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The effect of individual-level smoking cessation interventions on socioeconomic inequalities in tobacco smoking (Protocol)

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[Intervention Protocol]

The effect of individual-level smoking cessation interventions on socioeconomic inequalities in tobacco smoking

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To investigate differences in the effectiveness of individual-level smoking cessation interventions by socioeconomic indicators, to estimate the potential that an intervention might increase or decrease health inequalities due to tobacco use.

BACKGROUND

Description of the condition

Despite effective tobacco control measures and reductions in smoking prevalence observed globally, tobacco use remains a leading cause of preventable morbidity and mortality, and a leading driver of health inequalities worldwide (ASH 2019; WHO 2020).

Socioeconomic status (SES), commonly measured through education, income, and occupation, is the combined economic and social standing of an individual or group in society (Baker 2014; Petkovic 2020). In higher-income countries, a social gradient in tobacco use has developed, whereby people of lower SES are more likely to smoke (AIHW 2019; Hiscock 2012a; Thirlway 2020; WHO 2014). In Australia, people from disadvantaged socioeconomic areas are 2.6 times more likely to smoke daily (AIHW 2019). Similarly, in the UK, a higher proportion of people who smoke are unemployed or have lower levels of education (ONS 2020), while in the USA, multiple forms of disadvantage have shown a cumulative effect on smoking prevalence (Leventhal 2019). This social gradient in tobacco prevalence is less clear in the context of low- to middle-income countries (LMIC). For example, national survey data found that men with lower levels of education reported greater tobacco use in 52 out of 54 LMIC (Sreeramareddy 2018). Conversely, more recent evidence focussed on low-income communities in India, found that unemployment was associated with lower rates of tobacco use (Sarkar 2017).

Multiple mechanisms contribute to unequal smoking rates across SES groups. Less advantaged groups are often more likely to start tobacco smoking (Hiscock 2012). In addition, once smoking, people in less advantaged groups are less likely to successfully quit (Hiscock 2012; Kotz 2009). This review focusses on interventions to address the latter, which some research has tried to explain by exploring quit attempts, use of cessation aids, and quitting success (Kotz 2009). A cross-sectional household survey in England concluded that despite comparable attempt rates and aids used to quit smoking, individuals from lower SES groups were half as likely to succeed in achieving abstinence (Kotz 2009). Further research also suggests that access to and uptake of smoking cessation treatments and services are balanced across SES groups (Clare 2014; Greenhalgh 2019), however, this may vary in different contexts (e.g. countries without government subsidised cessation treatments). Race and ethnicity are also associated with SES, and their relationship with smoking cessation outcomes is complex (Nollen 2019).

Given socioeconomic disparities in smoking, it is not surprising that tobacco is a major cause of health inequalities (ASH 2019; Gruer 2009; Stringhini 2010). The term 'health inequalities' describes health differences, alongside varying degrees of fairness (ASH 2019; McCartney 2019; Mindell 2019; Petkovic 2020). Sometimes, where a difference in health is perceived to be systematic, avoidable, or unfair within a particular context, it has been referred to as a 'health inequity' instead (Arcaya 2015; Petkovic 2020; WHO 2014). In this review, we will define all differences in health between groups as 'health inequalities'.

Differences in health across groups have significant implications for public health systems and expenditure. In 2010, the Marmot review concluded that if all people in England had death rates equivalent to the most advantaged, an extra 1.3 to 2.5 million years of life would be recovered each year by those dying early due to health inequalities (Marmot 2010). According to the WHO, this translates to a total economic benefit of £98 to £118 billion (WHO 2016). Ten years after the 2010 review, the 2020 update of the Marmot review found that health equity in England had worsened, demonstrated by the widening of differences in life expectancy between those living in the most and least deprived areas (Marmot 2020). A 2016 WHO review of 11 European countries estimated substantial economic benefits, ranging from €0.64 billion to an upper estimate of €60.03 billion, which could be achieved by improving mortality rates in lower socioeconomic groups (WHO 2016). In the USA, a simulation modelling study estimated that USD 1.02 trillion would be gained in health improvements, if the health of all Americans was equal to that of a college-educated individual, as of 2006 (Schoeni 2011). Many current public health strategies are focussed on reducing health gaps across populations (PHE 2019). Reducing tobacco use is a priority area to improve public health and health inequalities for many countries (PHE 2019; WHO 2019).

Description of the intervention

Smoking cessation interventions aim to motivate and/or help support people who smoke to quit. These interventions can be delivered at an individual- or population-level. Population-level tobacco control interventions include increased tobacco taxes, and messaging to inform people about the harms of smoking, and direct them to resources to help them quit. Tax increases appear to reduce smoking prevalence in lower SES groups (Lorenc 2013; Smith 2020), and the population as a whole (WHO 2019).

Individual-level support is often provided alongside population-level interventions. Individual-level support may include behavioural support, pharmacological support, or both, aimed at helping people to quit smoking (Hartmann-Boyce 2019). Behavioural support for smoking cessation varies greatly in content, delivery, and intensity (Hartmann-Boyce 2021a). These interventions are often based on different behaviour change theories, and can be delivered in-person, digitally, or over the phone; one-on-one or in groups; in any setting from the home to a specialised facility; delivered by health specialists or lay volunteers; with or without financial incentives to quit. Widely used pharmacological interventions for smoking cessation include nicotine-replacement therapy (NRT; Hartmann-Boyce 2018), varenicline and bupropion (Cahill 2016; Howes 2020; WHO 2019), and more recently in some countries, nicotine electronic cigarettes (Hartmann-Boyce 2021).

How the intervention might work

Individual-level interventions aim to help manage the psychological and physical withdrawal symptoms experienced when people stop smoking, and to overcome the habitual nature of cigarette smoking. Some also aim to boost motivation to continue with the quit attempt, and provide helpful strategies to support its continuance.

Contextual factors at work in some populations may moderate the efficacy of an individual-level smoking cessation intervention, therefore, the same intervention may perform differently in different populations and contexts. There are several pathways by which smoking cessation interventions may exacerbate or minimise socioeconomic inequalities in smoking. One substantial barrier to successful long-term quitting in people who smoke

tobacco is withdrawal symptoms, such as cravings, low mood, and irritability. These are commonly experienced during a quit attempt, and successful management of these withdrawal symptoms, through medication, is known to increase chances of successfully quitting (Hartmann-Boyce 2016). Some evidence suggests that nicotine withdrawal symptoms are experienced more severely in people of lower SES groups. This may be because lower SES is associated with greater nicotine dependence (Chen 2019; Jarvis 2003; Kotz 2009; Siahpush 2006). However, greater nicotine dependence may not always hinder quitting success, when treated appropriately. For example, a post hoc subgroup analysis from a Cochrane Review found that a 4 mg dose of nicotine gum was more effective for smoking cessation than a 2 mg dose in people with high nicotine dependence (Lindson 2019). Therefore, providing appropriate medication dosing could help to ameliorate socioeconomic discrepancies in quitting success.

Greater nicotine dependence may not be the only mediator eliciting more severe withdrawal symptoms that are observed in people of lower SES during a quit attempt. A secondary analysis of a smoking cessation trial found that nicotine withdrawal-related anger and anxiety levels were greater in people who perceived themselves to be of lower socioeconomic position, independent of pre-quit nicotine dependence levels, and that lower levels of both anger and anxiety symptoms were associated with short-term (four weeks) quitting success (Alexander 2020). Financial strain has also been associated with more severe withdrawal symptoms, which in turn, was associated with a greater chance of relapse after a quit attempt (Kendzor 2018).

Social norms, less social support, and lower levels of self-efficacy experienced by individuals of lower SES, as well as lower adherence to smoking cessation treatment, may impose additional barriers to successful quitting (Greenhalgh 2016; Hiscock 2011; Hiscock 2012; Hiscock 2015; Thirlway 2020). Different behavioural interventions for smoking cessation will vary in their ability to manage these factors, thereby, potentially leading to differences in quitting outcomes by SES.

Conceptual models, such as the Reserve Capacity Model, help to further explain how SES can impact health. The Reserve Capacity Model postulates that people of low SES encounter stressful experiences and environments more frequently, but have fewer tangible, intra- and inter-personal resources available to them. This combination of fewer resources or reserves and frequent stressors taxes the system, and impacts health both directly and indirectly through physiological (e.g. immune function, metabolic function) and behavioural (e.g. diet, physical activity, smoking, sleep) pathways (Gallo 2003; Gallo 2009).

There is strong evidence that combinations of smoking cessation treatment increase quitting success. High certainty evidence suggests that using a combination of NRT versus a single form of NRT (Lindson 2019), a combination of behavioural therapy and pharmacotherapy compared to brief advice or usual care (Stead 2016), and increasing the amount of behavioural support for people using stop-smoking medication (Hartmann-Boyce 2019), all increase the chance of abstaining from smoking. Multi-component, more intensive smoking cessation treatment may come at a greater cost, and may be less accessible for people of lower SES in countries where treatments are not heavily subsidised or freely provided.

Why it is important to do this review

As outlined above, there is a complex interplay of mechanisms that affect the efficacy of individual-level smoking cessation interventions across socioeconomically diverse groups that is not yet well understood. The ability of different smoking cessation interventions to address potential drivers of inequalities may influence how well different smoking cessation interventions perform in different socioeconomic groups, and whether they increase, reduce, or have no impact on health inequalities due to tobacco use.

To date, reviews in this area have been UK-centric, or limited by eligibility restrictions on intervention type, study analyses, study country, publication year, language, or some combination. A 2014 systematic review investigated the impact of individual-level smoking cessation interventions on health inequity across European countries (Brown 2014). Authors concluded that these interventions, which were either behavioural, pharmacological, or both, were likely to contribute to smoking inequalities, and suggested the use of tailored services for smokers of lower SES to help mitigate disparities (Brown 2014). However, another review found that the effectiveness of individual-level behavioural interventions tailored for socioeconomically disadvantaged groups produced no additional benefit over non-tailored interventions, although the certainty of the evidence was low (Kock 2019). Most recently, another systematic review found that despite less quitting success in low SES groups, the impact on health equity was offset by an increase in reach of specialist and primary care stop-smoking support in low SES groups in the UK (Smith 2020a). However, the UK is one of only a few nations that provide heavily subsidised or free smoking cessation services, limiting the generalisability of this finding.

This review aims to build on previous work, by updating and broadening our understanding of the impact of individual-level smoking cessation interventions on socioeconomic inequalities in tobacco smoking from a global perspective, by searching, appraising, and synthesising the most recent evidence, using systematic and novel approaches.

A better understanding of the interventions that work best, worst, or equivalently in different socioeconomic groups can help governments and healthcare providers focus resources on treatments that do not exacerbate, and may mitigate inequalities, where possible. It can also inform the development of treatments that are better suited to lower socioeconomic groups, ultimately increasing quitting success, and thereby, reducing health inequalities.

OBJECTIVES

To investigate differences in the effectiveness of individual-level smoking cessation interventions by socioeconomic indicators, to estimate the potential that an intervention might increase or decrease health inequalities due to tobacco use.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), as they are considered the highest standard of evidence for evaluating intervention effectiveness. RCTs can randomise either individual participants or groups of participants (clusters). There will be no restriction on language, study country of origin, publication status, or publication date.

Types of participants

We will include adults, 18 years or older (sample majority), who smoke tobacco cigarettes, regardless of motivation to quit.

Types of interventions

We will include any individual-level smoking cessation intervention, of any intensity, which encourages complete cessation of the use of tobacco cigarettes. We define an individual-level smoking cessation intervention as any behavioural or pharmacological support that aims to help and/or motivate participants to achieve abstinence from smoking. Behavioural support may be delivered in person, in print, digitally, or over the phone, one-on-one or in groups, in any setting, and via any individual or alternate medium. To be included in this review, interventions must be those that could feasibly be delivered by government, healthcare systems, or providers. This means, we will exclude pharmacological interventions no longer licensed or studied because of concerns about safety, or behavioural interventions that are no longer considered acceptable practice (e.g. aversive smoking, identified in Hartmann-Boyce 2021a). For transparency, we will list any interventions excluded for this reason in our review. Eligible pharmacological interventions for smoking cessation are any medication, licensed or commonly used for smoking cessation worldwide, i.e. NRT, varenicline, cytisine, bupropion, nortriptyline (WHO 2019), or electronic cigarettes (Hartmann-Boyce 2021).

Eligible studies must include a comparator arm that meets one of the following criteria:

- no smoking cessation treatment
- placebo
- another smoking cessation intervention, of any length or intensity, including usual care.

Types of outcome measures

Primary outcomes

The primary outcome of interest is combustible tobacco cigarette smoking cessation rates, split by socioeconomic status (SES), at the longest follow-up. In accordance with standard methods of the Cochrane Tobacco Addiction Group, smoking cessation must be measured at least six months from baseline, to ensure the review captures long-term abstinence rates. We will include any definition of smoking cessation, as defined in the included studies. When multiple measures of abstinence are reported, but only one includes assessment of SES, we will use the measure that is evaluated by SES. If multiple abstinence definitions are used by study authors, and evaluated by SES, we will use the strictest definition of smoking cessation. That is, we will use prolonged or continuous abstinence over point prevalence abstinence, and abstinence that is biochemically validated (e.g. using exhaled carbon monoxide or cotinine measures) over self-reported. Biochemically validated point prevalence abstinence will be used over self-reported continuous or prolonged abstinence.

To be eligible for inclusion, studies must have investigated the interaction between at least one of the following SES indicators and the smoking cessation outcome at six months, or longer, from baseline.

- Education level;
- Income level;
- Employment status;
- Occupation classification;
- Place of residence, e.g. where markers, such as postcode can be used to indicate the level of deprivation;
- Level of deprivation;
- Other relevant indices that study authors described as SES indicators.

When present, we expect SES indicators to be assessed at baseline.

Secondary outcomes

We did not define any secondary outcomes.

Search methods for identification of studies

Electronic searches

With the help of an information specialist, we will search the Cochrane Database of Systematic Reviews (CDSR) in the Cochrane Library for any reviews with 'smoking' or 'tobacco' in the title, abstract, or keyword fields; see Appendix 1 for a detailed search strategy. We will screen the results to identify reviews of interventions that meet our inclusion criteria.

We will then screen the included studies from each of these reviews for eligibility in our review. If the latest search date for the contributing reviews is prior to 2018, we will update the contributing reviews' searches to identify further studies that may be eligible, and were conducted after the contributing review was published.

Searching other resources

We will contact experts and organisations in the field of smoking cessation research to review our list of included studies, and comment on additional relevant forthcoming or unpublished trials that may be eligible for inclusion.

Supplementary artificial intelligence (AI) facilitated searching

We will screen a repository of behaviour change intervention evaluation reports, identified through Natural Language Processing and Machine Learning methods, as part of the Human Behaviour Change Project (HBCP (Michie 2017)). Additional records not already identified via the electronic search will be assessed for eligibility.

Once a list of included and excluded studies has been identified, a review author (JT) will conduct a machine-learning driven search of the Microsoft Academic dataset, using the web-based software

programme EPPI-Reviewer (EPPI-Reviewer 2020). EPPI-Reviewer will use the information drawn from the studies that have been included and excluded to help find new and related studies, We will use an AI-generated graph within EPPI-Reviewer to help identify closely linked citations, based on the studies included and excluded from the review, to identify additional studies that have not been screened. This graph has been generated based on previous screening of full-text research reports.

Data collection and analysis

Selection of studies

Two review authors will independently screen the titles and abstracts of records identified through the search against our eligibility criteria, using a piloted screening checklist. We will retrieve the full texts of records deemed eligible, and two review authors will independently screen them against the selection criteria. We will use Covidence, a systematic review screening software programme, to manage the records and facilitate duplicate screening (Covidence). We will report reasons for exclusion of studies that a reader might plausibly expect to see among the included studies in a 'Characteristics of excluded studies' table. We will resolve any disagreements at any screening stage through further discussion, or by referral to a third review author.

We will collate multiple reports of the same study under a primary study record. We will present the search and screening selection process using the PRISMA flow diagram (Moher 2009).

Data extraction and management

Two review authors will independently extract study data, using a piloted extraction form, and then compare their findings. We will resolve any differences in data extracted through discussion, or by involving a third author, where necessary. We will extract the following information where available:

- **Methods**: study design, recruitment procedure, study start and completion dates, setting, and country (country economic classification of income-level; high, upper-middle, lower-middle, and low (The World Bank 2021))
- **Participants:** number of participants (N) randomised, N per study arm, relevant inclusion and exclusion criteria, whether inclusion was based on a specific population characteristic, motivation to quit, definition of smoker used, specific demographic characteristics (e.g. mean age, age range, sex), mean cigarettes per day, mean Fagerstrom Test for Nicotine Dependence (FTND), race or ethnicity (or both)
- **Interventions**: description of what was received by each study arm, including details of behavioural support and pharmacological treatment provided. We will extract details of components, materials, dose, timing and frequency, as well as who provided the intervention. We will identify whether any intervention components may plausibly specifically improve smoking cessation in lower SES groups (for example, interventions to improve self-efficacy, stress or anxiety management, adherence to the intervention, social network). We will also note whether interventions were provided free of charge.
- **Intervention component classification:** intervention components will be classified as: behavioural, pharmacotherapy, or pharmacotherapy and behavioural. We will categorise pharmacotherapy by drug type, dose, duration, and mode of administration. We will extract behavioural components, delivery mode, intervention provider and intensity of the intervention. We will categorise the behavioural intervention components using the system described in the Cochrane overview on behavioural interventions for smoking cessation (Hartmann-Boyce 2021a):
  - *Motivational components*: focus: how to quit; focus: why quit; nature: motivation; nature: self-regulation; nature: adjuvant activities;
  - *Behavioural components:* counselling; biofeedback; hypnotherapy; exercise; financial incentives: guaranteed; financial incentives: not guaranteed; tailoring;
  - *Delivery mode:* group; individual; face-to-face; telephone; web/computer; print; SMS; app; video (static); video (interactive); audio; interactive voice response; quitline; e-mail; other;
  - *Intervention provider:* nurse; stop smoking advisor; psychologist/counsellor; physician; pharmacist; dentist; lay health advisor; hypnotist; exercise specialist; other;
  - *Intensity of the intervention:* duration of the intervention; mean length of each session offered (minutes); number of sessions offered.
- **Outcomes**: definition of abstinence (e.g. biochemically verified), and abstinence rate at longest follow-up time point for which SES is available, which should be at least six months from baseline, broken down by SES indicator(s)
- **SES indicators**: measures of SES, specifically: education level, income level, employment status, occupation classification, place of residence, level of deprivation, or other relevant indices. We will extract the definition or scale of measurement of each indicator of interest reported, in addition to the breakdown of participants by SES. It is anticipated that these will be reported at baseline, however, we will extract data on these variables if reported at other time points.
- **Sources of study funding:** extracted verbatim
- **Author declarations:** extracted verbatim
- **Notes:** whether additional information or data were provided by the author, and other relevant information, where necessary.

If inconsistent information is reported across multiple records of a single study, we will contact study authors for clarification, where possible. If no response is received from the study author after two contact attempts, a minimum of two review authors will discuss the discrepancy, and decide whether the information can be included and if so, what information to include. We will note the discrepancy in the 'Characteristics of included studies' table.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias for each included study using the Cochrane risk of bias 1 (RoB 1) tool. We will follow the guidance as set out in the *Cochrane Handbook for Systematic Reviews of Interventions* and by the *Cochrane Tobacco Addiction Review group* to evaluate the appropriate domains (Higgins 2017; Higgins 2021).

Studies will be assessed on the following RoB 1 domains:

- Random sequence generation (selection bias)

- Allocation concealment (selection bias)
- Blinding of participants and personnel (performance bias); we will not assess performance bias for studies investigating behavioural interventions, as true blinding of participants is not possible.
- Blinding of outcome assessment (detection bias): if blinding of participants is not possible (e.g. studies of behavioural interventions), study risk of bias will be judged as:
  - Low: when smoking status is measured objectively (i.e. biochemical validation);
  - Low: when smoking status is measured by self-report, but the intervention and control arms received similar amounts of face-to-face contact (or none);
  - High: when smoking status is measured by self-report, and participants in the intervention arm have more personal contact than in the control or comparator arm.
- Incomplete outcome data (attrition bias): we will judge studies at low risk of bias when:
  - Numbers lost to follow-up are clearly reported for each group (not just overall, unless the overall percentage lost is less than 10%);
  - The overall number of participants lost is not greater than 50%;
  - The difference in percentage followed up between groups is not greater than 20%;
  - The authors report sensitivity analyses that indicate the overall direction of effect is not sensitive to different imputation methods for loss to follow-up.
- Availability of smoking abstinence data by SES: we will assess the extent to which complete information on smoking abstinence by SES indicator is available through reporting, or from study authors upon request. We will deem information as 'complete', and therefore at low risk for this domain, if the data available are sufficient to include in the meta-analysis. We will judge this domain at high risk if insufficient data are available to include in meta-analysis, and we judge that the lack of detail is due to the association detected, or lack thereof. We will judge all other studies as unclear risk in this domain. This domain substitutes the standard domain of 'selective reporting' which is less relevant to the objective of this review.
- Other sources of bias

We will resolve any disagreements in judgements made between review authors by discussion, or by involving a third reviewer, where necessary. We will provide supporting justifications for judgements made.

Measures of treatment effect

Smoking cessation rates by SES

We will compare the rate of smoking abstinence between intervention and comparator groups by SES for each study. Where sufficient data are available, we will calculate rates on an intention-to-treat basis, with losses to follow-up counted as continuing to smoke. If multiple indicators of SES are reported, we will extract all data and include one SES indicator in the primary comparison, preferentially selected as per the order listed in the Primary outcomes section above. If there are more than two categories describing a difference within a single SES indicator (e.g. high, medium, and low levels of education) we will again extract all data, and choose the comparison of categories at each end of the scale for the primary analysis.

We will report dichotomous data on smoking abstinence within SES groups, and also use them to calculate an odds ratio (OR) with a measure of variance (standard error (SE)). The following data will be extracted directly or used to calculate the ORs (SE), as appropriate. Types of data will be preferentially extracted as follows:

1. Count data: total number of participants and number of abstinent participants by study arm by a 2-factor SES indicator (covariate) at longest follow-up with available data. If analysed but not reported, we will contact study authors (see Dealing with missing data) and extract other measures, where possible.
2. Adjusted and unadjusted ORs with a measure of variance, preferably SE. Where both are available, we will include unadjusted ORs in the primary analysis. We will investigate the effect of adjusted ORs with sensitivity and subgroup analyses.
3. Any other type of effect estimate that can be converted to an OR, such as risk ratio, or hazard ratio.
4. Any other data on difference by SES (see Data synthesis section)

Where sufficient data are available, we will then calculate ratios of ORs for each study, comparing lower to higher SES. We will interpret a ratio of ORs ≥ 1.05 (lower bound of 95% confidence interval (CI) ≥ 1.05) as a clinically significant increase in the relative odds of quitting in lower versus higher SES groups. We will interpret a ratio of ORs and 95% CIs of 0.96 to 1.04 as clinically non-significant, and a ratio of ORs and CIs ≤ 0.95 as a clinically significant decrease in the relative odds of quitting in lower versus higher SES groups. These thresholds are based on those used in a previous Cochrane Review (Hartmann-Boyce 2021a).

Intervention impact on health equality

The effect of smoking cessation interventions on health inequality will be categorised by comparing smoking cessation rates by socioeconomic groups using a modified rating scale, developed by Brown and colleagues in 2014, and adapted in 2019 (Brown 2014; Smith 2020a). This equity impact classification system was further modified for this review, most notably with the addition of thresholds for imprecision and a focus on trial evidence. We will categorise pooled estimates and individual study estimates as follows:

- Positive = evidence that the relative effect of the intervention on quit rates is greater in lower SES groups (point estimate favours lower SES, and 95% CI excludes no clinically significant difference (lower bound of 95% CI ≥ 1.05));
- Possibly positive = some evidence that the relative effect of the intervention on quit rates is greater in lower SES (point estimate ≥ 1.05, but 95% CI include no clinically significant difference (lower bound of 95% CI < 1.05));
- Neutral = evidence suggests no difference in the relative effect of the intervention on quit rates between lower and higher SES groups (point estimate and 95% CIs between 0.96 and 1.04);
- Possible neutral = some evidence of no difference in the relative effect of the intervention on quit rates between higher and lower SES groups (point estimate between 0.96 and 1.04, but 95% CIs include clinically significant difference (i.e. lower bound ≤ 0.95, higher bound ≥ 1.05, or both);

- Possible negative = some evidence that the relative effect of the intervention on quit rates is greater in higher SES groups (point estimate ≤ 0.95, but upper bound of 95% CI ≥ 0.95);
- Negative = evidence that the relative effect of the intervention on quit rates is greater in higher SES groups (point estimate and CIs ≤ 0.95);
- Unclear = unable to assess intervention equality impact based on available evidence (example: interaction between treatment type and SES reported as non-significant, but OR and CIs not reported, so unable to assess direction).

Unit of analysis issues

We may find studies with more than two intervention arms that are eligible to include in a single analysis. In these instances, we will include the study arms with the most and least intensive interventions in the analysis, and narratively report information of additional studies arms in the text.

If included studies are of a cluster-RCT design, we will attempt to extract an effect estimate from an analysis that accounts for the cluster randomisation. If this is not reported we will adjust the treatment effect ourselves, using the reported intra-class correlation (ICC). If an ICC is not provided for a particular study, we will use an ICC from a comparable study included in the review or identified from the literature. We will test whether the results are sensitive to the choice of ICC with a sensitivity analysis.

Dealing with missing data

Where necessary, we will contact the corresponding author or trial contact of included studies via email, with a request for further information. If a primary contact is unreachable, we will contact co-authors or other collaborators, where possible. We will send all contacts at least one follow-up email if we do not receive a response.

We will report the number of participants lost to follow-up for each study, at each relevant time point, and assess it within the risk of bias assessment. For smoking abstinence, we will treat participants lost to follow-up, or with missing smoking status data as having relapsed, and as actively smoking, as is standard in the literature (West 2005).

If missing data prevents statistical analysis of included studies, we will report findings narratively.

Assessment of heterogeneity

We will assess studies for clinical variance, methodological variance, or both, prior to statistical synthesis. Where meta-analysis is deemed appropriate, we will assess statistical heterogeneity using the I^2 statistic, a percentage of total variation across study effect estimates attributable to between-study variance and not chance (Deeks 2021). We will interpret an I^2 statistic over 50% as an indication of substantial heterogeneity. We will interpret a value greater than 75% as evidence of considerable heterogeneity. We will reassess the decision to report a pooled estimate when considerable heterogeneity is detected, with consideration of the direction of effects. We will investigate causes of observed statistical heterogeneity through qualitative comparative analysis, subgroup, and sensitivity analyses, as described below.

Assessment of reporting biases

We will assess reporting bias through tests for funnel plot asymmetry when we include at least 10 or more studies in a meta-analysis. Funnel plots depict the relationship between a study size or precision and the study effect estimate, with the degree of asymmetry illustrating the potential risk of non-reporting bias. If funnel plot asymmetry is present, we will explore possible sources of asymmetry (Page 2021).

Data synthesis

Our analysis plan will involve a multi-stage process.

Smoking cessation rates by SES

We will group studies by intervention types (e.g. different forms of pharmacotherapy and behavioural support, as in existing Cochrane Reviews). We envision comparisons of the intervention types will include common pharmacotherapies, such as NRT, varenicline, and bupropion, and electronic cigarettes compared to placebo, and forms of behavioural support, including counselling and financial incentives compared to control.

The effect estimates (OR and accompanying measure of variance (SE)) for the treatment effect in lower SES groups, and a separate estimate for the treatment effect in higher SES groups, will undergo natural log transformation, which we will then include in separate random-effects meta-analyses using the generic inverse variance method. We will combine estimates from these meta-analyses as a ratio of ORs with 95% CIs.

If we are unable to calculate the ratio of OR with the data available, we will extract and synthesise the following information, in accordance with Cochrane guidelines (McKenzie 2021):

- Effect estimates with no available measure of variance will be summarised using descriptive statistics and complemented with box-and-whisker or bubble plots, as appropriate;
- P value from an analysis comparing the treatment effect by SES covariate;
- Vote counting, based on the classification system above (e.g. we will categorise each effect estimate as showing benefit (higher quit rate) or harm (lower quit rate) in lower SES groups).

We will conduct all meta-analyses using Review Manager 5 (Review Manager 2020).

Subgroup analysis and investigation of heterogeneity

Intervention characteristic effects

We will use a meta-regression random-effects model to evaluate the association between specific intervention characteristics and differences in effectiveness of interventions by SES, adjusting for country economic classification (see Data extraction and management). We will only undertake this meta-regression if there are sufficient data, i.e. a minimum of 10 or more studies contributing to a meta-analysis, and will use the study sets that are within the pair-wise meta-analyses.

If meta-regression is not possible, we will use qualitative comparative analysis (QCA) to explore and present the intervention characteristic effects by SES and country economic classification, if data allow (e.g. evidence of between-study heterogeneity (Thomas

2014)). We will use fuzzy-set QCA to identify which configurations of conditions (i.e. intervention characteristics and country economic classification) are most commonly associated with each of the six categories of intervention impact on health equality: positive, possibly positive, neutral, possibly neutral, possible negative, and negative.

We will undertake meta-regression using the statistical software package Stata, and QCA using fsQCA 2016 software.

Subgroup analysis

We will investigate clinical or methodological diversity (or both) between included studies through the following subgroup analyses, where data allow:

- Type of SES indicator
- Length of follow-up
- Adjusted and unadjusted ORs (SE)
- Country (economic classification)

Sensitivity analysis

We will conduct sensitivity analyses to determine the effect of removing studies deemed to be at overall high risk of bias on pooled findings. For studies that report multiple SES indicators, we will run sensitivity analyses to include SES indicators lower down the preference list. For studies that provide both unadjusted and adjusted estimates, we will conduct a sensitivity analysis using adjusted estimates in preference to unadjusted estimates. We will also test whether results are sensitive to the choice of ICC used to account for cluster randomisation.

Summary of findings and assessment of the certainty of the evidence

We will create summary of findings tables to present pooled estimates for smoking cessation rates by intervention type, alongside the equality impact rating of the intervention. We will evaluate the certainty of the body of evidence assessed for each comparison against the five GRADE considerations (risk of bias, inconsistency, imprecision, indirectness, and publication bias) using GRADEpro GDT software. We will judge Indirectness on the extent to which the sample is representative of the population. Where possible, we will assess this by comparing baseline SES indicators of each study sample with national population averages (e.g. average income, education level) per country in each relevant year (i.e. year in which the study was conducted).

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APPENDICES

Appendix 1. Search strategy for reviews from the Cochrane Database of Systematic Reviews

Free text terms	MeSH descriptors (explode all trees)
(Smok*):ti,ab,kw OR	Smoking OR
(Tobacco*):ti,ab,kw OR	Smoke OR
	Cigarette Smoking OR
	Tobacco Smoking OR
	Tobacco Use OR

(Continued)

	Smokers OR
	Smoking cessation OR
	Tobacco Use Cessation Devices OR
	Tobacco Use Cessation OR
	Tobacco Use Disorder OR
	Tobacco
Limited to Cochrane reviews and Cochrane protocols.	

CONTRIBUTIONS OF AUTHORS

JHB and NL identified the review objective. AT drafted the protocol with comments and revisions from NL, TRF, JT, NN, JA, EL and JHB.

DECLARATIONS OF INTEREST

AT holds a Global Grant from The Rotary Foundation to support DPhil studies. This is not deemed to be a conflict of interest.

NL has no conflicts of interest to declare.

TRF has no conflicts of interest to declare.

JT has no conflicts of interest to declare.

NN has received grants for trials for which Pfizer provided medication. They were not involved in the design, execution, analysis or reporting of results.

JA has no conflicts of interest to declare.

EL has no conflicts of interest to declare.

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