prevalence of abstinence, continuous abstinence and average number of cigarettes smoked per day.	Cessation: smoking less than one cigarette a week at 24 months after randomization.	NA
White 2013	Teachers	Intervention: 132 Control: 69	One group counseling session and team commitment contracts to receive a cash bonus of $40 if team members abstained from smoking within 3 months.	Group counseling session.	Primary: adherence to proven secondary prevention drugs. Secondary: lifestyle change.	Quitting: the 7-day point prevalence of biochemically-verified abstinence.	The abstinence rate was 42.0% (55/131) and 24.6% (17/69) at 14 months (adjusted OR 2.2 [1.0–4.8]).
White 2018	Tobacco smokers	NA	One group counseling session and team commitment contracts to receive a cash bonus of $40 if team members abstained from smoking within 3 months.	Smoking cessation counseling; deposit contract plus a teammate, but without any further incentive.	Smoking status at 3 months, with biochemically verified abstinence collected at 3, 6, and 12 months.	NA	Biochemically verified 7-day smoking abstinence at 6 months was 9% greater in the $40 individual bonus arm than the control group.
Wu 2017	Tobacco users	Smoking reduction intervention: 18 Exercise and diet advice control: 188	1 min face-to-face smoking reduction intervention. Phone follow up after 1 week, 1 month, 3, 6, and 12 months.	Phone follow up at 1 week, 1, 3, 6, and 12 months but no discussion of reducing or quitting smoking.	Smoking cessation rate.	Smoking reduction: reduced by at least 50% compared to baseline. New quitters: those still smoking cigarettes at 1-, 3- or 6-month follow-up, but not smoking any cigarettes for at least 7 days at 3-, 6- or 12-month follow-up.	The self-reported 6-month prolonged abstinence rate at 12-month follow-up in the SRI groups (15.7%) was higher, but not significantly, than the EDA control group (7.8%).
Xavier 2016	Tobacco users	Intervention: 405 Control: 401	45–60 min discussions between community health workers, the patient, and the primary caregiver to identify barriers for drug adherence.	Usual treatment.	Primary: 7-day quitting point prevalence at 6 months. Secondary: 7-day point prevalence, sustained abstinence, smoking reduction by half and cessation clinic attendance.	NA	The intervention group had significantly greater adherence to smoking cessation (85% [110/129] vs 52% [71/138], OR 5.46, 95% CI 3.03–9.86; P<0.0001).
Xiao 2016	Tobacco users	Intervention: 241 Control: 242	The high-dependence group received 4 mg nicotine lozenge, and the low-dependence group received 2 mg nicotine lozenge.	Placebo.	Successful smoking cessation at 6 weeks post-quit.	Smoking cessation at 6 weeks post-quit: continuous abstinence from smoking for the 28-day period up to and including the 6-week visit (verified by	Low-dependence (2 mg) stratum: 24.5% (active nicotine group) and 21.5% (placebo group) quit successfully. High-dependence (4 mg)

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Table 2 (*continued*)

Author, year	Population	No.* of participants in intervention or exposure groups and comparator	Description of intervention or exposure groups	Description of comparator group	Measured outcomes	Definition of quitting/ abstinence	Results
						carbon monoxide measurement).	stratum: 30.8% (active nicotine group) and 20.2% (placebo group) quit successfully, 37 subjects (30.8%) (P = 0.0565).
Yu 2006	Tobacco users	NA	Nicotine replacement therapy given with psychological and behavior intervention.	Only nicotine replacement therapy.	Self-reported point-prevalence abstinence (the previous 4 weeks) verified by exhaled CO level at 3 and 6 months follow-up points.	NA	Smoking withdrawal rate of (NRT) combining with psychological and behavior intervention was higher than only NRT during weeks seven and twelve.
Yu 2017	Tobacco users	Intervention Group A (I-A): 114 Intervention Group B (I-B): 114 Control: 114	In-person counseling from health care workers on the harms of second-hand smoke to infants, how to establish a smoke-free home and text messages for smoking cessation.	Only standard care for initial postnatal visits.	Primary: self-reported abstinence from tobacco use at 3 months. Secondary: ASSIST and FTND scores.	NA	Smoking abstinence at 12 months was 22.7% in I-B compared to 9.7% in the control group (adjusted OR: 2.93, 95% CI: 1.24–6.94; p = 0.014).
Yuan 2015	Waterpipe smokers	Intervention: 494 Control: 514	Patients took part in a program that included systematic health education, smoking cessation counseling, and education on management of COPD	Usual care.	Fagerstrom test and carbon monoxide grade estimated by using smokerlyzer.	NA	The intervention group showed significant improvement in smoking cessation compared to the control, and the intervention group had lower smoking indices than in the control group (350 vs 450, P = 0.05).
Yuhongxia 2011	Waterpipe smokers	Intervention: 96 Control: 96	Mobile phone messaging intervention and varenicline.	Varenicline only.	Cigarette dependence scale test score.	NA	NA
Zahid 2017	Waterpipe smokers	NA	Varenicline (0.5 mg daily dosed up over a week) and behavioral support sessions.	Placebo (dispensed in the same manner as varenicline) and behavioral support sessions on first visit and quit day.	Primary: self-reported 7-day point prevalence abstinence at 1 month post-randomization. Secondary: biochemically verified abstinence at 3 months post-randomization; cigarettes smoked per day.	Self-reported continuous abstinence for at least 6 months: no smoking allowed in the 7 days prior to each of the three assessments; carbon monoxide (CO) level of <10 ppm.	NA
Zheng 2007	Waterpipe smokers	Intervention: 118 Control: 107	3-week training course of 5 sessions and followed up for information on their smoking habits, intention of quitting and self-efficacy in smoking cessation.	Brief advice to quit and same training course 6 months later.	Prolonged self-reported abstinence of 30 days at the six month follow-up.	Quitter: 0 cigarettes smoked in the past week, subject in early action or maintenance stage, cotinine level of urine < 25 ng/mL.	At 1-year follow-up, the proportion of quitting and the 6-month abstinence rate in the intervention group were 35.8% and 22.0%, respectively.

4.3. Thailand

Nine studies were conducted in Thailand. Most of these were psychosocial/pharmacological (44%), followed by pharmacological (22%), psychosocial/behavioral (22%), and psychosocial (11%). There were two pharmacological studies, involving nicotine gum. There was a single psychosocial RCT which involved brief counseling and reported a significant differences between three study groups over a 6-month follow-up period [Wald χ^2 = 8.43, P = 0.004] (Pengpid et al., 2015). There were two psychosocial/behavioral RCTs, both involved counseling and provided cash bonuses upon meeting abstinence criteria. One of these implemented a workplace intervention and used a deposit contract and team bonuses as a cessation incentive (White, Srivirojana, Jampaklay, & Dow, 2018). It reported a 72% increase in smoking abstinence at 6 months in a treatment group relative to the control group (White et al., 2018). There were four psychosocial/pharmacological RCTs where nicotine gum was provided with counseling and one culturally specific RCT where counseling was provided with nicotine gum and fresh lime fruit. A psychosocial/pharmacological study reported a statistically significant difference in smoking cessation rates between groups [25.62% (intervention) vs 11.32% (control); aOR = 2.95, 95%CI = 1.55–5.61] (Aung et al., 2019).

4.4. Brazil

Eight studies were conducted in Brazil. Most (75%) were psychosocial and the rest were psychosocial/pharmacological (25%). Of the psychosocial RCTs, some involved cognitive behavioral therapy, while others utilized counseling, telephone calls, or community health worker visits. A psychosocial RCT observed a large difference in groups, with a higher prevalence of abstinence at the 1-month follow-up [25.1% (intervention) vs 9.1% (control)] (Cruvinel, Richter, Colugnati, & Ronzani, 2018). We indicated two psychosocial/pharmacological RCTs, with one reporting significant outcomes and used cognitive behavioral and nicotine replacement therapy for smoking cessation (Otero et al., 2006), while the other used cognitive behavior therapy and bupropion or nortriptyline, with no significant results (Haggstram et al., 2006).

4.5. Iran

Seven RCTs were conducted in Iran. Most (71%) were psychosocial/pharmacological, followed by pharmacological (14%) and psychosocial (14%). There was a single statistically non-significant pharmacological RCT involving gemfibrozil (Ghoreishi, Davoudi, Assarian, & Shahriyari, 2019). There was also a single psychosocial RCT, employing acceptance and commitment therapy (Davoudi, Omidi, Sehat, & Sepehrmanesh, 2017). It demonstrated a significant difference in the number of patients who quit smoking [65% (intervention) vs 36% (control), χ^2 = 5.38, P < 0.050]. There were several psychosocial/pharmacological RCTs and all used counseling in combination with various pharmacological therapies. One psychosocial/pharmacological RCT used individualized counseling and bupropion for smokers with tuberculosis, and reported large differences in post-intervention abstinence rates [71.7 % (combined intervention) vs 33.9 % (counseling) vs 9.8 % control group (P<0.001)] (Aryanpur et al., 2016).

4.6. Pakistan

Six studies were conducted in Pakistan. Most (83%) were psychosocial/pharmacological, followed by psychosocial (17%). There was a single statistically non-significant psychosocial RCT detailing five steps to quit. We found five psychosocial/pharmacological RCTs, which involved behavioral support sessions and pharmacological therapies.

4.7. Malaysia

Six RCTs were conducted in Malaysia. Most (83%) were psychosocial RCTs, followed by behavioral RCTs (17%). There was a single behavioral RCT, culturally specific, that used Al-Quran recitation to facilitate cessation with a statistically significant difference in number of cigarettes smoked [9 (intervention) vs 7 (control), P < 0.01] (Aida Maziha, Imran, Azlina, & Harmy, 2018). Of the psychosocial RCTs, counseling was provided in-person or on the phone. One psychosocial RCT, which used phone based counseling, reported large differences in outcomes [71.7% (intervention) vs 48.6% (control), P < 0.001] (Ali Qais, Syed Azhar, Mohamed Azmi, Juman Abdulelah, & Alfian Mohamed, 2014).

4.8. South Africa

We detailed four studies conducted in South Africa. There was a single behavioral RCT investigating the effect of aid-to-quit materials and quit attempt monitoring in generic smokers (Hofmeyr, Kincaid, & Rusch, 2018). It reported a significant difference between treatment and control groups in the likelihood of abstinence (P < 0.001). We indicated a single pharmacological RCT comparing the effects of varenicline and nicotine patches vs varenicline alone in generic smokers (Koegelenberg et al., 2014). It demonstrated significant differences in point prevalence abstinence rates between groups at six months [(65.1% (intervention) vs 46.7% (control), OR = 2.13, 95%CI = 1.32, 3.43; P = 0.002)]. There was a single psychosocial RCT employing motivational interviewing or brief cessation advice for smokers with tuberculosis (Louwagie, Okuyemi, & Ayo-Yusuf, 2014). It had a large difference in self-reported 6-month abstinence rates between groups [21.5% (intervention) vs 9.3% (control)]. We found one psychosocial/pharmacological RCT exploring the effect of nicotine patches and counseling (Schuurmans, Diacon, Biljon, & Bolliger, 2004). It had a large difference in sustained cessation rates between groups for individuals who smoked more than 16 cigarettes a day [22% (intervention) vs 9% (placebo), P = 0.01].

4.9. Other countries

There were nine RCTs conducted in other countries. Most (67%) were psychosocial, followed by psychosocial/pharmacological (22%) and pharmacological (11%). There was a single pharmacological RCT, with non-significant results, that used cysteine tablets. There were six psychosocial RCTs (conducted in Syria, Argentina, Egypt, Indonesia, Nigeria, and Vietnam). These RCTs either used in-person counseling or virtual reality-based counseling. An RCT exploring the efficacy of outpatient smoking cessation counseling found large differences in continuous abstinence six months after treatment [22.8% (treatment) vs 6.7% (control), P < 0.0001] (Ghanem, 2014). We found two statistically non-significant psychosocial/pharmacological studies, both used counseling with either bupropion or nicotine patches.

5. Discussion

In this scoping review, we provided the first current and comprehensive synthesis of the published literature on tobacco cessation RCTs in LMICs. This review is critical as much of the current evidence for tobacco cessation RCTs is drawn from high-income countries. Cultural differences, variations in smoking prevalence, differing healthcare systems may have an influence on translating RCTs in high-income countries to LMICs which have a rising smoking prevalence (Parascandola & Bloch, 2016). Thus, tobacco cessation scholarship is essential in LMICs (McRobbie, Raw, & Chan, 2012). This work builds on previous systematic reviews in individual LMICs (Alzahrane et al., 2019; Kim et al., 2012; McKay, Patel, & Majeed, 2015) and reviews on smoking interventions across LMICs (Akanbi et al., 2019). Ensuring

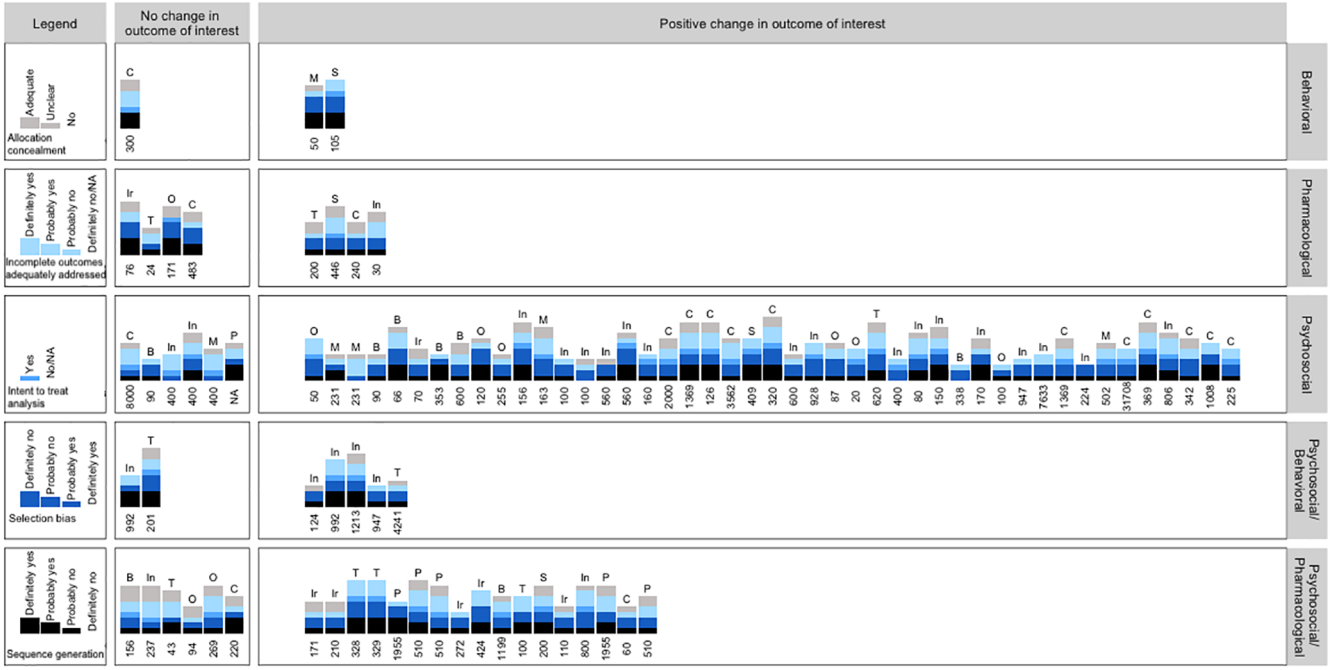

Fig. 4. Evidence for tobacco cessation RCTs. A *supermatrix* covering all RCT categories consisting of five rows (one for each RCT type) and two columns (studies with no change and studies with a positive change in the outcome of interest). Each RCT is represented by a stacked bar. The height of each component corresponds to a quality score representing the suitability of RCT design with respect to five quality measures: allocation concealment, addressing of incomplete outcome data, intent to treat analysis, selection bias and sequence generation. Each bar is annotated below by the sample size and annotated above regarding country in which the RCT was conducted: B (Brazil), C (China), In (India), Ir (Iran), M (Malaysia), O (Other), P (Pakistan), S (South Africa) and T (Thailand). Countries classed as Other include Argentina, Egypt, Indonesia, Kyrgyzstan, Mexico, Nigeria, Syria and Vietnam.

high-quality evidence, we included only RCTs and centered on broad tobacco use, given the wide variety of tobacco consumption in LMICs. However, except for psychosocial RCTs in China, quality of evidence was generally not strong. There has been an increase in tobacco control research on LMICs (Warner, Tam, & Koltun, 2014), but our findings suggest that the overall body of work on LMIC tobacco cessation RCTs is still lacking compared to high-income countries. The majority of RCTs (78%) reported statistically significant results for tobacco cessation. Tobacco cessation RCTs were limited across all LMICs, in comparison to the large tobacco mortality burden in the region, with some nations having a single or no RCT recorded. Several factors may explain the limited tobacco cessation RCTs, such as tobacco industry activities (Batmanghelidj & Heydari, 2014), perceived patient resistance to tobacco cessation (Ahmadi, Ashkani, Ahmadi, & Ahmadi, 2003), tobacco use among medical practitioners (Zavery et al., 2017), lack of familiarity around pharmacological treatments (Zain, 2002), and ineffective government policy (Rosser, 2015).

India and China represented the bulk of tobacco cessation RCTs, likely due to these nations being the largest and having the most research facilities. It is not clear why there were more RCTs in India compared to China despite China having a greater proportion of the world's tobacco users (Giovino et al., 2012). Factors such as tobacco industry-sponsored elementary schools in China (Fang, Yang, & Wan, 2020), government controlled tobacco monopoly (He, Takeuchi, & Yano, 2013), industry strategies to counter tobacco control (Chu, Jiang, & Glantz, 2011), and cultural practices around gifting and sharing cigarettes may explain why there were more RCTs in India versus China. Some nations had limited cessation RCTs, despite the size of their cigarette markets (see Table 13). For example, Indonesia had a single cessation RCT despite having the second-largest cigarette retail volume globally (Euromonitor, 2019). We suggest several factors that may explain the lack of RCTs in Indonesia, such as widespread tobacco advertising (McCall, 2014; Astuti, Assunta, & Freeman, 2018), and tobacco industry lobbying efforts (Webster, 2013; Hurt, Ebbert, Achadi, & Croghan, 2012). There were also several countries where we did not find any tobacco cessation RCTs, such as Bangladesh, Turkey, and Russia. Bangladesh had a greater retail volume than India (91.6bn vs 82.5bn), but India had 26 tobacco cessation RCTs compared to none in Bangladesh. Dependence on large-scale tobacco farming and production (Lecours, 2014; Roy et al., 2012), and widespread use of tobacco as relief from dietary issues (Roy, 2012) may explain the lack of research in Bangladesh. We suggest an increased research focus on nations with no tobacco cessation RCTs despite their large cigarette retail market.

Most RCTs were psychosocial, with limited behavioral and pharmacological variants. A previous systematic review on smoking cessation interventions in LMICs also indicated the focus on psychosocial studies (Akanbi et al., 2019). Within psychosocial RCTs, there was a diversity of therapies, where in-person counseling was most common, with group counseling, phone-based counseling also provided. There was also a novel virtual-reality based counseling RCT. Akanbi et al. (2019) noted the lack of studies on Quitline access in LMICs (Akanbi et al., 2019), and we similarly found no RCTs using a Quitline, despite its focus within the WHO Framework Convention on Tobacco Control (Yach, 2003). Previous work (Akanbi et al., 2019) also noted the lack of studies on mobile phone (m-Health) in LMICs. Growth in m-Health research within LMICs is key, as mobile phone penetration is significant in LMICs and m-Health appears to be highly effective for smoking cessation (Whittaker et al., 2019).

There were limited pharmacological RCTs with some nations having no pharmacological RCTs, which may be due to resource limitations (Higashi & Barendregt, 2012) and unfamiliarity with such RCTs (Zain, 2002). This is a concern as pharmacological RCTs seem more cost-effective than other intervention variants (Song et al., 2002). Pharmacological RCTs in LMICs can be implemented cost-effectively, if medications can be obtained cheaply (Gilbert et al., 2004). For example, in India, bupropion seems to be the most affordable pharmacological therapy (Sarma et al., 2017), while varenicline may be more expensive in LMICs (Pine-Abata et al., 2013), despite its efficacy over other

Table 3
Risk of bias assessment for randomized controlled trials.

Author, year	Selection Bias	Sequence generation	Allocation concealment	Incomplete outcome data adequately addressed	Intent-to-treat analysis	Other limitations
Aggarwal 2017	Probably no	Probably no	Unclear	Definitely no	No	Limitations not listed.
Ahmadi 2003	Probably no	Probably no	Adequate (central allocation)	Probably no	No	Limitations not listed.
AidaMaziha 2018	Definitely no	Definitely yes	Probably no	Probably no	No	Small sample size. Self-reported measures of withdrawal symptoms are more vulnerable to differential misclassification bias.
Areechon 1988	Probably no	Probably no	Adequate (central allocation)	Probably no	NA	A relatively high proportion of the subjects dropped out of the study.
Aryanpur 2016	Probably no	Probably no	Adequate (central allocation)	Probably no	No	Only measured the outcome of smoking cessation in these patients until the end of TB treatment, while previous studies have shown that many patients start smoking again after completing their TB therapy. This might over-estimate the effects of evaluated cessation measures in quitting. Expiratory carbon monoxide concentration used to confirm smoking status of the subjects. It is not an absolute indicator of smoking status.
Asfar 2014	Definitely no	Probably no	No	Definitely yes	Yes	This was a pilot study, designed to provide an initial test of a novel intervention and determine its feasibility, acceptability, and potential effectiveness. Expired CO's short half-life reduces its usefulness to confirm self-reported abstinence in our sample, which consisted mainly of non-daily smokers.
Augustson 2017	Probably yes	Probably no	Unclear	Definitely yes	Yes	Baseline data were not collected on variables such as smoking history, patterns of tobacco use, and demographic characteristics. Dependence on self-report via text may have elicited biased responses about quit status. High opt-out rates and low post-intervention response rates.
Aung 2013	Definitely no	Definitely yes	No	Definitely yes	Yes	Limitations not listed.
Aung 2019	Definitely no	Definitely yes	No	Definitely yes	Yes	The relaying of information between participants in different study arms may have caused contamination.
Blebil 2013	Probably no	Probably no	Unclear	Probably no	No	Limitations not listed.
Blebil 2014	Probably yes	Definitely no	Unclear	Definitely yes	No	Limitations not listed.
Campos 2014	Probably no	Probably no	No	Probably no	No	Limitations not listed.
Campos 2018	Probably no	Probably no	Unclear	Probably no	No	Limitations not listed.
Cruvinel 2018	Definitely no	Definitely yes	Unclear	Definitely yes	No	Texts were sent manually using a mobile phone by study staff, which limited the extent of message tailoring, length, and frequency.
Davoudi 2017	Probably no	Probably no	Adequate (central allocation)	Probably no	No	Did not include women smokers due to the very low prevalence of cigarette smoking among Iranian women. Follow-up period in this study was six weeks. Long-term follow-up can produce more credible information about the effects of ACT on smoking cessation.
deAzevedo 2010	Probably yes	Definitely yes	No	Probably no	No	No inter-rater (counselor) check was conducted to determine whether there were different counseling styles. Self-reporting bias.
Dogar 2014	Probably no	Definitely yes	No	Probably no	No	The sample size calculation for this trial did not take into account the power to detect heterogeneity of intervention effects by smoking forms.
Dogar 2018 (#2)	Probably no	Probably yes	Adequate (central allocation)	Definitely yes	Yes	Assessment of medication adherence, although using a valid 7-day recall approach, was subjective and may have overestimated medication adherence.
Dogar 2018 (#3)	Probably no	Probably no	Adequate (central allocation)	Definitely yes	Yes	Limitations not listed.
Faustino da Silva 2018 (#1)	Probably no	Probably no	Adequate (central allocation)	Probably yes	No	Limitations not listed.
Faustino da Silva 2018 (#2)	Definitely no	Definitely yes	Unclear	Probably no	No	Limitations not listed.
Ghanem 2014	Probably no	Probably no	Unclear	Probably no	No	Limitations not listed.
Ghoreishi 2019	Definitely no	Definitely yes	Adequate (central allocation)	Probably yes	No	Limited in the duration of treatment with Gemfibrozil which was lower than other similar studies as well as the matching of lipid profile between the groups due to the limited sample available in Kashan.
Goel 2017	Definitely no	Definitely yes	Adequate (central allocation)	Probably yes	Yes	Low statistical power. Self-reporting bias.
Haggstram 2006	Probably no	Probably no	Adequate (central allocation)	Probably yes	Yes	Small sample size.
Han 2014	Definitely no	Probably no	Adequate (central allocation)	Definitely yes	Yes	Contamination between the intervention and the control groups as they were both recruited in the same workplace. Self-reporting bias.

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Table 3 (*continued*)

Author, year	Selection Bias	Sequence generation	Allocation concealment	Incomplete outcome data adequately addressed	Intent-to-treat analysis	Other limitations
Heydari 2012	Probably no	Probably no	No	Probably no	No	Limitations not listed.
Heydari 2014	Definitely no	Probably yes	No	Definitely yes	No	Exclusion of female participants.
Hofmeyr 2018	Definitely no	Definitely yes	No	Probably yes	Yes	Small sample size. Unconscious bias from lack of blinding.
Iyapparaja 2018	Probably no	Probably no	No	Probably no	No	Limitations not listed.
Jain 2014	Probably yes	Probably no	Adequate (central allocation)	Definitely yes	Yes	Low statistical power. Low treatment adherence. False reporting of abstinence.
Jhanjee 2017	Probably no	Definitely no	Unclear	Probably no	No	Self-reporting bias.
Josephson 2019	Probably no	Probably no	Unclear	NA	No	Limitations not listed.
Khetan 2019	Definitely no	Definitely yes	Unclear	Probably no	Yes	Intervention limited to phone-owning tobacco users.
Koegelenberg 2014	Probably no	Probably no	Adequate (central allocation)	Definitely yes	Yes	Limitations not listed.
Kumar 2010	Probably yes	Definitely no	No	Definitely yes	Yes	Study only looked at short term self reported outcomes. Limited reach.
Kumar 2012	Probably no	Probably yes	Adequate (central allocation)	Probably yes	Yes	Smoking cessation rates were measured at 1 month follow-up only. Low statistical power. Small sample size, with no females enrolled.
Kumar 2017	Probably no	Probably no	No	Probably no	Yes	Short length of follow-up. Low statistical power. Small sample size, with no females enrolled.
Liao 2016	Probably no	Probably no	Adequate (central allocation)	Probably yes	Yes	Self-reporting bias.
Liao 2018	Probably no	Definitely yes	Adequate (central allocation)	Definitely yes	Yes	Small sample size. Testing limitations.
Lin 2013	Probably no	Definitely yes	Adequate (central allocation)	Definitely yes	Yes	Self-reporting bias. Small sample size, exclusion of females.
Lou 2013	Probably no	Probably no	Unclear	Definitely yes	Yes	Moderate duration (four years) that could not evaluate the long-term efficacy of smoking cessation.
Louwagie 2014	Probably no	Definitely yes	No	Probably yes	Yes	Follow-up measurement was not blinded, which may have introduced respondent –or interviewer–bias. Self-reporting bias.
Luo 2018	Definitely no	Definitely yes	Adequate (central allocation)	Definitely yes	Yes	Self-reporting bias. Selection bias. Bias from lack of blinding. Short follow-up.
Naik 2014	Probably no	Probably no	Unclear	Probably no	No	Small sample size, without female or juvenile offenders. Higher possibility of relapse in prison setting.
Nair 2015	Definitely no	Probably no	No	Probably yes	Yes	Small sample size, without females. Bias from lack of blinding.
Nichter 2016	Definitely no	Probably no	Unclear	Probably yes	No	Self-reporting bias.
Nurul Asyikin 2018	Probably yes	Definitely no	Unclear	Definitely yes	Yes	High levels of attrition.
Onyechi 2017	Probably no	Probably no	No	Probably yes	Yes	Selection bias. Exclusion of females.
Otero 2006	Probably no	Probably no	Unclear	Probably yes	Yes	Selection bias. Self-reporting bias.
Peng 2007	Probably no	Probably no	Adequate (central allocation)	Probably no	No	Limitations not listed.
Pengpid 2015	Definitely no	Probably yes	Adequate (central allocation)	Definitely yes	Yes	Self-reporting bias. Short length of follow-up. Selection bias.
Pimple 2016	Probably no	Definitely no	No	Probably no	Yes	Limitations not listed.
Rajanandh 2012	Probably no	Probably yes	Unclear	Definitely yes	Yes	Limitations not listed.
Rungruanghiranya 2008	Probably yes	Probably yes	Adequate (central allocation)	Definitely yes	No	Short follow-up period.
Rungruanghiranya 2012	Probably no	Probably yes	No	Definitely yes	No	Small sample size. Study design did not assure matched-pairs.
Sarkar 2013	Probably no	Definitely yes	No	Definitely yes	Yes	Limitations not listed.
Sarkar 2014	Probably yes	Definitely yes	No	Probably yes	No	Limitations not listed.
Sarkar 2017	Probably no	Definitely yes	Adequate (central allocation)	Probably yes	Yes	Effect of specific intervention components cannot be dissociated.
Savant 2013	Probably no	Definitely yes	Adequate (central allocation)	Probably yes	Yes	Contamination between groups. Unreliable biochemical verification test. Self-reporting bias.
Scarinci 2019	Probably no	Definitely no	No	Probably no	No	Limitations not listed.
Schuurmans 2004	Probably no	Probably yes	Adequate (central allocation)	Probably yes	Yes	Limitations not listed.

(*continued on next page*)

Table 3 (*continued*)

Author, year	Selection Bias	Sequence generation	Allocation concealment	Incomplete outcome data adequately addressed	Intent-to-treat analysis	Other limitations
Selvamary 2020	Probably no	Definitely yes	Adequate (central allocation)	Probably no	No	Limitations not listed.
Sharifirad 2012	Probably no	Probably no	Unclear	Probably no	No	Self-reporting bias. Small sample size.
Sharma 2018	Definitely no	Probably no	Unclear	Definitely yes	Yes	Selection bias.
High drop-out rates.						
Shelley 2020	Probably no	Probably no	No	Probably no	No	Limitations not listed.
Siddiqi 2010	Probably yes	Definitely yes	Unclear	Probably yes	No	Limitations not listed.
Siddiqi 2013	Probably no	Probably yes	Adequate (central allocation)	Definitely yes	No	Self-reporting bias. Selection bias.
Singh 2010	Probably no	Probably no	Adequate (central allocation)	Definitely yes	No	Small sample size.
Sorensen 2013	Probably no	Probably no	No	Probably no	No	Low statistical power. Self-reporting bias.
Sorensen 2013	Probably no	Probably no	No	Probably no	No	Low statistical power. Compromised test samples.
Sorensen 2017	Probably no	Probably no	No	Probably yes	No	Self-reporting bias. Low statistical power.
Tang 2018	Probably no	Probably no	Adequate (central allocation)	Probably yes	Yes	Unreliability cotinine tests.
Thankappan 2014	Probably no	Probably no	No	Definitely no	No	Limitations not listed.
Tundulawessa 2010	Probably yes	Probably no	Unclear	Probably yes	No	Limitations not listed.
Urdapilleta-Herrera 2013	Probably yes	Probably no	Adequate (central allocation)	Probably no	No	Limitations not listed.
Vinnikov 2008	Definitely no	Definitely yes	Adequate (central allocation)	Definitely no	Yes	Short follow-up period.
Wang 2018	Definitely no	Definitely yes	Adequate (central allocation)	Definitely yes	Yes	High dropout rate. Selection bias.
Ward 2013	Probably no	Probably no	Adequate (central allocation)	Definitely yes	Yes	Selection bias.
Wee 2018	Probably no	Probably no	Unclear	Probably yes	Yes	Limitations not listed.
Wei 2013	Probably no	Probably no	No	Probably yes	Yes	Resource limitations.
White 2013	Definitely no	Definitely yes	Adequate (central allocation)	Probably yes	Yes	External validity. Two-arm trial cannot disentangle the causal pathways through which the intervention acted.
White 2018	Probably no	Probably no	Unclear	Probably no	No	Limitations not listed.
Wu 2017	Probably no	Definitely yes	Adequate (central allocation)	Definitely yes	Yes	Small sample size. Self-reporting bias. High rates of attrition.
Xavier 2016	Probably no	Probably yes	Unclear	Definitely yes	Yes	Self-reporting bias.
Xiao 2016	Definitely no	Probably yes	Adequate (central allocation)	Probably no	No	Limitations of biochemical verification.
Yu 2006	Probably no	Probably no	Unclear	Probably no	No	Limitations not listed.
Yu 2017	Definitely no	Probably no	Adequate (central allocation)	Probably yes	No	Self-reporting bias.
Yuan 2015	Probably no	Definitely yes	No	Probably yes	No	Selection bias.
Yuhongxia 2011	Probably yes	Definitely yes	Adequate (central allocation)	Probably no	No	Limitations not listed.
Zahid 2017	Probably no	Probably no	Adequate (central allocation)	Probably yes	No	Limitations not listed.
Zheng 2007	Probably no	Probably no	No	Probably yes	Yes	Limitations not listed.

Note: *Selection bias* occurs when recruiters selectively enroll patients into the trial based on what the next treatment allocation is likely to be. Example of selection bias addressed: blinding of recruiters; simple randomization. *Sequence generation* refers to the method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. Examples of adequate sequence generation: random number table; computerized random number generator. *Allocation concealment* denotes the mechanism of implementing the allocation sequence, describing any steps to conceal the sequence until interventions are assigned. Example of adequate allocation concealment: treatment assignments enclosed in opaque sequentially numbered, sealed envelope. *Incomplete outcome data addressing* refers to issues such as systematic differences in attrition between groups, and overall loss to follow up. These can be addressed by techniques such as the data analyzed in accordance with a pre-specified plan finalized before unblinded outcome data was available. *Intent-to-treat analysis* is adequate when all eligible patients that were randomized are included in analysis.

Table 4
Synthesis – India.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Pharmacological			
Singh 2010	Yes	Bupropion SR 300 mg/day for seven weeks.	Exaggerate
Type of RCT: Psychosocial			
Kumar 2010	No	Counseling and a self-help booklet.	Exaggerate
Kumar 2012	No	A physician offered two sessions of health education 5 weeks apart along with self-help material on tobacco cessation to the intervention group.	Exaggerate
Goel 2017	Yes	ABC intervention: ask about smoking habits, give brief advice on smoking cessation and provide cessation support.	Understate
Iyapparaja 2018	Yes	SMS text messages and regular tobacco cessation counseling.	Exaggerate
Jhanjee 2017	Yes	A single 30-min counseling session and patient education brochure.	Exaggerate
Josephson 2019	Yes	Motivational interviewing delivered by a community health worker and weekly support provided through regular mobile text messages.	Unclear
Khetan 2019	Yes	Health education and motivational interviewing through community health workers with low frequency text messaging, focused on health education and the benefits of quitting.	Unclear
Kumar 2017	Yes	Physician advice using a modified version of the 5As strategy for smoking cessation plus a brochure containing smoking cessation information, and counseling from a counselor.	Exaggerate
Naik 2014	Yes	Motivational interviewing.	No effect
Nair 2015	Yes	Group-counseling session cum medical examination.	Exaggerate
Pimple 2016	Yes	Medium Intervention: Tobacco cessation counseling in the form of 3 contact sessions, Low intensity Intervention: Only a single contact session of tobacco cessation counseling.	Unclear
Rajanandh 2012	Yes	Motivational interviewing and counseling about beneficial outcomes of smoking cessation.	No effect
Savant 2013	Yes	Individual and group counseling over 6 months.	Exaggerate
Selvamary 2016	Yes	Health education with cognitive behavior therapy in tobacco cessation.	Unclear
Sorensen 2013	Yes	Monthly school visits by health educators and implementation of school tobacco policy banning tobacco use on school property, tobacco advertising or endorsement of tobacco in the school.	No effect
Sorensen 2017	Yes	Implementation of tobacco control policy and 6 health education events.	Understate
Thankappan 2014	Yes	Smoking cessation counseling sessions administered by doctors using the five ”As” (Ask, Assess, Advise, Assist, Arrange) and the five ”Rs” (Relevance, Risks, Rewards, Roadblocks, Repetition).	Exaggerate
Xavier 2016	Yes	45–60 min discussions between community health workers, the patient, and the primary caregiver to identify barriers for drug adherence.	No effect
Type of RCT: Psychosocial/Behavioral			
Sarkar 2014	No	Single session of face-to-face tobacco quit advice including training in yogic breathing exercises to control cravings.	Unclear
Aggarwal 2017	Yes	Behavioral counseling and bi-weekly yoga classes.	Exaggerate
Sarkar 2013	Yes	Single session of quit advice and training in craving control using simple yogic breathing exercises.	Exaggerate
Sarkar 2017	Yes	Single session quit advice (15 min) plus a single training session in yogic breathing exercises.	Exaggerate
Sorensen 2013	Yes	Monthly school visits by health educators and implementation of school tobacco policy banning tobacco use on school property, tobacco advertising or endorsement of tobacco in the school.	Exaggerate
Type of RCT: Psychosocial/Pharmacological			
Jain 2014	No	Varenicline 1 mg twice per day, behavioral counseling every other week.	Exaggerate
Sharma 2018	Yes	Nicotine replacement therapy and behavior change counseling.	Exaggerate

medications (Cahill, Stevens, Perera, & Lancaster, 2013). Despite possible beliefs that pharmacological RCTs may be less cost effective compared to other variants (Higashi & Barendregt, 2012), LMICs can implement such RCTs if perhaps made aware of their cost-effectiveness, given the efficacy of pharmacological RCTs in LMIC environments (Ward et al., 2013). We suggest community-based crowdsourcing to increase use and uptake of pharmacological RCTs in LMICs. Crowdsourcing involves non-experts and experts collaborating to solve an issue and then sharing solutions publicly (Tucker, Day, Tang, & Bayus, 2019). Crowdsourcing has been implemented in LMICs to improve drug delivery (Edoh & Pawar, 2020) and sexually transmitted testing uptake (Yang et al., 2020), among other uses (Wang et al., 2020). Crowdsourcing may thus be applied to design cost-effective pharmacological smoking cessation treatments in LMICs.

We noted relatively few behavioral RCTs, perhaps due to unfamiliarity with such RCTs in LMICs (Zain, 2002). We indicated several culturally specific behavioral RCTs such as those involving yoga (India) and acupuncture (China) (Aggarwal & Kumar, 2017; Wang et al., 2018; Rungruanghiranya, Ekpanyaskul, Sakulisariyaporn, Watcharanat, & Akkalakulawas, 2012). Yoga, a spiritual practice developed in India, was used to complement behavioral counseling and increased smoking abstinence (Aggarwal & Kumar, 2017). The use of acupuncture, a form of traditional Chinese medicine, in a tobacco cessation RCT increased smoking abstinence (Wang et al., 2018). While there are several effective techniques established for smoking cessation, their comparatively high price may limit use in LMICs. Culturally specific behavioral RCTs may be cheaper (Rungruanghiranya et al., 2012), possibly more effective (Nierkens et al., 2013) and we suggest increased research in this vein. Culturally-specific interventions have improved health outcomes in various other settings (Barrera, Castro, Strycker, & Toobert, 2013), such as adherence to medication for opioid use disorder (Conn, Enriquez, Ruppar, & Chan, 2014; Rowan et al., 2014), and mental health (Hall et al., 2020; Hall, Ibaraki, Huang, Marti, & Stice, 2016). It is not clear if culturally-specific smoking cessation interventions will be more effective than standard interventions, but given improved outcomes in other research areas, LMICs may benefit from increased rates of smoking cessation if such interventions are applied. RCTs that combined techniques e.g. behavioral/pharmacological were relatively few and some nations did not have any such RCTs. RCTs which combined pharmacological and behavioral techniques are more effective for smoking cessation compared to minimal interventions or standard of care (Stead, Koilpillai, Fanshawe, & Lancaster, 2016). We propose more research around combined therapies in LMICs to increase tobacco cessation efficacy. Our findings should be read in line with some limitations. The conclusions we provided regarding the effectiveness of RCTs are based on the quality of included studies. Several authors did not provide sufficient information on how studies were safeguarded from bias. As the majority of studies were psychosocial, participant, or treatment provider blinding may be more complex. Although we searched several databases and gray literature sources, we

Table 5
Synthesis – China.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Behavioral			
Wang 2018	No	Acupuncture twice per week for 8 weeks.	Exaggerate
Type of RCT: Pharmacological			
Xiao 2016	No	The high-dependence group received 4 mg nicotine lozenge, and the low-dependence group received 2 mg nicotine lozenge.	No effect
Peng 2007	Yes	Zero to twenty nicotine sublingual tablets per day with doses decreasing progressively.	Exaggerate
Type of RCT: Psychosocial			
Augustson 2017	No	High-frequency text contact (HFTC) group: 1–3 messages daily with smoking cessation advice and health education information. Low frequency text contact (LFTC) group: 1 weekly health education message.	Understate
Liao 2016	Yes	Regular, personalized text messages providing smoking cessation advice, support and distraction.	Unclear
Liao 2018	Yes	High frequency: 3–5 messages per day for 12 weeks and 3–5 messages per week for 12 weeks; low frequency: 3–5 messages per week for 12 weeks and 1–2 messages per week for 12 weeks.	No effect
Lin 2013	Yes	Physicians give patients a standardized warning message while taking smoking history, advice to quit and refer patients to smoking cessation clinics.	Exaggerate
Lou 2013	Yes	Brief smoking cessation advice after the baseline interview and a plan to quit smoking.	No effect
Luo 2018	Yes	5As and 5Rs (IPANR) intervention: Participants received three counseling during hospitalization conducted by cardiologists with extensive experience in smoking cessation.	Exaggerate
Tang 2018	Yes	High frequency messages (HFM): 5 messages sent per day for 12 weeks. Low frequency messages (LFM): 3 to 5 messages sent per week for 12 weeks.	Exaggerate
Wei 2013	Yes	Healthy lifestyle counseling, prescription of a combination of drugs (anti-hypertensives, aspirin, and statin), and adherence support for drug compliance.	Unclear
Wu 2017	Yes	1 min face-to-face smoking reduction intervention. Phone follow up after 1 week, 1 month, 3, 6, and 12 months.	No effect
Yuan 2015	Yes	Patients took part in a program that included systematic health education, smoking cessation counseling, and education on management of COPD.	Exaggerate
Yu 2017	Yes	In-person counseling from health care workers on the harms of second-hand smoke to infants, how to establish a smoke-free home and text messages for smoking cessation.	Exaggerate
Zheng 2007	Yes	3-week training course of 5 sessions and followed up for information on their smoking habits, intention of quitting and self-efficacy in smoking cessation.	Unclear
Type of RCT: Psychosocial/Pharmacological			
Yu 2006	Yes	Nicotine replacement therapy given with psychological and behavior intervention.	Exaggerate
Yuhongxia 2011	No	Mobile phone messaging intervention and varenicline.	Unclear

Table 6
Synthesis – Thailand.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Pharmacological			
Tundulawessa 2010	No	Nicotine polyestex gum. Highly dependent smokers were assigned to the 4-mg dose, and the others to the 2-mg dose.	Exaggerate
Areechon 1988	Yes	Chewing gum containing 2 mg of alkaline-buffered nicotine and 1 mg of unbuffered nicotine.	Exaggerate
Type of RCT: Psychosocial			
Pengpid 2015	Yes	Three sessions of brief counseling for alcohol use reduction and tobacco use cessation.	Exaggerate
Type of RCT: Psychosocial/Behavioral			
White 2013	No	One group counseling session and team commitment contracts to receive a cash bonus of $40 if team members abstained from smoking within 3 months.	Exaggerate
White 2018	Yes	One group counseling session and team commitment contracts to receive a cash bonus of $40 if team members abstained from smoking within 3 months.	Exaggerate
Type of RCT: Psychosocial/Pharmacological			
Rungruanghiranya 2008	No	Behavioral support (personalized message from physician, self help material, individual counseling) and nicotine polyestex gum.	No effect
Aung 2013	Yes	Individual counseling from nurses and nicotine replacement chewing gum for nicotine cravings.	Unclear
Aung 2019	Yes	Regular patient motivation over 3 months, assistance from a family member using a smoking cessation diary and optional nicotine replacement chewing gum therapy.	No effect
Rungruanghiranya 2012	Yes	Individual counseling and self-report card for the use of gum or fresh lime.	No effect

may have missed some studies. We also did not manage to contact all authors we reached out to and thus may have missed out on some unpublished work. Our conclusions are based on information drawn solely from RCTs. Several of our studies were translated from non-English languages. Wherever possible we used native language speakers to translate these articles. However, as we did not use a professional translation service, we may have translated some text incorrectly. We noted the limitations inherent in RCTs (Bothwell et al., 2016). However, RCTs are key to improving tobacco control efforts, compared to other study designs. Thus, results must be interpreted in line with the weaknesses of RCTs, but also recognizing that RCTs are the main mode of judging intervention efficacy.

The main strength of our proposed study is that we utilized a reproducible and clear procedure for a scoping review. We indicated the population, intervention, and outcomes included, along with data extraction and search strategies. Moreover, we centered solely on the scope of tobacco cessation RCTs in LMICs. Although we noted several limitations, our review has important implications for LMIC tobacco control. We found several RCTs that successfully implemented research originally conducted in high-income countries, despite concerns about

Table 7
Synthesis – Brazil.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Psychosocial			
Campos 2014	No	Intensive cognitive behavioral therapy comprising a 10-min oral intervention and a 30-min educational video presentation.	Exaggerate
Campos 2018	Yes	Intensive cognitive behavioral therapy comprising a 10-min oral intervention and a 30-min educational video presentation.	Exaggerate
Cruvinel 2018	Yes	A single telephone call from study staff during the first week following discharge, plus multiple text messages post-discharge.	No effect
deAzevedo 2010	Yes	Low intensity intervention: 15 min individual counseling session; High intensity intervention: 30 min individual counseling session (motivational interview).	Exaggerate
Faustino da Silva 2018 (#1)	Yes	Combination of cognitive interventions to develop behavioral skills.	Unclear
Scarinci 2019	Yes	12-home visits by the Community Health Worker and referring to an appointment for the participant to attend the tobacco cessation program.	Unclear
Type of RCT: Psychosocial/Pharmacological			
Haggstram 2006	No	Cognitive behavior therapy, supportive phone call, pamphlet and bupropion or nortriptyline.	Understate
Otero 2006	Yes	Three intensive cognitive behavioral therapy sessions with or without transdermal nicotine patches.	Exaggerate

Table 8
Synthesis – Iran.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Pharmacological			
Ghoreishi 2019	No	300 mg Gemfibrozil at the same amount twice a day for 7 weeks.	Understate
Type of RCT: Psychosocial			
Davoudi 2017	Yes	Acceptance and commitment therapy (ACT) in eight 90-min one-to-one sessions.	Exaggerate
Type of RCT: Psychosocial/Pharmacological			
Aryanpur 2016	Yes	Smoking cessation counseling with bupropion over a short course of Directly Observed Treatment (DOTS).	Exaggerate
Sharifirad 2012	Yes	5 personal counseling sessions and used free nicotine chewing gum for 2 months with a phone line follow-up.	Exaggerate
Ahmadi 2003	Yes	Nicotine gum (2 mg pieces), oral naltrexone (50 mg), or oral clonidine (0.4 mg) for up to 24 weeks.	Exaggerate
Heydari 2012	Yes	Brief counseling session and nicotine patches 15 mg/daily for 8 weeks or one 0.5 mg varenicline pill daily dosed up over 8 weeks.	Exaggerate
Heydari 2014	Yes	6-month methadone treatment and smoking cessation behavior therapy with concurrent nicotine replacement.	No effect

Table 9
Synthesis – Pakistan.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Psychosocial			
Siddiqi 2010	No	Systematic, standardized approach to deliver 'five steps to quit' to make it effective and equitable.	Unclear
Type of RCT: Psychosocial/Pharmacological			
Dogar 2014	Yes	BSS: behavioral support sessions; BSS+: behavioral support sessions +7 weeks bupropion therapy	Exaggerate
Dogar 2018 (#1)	Yes	Behavioral support sessions and 0.5 mg varenicline tables for 1 week, and 1 mg for remaining weeks.	Exaggerate
Dogar 2018 (#2)	Yes	Behavioral support sessions and 0.5 mg varenicline tables for 1 week, and 1 mg for remaining weeks.	Unclear
Siddiqi 2013	Yes	Behavioral support sessions and a free 7-week course of bupropion.	Exaggerate
Zahid 2017	Yes	Varenicline (0.5 mg daily dosed up over a week) and behavioral support sessions.	Unclear

Table 10
Synthesis – Malaysia.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Behavioral			
AidaMaziha 2018	Yes	Counseling using Al-Quran recitation.	No effect
Type of RCT: Psychosocial			
Nurul Asyikin 2018	No	Motivation counseling using the 5A's and 5R's and self-help pamphlets.	Exaggerate
Blebil 2013	Yes	Control care plus extra counseling sessions through phone calls during the first month of quit attempt.	Exaggerate
Blebil 2014	Yes	Control care plus extra clinic visits and proactive phone calls for counseling.	Exaggerate
Han 2014	Yes	Ten-minute physician counseling session to quit smoking with measurements of smoking behavior via questionnaire at baseline at intervals.	Exaggerate
Wee 2018	Yes	NHS Centre for Smoking Cessation and Training behavior modification administered by health staff.	Understate

adapting such studies in LMICs (Ossip et al., 2016). Several RCTs were conducted within LMIC healthcare infrastructure, as echoed by a previous review (Akanbi et al., 2019). However, pharmacological therapies were limited, despite their possible low costs (Tutka, Vinnikov, Courtney, & Benowitz, 2019; Gilbert et al., 2004). While we noted some m-Health RCTs, they were rather limited and can be a focus of future work, given the ubiquity of mobile phones in LMICs (Akanbi et al., 2019). (Tables 4–12).

Table 11
Synthesis – South Africa.

Author, year	Significance of Outcome	Description of intervention	Impact of Bias
Type of RCT: Behavioral			
Hofmeyr 2018	Yes	Aid-to-quit document and quit attempt monitoring and opportunity to earn abstinence-contingent incentives	Exaggerate
Type of RCT: Pharmacological			
Koegelenberg 2014	Yes	Varenicline and 15 mg nicotine patch for 12 weeks.	Exaggerate
Type of RCT: Psychosocial			
Louwagie 2014	Yes	Brief motivational interviewing by lay health–care workers.	Exaggerate
Type of RCT: Psychosocial/Pharmacological			
Schuurmans 2004	Yes	counseling and a daily nicotine patch for 12 weeks.	Exaggerate

Table 12
Synthesis – Other countries.

Author, year	Significance of Outcome	Country	Description of intervention	Impact of Bias
Type of RCT: Pharmacological				
Vinnikov 2008	No	Kyrgyzstan	Cysteine tables according to manufacturer's instructions.	No effect
Type of RCT: Psychosocial				
Asfar 2014	Yes	Syria	Three 45-min, individual, in-person sessions and five brief phone calls.	Exaggerate
Faustino da Silva 2018 (#2)	Yes	Argentina	An app that delivered 21 days of virtual reality Mindful Exposure Therapy (VR-MET) sessions, daily surveys, and online peer-to-peer support moderated by psychologists.	Unclear
Ghanem 2014	Yes	Egypt	Intensive anti-smoking counseling program with three follow up visits for reinforcement of abstinence	Unclear
Nichter 2016	Yes	Indonesia	TB-specific quit smoking messages delivered by doctor and a TB and smoking educational booklet and quit smoking guide.	Exaggerate
Onyechi 2017	Yes	Nigeria	Group-focused cognitive behavioral health education program.	Exaggerate
Shelley 2020	Yes	Vietnam	Text messages for smoking cessation.	Unclear
Type of RCT: Psychosocial/Pharmacological				
Urdapilleta-Herrera 2013	No	Mexico	Cognitive behavioral therapy combined with bupropion.	Exaggerate
Ward 2013	No	Syria	Patients received a six-week supply of Nicotinell™ patches, 24-h dose, using a step-down algorithm.	Understate

6. Conclusion

Most tobacco users are in LMICs and LMICs have a high smoking prevalence (Reitsma et al., 2017). As such, tobacco control within LMICs is essential to reduce the tobacco mortality burden. Overall, quality of evidence of tobacco cessation RCTs in LMICs was weak. While there has been more research on LMIC tobacco control, the overall body of work is still minimal with some nations having a single or no RCT recorded. RCTs around LMIC tobacco cessation tended to be psychosocial, with limited behavioral and pharmacological variants. Researchers should be cognizant that tobacco cessation in LMICs is still not an environment where best practice has been established. We suggest that developing solutions specific for LMICs is key to effective tobacco control in LMICs.

Declaration of Competing Interest

Navin Kumar has received funding from the Foundation for a Smoke-Free World for this project.

Acknowledgments

We thank the reviewers, editors, Melissa Funaro, and Tracy Markowitz for their comments.

Appendix A

Medline search example.

1. (afghanistan or africa or Agalega Island* or algeria or angola or Anguilla or antigua or argentina or Armenia or Armenian or Aruba or Asia or Azerbaijan or bahamas or bahrain or bangladesh or barbados or barbuda or Basutoland or belarus or belize or Belorussia or Belorussian or benin or bhutan or bolivia or borneo or bosnia or botswana or Bouvet Island* or Brasil or brazil or brunei or burkina faso or Burkina Fasso or Burma or burundi or Byelarus or Byelorussian or cabo verde or cambodia or Camerons or Cameroon or Cameroons or cape verde or caribbean or cayman or central african republic or central america or Ceylon or chad or chile or china or Christmas Island* or Cocos Island* or colombia or Comores or Comoro Island* or comoros or congo or Cook Island* or costa rica or cote d'ivoire or cuba or democratic people's republic of korea or djibouti or dominica or dominican republic or dprk or East Timur or ecuador or egypt or el salvador or eritrea or ethiopia or falkland island* or fiji or french guiana or French Polynesia or French Somaliland or gabon or Gabonese Republic or gambia or gaza or Georgia or ghana or Gold Coast or grenada or grenadines or guadeloupe or guam or guatemala or Guiana or guinea or guyana or haiti or Heard Island* or Hercegovina or herzegovina or honduras or Ifni or india or Indian ocean or indochina or indonesia or iran or iraq or ivory coast or jamaica or jordan or Kampuchea or katanga or Kazakh or kazakhstan or Keeling island* or kenya or Khmer Republic or Kirghiz or Kirghizia or Kirgizstan or kiribati or Korea or Kosovo or kuwait or Kyrgyz Republic or kyrgyzstan or Lao PDR or laos or latin america or lebanon or lesotho or liberia or libya or madagascar or Malagasy Republic or malawi or Malay or Malaya or malaysia or maldives or mali or malvinas or marshall island* or martinique

or mauritania or mauritius or Mayotte or McDonald Island* or mekong valley or melanesia or mexico or micronesia or middle east or mongolia or montserrat or morocco or mozambique or Muscat or Myanma or myanmar or namibia or nauru or Navigator Island* or near east or nepal or Netherlands Antilles or nevis or new caledonia or New Hebrides or nicaragua or niger or nigeria or Niue or Norfolk Island* or north korea or Northern Mariana Island* or Nyasaland or oman or pakistan or Palau or palestine or Palestinian or panama or papua new guinea or paraguay or peru or Philipines or philippines or Phillipines or Phillippines or pitcairn island* or puerto rico or qatar or reunion or Rhodesia rio muni or Ruanda or rwanda or Sabah or Saint Barthelemy or Saint Helena or saint kitts or saint lucia or Saint Martin or saint vincent or samoa or samoan island* or Sandwich Island* or sao tome or Sarawak or saudi arabia or senegal or seychelles or sierra leone or sikkim or solomon island* or somalia or south africa or south America or sri lanka or St Barthelemy or St Helena or St Kitts or St Lucia or St Martin or St Vincent or sudan or Surinam or suriname or swaziland or syria or syrian arab republic or Tadjikistan or Tadzhik or Tadzhikistan or tajikistan or tanzania or thailand or tibet or timor or tobago or togo or Togolese Republic or Tokelau or tonga or trinidad or tunisia or Turkmen or turkmenistan or "turks and caicos" or Tuvalu or uganda or ukraine or united arab emirates or United Arab Republic or Upper Volta or uruguay or Urundi or Uzbek or uzbekistan or vanuatu or venezuela or viet nam or vietnam or virgin island* or "Wallis and Futuna" or West Bank or West Indies or yemen or Yugoslavia or zaire or zambia or Zimbabwe).hw,ti,ab,cp.

2. Developing Countries.sh,kf.
3. ((southeast or southeastern or western) adj asia).tw,kw.
4. ((developing or less* developed or under developed or underdeveloped or middle income or low* income) adj (economy or economies)).tw,kw.
5. (low* adj (gdp or gnp or gross domestic or gross national)).tw,kw.
6. (low adj3 middle adj3 countr*).tw,kw.
7. (lmic or lmics or third world or lami countr*).tw,kw.
8. transitional countr*.tw,kw.
9. or/1–8
10. exp "tobacco use cessation"/ or exp smoking cessation/ or exp smoking reduction/ or exp harm reduction/ or ((argileh or beedis or betel or chhutta or chillum or cigar* or cigarette* or cigarillo* or dhumti or dokha or e-cigarette* or e-cig* or e-hookah* or gutka or hookah or hookli or imqmik or khaini or kiseru or kizami or makla or midwakh or mishri or mu'assel or narghile or naswar or nicotania or nicotine or paan or pan masala or perique or shisha or smoking or snuff or snus or thoc lao or tobacco or vape or vaping) adj5 (abstinence or cessation or decrease or harm reduc* or harm minimiz* or stop or stopping or withdrawal or quit or quitting)).tw,kw. (49363)
11. 9 and 10

Appendix B

Definitions of Low- to middle-income countries (LMICs) and High-income nations.

This definition has been adapted from the World Bank and can be accessed at https://datahelpdesk.worldbank.org/knowledgebase/articles/906519. We defined LMICs as nations falling under the categories below: Low income; Lower-middle income; Upper-middle income.

Classification as per World Bank	Definition
Low-income	Low income economies are those with gross national income (GNI) per capita, calculated using the World Bank Atlas method, of $1,025 or less in 2018
Lower middle-income	Lower-middle-income economies are those with a GNI per capita, calculated using the World Bank Atlas method, of more than $1,026 and $3,995
Upper middle-income	Middle-income economies are those with a GNI per capita, calculated using the World Bank Atlas method, of more than $3,996 and $12,375
High-income	High-income economies are those with a GNI per capita, calculated using the World Bank Atlas method, of $12,736 or more

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