INPLASY

Breaking the Habit: A Systematic Review and Meta-Analysis of Pregnancy-Related Smoking Cessation Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Review Stage at time of this submission - Completed but not published - Since we had to publish the findings as soon as possible and were dedicated to applying for promotion, we were unable to file for prospective registration which takes a long time. At the same time, we were unaware of INPLASY's existence, which facilitates quick registration and supports researchers.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202530054

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 March 2025 and was last updated on 12 March 2025.

INTRODUCTION

Review question / Objective The aim of this systematic review and meta-analysis is to compare [pharmacological and behavioral interventions for smoking cessation during pregnancy] and [usual prenatal care, less intensive or different interventions, or a placebo] for [pregnant smokers] in terms of efficacy and acceptability in the [smoking cessation and pregnancy outcomes] to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce [smoking in pregnancy and adverse pregnancy outcomes] in [pregnant smokers], [pharmacological and behavioral interventions] or [usual prenatal care, less intensive or different interventions, or a placebo] ?".

Rationale Pregnancy-related tobacco smoking is linked to major consequences for both the mother and the fetus [1-3]. Many pregnant women still smoke despite the tremendous efforts made to increase knowledge of the negative effects of tobacco use on pregnancy outcomes [4]. A 2018 meta-analysis found that maternal smoking prevalence was 1.7% globally, 5.9% in the United States, and 8% in Europe, with almost half of smoking women continuing to smoke during pregnancy [5]. There are several therapies to encourage quitting smoking during pregnancy. This study aims to resolve the discrepancies in the evidence about the efficacy of utilizing different interventions to quit smoking during pregnancy. As far as we are aware, this study is among the few that examine various smoking cessation strategies and their effects on quitting smoking and pregnancy outcomes.

Condition being studied Preterm labor, ectopic pregnancy, placental abruption, stillbirth, and low birth weight, are among the severe maternal and fetal outcomes linked to tobacco use during pregnancy [1-3]. There are several strategies to help pregnant women stop smoking. Pharmacological interventions, such as nicotine replacement therapy (NRT), and antidepressants like bupropion and varenicline (Chantix) [6]. Alternative behaviorally based interventions for expectant mothers have evolved as a result of the uncertainty surrounding pharmaceutical therapies. They come in a variety of forms, including financial incentives, physical activity programs, digital interventions through digital platforms, and cognitive therapy [7-10].

METHODS

Search strategy PubMed, Google Scholar, Science Direct, the Cochrane Central Register of Controlled Trials (CENTRAL), and the International Clinical Trials Registry Platform (World Health Organization) were among the resources that the authors explored from January 2010 until December 30, 2024. "Smoking OR cigarette OR tobacco OR nicotine" AND "cessation OR quitting OR stopping OR giving up" AND "interventions OR programs OR trials OR strategies" AND "pregnancy OR pregnant OR gestation OR antenatal OR prenatal OR maternal)" were the search terms used.

Participant or population Pregnant women at least eighteen years old who were actively smoking cigarettes and got any type of smoking cessation program.

Intervention Smoking cessation interventions include pharmacological interventions, such as nicotine replacement therapy (NRT), and bupropion. As well as alternative behaviorally based interventions in a variety of forms, including financial incentives, physical activity programs, text message interventions, and cognitive behavioral counseling.

Comparator Pregnant women at least eighteen years old who were actively smoking cigarettes and got standard prenatal care, less intensive interventions, or a placebo in pharmacological studies.

Study designs to be included Randomized Control Trials (RCTs).

Eligibility criteria Inclusion criteria for the studies: Only free-whole text RCTs in English that the researchers took into consideration.
Exclusion criteria: Research published in languages other than English, studies involving pregnant nonsmokers or passive smokers, manuscripts that are not RCTs, and studies that are not original research.

Information sources PubMed, Google Scholar, Science Direct, the Cochrane Central Register of Controlled Trials (CENTRAL), and the International Clinical Trials Registry Platform (World Health Organization) were among the resources that the authors explored.

Main outcome(s) The main outcome was smoking cessation at the end of pregnancy which was biochemically validated.

Additional outcome(s) The secondary outcomes were pregnancy outcomes such as birth weight, stillbirth or miscarriage, premature birth, Apgar score <7 (5 min), and the rate of cesarean sections.

Data management Three reviewers independently examined the literature, gathered information, and assessed the included study for possible bias: O.S.E., F.E.Y., and E.M.M. If an argument came up, it was addressed and resolved, taking into consideration the opinion of 4th reviewer "N.MS.A". The three reviewers searched through the literature, looking at each paper's abstract and title to eliminate any that were inappropriate, and then scanning the full document to locate the study that fit.
The degree of certainty of the included studies was evaluated using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) technique [11]. Data were analyzed utilizing RevMan (Version 5.4.1; Cochrane Collaboration, Oxford, United Kingdom).

Quality assessment / Risk of bias analysis Implementing the Cochrane risk of bias instrument for randomized trials (RoB 2) version 2 [11], three reviewers (O.S.E., F.E.Y., and N.MS.A.) evaluated the risk of bias in the selected studies. The quality assessment of the included studies was evaluated using (GRADE) technique [12]. GRADE ratings of confidence are generated by taking into account five domains: indirectness, publication bias, inconsistency, imprecision, and risk of bias. The selected studies were categorized according to the four categories for the level of certainty: very low, low, moderate, and high.

Strategy of data synthesis RevMan (Version 5.4.1; Cochrane Collaboration, Oxford, United Kingdom) was used to evaluate the continuous and categorical dichotomous data to calculate the pooled relative risk (RR) of different smoking cessation strategies among pregnant smokers. To assume study-specific genuine effects based on heterogeneity, a model with random effects was used for the meta-analysis. I2 values of more than 50% are considered to indicate significant heterogeneity [13]. P values less than 0.05, were considered significant.

Subgroup analysis Subgroup analysis was conducted for subtypes of pharmacological intervention "bupropion and NRT" and behavioral interventions "text messages, financial incentives, cognitive-behavioral counseling, and physical activity to determine their effect on the outcomes.

Sensitivity analysis A sensitivity analysis was performed in order to ascertain the potential impact of excluding any intervention on the pooled effect estimates. Additionally, bias in publications was evaluated using funnel plots [14], and the results were confirmed using Egger's regression asymmetry test [15].

Language restriction Only randomized clinical trials published in English will be considered for inclusion.

Country(ies) involved Saudi Arabia.

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Keywords smoking; pregnancy; behavioral approaches; pharmacological therapies; RCT.

Dissemination plans This systematic review and meta-analysis will be published in a relevant scientific journal.

Contributions of each author
Author 1 - Omnia Elseifi - Conceptualization, methodology, software, validation, formal analysis, writing original draft preparation, writing—review, and editing of the final study report.
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