

# BMJ Open Smoking cessation interventions for Hispanic/Latino(a) adults in the USA: protocol for a systematic review and planned meta-analysis

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## ABSTRACT

**Introduction** Hispanic smokers face multiple cultural and socioeconomic barriers to cessation that lead to prominent health disparities, including a lack of language-appropriate, culturally relevant, evidence-based smoking cessation interventions. This systematic review will examine the literature on smoking cessation interventions for Hispanic adults in the USA to assess (1) the availability of interventions, (2) the methodological quality of the studies evaluating the interventions and (3) the efficacy of the interventions.

**Methods and analysis** A systematic literature search will be conducted, in English with no date limits, through the following databases starting at year of inception: Medical Allied Health Literature, Embase, American Psychology Association Psychology Articles, Cumulative Index to Nursing and Allied Health Literature Complete, ScienceDirect, Health & Medicine Collection and Web of Science Core Collection. Trial registries and grey literature sources will be searched to identify ongoing or unpublished studies. Literature search will be rerun prior to eventual submission of the review to ensure the inclusion of relevant studies. Quantitative studies evaluating the efficacy of a smoking cessation intervention (ie, smoking cessation as a measured outcome) for Hispanic adult smokers in the USA will be included in the systematic review. Two authors will independently identify relevant studies, extract data and conduct quality and risk of bias assessments. Discrepancies in coding will be discussed between the two reviewers and pending disagreements will be resolved by a third reviewer. First, the quality of all studies will be assessed, then randomised controlled trials (RCTs) will be further evaluated for risk of bias using Cochrane's Risk of Bias Tool. All eligible studies will be summarised descriptively. If data allow, the efficacy of smoking cessation interventions tested in RCTs, with a minimum follow-up of 6 months, will be quantitatively estimated using ORs and 95% CIs. The association between intervention type/modality and efficacy will be assessed via subgroup analyses.

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## INTRODUCTION

Hispanics/Latinos(as) are individuals of Latin American or Spanish origin (hereafter

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This systematic review will provide a comprehensive synthesis of smoking cessation interventions for Hispanic smokers, including an assessment of the methods used to evaluate the interventions and a quantitative summary of the efficacy of such interventions, which will be informative to the development of interventions and the design of cessation trials in the future.
- ⇒ The study will assess confidence in the evidence by exploring publication and outcome reporting biases, as well as the strength of the cumulative evidence for the main outcome of smoking cessation.
- ⇒ It is possible that a limited number of randomised controlled trials or high between study-variability may limit our ability to conduct subgroup analysis.
- ⇒ Trials of smoking cessation interventions with samples that include special populations (eg, pregnant women, military personnel, participants with any health conditions) will not be included in the planned meta-analysis.

referred to as Hispanics) and make up the largest and one of the fastest growing ethnic minority groups in the USA.<sup>1,2</sup> Nonetheless, this population is vastly underrepresented in smoking cessation research.<sup>3-9</sup> Although overall statistics suggest lower smoking prevalence among Hispanics compared with non-Hispanic whites (NHW),<sup>10</sup> rates tend to vary by subgroup, with the lowest prevalence among Central/South Americans (9% men; 4% women) and highest among Puerto Ricans (19% men; 16% women), which exceeds the smoking rate for NHW (17% men; 15% women).<sup>11</sup>

Despite smoking fewer cigarettes per day and being less likely to be daily smokers, Hispanics overall are disproportionately affected by illnesses that can be caused by smoking (relative to NHW).<sup>12</sup> The leading

causes of death among all Hispanics are smoking-related diseases (ie, cancer, heart disease, stroke and diabetes).<sup>13 14</sup> Hispanic smokers, compared with NHW smokers, are more likely to have made a quit attempt, yet they are less likely to be successful at maintaining abstinence.<sup>15–17</sup> They less frequently report receipt of physician advice to quit and have a lower prevalence of using counselling, medication, and/or nicotine replacement therapy to aid smoking cessation.<sup>18–21</sup> Other factors associated with poor cessation outcomes include limited access to healthcare, financial strains and language barriers.<sup>22–24</sup> Compared with NHW, Asians and blacks, Hispanic individuals have the highest likelihood of being uninsured.<sup>25</sup>

In 2000, the US Public Health Service (USPHS) published *Clinical Practice Guidelines for Treating Tobacco Use and Dependence*, which made specific recommendations for conducting research with special populations, such as ethnic/racial minorities, including Hispanics.<sup>3</sup> Through a review of the literature from 1985 to 2001 on behavioural treatments for smoking cessation among racial and ethnic minorities, Lawrence and colleagues<sup>5</sup> identified only 10 studies that reported quit rates for Hispanics and half did not use an experimental study design.<sup>5</sup> The updated USPHS guidelines emphasised the need for more research examining the efficacy of language-appropriate and culturally relevant smoking cessation interventions among Hispanics.<sup>4</sup> A 2010 systematic review previously evaluated available smoking cessation interventions solely targeting healthy Hispanic/Latinx adults within the USA through 2008. Webb and colleagues identified 12 studies with various primary intervention types/modalities (eg, self-help, counselling, nicotine replacement therapy) and only identified five randomised controlled trials (RCTs) that met criteria to be included in a meta-analysis.<sup>8</sup> They concluded that the interventions had moderate end-of-treatment (EOT) effects, but no significant long-term effects. Similarly, a literature review of interventions among ethnic and minority populations published a year later corroborated the paucity of studies of smoking cessation programmes for Hispanics.<sup>9</sup>

The present systematic review proposes to evaluate the efficacy of smoking cessation interventions for Hispanics residing in the USA. Researchers and clinicians will benefit from evidence on the availability and efficacy of cessation interventions specifically for Hispanics, including which types/modalities of interventions are most efficacious. Availability and efficacy are of particular importance in the context of understanding and addressing tobacco-related health disparities experienced by Hispanics, which are likely driven by a lack of culturally appropriate evidence-based treatments.<sup>3–9 13–21</sup> This review will build on previous work to provide a summary of treatment studies, including those conducted in the last decade.

The aim of our study is to systematically review the literature on smoking cessation interventions for Hispanic adults living in the USA to assess (1) what interventions are available for this population, (2) the methodological

quality of the studies evaluating the interventions and (3) the efficacy of the interventions.

Meta-analytic methods will be applied to quantitatively estimate the efficacy of smoking cessation interventions tested in RCTs among the general population of Hispanic adults. The objectives of the meta-analysis are to evaluate existing evidence for the efficacy of interventions compared with any control condition, and to investigate the moderating effect of intervention type/modality. To this end, we will address the following questions:

- ▶ Do smoking cessation interventions for Hispanics increase the likelihood of smoking abstinence at EOT, 6-month follow-up, and furthest/final follow-up?
- ▶ Is the type/modality of intervention (eg, self-help, counselling, pharmacotherapy, mobile Health) associated to treatment efficacy at 6-month follow-up?

## METHODS

We followed the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines for systematic review protocol development.<sup>26</sup> See online supplemental file 1 for PRISMA-P checklist. This systematic review has been registered with Prospective Register of Systematic Reviews, an international prospective register of systematic reviews. Any amendments to the protocol will be documented on this register.

### Eligibility criteria

Only quantitative studies will be included in this systematic review. Published and unpublished studies will be included. Only studies conducted in the USA (including Puerto Rico) will be included. We will not exclude studies based on publication date. Studies published in a language other than English will be excluded. For the purpose of this study, the definition of ‘smoking’ is restricted to tobacco cigarettes. Studies will be selected according to the following criteria.

### Population

Studies that include Hispanic adults ( $\geq 18$  years old) residing in the USA (including Puerto Rico) will be included in the systematic review, regardless of the proportion of Hispanic participants in the study samples. Studies targeting pregnant women, military personnel and participants with a specific health condition (eg, cancer, diabetes, HIV) will be included in the systematic review but excluded from meta-analyses. Studies with these special populations will be excluded because they may not generalise to the larger population of Hispanic smokers, and it is unlikely that there will be sufficient studies with each population to support separate analyses.

### Intervention

The systematic review will include studies evaluating behavioural smoking cessation interventions of any type/modality as well as pharmacological interventions with a behavioural adjunct. Studies evaluating broader health behaviour change interventions that include a smoking

cessation component will also be included in the systematic review.

For the purpose of this review, we will include interventions developed specifically for Hispanics or translated to Spanish as well as interventions with cultural adaptations made to convey shared characteristics, experiences or beliefs of the Hispanic population. Examples of cultural adaptation include content based on cultural values (eg, *familismo*, *personalismo*, *respeto*, *simpatia*), acculturation level, immigration to the USA, among others.<sup>27 28</sup>

### Comparator

Studies with no control condition will be included in the systematic review, but only RCTs comparing a smoking cessation intervention to a control or comparison arm (eg, no intervention/treatment, placebo, usual care, cointervention, reduced intervention) will be included in the meta-analysis.

### Outcome

The primary outcome is self-reported or biochemically verified smoking abstinence at the 6-month follow-up period or longer. If multiple follow-up timepoints are reported, data from the timepoint subsequent and closest to the 6-month follow-up will be used. Secondary outcomes include self-reported or biochemically verified smoking abstinence at EOT and at the furthest/final follow-up time point after 6 months.

Following standards of the Cochrane Tobacco Addiction Review Group,<sup>29</sup> we will give preference to the most rigorous definition of abstinence available. Studies that include Hispanic participants, regardless of the proportion of Hispanics in the sample, but do not provide primary outcome results for Hispanics separately will be excluded from the systematic review. Only studies for which smoking abstinence is provided for the intervention and control arms will be included in the meta-analysis.

### Study design

All types of study designs will be evaluated in the systematic review, including non-experimental, experimental and quasi-experimental studies. Only studies employing an experimental study design (ie, RCTs) will be included in the meta-analysis.

### Time frame

There will be no restrictions on study duration or length of follow-up for inclusion in the systematic review. However, following standard methods from the Cochrane Tobacco Addiction Group,<sup>29</sup> only RCTs that provide at least 6 months follow-up data will be included in the meta-analysis.

### Information sources and search strategy

The following electronic bibliographic databases will be searched from the year of inception: Medical Allied Health Literature (MEDLINE) (PubMed interface, 1946 onwards), Embase (Elsevier interface, 1947 onwards), Cumulative Index to Nursing and Allied Health Literature

Complete (EBSCOHost interface, 1937 onwards), American Psychology Association Psychology Articles (EBSCOHost interface, 1894 onwards), ScienceDirect (Elsevier interface, 1823 onwards), Health & Medicine Collection (ProQuest interface, depends on journal) and Web of Science Core Collection (Clarivate Analytics interface, 1945 onwards). The following registers will also be searched to locate relevant ongoing or unpublished studies: Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, ClinicalTrials.gov and National Institutes of Health RePORTER. A review of grey literature (eg, graduate theses and dissertations) will be conducted through a search from WorldCat, Embase, Web of Science, and ProQuest Dissertations and Theses. We will hand search the reference lists of studies included after full-text review to identify publications associated with other relevant studies.

The search strategy will be developed through the use of MeSH, if available, and search terms related to Hispanic/Latinx ethnicity, smoking and cessation interventions. The MEDLINE (PubMed) strategy will be created by an information specialist/medical librarian with input from the project team. After the strategy for MEDLINE is finalised, it will be adapted to the syntax, subject/thesaurus heading (indexing) and search options of the other electronic databases. Searches will include studies from the earliest time available to the present and will be limited to studies published in English. The search will be rerun prior to eventual submission of the review to ensure relevant studies are included. An example of the MEDLINE (PubMed) strategy is presented in online supplemental file 2.

### Data management and screening process

References obtained using the search methods stated above will first be imported into EndNote,<sup>30</sup> a reference management software, and then uploaded into Covidence,<sup>31</sup> an online systematic review management software, which will identify and remove any duplicate records. For the first phase of the systematic review, two reviewers will independently screen titles and/or abstracts of the references yielded by the search strategy to determine relevance. For the second phase, two reviewers will independently screen full-text articles of all relevant references against the predefined inclusion and exclusion criteria to decide whether these meet eligibility for final inclusion. In case clarification is needed to determine eligibility, we will make three email attempts to contact study authors to obtain the necessary information. Throughout title and abstract screening and full-text review, the reviewers will be blinded to each other's decisions. Disagreements will be discussed between the two reviewers and pending disagreements will be resolved by a third reviewer. Reasons for excluding studies at full-text review will be recorded in Covidence to produce a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of the study selection process.



## Data extraction and synthesis

For the third phase of the systematic review, data extraction will also be carried out independently by two reviewers using an extraction form in Covidence tailored to our specific data items. Extracted data will then be compared, disagreements will be reconciled by discussion between the two reviewers, and unresolved discrepancies will be decided by a third reviewer. The reviewers will further screen included studies identified as RCTs against the eligibility criteria for the meta-analysis. This will also be done independently. Any discrepancies will be discussed between the reviewers, and unresolved discrepancies will be decided by a third reviewer. Prior to starting data extraction, a calibration exercise will be undertaken to pilot and refine the data items and to ensure consistency across reviewers.

The design of our data extraction form was informed by variables used by Webb and colleagues and their recommendations for future research,<sup>8</sup> as well as based on recommendations from the Cochrane Handbook for Systematic Reviews of Interventions.<sup>32</sup> We will extract details on publication, study (ie, general characteristics, participants/population, methodology and assessments), intervention and outcomes/results. For RCTs, we will extract abstinence rates at EOT, 6-month follow-up, and at furthest/final follow-up time points, as well as sample size for the intervention and control groups. Information to be extracted is presented in online supplemental file 3. To avoid risk of bias in the meta-analysis, we will attempt to obtain missing results and/or unreported data, or to clarify uncertainties about extracted information, by making three email attempts to contact study authors.

Studies that meet inclusion criteria will first be summarised descriptively in a qualitative synthesis, which will be organised by primary intervention type/modality, participant, study, intervention and comparison group characteristics, as well as outcomes.<sup>5</sup> In addition, a descriptive ‘summary of findings’ table will be presented. Data from eligible RCTs will be analysed quantitatively through meta-analyses.

## Assessment of methodological quality

### Quality assessment

The quality of all studies, regardless of design, will be assessed using the Quality Assessment Tool for Quantitative Studies,<sup>33</sup> as recommended by the Cochrane Handbook for Systematic Reviews of Interventions.<sup>32</sup> Findings from the quality assessment will be summarised and presented in a table.

### Risk of bias assessment

RCTs will be further assessed for possible risk of bias using the revised Cochrane Risk of Bias Tool 5.0.2.<sup>34</sup> The procedures respective to each of the five domains in the risk of bias tool (ie, randomisation process, intervention deviation, missing outcome data, outcome measurement and selective reporting) will be assessed. Every domain will be rated as ‘low risk’, ‘high risk’ or ‘some concern’ of bias.

Every trial will also be rated as ‘low risk’, ‘high risk’ or ‘some concern’ of bias based on the rating of the individual domains. Findings will be visually presented on a ‘risk of bias summary’ figure for individual studies and a ‘risk of bias graph’ figure for all studies.

Two reviewers will independently complete quality and risk of bias assessments. Coding disagreements will be resolved through discussion between the reviewers and pending discrepancies will be resolved by a third reviewer. If not enough detailed information is present to make a decisive judgement, the study will be rated as ‘unclear’, and we will attempt to contact the study authors for clarification.

## Data analyses

### Measure of treatment effect

Abstinence rates and group sample sizes reported from eligible RCT studies will be used to compute intervention effect sizes and standard errors. The effect size will be determined by using OR and a 95% CI for the outcome of self-reported or biochemically verified smoking abstinence (ie, smoking status: yes/no), which will compare the odds of smoking cessation in the treatment group vs the control group. We will compute effect size estimates using all participants randomised according to the treatment arm originally assigned (ie, intention-to-treat approach). We will attempt to contact the original authors of the studies to obtain missing data relevant to the primary outcomes.

### Unit of analysis

Only individually randomised controlled trials will be included in the meta-analysis. Cluster-randomised trials will not be included to maintain a consistent randomisation unit and avoid cluster-specific heterogeneity. In the case of cross-over trials, we will only use data from the initial intervention, prior to cross-over. For RCTs with multiple treatment groups, treatment-specific data will be extracted for relevant study arms (eg, intervention and control groups).

### Heterogeneity

We will compute  $\chi^2$  statistics and perform Cochrane’s Q homogeneity test ( $p < 0.10$ ) to assess for the degree of heterogeneity (0%–25%: might not be important; >25%–50%: moderate heterogeneity; >50%–75%: substantial heterogeneity; >75% high, considerable heterogeneity).<sup>35</sup>

### Quantitative data synthesis

Meta-analyses will be completed using the RevMan V.5.4 software<sup>36</sup> in accordance with the guidelines provided by the Cochrane Handbook for Systematic Reviews of Interventions,<sup>32</sup> as well as R V.4.2.1 statistical package.<sup>37</sup> Considering between-trial heterogeneity, a random-effects model will be used to calculate an overall summary (pooled) intervention effect estimate across all eligible RCTs, with 95% CI. In case of high, considerable inter-study heterogeneity ( $I^2 > 75\%$ ), a pooled estimate will not be reported, however, we will present a forest plot

for individual studies, and only the narrative, qualitative summary will be reported.

### Subgroup and sensitivity analysis

If data allow and heterogeneity among the RCTs is substantial ( $I^2 \geq 50\%$  or  $p < 0.05$ ), we will conduct subgroup analyses to explore the source of heterogeneity in terms of the following characteristics: intervention type/modality, cultural specificity of intervention (culturally targeted and not culturally targeted), follow-up timepoints, measure of abstinence, duration of abstinence, method for biochemically verifying abstinence and method to handle missing outcome data (eg, intention-to-treat, multiple imputation, none). We will conduct a sensitivity analysis to assess the impact of including trials judged to be at high risk of bias. Sensitivity analysis will also be conducted to assess how the overall treatment effects from an available case analysis are impacted by including trials that do not report intention-to-treat analysis, have high attrition rates or other types of missing data.

### Assessing confidence in evidence

#### Publication bias

Publication bias can affect the validity and generalisation of a systemic meta-analysis result. If 10 or more RCTs are identified, we will examine funnel plot asymmetry and perform correlation-based tests (eg, Begg's rank test and Egger's regression test)<sup>38 39</sup> to assess the presence of publication bias. If publication bias is detected, we will run a p-curve analysis and calculate p-curve estimate of true effect size.<sup>40</sup>

#### Outcome reporting bias

Outcome reporting bias will be evaluated as part of the Risk of Bias assessment using the revised Cochrane Risk of Bias Tool V.5.0.2 (RoB 2).<sup>34</sup>

#### Strength of the evidence

To assess the strength of the body of evidence, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach will be used.<sup>41</sup> Quality of the evidence will be assessed for each of the framework's sections, which are risk of bias, imprecision, inconsistency, indirectness and publication bias. Certainty for each domain will be rated as very low, low, moderate or high based on the GRADE approach and including all RCTs in the meta-analysis.

### Patient and public involvement

Patients or the public were not (will not be) involved in the design, conduct, reporting, or dissemination plans of this systematic review.

## DISCUSSION

This protocol describes the methods for a systematic review of smoking cessation interventions for Hispanic adults in the USA. The review will systematically identify the available evidence with the aim to generate a

comprehensive, descriptive summary of interventions and studies, assess the methodological quality of the studies and quantitatively summarise the efficacy of the interventions using meta-analyses.

Given that the most recent review of smoking cessation interventions for Hispanic/Latinx smokers was published over a decade ago,<sup>8</sup> an updated, more recent review is needed to advance this line of research and identify areas for future direction. With the current review we plan to document the state of the science for smoking cessation interventions for Hispanics. In addition, we will assess the quality of the studies and whether the development and evaluation of interventions aligns with recommendations from the Treating Tobacco Use and Dependence Clinical Practice Guideline<sup>4</sup> and suggestions put forward by previous reviews.<sup>6 8</sup>

Of note, this review has some limitations. Given the scarcity of studies evaluating smoking cessation interventions for Hispanics documented by previous reviews,<sup>5 8 9</sup> it is possible that a limited number of RCTs will be identified, which would limit our ability to conduct subgroup analysis, including by intervention type/modality. However, it is expected that enough research has been conducted and published since the publication of the more recent review in this area,<sup>8</sup> over a decade ago, which would allow for a quantitative synthesis of the efficacy of smoking cessation intervention for Hispanics.

The findings of this review have the potential to not only expand the evidence base in the field of smoking cessation with Hispanics, but also inform the development of new interventions, and increase understanding of the content and types/modalities that are most likely to be efficacious. It is also expected that the findings of this review, specifically the assessment of the methodological quality of the included studies (ie, quality and risk of bias assessments), may aid in guiding the design of rigorous randomised cessation trials with Hispanics. Ultimately, we hope that the results of this review will be valuable for public health to improve the availability of and access to evidence-based smoking cessation interventions for Hispanics in the USA, with the goal of reducing the tobacco-related burden affecting this population.

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**Contributors** VNS is the guarantor of the review. PMR conceived this systematic review. PMR and LC conceptualised this systematic review and drafted the protocol. PCC, MKH, YK assisted in drafting the protocol. VNS and TB contributed to enhancing the protocol. PMR, LC and VNS developed the study selection and data extraction criteria. MKH developed the search strategy and provided literature search expertise. YK provided statistical expertise and guidance in refining the meta-analytic methodologies. HW assisted in developing the data extraction and quality assessment forms. UM contributed to revising the data extraction manual. VNS and TB provided expertise on smoking cessation interventions and acquired

the funding that is supporting this project. All authors contributed by reviewing and editing the manuscript. All authors read and approved the final manuscript.

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