INPLASY

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A systematic review of very low nicotine content cigarettes and compensatory smoking

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ADMINISTRATIVE INFORMATION

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2024100100

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 October 2024 and was last updated on 23 October 2024.

INTRODUCTION

*R*eview question / Objective Do smokers experience compensatory smoking behavior, either increases in the number of cigarettes smoked per day and/or exhaled breath carbon monoxide levels, when smoking very low nicotine content cigarettes for at least 3 weeks?

Condition being studied Cigarette smoking.

METHODS

Participant or population Adolescents and adults who smoke cigarettes.

Intervention Random assignment to very low nicotine content cigarettes.

Comparator Random assignment to normal nicotine cigarettes or another control condition.

Study designs to be included Randomized controlled trials.

Eligibility criteria Randomized controlled trials with the intervention condition randomly assigned VLNC cigarettes (Spectrum/Quest 3/Magic 0/ Xodus-22 brands) to smoke for at least 3 weeks.

Information sources PubMed Medline, EMBASE, Web of Science, Cochrane Library and CINAHL grey literature.

Main outcome(s) The mean number of cigarettes smoked per day at the end of the intervention. The mean exhaled breath carbon monoxide levels at the end of the intervention.

Quality assessment / Risk of bias analysis We are using Covidence's quality assessment tool to assess risk of bias.

Strategy of data synthesis We will review each manuscript to determine the impact of the intervention on the two primary outcomes of interest: the mean number of cigarettes smoked per day (CPD) at the end of the intervention and the mean exhaled breath carbon monoxide (CO) reading at the end of the intervention. Trials reporting increases in mean CPD and/or CO outcomes at the end of the trial compared to the control conditions will be identified as trials reporting compensatory smoking behavior, a negative outcome of smoking very low nicotine content cigarettes. Trials reporting no differences in mean CPD and/or CO outcomes at the end of the trial compared to the control conditions will be identified as having no impact on compensatory smoking behavior when smoking very low nicotine content cigarettes. Trials reporting decreases in mean CPD and/or CO outcomes at the end of the trial compared to the control conditions will be identified as having positive impact on smoking behaviors when smoking smoking very low nicotine content cigarettes. We will report a count of the total number of cigarettes reporting increases, no changes or decreases for each outcome of interest (CPD and CO).

Subgroup analysis None.

Sensitivity analysis None.

Language restriction English language only.

Country(ies) involved USA.

Keywords very low nicotine content; clinical trials.

Contributions of each author
Author 1 - Rachel Denlinger-Apte - Author 1 developed the systematic review idea, will be overseeing abstract review and extraction and will be the lead author for drafting the manuscript.
Author 2 - Ziyu Ji - Author 2 completed separate pooled analyses for manuscript - will review and edit manuscript drafts.
Author 3 - Emily Harwood - Author 3 will be conducting the abstract review, extraction and data synthesis; will review and edit manuscript drafts.

Author 4 - Darcy Lockhart - Author 4 will be conducting the abstract review, extraction and data synthesis; will review and edit manuscript drafts.
Author 5 - Neal Benowitz - Author 5 will review and edit manuscript drafts.
Author 6 - Dana Mowls Carroll - Author 6 will review and edit manuscript drafts.
Author 7 - Rachel Cassidy - Author 7 will review and edit manuscript drafts; provided data for separate pooled analysis.
Author 8 - Suzanne Colby - Author 8 will review and edit manuscript drafts.
Author 9 - Diann Gaalema - Author 9 will review and edit manuscript drafts.
Author 10 - Brandy Hardy - Author 10 will develop and conduct the search strategy for the systematic review; will review and edit manuscript drafts.
Author 11 - Dorothy Hatsukami - Author 11 will review and edit manuscript drafts; provided data for separate pooled analysis.
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Author 22 - Jack Wolf - Author 22 will review and edit manuscript drafts.
Author 23 - Eric Donny - Author 23 will review and edit manuscript drafts; provided data for separate pooled analysis.
Author 24 - Joseph Koopmeiners - Author 24 conceptualized the separate pooled analysis and provided statistical oversight; will draft and edit the manuscript sections about the pooled analyses.