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Pharmaceutical interventions in smoking cessation: systematic review protocol

Intervenções farmacêuticas na cessação do tabagismo: protocolo de revisão sistemática

Intervenciones farmacéuticas en el proceso de dejar de fumar: protocolo de revisión sistemática

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Abstract
Objective: To describe the methodological steps to carry out a systematic review of pharmaceutical interventions for smoking cessation. Review Method: The protocol for this Systematic Review was developed according to the recommendations of the Prism P guidelines. Will be used as exclusion criteria: comments, editorials, articles that were not in Portuguese, Spanish, and English or articles that were not available in full. Also, articles indexed repeatedly in two or more databases will only be considered once. Two independent reviewers will evaluate titles, abstracts and full texts. Differences in selection will be resolved through a third reviewer. Discussion: This review will aim to critically synthesize the clinical evidence surrounding pharmaceutical interventions for smoking cessation, including data on ethnicity, age, socioeconomic conditions, level of health care, and the intervention environment. Therefore, the use of validated procedures and instruments to assess pharmaceutical interventions in support of smoking patients is essential. Conclusion: This protocol aims to describe the methodological steps to carry out a systematic review of pharmaceutical interventions for smoking cessation, aiming to reduce biases in the search and selection of references, making these criteria clear and uniform among reviewers.
Keywords: Pharmaceutical services; Smoking cessation; Tobacco use disorder; Protocol.

Resumo
Objetivo: descrever os passos metodológicos para a realização de uma revisão sistemática de intervenções farmacêuticas para a cessação do tabagismo. Método de Revisão: O protocolo desta Revisão Sistemática foi elaborado de acordo com as recomendações das diretrizes do Prisma P. Serão utilizados como critérios de exclusão: comentários, editoriais, artigos que não estavam em português, espanhol e inglês ou artigos que não estavam disponíveis na íntegra. Além disso, artigos indexados repetidamente em dois ou mais bancos de dados serão considerados apenas uma vez. Dois revisores independentes avaliarão títulos, resumos e textos completos. As divergências na seleção serão resolvidas através de um terceiro revisor. Discussão: o objetivo dessa revisão será sintetizar criticamente as evidências clínicas em torno das intervenções farmacêuticas realizadas na cessação do tabagismo, incluindo dados sobre etnia, idade, condições socioeconômicas, nível de atenção à saúde e ao ambiente da intervenção. Para tanto, o uso de procedimentos e instrumentos validados para avaliar as intervenções farmacêuticas no apoio ao paciente tabagista é essencial. Conclusão: esse protocolo visa descrever as etapas metodológicas para realização de uma revisão sistemática de intervenções farmacêuticas para a cessação do tabagismo, objetivando diminuir vieses na busca e seleção de referências, tornando claros e uniformes esses critérios entre os revisores.
Palavras-chave: Serviços farmacêuticos; Cessação tabágica; Tabagismo; Protocolo.

Resumen

Objetivo: Describir los pasos metodológicos para realizar una revisión sistemática de intervenciones farmacéuticas para dejar de fumar. Método de revisión: El protocolo para esta revisión sistemática se desarrolló de acuerdo con las recomendaciones de las guías Prism P. Se utilizarán como criterios de exclusión: comentarios, editoriales, artículos que no estuvieran en portugués, español e inglés, o artículos que no estuvieran disponibles en su totalidad. Además, los artículos indexados repetidamente en dos o más bases de datos solo se considerarán una vez. Dos revisores independientes evaluarán títulos, resúmenes y textos completos. Las diferencias en la selección se resolverán mediante un tercer revisor. Discusión: El objetivo de esta revisión será sintetizar críticamente la evidencia clínica en torno a las intervenciones farmacéuticas para dejar de fumar, incluidos los datos sobre el origen étnico, la edad, las condiciones socioeconómicas, el nivel de atención médica y el entorno de intervención. Por lo tanto, el uso de procedimientos e instrumentos validados para evaluar las intervenciones farmacéuticas en apoyo de los pacientes fumadores es esencial. Conclusión: este protocolo tiene como objetivo describir los pasos metodológicos para realizar una revisión sistemática de las intervenciones farmacéuticas para el abandono del hábito de fumar, con el objetivo de reducir los sesgos en la búsqueda y selección de referencias, haciendo que estos criterios sean claros y uniformes entre los revisores.

Palabras clave: Servicios farmacéuticos; Dejar de fumar; Tabaquismo; Protocolo.

1. Introduction

World Health Organization data show that chronic non-communicable diseases (NCDs) caused 71% of deaths worldwide and are widely associated with behavioral risk factors such as tobacco use, unhealthy diet, insufficient physical activity and harmful use of alcohol (WHO, 2018). In terms of attributable deaths, tobacco use is the second leading risk factor for NCDs worldwide, considered one of the highest attributable to public health (WHO, 2011; Francisco et al., 2019).

Each year, about 8 million people die because of straight exposure to tobacco, while nearly a million die as a result of passive exposure to fume. Approximately 80% of the 1,1 billion smokers in the whole world live in low- and medium-income countries, where the charge of diseases and deaths related to tobacco is larger (WHO, 2020; IHME, 2019). Considering the severity of tobacco use and knowing the clinically established benefits to quit smoking, the cessation of tobacco use is a strategy to prevent more than 50 kinds of diseases related to tobacco use (Lopez; Mathers, 2006).

Health workers play an important role in smoking control because they can educate the population about the damages of tobacco use and the risks of passive fume exposure. In this sense, health professionals must be sensible and prepared to encourage and support the patient to quit smoking (Lee et al., 2020).

WHO recognizes that the community pharmacies, due to the capillarity and geographic distribution, are easily accessible and, as such, can play a fundamental role in promoting health and wellbeing (Kelling, 2015). The pharmacy can promote support to healthy lifestyles, with an emphasis in the quitting of tobacco use. Although there is a rising interest in expanding the pharmacist's role in smoking treatment, few published studies evaluated the effectiveness of pharmaceutical interventions in the suspension of tobacco use. Furthermore, in 2007, a systematic review in the United States revealed the necessity of studies of pharmaceutical interventions in quitting smoking (Dent et al., 2007). Already in 2014, a meta-analysis about the efficiency of the interventions in community pharmacies to quit smoking revealed that the isolated pharmaceutical interventions can significantly impact the abstinence rates in smokers (Saba et al., 2014).

More recently, another systematic review evinced the importance of community pharmacists on the provision of health improvement services, particularly in the suspension of tobacco use. However, this conclusion is based in low certainty evidences, limited by the risk of slant and imprecision, being necessary more studies that can increase this certainty (Kv et al., 2019).

In this context, the Cochrane Tobacco Addiction Group (TAG) conducted a project to identify future research priorities for the control of tobacco use. Among the priorities was defined the need to identify studies that assess the effectiveness of the intervention of health professionals in smoking cessation and prevention (Cochrane Tobacco Addiction Group, 2017).

The objective of this protocol is to define the methodological aspects necessary to conduct a systematic review of pharmaceutical interventions in smoking cessation, allowing clarity and transparency in the entire process of conducting the review, thus being able to develop high-level scientific evidence that can be used as parameters of clinical decision makers.

2. Objectives

Evaluate the effectiveness of pharmaceutical interventions to the smoker in quitting the habit of smoking.

Thereby, the specific goals of this review are:

1. To identify the kinds of pharmaceutical interventions in quitting the habit of smoking.
2. To analyze the quitting rates and the used methods

3. Methods

3.1 Review elaboration

It will be a systematic review of randomized clinical trials, with the purpose of identifying articles which approach pharmaceutical interventions in quitting the habit of smoking. This systematic review's protocol it will be elaborated according to Cochrane's (Cochrane Handbook for Systematic Reviews of Interventions) recommendations. The record of this work was registered in PROSPERO - *International prospective register of systematic reviews* (CRD42020142226).

The review will be prepared according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis). This statement provides essential information about the methodology and development of systematic reviews, such as: terminology, research questions' formulation, data identification and mining, the study's quality, bias risk on the data combination (besides the selective study) and bias publishing results (Moher et al., 2015; Page et al., 2021).

3.2 Eligibility criteria

There will be included RCT that compared the interventions to quit smoking made by pharmacists and the ones made by other health professionals, or that received a brief pharmaceutical intervention, or even those which didn't receive any kind of intervention, published in any language until August, 2021. The acronym PICOS was used for the research's definition.

Table 1 – PICOS strategy used to build the review question.

ABBREVIATION	DESCRIPTION	ISSUE ELEMENTS
P	Population	Smokers of both sexes and without age limits.
I	Intervention	Pharmaceutical interventions for smoking cessation at different levels of care (community pharmacy, primary health care, clinics and hospitals), associated or not with drug treatment, individual or group approach of at least 10 minutes, with time greater than three months.
C	Comparator	Interventions performed by other health professionals, brief* pharmaceutical intervention or no intervention at all.
O	Outcomes	Self-reported tobacco abstention or detected through biochemical tests.
S	Study design	Randomized clinical trials.

* Brief intervention: appointments less than 10 minutes.
Source: Authors.

3.3 Exclusion Criteria

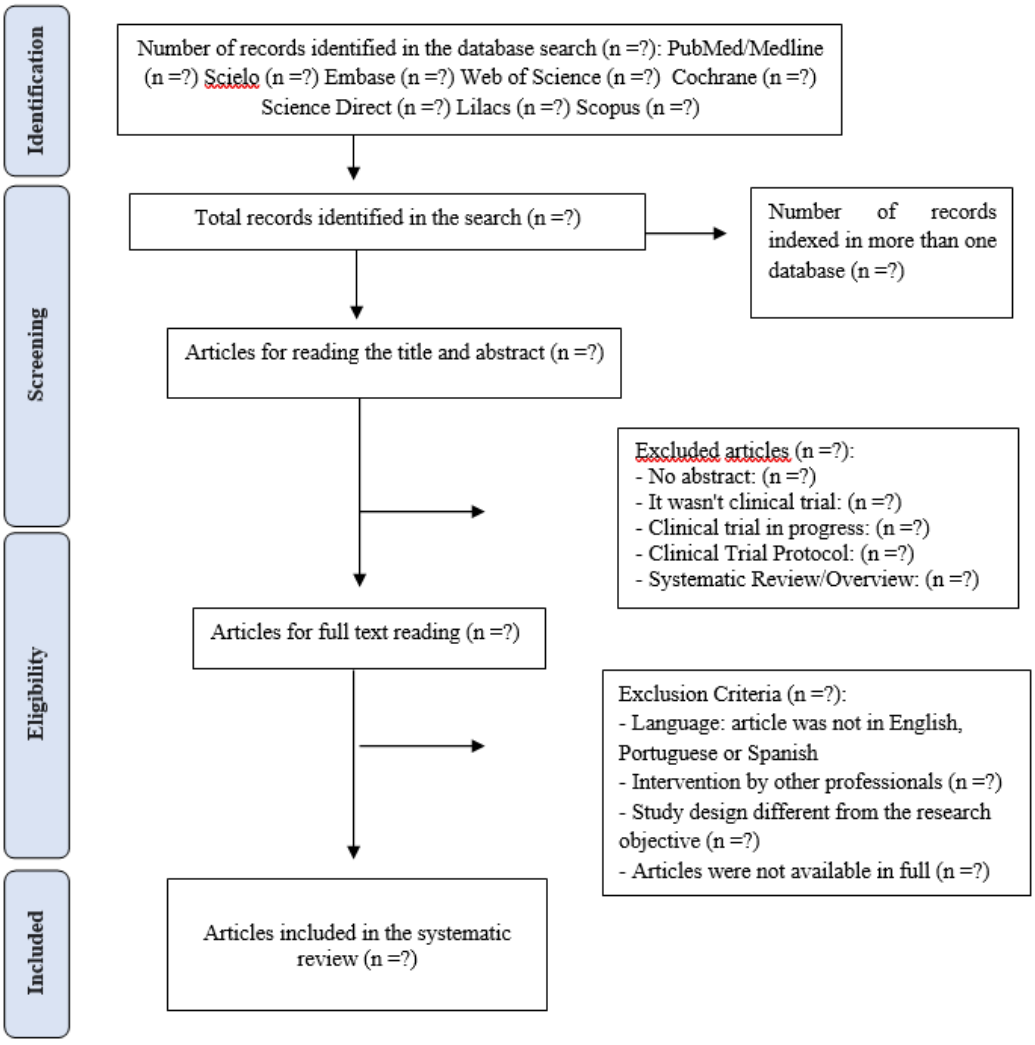
RCTs that presented interventions for smoking cessation performed by a multidisciplinary team, without the possibility of isolation from pharmaceutical activities, were excluded. Not in English, Portuguese or Spanish. Clinical trial protocols, systematic reviews and overwiews. Study design different from the research objective and articles that are not available in full.

3.4 Searching strategy

The studies available on the scientific literature will be identified without time limitations, using the databases: Embase, Latin American Literature in Health Sciences (LILACS), PubMed/Medline, Scopus, Science Direct, Sientific Eletronic Library Online (SciElo), Web of Science and Cochrane.

To identify the data, it will be made a search with the terms MESH and DECS with the following key-words: ("*tobacco use disorder*" OR "*smoking cessation*" OR "*tobacco use cessation*") AND ("*pharmaceutical services*" OR "*Community Pharmacy Services*") AND *"intervention"*. This descriptors' combination should mandatorily be in the title, abstract or key-words of the articles. Besides that, the manual research will be accomplished through the analysis of the included articles' reference. Selected and excluded articles will be organized using the PRISMA flowchart and presented as shown in Figure 1.

Figure 1 – Flowchart illustrating the selection, exclusion and total of articles included and analyzed.



Source: Authors according to PRISMA (2021).

3.5 Data extraction

Search records were imported into the reference management software Rayyan (Ouzzani et al., 2016). Two independent revisors (DSSFA and FHOA) will conduct the initial evaluation of the relevant records, excluding the titles which do not attend the inclusion criteria. After that, the abstracts will be read and those which do not fit within the inclusion criteria will be excluded. In the end the whole texts will be read, considering the inclusion and exclusion criteria. From this action, a collection of studies to be evaluated by the reviewers will be created. The selection's disagreements will be solved by a third reviewer (CASS) and by consensus. After a consensus meeting, articles that were not within the scope of this review could be excluded. Cohen's Kappa statistic will be used to measure inter-rater reliability (McHugh, 2012).

The following information will be extracted from selected studies, using a standardized form: This review intends to identify the country in which the study was made, publication date, level of attention to health, when and where the study was fulfilled, the study's outline, sample calculation, number of participants, intention to treat (ITT), randomization, losses and exclusions, the participants average age and sex, characteristics of the pharmaceutical intervention and abstinence rates.

The main outcome that will be evaluated is abstinence from smoking after at least six months of follow-up. The strictest definition of abstinence for each study and biochemically validated rates, if available, will be used.

3.6 Analysis and data synthesis

The methodological quality (bias risk) of the RCT's individual studies will be evaluated through the bias risk tool from Cochrane (Cochrane Risk of Bias Tool) – ROB 2.0, available on the Cochrane Handbook of systematic reviews and health interventions (Higgins et al., 2011). Besides this, the GRADE (Grading of Recommendations Assessment Development and Evaluation) will be used to evaluate the evidence quality (Broek et al., 2009; Guyatt et al., 2009).

The analysis and synthesis will be made using the Review Manager (RevMan) (computer program). V.5.3 Copenhague: Nordic Cochrane Center, The Cochrane Collaboration, 2014; and the Microsoft Excel program. The studies will then be judged with a low, uncertain or high bias risk.

4. Conclusion

From the development of the study, it is intended to evaluate the pharmaceutical intervention, the instruments used and the main primary and secondary results obtained. Some studies evidence the community pharmacist's importance on the provision of health improvement services, particularly in the smoking cessation. However, this conclusion is based in low certainty evidence, limited by the bias risk and imprecision, making necessary more studies which can increase this certainty. In this way, this systematic review can help to critically synthesize the clinical evidence around the pharmaceutical interventions on the cease of smoking, to accomplish a survey of the treatments and protocols used in interventions, knowing these factors are of great relevance for the intervention's success. The results of this review will contribute to outline future studies about pharmaceutical intervention on quitting smoking in different health attention levels, as well as studies on the science field of implantation and implementation of pharmaceutical services.

5. Final Considerations

The current protocol aims to guide future research in the development of evidence around interventions performed by pharmacists in smoking cessation, the objective of this work is to promote the development of systematic reviews of the highest level of evidence, so that it can serve in the future as a basis for the implantation/implementation of pharmaceutical services in community pharmacies, in clinics, pharmacist's office, basic health units and other health establishments.

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