



**UNIVERSIDADE ESTADUAL DE CAMPINAS
FACULDADE DE CIÊNCIAS FARMACÊUTICAS**

GABRIELA PEREIRA

**AVALIAÇÃO DA AUTOMEDICAÇÃO ENTRE GESTANTES EM
ATENDIMENTO PRÉ-NATAL EM UM HOSPITAL ESPECIALIZADO NA
SAÚDE DA MULHER**

**EVALUATION OF SELF-MEDICATION PRACTICE AMONG
PREGNANT WOMEN ATTENDING IN A HOSPITAL SPECIALIZED IN
WOMEN'S HEALTH**

**Campinas
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Dissertação apresentada à Faculdade de Ciências Farmacêuticas da Universidade Estadual de Campinas como parte dos requisitos exigidos para obtenção do título de Mestra em Ciências, na área de Ciências Farmacêuticas.

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RESUMO

O uso de medicamentos sem prescrição é uma prática frequente em diferentes países e populações, sendo uma das principais barreiras para a promoção do uso racional de medicamentos. A automedicação na gestação expõe gestante e feto à medicamentos com potencial teratogênico e a Problemas Relacionados à Medicamentos, podendo resultar no atraso do diagnóstico de patologias, má formação fetal, internações e outras complicações. O objetivo deste trabalho foi avaliar a prática da automedicação entre gestantes nos últimos 60 dias antes de primeira consulta de pré-natal em um hospital especializado na saúde da mulher. Estudo de corte transversal, realizado com mulheres em atendimento pré-natal no Centro de Atenção Integral à Saúde da Mulher (CAISM - UNICAMP) entre abril de 2019 a fevereiro de 2020. A prática da automedicação foi considerada como o uso de qualquer medicamento (incluindo plantas medicinais, fitoterápicos e vitaminas) sem a prescrição de um médico ou dentista, nos últimos 60 dias antes da primeira consulta de pré-natal no referido hospital. Entre as 297 gestantes incluídas, 107 (36,0%) informaram ter feito o uso de medicamento sem prescrição nos últimos 60 dias. Os medicamentos mais utilizados na prática da automedicação foram os OTC, incluindo paracetamol (35,1%) e dipirona (28,0%) e a principal indicação para a prática da automedicação foi a dor de cabeça (58,8%). A automedicação esteve associada com alto grau de escolaridade, número de gestações prévias e idade gestacional. O trabalho realizado possibilitou avaliar a prevalência da automedicação entre gestantes em atendimento pré-natal em um ambulatório especializado na saúde da mulher e os fatores associados à essa prática. Uma vez que os fatores associados à automedicação estão relacionados com o perfil sociodemográfico e materno, recomenda-se que outras avaliações sejam realizadas em diferentes níveis de serviço, a fim de compreender todas as causas e então traçar as possíveis estratégias de prevenção.

Palavras-chaves: automedicação, gestação, saúde da mulher, uso racional de medicamentos

Linha de Pesquisa: Pesquisa e Desenvolvimento em Fármacos, Medicamentos, Alimentos e Cosméticos

ABSTRACT

The use of medication without prescription is a frequently practice among different countries and population, and it is one of the main barriers to the promotional of the rational medication use. The self-medication during pregnancy can expose the fetus to teratogenic effects and drug related problems, leading in the delay of diagnosis, malformations, hospitalizations and other complications. The main objective of this study was to assess the self-medication practice among pregnant women in the last 60 days before the first antenatal care appointment in a hospital specialized in women's health. It was a cross sectional study performed with women attending the antenatal care in a referral tertiary teaching hospital, between April 2019 to February 2020. The self-medication practice was considered as the use of any medicine (including medicinal plants, phytotherapy and vitamins) without a medical or dentist prescription in the last 60 days. The most common medications used was the over-the-counter drugs, including acetaminophen (35.1%) and metamizole (28.0%) and the main indication was to treat headache (58.8%). Self-medication practice was associated with a high school degree, number of previous pregnancies and gestational age. The study assessed self-medication among pregnant women in a hospital specialized in women's health and the related factors associated with this practice. Once the factors are associated with sociodemographic profile and maternal characteristics, it is recommended to perform further studies in different levels of service, in order to assess all causes related to this phenomenon to create appropriated prevention strategies.

Key-words: self-medication, pregnancy, women's health, rational medication use.

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LISTA DE ABREVIATURAS E SIGLAS

ANC Antenatal care

ADR Adverse drug reaction

BMI Body mass index

CAM Complementary alternative medicine

CI Confidence interval

DRP Drug related problem

FDA Food and Drug Administration

GPG General population group

MP Medicinal plants

OR Odds ratio

OTC Over-the-counter drugs

PICO Patient Intervention Comparison and Outcome

POM Prescription only medicines

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PWG Pregnant women group

SD Standard deviation

SM Self-medication

STROBE Strengthening the Reporting of Observational Studies in Epidemiology

WHO World Health Organization

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1 INTRODUÇÃO

De acordo com a definição estabelecida pela Organização Mundial da Saúde em 1998, a automedicação pode ser definida como “o uso de medicamentos sem a prescrição de um médico ou dentista, para tratar doenças ou sintomas autoconhecidos”, sendo um componente importante do autocuidado quando praticada corretamente (WHO 1998). A automedicação é considerada responsável quando o medicamento utilizado é seguro e eficaz para o sintoma tratado e na existência de um diagnóstico prévio, a depender da condição do indivíduo (WHO 1998, Galato, Galafassi et al. 2009).

Para ser considerada prática do autocuidado, o paciente deve estar informado sobre a posologia, possíveis reações adversas, interações medicamentosas e tempo de tratamento (WHO 1998). A automedicação responsável possui diferentes benefícios, em nível individual e coletivo, como por exemplo, evitar a sobrecarga do sistema de saúde, absenteísmo das atividades diárias e economia de recursos médicos (Bennadi 2013).

O uso de medicamentos sem prescrição, ainda que de forma responsável, deve ser restringido para algumas populações. Idosos, gestantes, crianças e pacientes polimedicados devem sempre procurar orientação médica antes do uso de qualquer medicamento (Galato, Galafassi et al. 2009). Quando o uso de medicamentos sem prescrição é feito fora das condições mencionadas, o paciente fica exposto à diferentes riscos, incluindo o atraso no diagnóstico, eventos adversos e interações medicamentosas, que podem levar a quadros de hospitalização e morte (Galato, Galafassi et al. 2009, Bennadi 2013).

De acordo com os últimos relatórios, o acesso e consumo de medicamentos no mundo aumentaram em relação aos últimos anos e atualmente a expectativa é que o mercado movimente aproximadamente 1 trilhão de dólares em 2024 (IMS 2015, IQVIA 2020). Considerando o fácil acesso à diferentes terapias e a sobrecarga enfrentada pelo sistema de saúde de diferentes países, espera-se que a prática do uso de medicamentos seja ainda maior, sendo essa a principal barreira para a promoção do Uso Racional de Medicamentos (URM) (WHO 2002).

Avaliar e compreender o uso de medicamentos sem prescrição no Brasil vem sendo um tópico discutido com frequência por diferentes estudos, mas a avaliação dessa prática por diferentes populações ainda é baixa (Arrais, Fernandes et al. 2016, Domingues, Galvão et al. 2017, Pons, Knauth et al. 2017). Os trabalhos que serão apresentados a seguir têm como

objetivo compreender a prática da automedicação entre gestantes no Brasil e no mundo, identificando os principais fatores relacionados à essa prática.

A dissertação será apresentado em dois capítulos, sendo o primeiro uma revisão de escopo intitulada “*Evaluation of self-medication among pregnant women in comparison to the general population: A scoping review*”(Gabriela Pereira, Cinthia Madeira de Souza, Amanda Canato Ferracini, Fernanda Garanhani Surita, Sherif Eltonsy, Priscila Gava Mazzola), seguido do artigo “*Self-medication among pregnant women: Prevalence and associated factors*” (Gabriela Pereira, Fernanda Garanhani Surita, Amanda Canato Ferracini, Cinthia de Souza Madeira, Letícia Silva de Oliveira, Priscila Gava Mazzola), que apresenta os principais resultados obtidos.

2 OBJETIVOS

2.1 Objetivo geral

Avaliar a prevalência da prática da automedicação entre gestantes nos últimos 60 dias antes da primeira consulta de pré-natal em um hospital especializado na saúde da mulher.

2.2 Objetivos específicos

- Elaborar uma revisão de literatura sobre a prática da automedicação na gestação em comparação à população geral;
- Avaliar os medicamentos mais utilizados e sintomas motivacionais relacionados à prática da automedicação na gestação;
- Avaliar os fatores associados à automedicação na gestação.

3 EXECUÇÃO

CAPÍTULO I. “EVALUATION OF SELF-MEDICATION AMONG PREGNANT WOMEN IN COMPARISON TO THE GENERAL POPULATION: A SCOPING REVIEW”

Gabriela Pereira, Cinthia de Souza Madeira, Amanda Canato Ferracini, Fernanda Garanhani Surita, Sherif Eltonsy, Priscila Gava Mazzola.

Abstract

Objectives: An in depth evaluation of the published evidence is needed on SM, specifically the evidence focusing on vulnerable groups as pregnant women. This scoping review aims to assess the differences in SM practice between pregnant women and the general population, while identifying gaps in the literature.

Methods: A literature search was performed in PubMed and Web of Science, including articles published in the last 10 years for the pregnant women group (PWG) and the general population group (GPG). Data on the study design, self-medication prevalence, medications used, and other variables were collected, tabulated and summarized.

Results: We screened 2888 articles and 75 were included. Out of the reviewed studies, 11 showed a reduced prevalence of SM among pregnant women when compared to the general population (average self-medication prevalence between 21%-50% compared to over 50% in the general population). The reviewed studies varied considerably in methodology, requiring careful interpretation. While most of the studies assessed SM during the entire pregnancy, SM definition was often inconsistent between the studies. Acetaminophen was the most used medication and headache was the most frequent symptom leading to SM initiation in the PWG.

Conclusions: SM when reported among pregnant women in various populations, it mostly occurs in lower prevalence when compared to the general population. The medications used and symptoms reported were similar between groups. However, methodologic differences has to be carefully considered. Pregnant women should carefully follow their physicians' advices before initiating SM to avoid preventable maternal and fetal adverse effects.

Keywords: Self-medication; Medication use; Pregnancy.

1 Introduction

Self-medication (SM) was defined by the World Health Organization (WHO) in 1998 as the “selection and use of medicines by individuals to treat self-recognized illness or symptoms” (WHO 1998), including the use of herbal and medicinal products. However, the definition of SM can be broader, and some authors consider the use of previous prescriptions, the administration of a medicine prescribed to a family member or just the administration of any Over the Counter (OTC) drug as SM (Cabut, Marie et al. 2017, Atmadani, Nkoka et al. 2020).

SM practice is considered part of the self-care when it is practiced in a responsible way. (WHO 1998) However, in many instances in developing countries, SM plays the key role as the main choice to treat different health problems (Galato, Galafassi et al. 2009, Rutter 2015). This practice is driven by different reasons that seems to change according to the study population, but usually related to sociodemographic factors in play and the easy access to medications according to the country’s regulation (for instance, many developing countries do not necessitate presenting a prescription to purchase any medication, if not having a controlled substance) (Rocha, Bezerra et al. 2013, Barrenberg, Knopf et al. 2018, Zewdie, Azale et al. 2018, Amaha, Alemu et al. 2019, Ha, Nguyen et al. 2019).

Due to different physiological characteristics, children, elderly and pregnant women are vulnerable populations with special medication use restrictions. Generally, those population groups are not often included in clinical trials, thus increasing the possibility of being exposed to unknown risks (Grimsrud, Sherwin et al. 2015). One example is thalidomide tragedy, which despite the safety profile presented in pre-clinical trials, caused several birth defects among thousands of infants from mothers who used this medication during the susceptible pregnancy period (Lenz, Pfeiffer et al. 1962, Ward 1962).

Beyond teratogenic effects, SM among pregnant women can be associated with increasing the Drug Related Problems (DRP), Adverse Drug Reactions (ADR), incorrect diagnoses and other problems related to drug therapy (Bennadi 2013, Schmiedl, Rottenkolber et al. 2014, Panda, Pradhan et al. 2016). SM among pregnant women is frequently evaluated by studies in different countries, but less is known about this behavior before pregnancy and the differences in comparison to the general population.

Considering the volume of publications in this field and the need to understand SM behavior among different populations, this scoping review aims to evaluate the characteristics and differences in SM practice between pregnant women and the general population, as well as identifying gaps in the literature that could be addressed to improve self-prescribing among pregnant women.

2 Methods

2.1 Research question

This review follows the recommendations of Arksey and O'Malley (Arksey and O'Malley 2005) and the PRISMA extension for scoping reviews (2018). The review protocol was registered at "OSF Registries" and can be accessed through: (<https://osf.io/jery7> Code: JERY7). Patient, Intervention, Comparison and Outcome (PICO) strategy was used; namely: "population" as pregnant, puerperal and nonpregnant women that got pregnant in the past years, "intervention" as self-medication during pregnancy, "comparison" as self-medication in general population and "outcome" as the prevalence of self-medication, medications used, symptoms reported and the recording period.

2.2 Search strategy

The literature search was conducted from September 2019 to March 2020 in the following databases: Pubmed, PubMed Central and Web of Science. Two search strategies were performed according to each group (pregnant women and general population). The Medical Subject Headings (MeSH) terms selected to Pregnant Women Group (PWG) were *self-medication*, *pregnancy* and *pregnant women*; and the search strategy used was "Self Medication" AND (Pregnancy OR "Pregnant Women").

The MeSH terms selected to General Population Group (GPG) were: *adolescents*, *young adult*, *adult*, *middle aged*, *aged* and *aged, 80 and over*; and the search strategy used was "Self Medication" NOT ("Self Medication" AND (Pregnancy OR "Pregnant Women")). The Boolean operator "NOT" was used to separate the groups and exclude pregnant women from general population strategy. A librarian was consulted to develop the search

strategy and ensure completeness of retrieved data. The complete search strategy of both groups is available in the appendix section.

2.3 Inclusion and exclusion criteria

We included original articles published in the last 10 years in English, Spanish and Portuguese. Systematic reviews and meta-analyses, qualitative studies, case reports and conference abstracts were excluded. Mixed methods studies (for instance a cross-sectional study with qualitative section study) were included when the quantitative section fits our inclusion criteria. Studies performed with a population of health professionals and/or health science students (e.g. pharmacists, nurses, physicians) were not included since their background in medical sciences could have influenced the results.

Several studies on self-medication during pregnancy considered pregnant women under 18 years old, therefore no minimum age limit was included in this review. While for the general population group, we considered only studies with participants older than 18 years. For the purpose of the scoping nature of this review, the MeSH term “adolescents” was used in our search strategy, which could include people 18 years of age. For feasibility reasons, we did not include articles discussing self-medication among specific populations with special medical conditions/diseases.

2.4 Charting the data

The information was recorded in a database regarding the following topics: author(s), year and country of publication, study design, recording period considered to assess the prevalence of self-medication, self-medication prevalence, medications used, symptoms reported, study aims and conclusion. The results are summarized in table 1 (PWG) and Supplementary material 1 (GPG).

3 Results

3.1 Study selection

The literature search identified 2888 articles, classified as 204 and 2684 articles for PWG and GPG, respectively. The duplications were excluded using EndNote® Software

and Rayyan's web application (Ouzzani, Hammady et al. 2016). The studies were evaluated by two independent reviewers (GP and CMS) and the discrepancies were resolved by a third independent reviewer (ACF). Finally, 75 studies were included after full review (25 from PWG and 50 from GPG). The screening and selection process is described in figure 1.

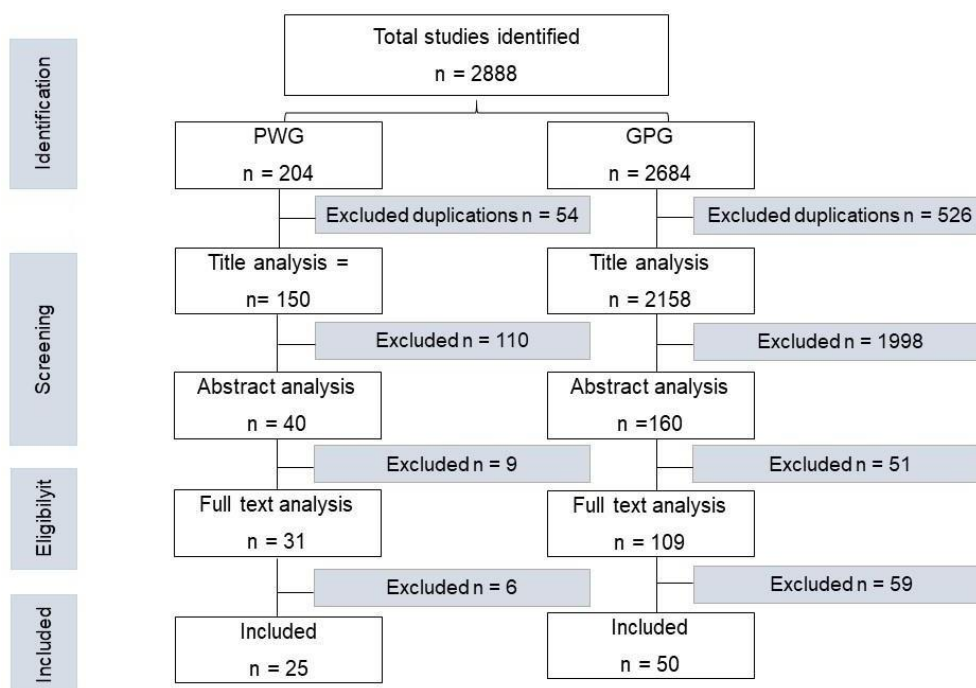


Fig 1. Flow chart for the screening and selection process. PWG – Pregnant Women Group, GPG – General Population Group

Table 1. Results from self-medication (SM) practice in the Pregnant Women Group (PWG).

Author, Year, Country	Sample size	Study aims	Exposure period	SM Prevalence n (%)	Medications used n (%)	Related Symptoms n (%)	Comments and general Conclusion
Abasiubong F et al, 2018; Nigeria (Abasiubong, Bassey et al. 2012)	518 pregnant women, from 18 to >40 years	Evaluate the extent, nature and factors involved in SM among PW	Anytime during pregnancy	375 (72.4)	Analgesics 157 (30.3), antibiotics 138 (26), herbs and other drugs 47 (9.1) and sedatives 15 (2.9)	-	SM is common among PW and there is need of education about potential harms to mother and fetus
Abeje G et al, 2015; Ethiopia (Abeje, Admasie et al. 2015)	510 pregnant women from 15 to 42 years	Assess SM practice and factors associated among PW	Anytime during pregnancy	128 (36) Allopathy: 88 (68.7) MP: 27 (21.1) Both: 13 (10.2)	-	-	SM was common. Multigravidas and women with maternal illness were more likely to practice SM
Adanikin AI et al, 2017; Nigeria (Adanikin and Awoleke 2017)	346 pregnant women from <20 to >40 years	Examines the burden of SM during pregnancy and the impact on fetal wellbeing	Anytime during pregnancy	79 (31.5)	Paracetamol 24 (-), artesunate 10, sulphadoxine and pyrimethamine 9, chloroquine 6, clotrimazole pessary 4, amoxicillin 2 and others 27	Malaria fever 179 (51.7), edema 66 (19.1), headache 56 (16.2), vaginal infection 49 (14.2), vomiting 30 (8.7) and others 146 (42.4)	SM was associated with increased FDA risk category and OTC drugs need strict controls during pregnancy
Afshary P et al, 2015; Iran (Afshary, Mohammadi et al. 2015)	810 pregnant women from <25 to >30 years	Determine the prevalence and causes of SM among PW	Anytime during pregnancy	245 (30.6) Allopathy: - (40), HM: (13.1), MP: (46.9)	-	Allopathy: Anti-infectious - (44.8), digestive diseases (19.3), anemia (14.2), and others (23.1)	It is necessary to take some measures raising the level of culture and preventing SM particularly in women
Alonso-Castro et al, 2018; Mexico (Alonso-Castro, Ruiz-Padilla et al. 2018)	1798 pregnant and non- pregnant women that got pregnant in the last 3 years, from <25 to >35 years	Evaluate the prevalence and the factors associated with SM among women	Anytime during pregnancy	393 (21.9) Allopathy: 110, MP: 264, other products: 76	Paracetamol 83 (42.8), bonadixin 16 (8.2), another NSAID 12 (6.2), omeprazole 10 (5.2) and others 139 (34.4).	Migraine 57 (51.8), nausea 28 (25.5), gastritis 22 (20), cold 18 (16.4), constipation 15 (13.6) and others 41 (37.2)	SM is common among PW. Adequate counselling of PW about the potential risks of SM drugs during pregnancy is strongly

							warranted
Araujo DD et al, 2013; Brazil (Araújo, Leal et al. 2013)	78 puerperal women, from 10 to >20 years	Evaluate the use of medicines during pregnancy and the factors associated	Anytime during pregnancy	22 (28.2)	Analgesics 16 (20.5), anti-inflammatory and antirheumatic 3 (3.9), vitamins 2 (2.6) and others 8 (10.4)	-	The practice of SM exists, even with access to health. SM was related to PW with lower number of antenatal visits and smokers
Atmadani RN et al, 2020; Indonesia (Atmadani, Nkoka et al. 2020)	333 pregnant women from 16 to 45 years.	Examine the proportion of PW who self-medicated and factors associated	Anytime during pregnancy	39 (11.7)	Antiemetic medicines - (33), cold and flu remedies - (29), anti-fever medication - (15), pain killers - (13), and others - (10)	-	39 women self-medicated during pregnancy. Knowledge and age were observed to be associated with the practice
Baghianimoghadam MH et al, 2013; Iran (Baghianimoghadam, Mojahed et al. 2013)	180 pregnant women from <25 to >35 years	Determine the knowledge, attitude, and practice of PW in terms of SM	Anytime during pregnancy	63 (35)	-	-	Increased prevalence of SM during pregnancy
Bello FA et al, 2011; Nigeria (Bello, Morhason-Bello et al. 2011)	410 pregnant women from 24 to 34 years	Assess the drug use profile, including prescribed drug compliance and SM among PW	Anytime during pregnancy	Allopathy: 78 (19), MP: 190 (46.3)	Hematinics 283 (69), acetaminophen 196 (48), anti-malarial, vitamin C and metronidazole 25 (6) and calcium supplements 4 (1)	-	Patients need counseling on the dangers of SM. Use of herbal concoctions needs to be explored in the community
Bercaw J et al, 2010; USA (Bercaw, Maheshwari et al. 2010)	485 puerperal women from 18 to 42 years	Assess drug use among PW (herbs, vitamins, OTC and prescription medications)	Anytime during pregnancy	OTC: 112 (23) HM/ vitamins: 313 (64)	Acetaminophen 63 (13), Robitussin 28 (6), Maalox 22 (5), Ibuprofen 17 (4) and others 38 (9)	-	Use of HM does not appear to be a replacement for conventional medicine among most PW. Patient education is necessary
Beyene KG et al, 2018; Ethiopia (Beyene and Beza 2018)	617 pregnant women from 18 to >34 years	Assess SM practice and associated factors among PW	Anytime during pregnancy	164 (26.6) Allopathy: 112 (18.2), HM: 67 (10.9) and both: 15	Paracetamol 55 (49.1), amoxicillin 26 (23.2), panadol 7 (6.3), ibuprofen 6	-	High prevalence of SM during pregnancy. Previous

				(2.4)	(5.4), albendazole 6 (5.4) and others 38 (34.2)		pregnancy and knowledge were significantly associated with SM practice
Bohio R et al, 2016; Pakistan (Bohio, Brohi et al. 2016)	351 pregnant women from 18 to 45 years	Evaluate the frequency of OTC use among PW, type of medicines and motivation for SM practice	Anytime during pregnancy	133 (37.9)	Acetaminophen 58 (43.6), acetaminophen + aspirin 24 (18), acetaminophen + ibuprofen 16 (12), multiple drugs 20 (15), ibuprofen 5 (3.8), others 10 (5.4)	Headache 80 (60.2), multiple complains 26 (19.5), headache + backache 14 (10.5), others 13 (10.1)	A significant number of pregnant women indulged in the practice of using OTC medication
Botyar M et al, 2018; Iran (Botyar, Kashanian et al. 2018)	210 pregnant women and 210 nonpregnant women from 15 to 45 years	Compare SM in pregnant and nonpregnant women	Anytime during pregnancy	73 (34.8) PWG Allopathy: 18 (8.6) HM: 14 (6.7) MP: 41 (19.6)	Ibuprofen – (9), cough syrup – (8.6), and antibiotics – (8.1).	Nausea, vomiting, and heartburn - (5.7), morning sickness (4.3), lack of appetite (3.8) and others (5.3)	MP are the most common medications used by PW. They should be advised against the arbitrary use of these substances
Cabut et al, 2014; France (Cabut, Marie et al. 2017)	60 non-pregnant women and 68 pregnant women from 18 to 45 years	Identify nonpregnant women intending to use SM during pregnancy and the proportion of PW using these products	Anytime during pregnancy	49 (72.1) PWG Supplements: 15 (22.7) Essential oils: 9 (13.9) Herbal teas: 19 (29.2)	Acetaminophen 44 (89.8), phloroglucinol 14 (28.6), medications for digestive disorders - 8 (16.3), homeopathy 13 (26.5) and others 5 (10.2)	Headache 39 (79.6), stomachache 18 (36.7), other pains 9 (18.4), nausea, vomiting 9 (18.4) sore throat 8 (16.3) and others 20 (53.0)	Frequent intended use and actual use of SM and alternative products during pregnancy
Ebrahimi H et al, 2017; Iran (Ebrahimi, Atashsokhan et al. 2017)	384 pregnant women with a mean age of 26.3	Compare the prevalence of SM before and during pregnancy and its determinants factors	Anytime during pregnancy	78 (20.3) During pregnancy	-	-	The prevalence of SM during pregnancy was still significant. It is necessary to provide trainings for all women of reproductive age
Jambo A et al, 2018; Ethiopia	244 pregnant women from 18 to	Assess the prevalence of SM	Anytime during pregnancy	170 (69.7) Allopathy: 71	Paracetamol - (33.8), cough syrup	Allopathy: common cold 30	High prevalence of SM. There is a

(Jambo, Mengistu et al. 2018)	>35 years	and contributing factors among PW		(29.1) HM: 142 (58.2)	(23.9), do not remember (22.5), amoxicillin (18.3), metronidazole (1.4)	(42.3), headache 26 (36.6), nausea/vomiting 10 (14.1), others 5 (7.0)	need for public trainings for all women of reproductive age about the risks of inappropriate SM
Liao S et al, 2015; China (Liao, Luo et al. 2015)	422 pregnant women from 20 to 42 years	Assess substance use and SM during pregnancy and factors associated	Anytime during pregnancy	11 (2.6)	-	-	Socio-demographic parameters were associated with substance use during pregnancy
Marwa KJ, 2018; Tanzania (Marwa, Njalika et al. 2018)	372 pregnant women from 18 to 27 years	Estimate the prevalence of SM and evaluated predictors of SM among PW	Anytime during pregnancy	172 (46.2) Allopathy HM: 94 (25.3)	Antiemetic 59 (34.3), antimalarial 42 (24.4), analgesics 33 (19.1), antibiotics 17 (9.5), cough & cold remedies 9 (5.2) and others 12 (6.9)	Malaria 56 (32.5), morning sickness 44 (25.5), headache 33 (19.1), urinary tract infection 16 (9.3) and others 23 (15.3)	Prevalence of SM with allopathy and HM among PW was high and common among illiterate, unemployed and in the 1 st trimester
Miní E et al, 2012; Peru (Miní, Varas et al. 2012)	400 pregnant women from 19 to >40 years	Evaluate the prevalence and possible causes of SM among PW	Anytime during pregnancy	42 (10.5)	Acetaminophen - (47.6), amoxicillin (16.7), ibuprofen (16.7), naproxen (11.9), dimenitrate (4.8) and vitamins (2.4)	Pain - (40.5), respiratory problems (28.6), urinary tract infection (16.7), fever (9.5) and nausea (4.8)	Low prevalence of self-prescribing behavior during pregnancy compared to the international literature
Navaro M et al, 2018; Italy (Navaro, Vezzosi et al. 2018)	503 pregnant women from 15 to 44 years	Characterize knowledge, attitudes, and medications use during the pregnancy and factors associated	Anytime during pregnancy	221 (43.9)	ATC Classification: N 180 (69.8), A 48 (18.6), M 16 (6.2), R 8 (3.1), J 5 (1.9) and C 1 (0.4)	Fever/common cold symptoms - (32.6), headache/migraine (29.5), digestive disorders (18.2), and nerve pain (15.5)	Almost half of participants practiced SM. Who were more likely to self-medicate were older, Italian, multiparous, with no history of abortion
Odalovic M et al, 2012; Serbia (Odalovic, Vezmar Kovacevic et al. 2012)	311 pregnant women from 16 to 44 years	Investigate prescription and OTC drug use among women in before and during pregnancy	6 months before pregnancy and 6 months during pregnancy	27 (8.7) OTC: 23 (7.4) Prescription and OTC: 4 (1.3) During pregnancy	Acetaminophen - (6.4)	-	Less SM with OTC drugs was observed in pregnancy when compared to before pregnancy

Rocha RS et al, 2013; Brazil (Rocha, Bezerra et al. 2013)	326 puerperal women between 13 and 45 years	Evaluate the use of medications, alcohol and smoking during pregnancy	Anytime during pregnancy	37 (11.3)	Anti-inflammatory 21 (39.6), Analgesic/ antipyretic 13 (24.5) and others 19 (35.8)	-	Being single was found to be a risk factor for exposure to high teratogenic potential
Verstappen GM et al, 2013; Netherlands (Verstappen, Smolders et al. 2013)	1246 pregnant women from 18 to >35 years	Describing possible predictors of OTC-medication use during pregnancy	Anytime during pregnancy	157 (12.5)	Analgesics 51 (27.3), vitamins 50 (26.7), GI medication 40 (21.4) and others 46 (24.6)	-	Five predictors were included in the model. There is a need for studies that ascertain OTC use more in detail
Yusuff KB et al 2011; Nigeria (Yusuff and Omarusehe 2011)	1594 pregnant women from 19 to 36 years	Assess the frequency and evaluate factors underlining SM with orthodox and herbal medicines among pregnant women	Last 90 days	1017 (63.8) Allopathy: (58.4) HM: (31.2) Both: (10.4)	Paracetamol 485 (31.1), hematinics + vitamins 365 (23.4), promethazine 130 (8.3), piroxicam 120 (7.7), diazepam 119 (7.6) and others 342 (21.9)	Pain/fever 432 (30.1), joint pain 208 (14.5), cough 147 (10.2), weakness 132 (9.2), indigestion 122 (8.5), headache 112 (7.8) and others 283 (19.7)	SM with prescription, OTC and HM is pervasive and significantly associated with gestational age and occupational pattern among studied women
Zewdie T et al, 2018; Ethiopia (Zewdie, Azale et al. 2018)	323 pregnant women from 15 to >35 years	Assess the prevalence and factors associated with SM among PW	Anytime during pregnancy	50 (15.5)	Acetaminophen 29.8%, diclofenac 21% and others – (-)	Vomiting 13 (25), heart burn 11 (21.2), back pain 9 (17.3), headache 6 (11.5), constipation 6 (11.5) and others 7 (13.4)	Prevalence of SM was comparable to the other studies. Better maternal education and health problems were associated with SM

3.2 Country of publication

For the *Pregnant Women Group (PWG)*, the publications were from 15 countries distributed in all 6 continents. The publications were higher in low-income countries (44%), followed by middle (40%) and high-income countries (16%). In the *General Population Group (GPG)*, the publications were from 28 countries distributed in all 6 continents. Middle-income countries lead the number of publications (40%), followed by low (36%) and high-income countries (24%).

3.3 Sample size and population

In the PWG, the sample size ranged from 78 (Araújo, Leal et al. 2013) to 1798 (Alonso-Castro, Ruiz-Padilla et al. 2018) participants, with 13100 women enrolled. The most studied population was current pregnant women, followed by puerperal and reference non-pregnant women (compared to pregnant women or women that got pregnant in the last 3 years). According to women's age, 12 studies considered women older than 18 years, 8 studies included women younger than 18 years and 5 studies had no age restriction in the inclusion criteria.

For the GPG, the sample size ranged from 138 (Chatziathanasiou, Chalikias et al. 2017) to 31573 (Pons, Knauth et al. 2017) participants, with 95459 people enrolled. According to participants' age, all studies considered participants older than 18 years and 9 studies focused on the elderly population. In relation to sex/gender, one study was performed considering only the male population (Prado, Francisco et al. 2016) and the remaining studies considered male and female population.

3.4 Study design

In the PWG, twenty-three studies have a cross-sectional design, while one study used a cohort design (Odalovic, Vezmar Kovacevic et al. 2012) and another was a mixed methods study (cross-sectional with qualitative study) (Beyene and Beza 2018). For the GPG, forty-eight studies have a cross-sectional design, one is a mixed method study (a cross-sectional with qualitative section study) (Sánchez 2014) and one is a cohort study (Secoli, Marquesini et al. 2018).

3.5 Recording period

There was a small difference regarding the recording period considered to assess SM practice in the PWG. Almost all studies considered self-medication during the whole pregnancy period, while one study considered SM in the first six months of pregnancy (Odalovic, Vezmar Kovacevic et al. 2012) and one study used the past 90 days before the survey (Yusuff and Omarusehe 2011). In the GPG, the period considered to evaluate practice varied between days and years. The shortest period considered was the last three days prior to survey (de Oliveira, Francisco et al. 2012, Prado, Francisco et al. 2016) and the longest was the last 12 months (Klemenc-Ketis and Kersnik 2011, Sánchez 2014, Garofalo, Di Giuseppe et al. 2015, Klemenc-Ketis and Mitrovic 2017, Ha, Nguyen et al. 2019). The recording period considered to assess SM practice was not clear in eight studies. Some studies considered more than one period (Machado-Alba, Echeverri-Cataño et al. 2014, Dawood, Hassali et al. 2017) or used an unspecified time period (Sridhar, Shariff et al. 2018). Eight studies considered medications used at the study moment as recording period.

3.6 Definition of self-medication

In both groups, there were no consensus regarding the definition of self-medication. Some studies considered SM only as the use of over-the-counter drugs (OTC), while other studies considered OTC, prescribed drugs, herbal medicines, medicinal plants and other types of Complementary Alternative Medicine (CAM). The definition of SM was not described in some studies.

3.7 Self-medication prevalence

In the PWG, SM prevalence ranged from 2.6 (Liao, Luo et al. 2015) to 72.4% (Abasiubong, Bassey et al. 2012) and most studies had the SM prevalence between 21% and 50% (Araújo, Leal et al. 2013, Baghianimoghadam, Mojahed et al. 2013, Abeje, Admasie et al. 2015, Afshary, Mohammadi et al. 2015, Bohio, Brohi et al. 2016, Adanikin and Awoleke 2017, Alonso-Castro, Ruiz-Padilla et al. 2018, Beyene and Beza 2018, Botyar, Kashanian et al. 2018, Marwa, Njalika et al. 2018, Navaro, Vezzosi et al. 2018). For the GPG, the SM prevalence ranged between 8.9 (de Oliveira, Francisco et al. 2012) and 100.0% (Eticha and Mesfin 2014, Mamo, Ayele et al. 2018, Mensah, Agyemang et al.

2019) and most studies had the SM prevalence higher than 50% (Hassali, Shafie et al. 2011, Klemenc-Ketis and Kersnik 2011, González-López, Rodríguez-Gázquez et al. 2012, Gazibara, Nurkovic et al. 2013, Lawan, Abubakar et al. 2013, Eticha and Mesfin 2014, Foroutan and Foroutan 2014, Afridi, Rasool et al. 2015, Alzahrani, Alhindi et al. 2015, El-Nimr, Wahdan et al. 2015, Garofalo, Di Giuseppe et al. 2015, Jafari, Khatony et al. 2015, Kamran, Sharifirad et al. 2015, Motavali, Abedi et al. 2016, Annadurai, Selvasri et al. 2017, Dawood, Hassali et al. 2017, Kazaura 2017, Klemenc-Ketis and Mitrovic 2017, Heidari, Borujeni et al. 2018, Kim, Yang et al. 2018, Mamo, Ayele et al. 2018, Oliveira, Barroso et al. 2018, Shafie, Eyasu et al. 2018, Sridhar, Shariff et al. 2018, Vanhaesebrouck, Vuillermoz et al. 2018, Akram, Maqsood et al. 2019, Ha, Nguyen et al. 2019, Mensah, Agyemang et al. 2019, Tesfamariam, Anand et al. 2019). The general SM prevalence was not reported in one study (Sánchez 2014) and in another study was reported by the frequency of medications purchased (Chatziathanasiou, Chalikias et al. 2017). The cohort study reported SM's prevalence throughout the studied years (Secoli, Marquesini et al. 2018) and one study evaluated SM's practice in two time periods (during life and in the last 30 days) (Machado-Alba, Echeverri-Cataño et al. 2014). Two studies evaluated two sub-populations (urban and rural residence) (Wijesinghe, Jayakody et al. 2012) or more than one aim (SM for general and for rheumatic symptoms) (Ouédraogo, Zabsonré/Tiendrebeogo et al. 2015).

3.8 Exposure period to self-medication during pregnancy

The exposure period to SM during pregnancy was reported only in 8 studies. Seven reported the SM practice according to each trimester and one study reported only the trimester with higher prevalence of SM. The studies and data on the exposure period to SM during pregnancy are described in Table 2.

3.9 Medications used during self-medication

In the PWG, medications were classified according to the medication name (n = 7), medication group (n = 6), drug name and/or medication group (n = 3), medication name and Food and Drug Administration Risk (FDA) (n = 2), drug name and Anatomic Therapeutic Chemical Classification System (ATC) (n = 1), just ATC (n = 1) and 5 studies did not report the medications used in SM practice. Acetaminophen was the most used

medication and studies that considered the medication group, analgesics were the most used medications followed by antiemetics.

Table 2. Exposure period to self-medication during pregnancy according to gestational trimesters

<i>Author</i>	Trimester		
	<i>1st</i> <i>N (%)</i>	<i>2nd</i> <i>N (%)</i>	<i>3rd</i> <i>N (%)</i>
Afshary P et al	41 (41.8)	49 (50.0)	8 (8.2)
Atmadani RN et al	4 (10.3)	35 (89.7)*	35 (89.7)*
Beyene KG et al	122 (-) [†]	96 (-) [†]	17 (-) [†]
Marwa KJ	59 (34.3)	87 (50.5)	26 (15.1)
Navarro M et al	45 (17.4)	121 (46.9)	43 (16.7)
Odalovic M et al	1 (0.3) / 13 (4.2) ⁱ	3 (1.0) / 17 (5.5)	Missing
Rocha RS et al	Higher in first trimester	-	-
Zewdie T et al	15 (30.0)	- (40)	- (30)

* Value 35 (89.7) related to SM in the 2nd and 3rd trimester; - missing information; [†] total obtained from SM with allopathy and MP; Ø authors considered SM until 2nd trimester; i SM with prescribed and OTC/ SM just with OTC.

For the GPG, twenty-five studies reported the drugs used according to the medication group. Sixteen studies did not report the medications used during SM practice and other studies reported according to drug name and ATC classification. The most used medication group were analgesics (n = 12) and antibiotics (n = 4). Cough and cold preparations were predominant in just one study. Acetaminophen was the most used medication, followed by metamizole. Studies that considered the ATC classification reported as the most used medications - musculoskeletal and nervous system.

3.10 Symptoms and self-medication

The symptoms triggering SM initiation in the PWG were missing in thirteen studies. Headache (n = 3), pain and fever (n = 3), malaria fever (n = 2), nausea and vomiting (n = 2), common cold (n = 1) and infections (n = 1) were the most common symptoms that prompted SM during pregnancy. For the GPG, the symptoms that triggered SM practice were missing in twenty-nine studies. Headache (n = 10), fever (n = 3), flu, cold and cough

(n = 4), gastrointestinal problems (n = 2), pain (n = 1), allergies (n = 1) and musculoskeletal problems (n = 1) were reported as the main causes of SM practice.

4 Discussion

In this review, we summarized and compared self-medication patterns in pregnant women compared to the general population. The reported average of self-medication prevalence among pregnant women was between 21%-50%, considerably lower than the reported average among the general population; with prevalence rates surpassing 50% in the majority of the studied populations. Seventy-five studies were included in this review (majority from GPG) with a total of 108,559 participants. Most of the studies had a cross-sectional design – as expected - and were most from low-income and middle-income countries. The recording period considered, and the definition of SM was different between the studies. Acetaminophen was the most used medication in both groups and headache was the leading symptom related to SM practice.

The PWG was the group with the smaller number of studies and total participants interviewed in this review. It can be justified by the fact that studies with pregnant women have limited inclusion. From all studies included, two of them used a mixed-method approach (Sánchez 2014, Beyene and Beza 2018). According to Van der Geest (Van der Geest and Hardon 1988), this design can provide a complete understanding of the phenomenon (in this case, self-medication) as the qualitative segment could bring crucial patient perspectives that were missed through the use of quantitative interviews only.

The SM prevalence changes according to the recording period considered (Van den Brandt, Petri et al. 1991). Almost all studies in the PWG used the entire pregnancy as recording period, while in the GPG it varied from 3 days (de Oliveira, Francisco et al. 2012, Prado, Francisco et al. 2016) to 1 year (Klemenc-Ketis and Kersnik 2011, Garofalo, Di Giuseppe et al. 2015, Klemenc-Ketis and Mitrovic 2017, Ha, Nguyen et al. 2019). Although the literature shows that longer periods can contribute to recall bias (Van der Geest and Hardon 1988, Bertoldi, Barros et al. 2008), studies in the GPG that considered long periods (over 2 months) had a higher SM prevalence (37.8 to 94.9%) compared to studies with shorter periods (8.9 to 57.0%).

Reports suggest that the difficulty in memorizing increases with age (Van den Brandt, Petri et al. 1991) and SM is practice for minor illness can be rapidly forgotten (Van

der Geest and Hardon 1988). Studies with elderly population included in this review considered shorter time periods (de Oliveira, Francisco et al. 2012, Jafari, Khatony et al. 2015, Heidari, Borujeni et al. 2018, Oliveira, Barroso et al. 2018, Secoli, Marquesini et al. 2018) due to population's profile (Bertoldi, Barros et al. 2008). There is no ideal period considered to assess the SM practice but two-week period is recommended (Bertoldi, Barros et al. 2008).

The SM prevalence was higher in the GPG and it can be attributed to the population's profile, recording period assessed and the considered SM definition. The three studies in the GPG that had a SM prevalence of 100% included only people who self-medicated (Mensah, Agyemang et al. 2019) or people that were buying the medicines to self-medicate (Eticha and Mesfin 2014, Mamo, Ayele et al. 2018).

In the PWG, the higher SM prevalence was reported in the second trimester in six of the eight studies. Although the first trimester is more critical regarding potential damage during fetus development, this risk can reach the fetus throughout pregnancy by different ways according to the exposure period (Pigarelli, Kraus; et al. 2008). Beyond the fetal risk, women are exposed to the risks of SM practice, including Drug Related Problems (DRP), delay in diagnosis, allergies and intoxication (Bradley and Bond 1995, Panda, Pradhan et al. 2016) .

Acetaminophen was the most commonly used medication in SM by pregnant women. Although it is the first choice as analgesic during pregnancy, some studies suggested an association between prenatal exposure to acetaminophen and an increased risk of behavioral problems in childhood (Liew, Ritz et al. 2014, Liew, Bach et al. 2016, Stergiakouli, Thapar et al. 2016, Bauer, Kriebel et al. 2018). The use of non-steroidal anti-inflammatory drugs (NSAIDs) was also common. NSAIDs (e.g. naproxen) are known to cross the placenta (Siu, Yeung et al. 2002) and studies show that when administered in early pregnancy, they can be associated with oral cleft, neural tube defects, encephalocele and spontaneous abortion (Li, Liu et al. 2003, Nakhai-Pour, Broy et al. 2011, Hernandez, Werler et al. 2012).

These findings reinforce the need for expanded control over marketing of potentially harmful medications, including OTC drugs and the importance to promote a non-pharmacological treatment during pregnancy. Cognitive behavioral therapy,

acupuncture, yoga and massage showed promising effectiveness in treating mild problems like perinatal anxiety, pain and insomnia during pregnancy (Hollenbach, Broker et al. 2013, Shah, Banh et al. 2015, Green, Donegan et al. 2020), warranting additional larger studies.

The absence of the medications used during SM was less common in the PWG (12.0%) when compared to the GPG (32.0%). Three studies (Domingues, Galvão et al. 2017, Navaro, Vezzosi et al. 2018, Oliveira, Barroso et al. 2018) classified the medications used according to the ATC classification system. According to this classification, we recommend classifying using a fourth level, as classification using three levels (Domingues, Galvão et al. 2017, Navaro, Vezzosi et al. 2018), is inadequate to assess which medication was used as the same class can have medications with different risk levels during pregnancy. Regarding the symptoms that prompted the SM practice, the absence of this information was similar in both groups, missing in 52.0% and 58.0% in the PWG and GPG, respectively. The symptoms related were similar, and the primary indication was headache.

5 Strengths and limitations

This review has limitations. Although WHO proposes a universal definition for SM, this concept created in 1998 is broad and the studies from both groups described different definitions, preventing comparison of studies within the literature. This limitation was reported by Locquet et al (Locquet, Honvo et al. 2017) and our findings reinforce the need for an updated universal definition, as differences in definition directly influence the SM prevalence rates reported. The difference in the classification of the medications used in SM, the symptoms related and the recording period considered prevented any intra-group comparisons between retrieved studies.

As study strength, this review provides a comprehensive overview of SM during the last 10 years in different populations. The results reported can help to improve health policies and promote the Rational Medication Use (RMU) to prevent non-essential exposure to medications with potential risks.

6 Conclusion

This scoping review identified that self-medication is common among pregnant women, however relatively less frequent when compared to the general population. The

medications used in self-medication and their indications were similar between the groups. There was a significant difference in the definitions used to describe self-medication, highlighting the need for a universal update for this concept.

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Author contributions

GP: Conceptualization, methodology, investigation, writing original draft and project administration. CSM: Methodology, writing, review and editing. ACF: Methodology, writing, review and editing. FGS: Conceptualization, resources, writing, review and editing, supervision, project administration and founding acquisition. SE: Conceptualization, resources, writing review and editing, supervision, project administration. PGM: Conceptualization, resources, writing review and editing, supervision, project administration, founding acquisition. APMO: Methodology.

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Competing interests

Gabriela Pereira, Cinthia Madeira de Souza, Amanda Canato Ferracini, Fernanda Garanhani Surita, Sherif Eltonsy and Priscila Gava Mazzola have no conflicts of interest and the research was conducted in the absence of any commercial or financial relationships.

Ethics approval statement

This is a review article and Ethics Committee is not required.

Patient consent for publication

Not applicable.

Patients and public involvement

Not applicable.

Data sharing statement

All data generated or analysed during this study are included in this published article (and its supplementary information files).

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CAPÍTULO II. “SELF-MEDICATION AMONG PREGNANT WOMEN: PREVALENCE AND ASSOCIATED FACTORS”

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Abstract

Objectives: The pregnancy period, with its peculiarities and specific symptoms that may or may not be physiological, can lead to medication use through prescription or even self-medication. This study aimed to assess self-medication practices among pregnant women, the most used medications, symptoms reported, and factors associated with this practice.

Methods: This was a cross-sectional study conducted with pregnant women with an antenatal care (ANC) appointment in a tertiary teaching hospital referral in women's health. From April 2019 to February 2020, 297 pregnant women were interviewed. Self-medication was considered as the use of any medicine (including medicinal plants (MPs), herbal products, and vitamins) without a medical or dental prescription. The period considered to assess self-medication practice was the last 60 days prior to the study interview.

Results: Among the 297 women interviewed, 107 (36.0%) had practiced self-medication in the previous 60 days. Acetaminophen was the most used medication, and headache was the most frequent symptom reported by self-medicated pregnant women. Pregnant women with high-school (73 (68.2%) (OR = 2.52; 95% CI 1.17–5.43; $p = 0.018$)) or university-level (23 (21.5%) (OR = 2.82; 95% CI 1.15–6.94; $p = 0.024$)) education had a higher risk of practicing self-medication when compared to women with lower education. Women in the first gestational trimester (35 (32.7%) (OR = 3.61; 95% CI 1.64–7.96; $p = 0.002$)) and with two or more pregnancies (87 (81.2%) (OR = 1.96; 95% CI 1.07–3.60; $p = 0.029$)) were more likely to practice self-medication than pregnant women in the second or third gestational trimester and in the first pregnancy, respectively.

Conclusion: Self-medication was practiced by a considerable proportion of our sample, with the majority being OTC drugs. The factors associated with self-medication can help to improve prevention strategies regarding self-medication during pregnancy.

Keywords: Self-medication, Pregnancy, Women's Health, Medication use, Antenatal Care.

1 Introduction

Self-medication is defined by the World Health Organization (WHO) as the “selection and use of medicines by individuals to treat self-recognized illness or symptoms”, including medicinal plants (MPs) and herbal products (WHO 1998).

Pregnant women report a variety of symptoms throughout their pregnancy due to physiological and anatomical changes (Moya, Phillips et al. 2014). Headache, nausea, vomiting, and edema are frequent symptoms during pregnancy and are commonly related to self-medication practice during this period (Bohio, Brohi et al. 2016, Cabut, Marie et al. 2017, Botyar, Kashanian et al. 2018, Zewdie, Azale et al. 2018). Beyond the symptoms presented, self-medication during pregnancy is typically motivated by easy access to medicines, previous medication experience (Beyene and Beza 2018), and time saving (Zewdie, Azale et al. 2018) and are associated with sociodemographic factors (Liao, Luo et al. 2015, Marwa, Njalika et al. 2018, Zewdie, Azale et al. 2018), previous maternal illness (Abeje, Admasie et al. 2015), and poor knowledge regarding medication use and its risks (Beyene and Beza 2018).

Studies have shown substantial differences in the prevalence of self-medication during pregnancy (Beyene and Beza 2018, Marwa, Njalika et al. 2018, Zewdie, Azale et al. 2018, Atmadani, Nkoka et al. 2020). One study performed in the Netherlands found a self-medication prevalence of 12.5%, whereas research performed in Nigeria and Iran reported a prevalence of 63.8% and 30.6%, respectively. (Yusuff and Omarusehe 2011, Verstappen, Smolders et al. 2013, Afshary, Mohammadi et al. 2015). This difference could be related to the study setting, the concept of self-medication considered by authors, and the recording period used to assess self-medication practice.

According to the gestational age at the exposure time and the dose administered, the use of a teratogenic agent during pregnancy can result in varying outcomes, such as fetal death,

morphologic malformations, or physiological abnormalities (Cohlan 1963, Shepard 1979, Mazzu-Nascimento, Melo et al. 2017). Although exposure to teratogenic effects is responsible for a minor number of birth defects, it can be considered a public health issue once this child will require specialized attention throughout their life (Brazil 2013, Mazzu-Nascimento, Melo et al. 2017).

There is a lack of literature regarding self-medication among pregnant women living in Brazil. This study will help to understand the current scenario in an urban city of Brazil and could assist future research in the field. The findings regarding the factors associated with self-medication during pregnancy will assist health professionals in preventing self-medication among pregnant women.

Considering the easy access to medicines and the symptoms associated with pregnancy changes, this study aims to evaluate the self-medication prevalence among pregnant women, the associated factors, most common medications used, symptoms reported, and motivational factors related to this practice among pregnant women in an urban city of Brazil.

2 Methods

2.1 Study design and setting

A cross-sectional study was conducted in a high-risk antenatal care (ANC) clinic at the Women's Hospital of the University of Campinas, São Paulo, Brazil. This is a public tertiary teaching hospital specializing in women's health; it has 142 beds and performs an average of 200 deliveries per month. Pregnant women can access the high-risk ANC service through a medical referral.

2.2 Participants and inclusion and exclusion criteria

From April 2019 to February 2020, 297 pregnant women were interviewed. The inclusion criteria were pregnant women in their first appointment at the ANC at the Women's Hospital, aged 18 years or more, with no restriction regarding their gestational age. The study took place in a city that receives immigrants from different countries, and the exclusion criterion selected was "does not speak fluent Portuguese (local language).

2.3 Data collection procedures

Pregnant women were selected by simple random sampling according to their availability in the waiting room. The data collection was performed in a private room, through face-to-face interviews, using semi-structured questionnaires developed by the research team. Questionnaires were developed based on the literature (Adanikin and Awoleke 2017, Beyene and Beza 2018, Marwa, Njalika et al. 2018) and they were analyzed by two professors with expertise in the research area through face, content, construct, and validity to assess the comprehensiveness, readability, and clarity of the instrument. A pretest was conducted with five pregnant women to assess the instruments' validity and reliability. Changes regarding the organization of the instruments (example: the creation of a table to organize the results) were made to improve the questionnaires' quality. The participants included in the pretest were not included in the final analysis. The participants answered two questionnaires: (i) sociodemographic, gestational, and life habits and (ii) about self-medication practice during pregnancy. All procedures were carried out according to the Helsinki Declaration. All Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement items were followed and confirmed in this manuscript.

2.4 Variables

2.4.1 Dependent variables

The outcome measure was the practice of self-medication. Self-medication was considered as the use of any medicine, MP, phytotherapy, or vitamin used without a medical or dental prescription and the use of a medicine prescribed to another person. The period considered to assess self-medication during pregnancy was the previous 60 days prior to the first appointment at the Women's Hospital, and this period was used to minimize recall bias.

For pregnant women who gave a positive answer to self-medication practice, the medications used during self-medication were assessed, asking: Which medications did you use during self-medication? The medications informed were registered and separated into three groups: (1) over-the-counter drugs (OTC), (2) prescription-only medicines (POM), and (3) MPs, phytotherapy, and vitamins. MPs were considered as the administration of any plant or part of it without the use of any specific fabrication process (e.g., chamomile tea). Phytotherapy was defined as the use of a plant or part of it through a specific

formulation (e.g., passionflower capsule). Vitamins considered in self-medication were both combined or isolated vitamins. The indication for self-medication practice was assessed by asking the question, “Which symptom did you feel to practice self-medication?”.

Motivational factors were assessed by asking pregnant women: “Why did you practice self-medication?”. Different options were given (considered a simple health problem, practicality, and lack of health-system access). There was an option—“Other”—to classify the answers that were not contemplated in the above list. The source or person who indicated a self-medication practice was assessed by the question “From whom was the indication for self-medication obtained?” Different options were given (own account, neighbor or friend, leftover from a previous treatment, family member, pharmacy, or internet). Another option—“Other”—was available to classify those answers that were not suitable for the other options in the above list.

2.4.2 Independent variables

The body mass index (BMI) was calculated based on the pre-gestational weight provided by 246 pregnant women in the first ANC appointment in the study setting. Family income was assessed by asking the pregnant women about the monthly income of all family members. The amount was categorized into three categories based on the response of 285 pregnant women. The currency considered was the Brazilian minimum wage of 2019 (R\$ 998,00), equivalent to approximately \$241,00 (current currency).

2.5 Sample size

The sample size was calculated using a single prevalence of 14.0% (BiBintsene-Mpika G, Mouankié JB et al. 2018). A sample error of 5% and a 95% confidence interval were considered. The analysis found that a sample of 186 pregnant women was able to represent the prevalence of self-medication during pregnancy. We did not consider the non-response rate.

2.6 Statistical analysis

A descriptive analysis was used to evaluate the categorical variables (frequency and percentage). The comparison between categorical variables and self-medication practice was analyzed using Fisher’s exact test and a Chi-Square test. Quantitative variables

(gestational age in weeks) were compared with self-medication practice with a Mann-Whitney test. The possible variables associated with self-medication were assessed using univariate logistic regression analysis. Multivariate logistic regression analysis was performed considering the Stepwise criteria to assess where these variables were associated with self-medication. The significance level was set at 5% ($p < 0.05$). Statistical analyses were performed using SAS System for Windows (Statistical Analysis System, version 9.2, SAS Institute Inc, 2002-2008, Cary, NC, USA).

2.7 Ethics

All women signed the informed consent before being included in the study. This research was approved by the Research Ethics Committee of the Faculty of Medical Sciences, UNICAMP (CAAE: 04012118.7.0000.5404). All procedure was carried out according to the Helsinki Declaration.

3 Results

3.1 Sociodemographic and gestational characteristics

Among the 297 pregnant women interviewed, 107 (36.0%) had practiced self-medication in the final 60 days before the first ANC appointment in a referral women's hospital. The women were aged 18–52 years, with a mean of 30.9 ± 6.3 ($\pm$ standard deviation - SD). One hundred and sixty pregnant women (53.9%) were non-white, 209 (70.3%) had a partner, and 162 (54.5%) were employed (**Table 3**). Most pregnant women were in the second gestational trimester. The mean gestational age was 20.2 ± 7.7 weeks, and 220 (74.0%) pregnant women were multigravida. The most common diseases presented during pregnancy were hypertensives syndrome and any kind of diabetes, reported by 87 (29.2%) and 84 (28.2) pregnant women, respectively (**Table 4**).

Table 3. Sociodemographic, gestational characteristics and self-medication during pregnancy of 297 women

Variables		Self-medication			<i>p</i> value
		Total N=297 (%)	Yes n=107 (%)	No n=190 (%)	
Age	<30	128 (43.1)	47 (43.9)	81 (42.6)	0.841
	30-39	143 (48.1)	52 (48.6)	91 (47.8)	
	≥ 40	26 (8.8)	8 (7.4)	18 (9.4)	

Skin color	White	137 (46.1)	51 (47.6)	86 (45.2)	0.690
	Non-white	160 (53.9)	56 (52.3)	104 (54.7)	
Marital status	With partner	209 (70.3)	77 (71.9)	132 (69.4)	0.652
	Without partner	88 (29.7)	30 (28.0)	58 (30.5)	
Occupation	Employed	162 (54.6)	63 (58.8)	99 (52.1)	0.456
	Housewives	111 (37.3)	35 (32.7)	76 (40.0)	
	Unemployed	24 (8.1)	9 (8.4)	15 (7.8)	
Education	Elementary school	49 (16.5)	11 (10.2)	38 (20.0)	0.030
	College/High school and University	248 (83.5)	96 (89.7)	152 (80.0)	
Family income⁺	0-2	208 (73.0)	75 (72.1)	133 (73.4)	0.481
	3-5	58 (20.3)	24 (23.0)	34 (18.7)	
	> 5	19 (6.7)	5 (4.8)	14 (7.7)	
BMI*	Low weigh	5 (2.0)	1 (1.1)	4 (2.4)	0.961
	Adequate	73 (29.7)	26 (30.5)	47 (29.1)	
	Overweigh	75 (30.5)	26 (30.5)	49 (30.4)	
	Obesity	93 (37.8)	32 (37.6)	61 (37.8)	
Trimester	First trimester	64 (21.5)	35 (32.7)	29 (15.2)	< 0.001
	Second trimester	171 (57.6)	58 (54.2)	113 (59.4)	
	Third trimester	62 (20.8)	14 (13.0)	48 (25.2)	
Gravidity	1	77 (25.9)	20 (18.6)	57 (30.0)	0.032
	≥ 2	220 (74.1)	87 (81.3)	133 (69.8)	

⁺ Family income was obtained using a sample of 285 women; BMI: Body Max Index; BMI was calculated using a sample of 246 women; *P* value from Chi-square test and Fisher exact test; Significant *p*-values are bold.

3.2 Self-medication practice

One hundred and seven pregnant women (36.0%) had reported the practice of self-medication at least once in the final 60 days before their first ANC appointment in a referral women's hospital. OTC drugs were the most used medication group in self-medication. Acetaminophen (38 (35.1%)), metamizole (30 (28.0%)), and metamizole association (19 (17.7%)) were the most used medications in this group. Naphazoline (5 (4.6%)) and dimenhydrinate (4 (3.7%)) were the leading medications used in self-medication with POM, whereas guaco syrup (3 (2.8%)) was the most medication used in the MP group. Eleven (10.2%) pregnant women did not remember the name of the medications used in self-medication (**Table 5**).

Table 4. Mainly health problems presented by pregnant women.

Health problem*	N (%)
Hypertensive syndrome during pregnancy	87 (29.2)
Diabetes Mellitus during pregnancy	84 (28.2)
Thyroid disease	38 (12.7)
Collagen disease and Antiphospholipid Syndrome (APS)	25 (8.3)
Multiple pregnancy	22 (7.4)
Bad Obstetric History (BOH) ⁺	20 (6.7)
Nervous System problems	19 (6.3)
Uterine anomaly and preterm labor	18 (6.0)
Infection during pregnancy	18 (6.0)
Pulmonary disease	14 (4.7)
Mental health	14 (4.7)
Obstetric complications	11 (3.7)
Diagnosis under investigation	18 (6.0)
Others	61 (20.5)

* More than one health problem per women. ⁺ Examples of Bad Obstetric History found: perinatal deaths, malformations and history of miscarriage. Others: Non-specified health problems 15 (5.0%). Anemia 7 (2.3%). Non specified cardiovascular and hematologic problems 4 (1.6%). Crohn disease and bariatric surgery 3 (1.0%) (each). History of orthopedic surgery, nephrolithiasis, history of renal lithiasis, hyperemesis gravidarum, history of cervical intraepithelial neoplasm 2 (0.6%) (each). Cirrhosis, chronic liver disease, problem in inguinal region, polycystic ovary syndrome, bilateral renal agenesis, intrauterine growth restriction, alcoholism, allergic rhinitis, kidney stone biliary lithiasis, cholestasis, keratoconus, chronic pain, fibromyalgia, history of hydatidiform spring, weight loss during pregnancy, history of splenectomy and colectomy, previous uterus neoplasm, non-specified surgery during pregnancy 1 (0.3%) (each).

Table 5. Mainly characteristics related to self-medication during pregnancy.

Medications used during self-medication*		N (%)
OTC Drugs	Acetaminophen	38 (35.1)
	Metamizole	30 (28.0)
	Metamizole + association	19 (17.7)
	Ibuprofen	10 (9.3)
	Scopolamine	6 (5.6)
	Others ¹	21 (19.1)
POMs	Naphazoline	5 (4.6)
	Dimenhydrinate	4 (3.7)
	Omeprazole	3 (2.8)

	Others ²	14 (14.4)
MP, vitamins and phytotherapy	Guaco syrup	3 (2.8)
	Multivitamin	2 (1.8)
	Passionflower	2 (1.8)
	Others ³	8 (7.2)
Do not remember the name of medication used		11 (10.2)
Indication for self-medication practice	Headache	63 (58.8)
	Nausea and vomiting	10 (9.3)
	Stomachache	8 (7.4)
	Flu	6 (5.6)
	Others ⁴	73 (67.3)
Motivational factors	Considered a simple health problem	67 (62.6)
	Practicality	54 (50.4)
	Lack of access to health system	26 (23.4)
	Others ⁵	13 (12.1)
Source or person who indicates self-medication practice	Own account (myself)	81 (89.0)
	Neighbor or friend	12 (11.2)
	Leftover from a previous treatment	11 (10.2)
	Family member	9 (8.4)
	Pharmacy	9 (8.4)
	Internet	6 (5.6)
	Others ⁶	5 (4.5)

* More than one medication per women. MP: Medicinal Plants. **Others¹**: Simethicone 4 (3.7%). Acetaminophen + association 3 (2.8%). Aluminum hydroxide + magnesium + simethicone, Sodium bicarbonate + sodium carbonate + citric acid and bicarbonate 2 (1.8%) (each). Loratadine, dexchlorpheniramine, guaifenesin, diclofenac, sorbitol + sodium lauryl sulfate, magnesium carbonate, mineral oil and Saccharomyces cerevisiae 1 (0.9%) (each); **Others²**: Meclizine, ondasetron, propranolol 2 (1.8%) (each). Pantoprazole, metformin, tramadol, bromopride, amoxicillin, dexamethasone, metoclopramide, tranexamic acid, zolpidem and cyclobenzaprine 1 (0.9%) (each); **Others³**: Peumus boldus tea 2 (1.8%). Herbs tea, vitamin c, avocado leaf, Greek hay oil (aromatherapy), arnica gel and clove tea: 1 (0.9%) (each). **Others⁴**: Nasal congestion, colic and general pain 5 (4.6%) (each). Backache, heartburn, insomnia, toothache and cough 4 (3.7%) (each). Migraine, indigestion, allergy and intestinal gas 3 (2.8%) (each). Myalgia, control Diabetes Mellitus, abdominal pain, intestinal constipation, Urinary Tract Infection (UTI) and high blood pressure 2 (1.8%) (each). Treatment for polycystic ovary, kidney stone, leg pain, flaccidity, arrhythmia, tendonitis, hair loss, sinusitis, to menstruate, anxiety, diarrhea, low fetal weight, fever and sore throat 1 (0.9%) (each); **Others⁵**: Previous experience with the medication 5 (4.6%), discomfort caused by symptoms 2 (1.8%), work, habit, curiosity, did not get the prescription 1 (0.8%) (each); **Others⁶**: Prescribed for another symptom 2 (1.8%), habit 2 (1.8%) and prescribed to a family member 1 (0.9%). That were cases that women reported more than one symptom, motivational factor and indication for self-medication practice.

The most common indications for self-medication practice were headache (63 (58.8%)), nausea and vomiting (10 (9.3%)), and stomachache (8 (7.4%)). A simple health problem (67 (62.6%)) and practicality (64 (60.4%)) were motivational factors frequently reported by

pregnant women who practiced self-medication, and the leading source for self-medication was “own account” (81 (89.0%)) followed by a neighbor or friend (12 (11.2%)) (**Table 5**). Self-medication was associated with higher education ($p = 0.033$), first gestational trimester ($p = <0.001$), lower gestational age ($p = <0.001$), and gravidity ($p = 0.030$). A univariate logistic regression analysis was performed to assess the variables related to self-medication practice and higher education; gestational trimester and gravidity were determinant factors for self-medication (**Table 6**). Pregnant women with high-school (73 (68.2%) (OR = 2.10; 95% CI 1.01–4.37; $p = 0.047$)) or university-level (23 (21.5%) (OR = 2.48; 95% CI 1.05–5.86; $p = 0.038$)) education were more likely to practice self-medication than pregnant women with elementary school. Women in the first gestational trimester 35 (32.7%) (OR = 4.14; 95% CI 1.91 – 8.96; $p = <0.001$;) and women with two or more pregnancies 87 (81.3%) (OR = 1.86; 95% CI 1.05 – 3.32; $p = 0.034$;) were more likely to practice self-medication than pregnant women in the second and third gestational trimester and women in the first pregnancy, respectively.

The multivariate logistic regression analysis was performed considering education, gestational trimester, and gravidity and confirmed that these variables were significant factors associated with self-medication. Pregnant women with high-school (73 (68.2%) (OR = 2.52; 95% CI 1.17–5.43; $p = 0.018$) or university-level (23 (21.5%) (OR = 2.82; 95% CI 1.15–6.94; $p = 0.024$)) education were more likely to practice self-medication when compared to women who had only attained primary school education. Pregnant women in the first gestational trimester (35 (32.7%) (OR = 3.61; 95% CI 1.64–7.96; $p = 0.002$)) and women with two or more pregnancies (87 (81.2%) (OR = 1.96; 95% CI 1.07–3.60; $p = 0.029$)) were more likely to practice self-medication than pregnant women in the second or third gestational trimester and in the first pregnancy, respectively.

4 Discussion

Our study found a self-medication prevalence of 104 (36.0%). This finding is similar to research performed in Ethiopia (Abeje, Admasie et al. 2015), Nigeria (Adanikin and Awoleke 2017), Iran (Afshary, Mohammadi et al. 2015, Botyar, Kashanian et al. 2018) and Pakistan (Bohio, Brohi et al. 2016), but higher than studies published in Peru (Miní, Varas et al. 2012), Serbia (Odalovic, Vezmar Kovacevic et al. 2012), Netherlands (Verstappen, Smolders et al. 2013) and China (Liao, Luo et al. 2015). This difference could be due to the

study setting, health policies regarding medication use, and the methods applied, such as the studied population and recording period considered to assess self-medication practice.

Table 6. Univariate and multivariate logistic regression analysis of variables associated with self-medication during pregnancy ($n = 297$).

Variables	Self-medication		COR (95% CI)	<i>p</i> value	AOR (95% CI)	<i>p</i> value
	Yes	No				
<i>Age</i>						
<30	47	81	1.00	1	-	-
30-39	52	91	0.99 (0.60 – 1.62)	0.952	-	-
≥ 40	8	18	0.77 (0.31 – 1.90)	0.565	-	-
<i>Skin color</i>						
White	51	86	1.00	1	-	-
Non-white	56	104	0.91 (0.57 – 1.46)	0.690	-	-
<i>Marital status</i>						
With partner	77	132	1.00	1	-	-
Without partner	30	58	0.89 (0.53 – 1.50)	0.652	-	-
<i>Occupation</i>						
Housewife	35	76	1.00	1	-	-
Employed	63	99	1.38 (0.83 – 2.30)	0.214	-	-
Unemployed	9	15	1.30 (0.52 – 3.26)	0.572	-	-
<i>Education</i>						
Elementary school	11	38	1.00	1	1.00	1
Secondary school	73	120	2.10 (1.01 – 4.37)	0.047	2.52 (1.17 – 5.43)	0.018
Superior level	23	32	2.48 (1.05 – 5.86)	0.038	2.82 (1.15 – 6.94)	0.024
<i>Family income⁺</i>						
0-2	75	133	1.00	1	-	-
3-5	24	34	1.25 (0.69 – 2.27)	0.459	-	-
> 5	5	14	0.63 (0.22 – 1.83)	0.399	-	-
<i>BMI*</i>						
Low weigh	1	4	1.00	1	-	-

Adequate	26	47	0.45 (0.05 – 4.26)	0.488	-	-
Overweigh	26	49	0.96 (0.49 – 1.88)	0.904	-	-
Obesity	32	61	0.95 (0.50 – 1.80)	0.871	-	-
<i>Trimester</i>						
First trimester	35	29	4.14 (1.91 – 8.96)	0.002	3.61 (1.64 – 7.96)	-
Second trimester	58	113	1.76 (0.90 – 3.45)	0.242	1.51 (0.76 – 3.01)	-
Third trimester	14	48	1.00	1	1.00	-
<i>Gravidity</i>						
1	20	57	1.00	1	1.00	1
≥ 2	87	133	1.86 (1.05 – 3.32)	0.034	1.96 (1.07 – 3.60)	0.029

COR: Crude odds ratio; AOR: Adjusted odds ratio; CI: Confidence Interval. Significant *p* values (*p* < 0.005) are bold.

OTC drugs were the most used medication class in self-medication. This result may have been due to the relatively easy access to these medicines in Brazil and other countries. Acetaminophen was the most used medication in the OTC drugs group, and this finding is similar to previous studies. (Yusuff and Omarusehe 2011, Odalovic, Vezmar Kovacevic et al. 2012, Cabut, Marie et al. 2017, Jambo, Mengistu et al. 2018, Zewdie, Azale et al. 2018). Beyond the possible association between prenatal exposure to acetaminophen and behavior problems in childhood (Liew, Ritz et al. 2014, Liew, Bach et al. 2016, Stergiakouli, Thapar et al. 2016, Bauer, Kriebel et al. 2018), acetaminophen can cause acute liver failure in mothers (Casey, Fontana et al. 2020), leading to serious health problems, such as organ transplantation (Gill, Contos et al. 2002, Thornton and Minns 2012), representing another risk to the fetus.

The use of MP and phytotherapy was reported at a lower frequency when compared to POMs and OTC drugs. According to the literature, the use of these products is common in rural areas, and women who are more highly educated are less likely to use this treatment. (Bello, Morhason-Bello et al. 2011). This finding provides an idea about why MP and phytotherapy were less used in our study; the Women's Health clinic is located in an urban area, and self-medication in our sample was common among women with a higher education level.

Although MPs were used less frequently by our sample, a study in Northeastern Brazil recorded a high prevalence regarding the use of this form of therapy. *Peumus boldus*,

Melissa officinalis, *Matricaria chamomilla*, and *Mentha piperita* L. have abortifacient and teratogenic properties and were reported by Araújo *et al.* as frequently used MPs by pregnant women in Brazil (Araújo, Santiago *et al.* 2016). It is important to highlight that teratogenic effects are related to different variables, such as gestational age at the exposure time and dose response, and MP use during pregnancy needs to be followed by a health care professional.

Headache was the most frequently indication for self-medication practice and this observation is similar to other studies (Bohio, Brohi *et al.* 2016, Cabut, Marie *et al.* 2017, Alonso-Castro, Ruiz-Padilla *et al.* 2018). Beyond hormonal changes and considering the high prevalence of diseases presented by our sample, the presence of headache can be related to secondary causes, such as hypertension and pre-eclampsia. In this case, self-medication can contribute to a misdiagnosis (Bennadi 2013), representing another risk beyond teratogenic effects, and pregnant women must be advised regarding these symptoms.

In our sample, the leading cause of self-medication practice was practicality, and a lack of health-system access was responsible for a minor self-medication prevalence. This finding reinforces that access to ANC services is not enough to prevent self-medication (Araújo, Leal *et al.* 2013), and this practice can occur even with health-system access. When asked about the indication related to self-medication practice, the leading answer was “myself”. This response could be related to the variables found to be associated with self-medication practice in our study, such as the number of previous pregnancies and education level.

Pregnant women with high-school or university-level education were more likely to practice self-medication when compared to pregnant women with elementary-school education. Although this finding is comparable with other studies (Afshary, Mohammadi *et al.* 2015, Alonso-Castro, Ruiz-Padilla *et al.* 2018), self-medication is generally related to lower levels of education (Bello, Morhason-Bello *et al.* 2011, Garofalo, Di Giuseppe *et al.* 2015, Marwa, Njalika *et al.* 2018, Zewdie, Azale *et al.* 2018). This difference could be due to the study setting. Because Brazil is a developing country, people may have more access to drugs, and pregnant women with a higher level of education may feel more able to choose their own medicines.

Pregnant women in the first gestational trimester were more likely to practice self-medication than women in the second and third gestational trimester. During the first gestational trimester, women typically experience more symptoms and discomfort and tend to feel the need to use medicines more often; however, this is the more critical trimester regarding fetus damage related to medicine use (van Gelder, van Rooij et al. 2010).

Despite the methodological difficulty in establishing a relationship, some medications used in self-medication by our sample seem to have the potential to expose the fetus to teratogenic effects. As an example, some studies have demonstrated a possible teratogenic effect regarding ondansetron prenatal exposure and a risk of birth defects, such as cleft palate and cardiac defects, and its use is recommended by some authors as a last treatment option (Danielsson, Wikner et al. 2014, Carstairs 2016, Lavecchia, Chari et al. 2018). One study regarding self-medication among pregnant women found a significant relationship between self-medication during pregnancy and an increase in US Food and Drug Administration (FDA) risk category (Adanikin and Awoleke 2017). This finding highlights the need for close monitoring during ANC, mainly in the first gestational trimester, with appropriate instructions to minimize fetus exposure to teratogenic effects.

The number of previous pregnancies was associated with self-medication. Women with two or more pregnancies were more likely to practice self-medication than women in the first pregnancy. These data are similar to the literature (Abeje, Admasie et al. 2015, Beyene and Beza 2018) and although there is a requirement for further studies, the experience of previous pregnancies seems to influence the women's behavior in their subsequent pregnancies, particularly regarding medication use. This information can be useful to create prevention strategies regarding self-medication during the gestational period, mainly after the women's first pregnancy.

The women's knowledge about the risks of OTC drugs to the fetus was related to a slightly increased likelihood to practice self-medication during pregnancy (Beyene and Beza 2018, Atmadani, Nkoka et al. 2020). There is a need to improve women's knowledge regarding this topic to prevent self-medication during pregnancy. Based on our findings, this prevention strategy could be initiated during the women's first pregnancy, preventing self-medication practice in future pregnancies.

Another alternative to minimize medication exposure during pregnancy, even through self-medication or prescription use, is to improve non-pharmacological treatment during this period. Regular exercise, fiber ingestion, and leg elevation are examples of non-pharmacological approaches recommended by WHO for the management of back pain, constipation, and edema, respectively (WHO 2016). Such alternative approaches should be encouraged and followed by health care professionals based on each women's needs and medical history.

Beyond the presented alternatives to prevent self-medication and promote the rational use of drugs, pharmacists play an important role in improving medication safety during pregnancy, and these professionals should be aware of this topic so that they can more effectively guide pregnant women (Samuel and Einarson 2011). As a suggestion for further studies, there is a need to evaluate women's behavior before, during, and after pregnancy, mainly regarding medication use to improve prevention strategies for self-medication during this period. Because this study excluded pregnant women who were not fluent in Portuguese, there is a need to carry out research with this specific population, considering that difficulty in communication can impact health-system access, leading to self-medication practice.

Although the prevalence of self-medication in our survey was comparable to the literature, this study has some limitations. When practiced to treat a minor illness, self-medication can be rapidly forgotten, and the difficulty in remembering increases with long periods (Van den Brandt, Petri et al. 1991). Although the 60-day period considered to assess self-medication practice minimized recall bias, some pregnant women did not remember the name of the medications used during their self-medication practice, and the period considered excluded medications used by pregnant women in early periods. Because this study was performed in a public teaching hospital, it would be interesting for further research to assess self-medication practice in other services to examine the correlation between sociodemographic factors and self-medication practice. As strengths, this study assessed self-medication practice among pregnant women of different ages, gestational trimesters, and comorbidities and included varying sociodemographic profiles. Beyond contributing to future research in the field, the factors associated with self-medication

practice could help in the development of prevention strategies related to self-medication during pregnancy.

5 Conclusion

The pregnant women were found to have practiced self-medication in the final 60 days before this survey, with the majority being OTC. Pregnant women with a higher education level, with two or more pregnancies, and in the first trimester were more likely to practice self-medication during pregnancy. Practicality was the main cause of self-medication, indicating that patient counseling is as important as ANC system access. There is a need to improve women's knowledge regarding medication use during pregnancy.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Author Contributions

GP: Conceptualization, methodology, investigation, writing original draft and project administration. FGS: Conceptualization, resources, writing, review and editing, supervision, project administration and founding acquisition. ACF: Methodology, writing, review and editing. CSM: Methodology, writing, review and editing. LSO: Investigation. PGM: Conceptualization, resources, writing review and editing, supervision, project administration, founding acquisition.

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Abbreviations

WHO: World Health Organization; ANC: Antenatal Care; OTC: Over-the-counter; POM: Prescription Only Medicine; MP: Medicinal Plant; STROBE: Strengthening the Reporting

of Observational Studies in Epidemiology; SD: Standard Deviation; OR: Odds Ratio; IC: Confidence Interval; DRP: Drug Related Problem; ADR: Adverse Drug Reaction.

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4 DISCUSSÃO

Avaliar o perfil de uso dos medicamentos existentes é tão importante quanto a descoberta de novas terapias. A compreensão da prática da automedicação em diferentes países confirma que avaliar o uso de medicamentos sem prescrição e suas diferentes causas é um dos principais passos para a promoção o Uso Racional de Medicamentos (WHO 2002). O trabalho realizado evidenciou diferentes conceitos atribuídos a prática da automedicação, o que pode impactar diretamente na prevalência do uso de medicamentos sem prescrição na população avaliada.

Embora apresente menor prevalência durante a gestação, a automedicação, ainda que responsável, deve ser desencorajada por diferentes motivos. Considerando a prevalência de comorbidades na população avaliada, o uso de medicamentos sem prescrição pode levar a casos de interação medicamentosa entre os medicamentos utilizados na automedicação e os medicamentos prescritos para tratar as doenças apresentadas (Vacher, Lagarce et al. 2020), além de estar associada à uma maior prevalência de outros Problemas Relacionados a Medicamentos (PRM) (Eickhoff, Hämmerlein et al. 2012, Panda, Pradhan et al. 2016).

A avaliação do perfil de segurança dos medicamentos na gestação possui algumas limitações. As informações sobre segurança são obtidas principalmente através de ensaios pré-clínicos e estudos observacionais, dificultando a associação entre o uso de medicamentos com os desfechos de interesse. Outra limitação frequentemente relatada na literatura é a dificuldade em avaliar se o desfecho de interesse ocorreu por exposição ao medicamento ou pela presença do sintoma ou doença (Panchaud, Rousson et al. 2018, Bauer, Swan et al. 2021).

O paracetamol foi o medicamento mais utilizado na prática da automedicação e as informações sobre a segurança do uso deste medicamento no período gestacional têm passado por algumas mudanças nos últimos anos (Rebordosa, Kogevinas et al. 2009). Um consenso publicado recentemente reuniu evidências de diferentes estudos sobre os riscos da administração do paracetamol na gestação, recomendando que seu uso seja feito pelo menor tempo possível e na menor dose, por conta de possíveis efeitos como: má formação do sistema reprodutor, autismo, hiperatividade e puberdade precoce (Bauer, Swan et al. 2021).

Além do risco de má formação fetal, a automedicação na gestação pode atrasar o diagnóstico de patologias importantes. A dor de cabeça foi o sintoma mais relatado como motivo da automedicação, sendo semelhante a estudos publicados na literatura (Odalovic, Vezmar Kovacevic et al. 2012, Bohio, Brohi et al. 2016, Cabut, Marie et al. 2017, Alonso-Castro, Ruiz-Padilla et al. 2018, Jambo, Mengistu et al. 2018). Considerando a alta prevalência de fatores de risco associados à pré-eclâmpsia (Poon, Shennan et al. 2019), a automedicação para tratar quadros de cefaleia pode atrasar o diagnóstico e tratamento precoce dos quadros de hipertensivos, colocando em risco a saúde materna e fetal.

Embora tenha apresentado baixa prevalência na população avaliada, o consumo de plantas medicinais e fitoterápicos na gestação é uma prática comum entre mulheres de diferentes países. O tratamento com essas terapias pode apresentar variações entre os períodos gestacionais, sendo frequentemente utilizadas no primeiro e terceiro trimestre gestacional para tratar sintomas como dor de cabeça, náusea e edema (Hall, Griffiths et al. 2011, Al-Ghamdi, Aldossari et al. 2017) e seu consumo é frequentemente indicado por amigos e familiares (de Boer and Cotingting 2014, Al-Ghamdi, Aldossari et al. 2017).

Considerando a prevalência de comorbidades na população avaliada, o uso de plantas medicinais e fitoterápicos sem o devido acompanhamento para manejo dos riscos já conhecidos, pode provocar quadros de interações medicamentosa com os medicamentos utilizados para o tratamento das patologias apresentadas. Apesar de muitos a considerarem uma prática inofensiva, o uso de plantas medicinais na gestação deve ser acompanhando durante o atendimento pré-natal, uma vez que o consumo indiscriminado pode trazer complicações como má formação, sangramentos e trabalho de parto prematuro (Illamola, Amaeze et al. 2020).

O número de gestações prévias foi uma das variáveis associadas com prática da automedicação. Apesar do dado ser semelhante à alguns trabalhos na literatura (Abeje, Admasie et al. 2015, Pons, Knauth et al. 2017, Beyene and Beza 2018) ainda há uma escassez sobre os principais motivos pelo qual isso acontece. Uma das possibilidades é que após a primeira gestação, o comportamento da mulher seja influenciado ainda mais por questões psicossociais e que a experiência prévia com o uso de medicamentos na gestação anterior sirva de encorajamento para a prática da automedicação (Pons, Knauth et al. 2017).

Para estudos futuros, uma alternativa para explorar os fatores relacionados à automedicação é conduzir estudos de múltiplas abordagens, principalmente através da metodologia qualitativa (Van der Geest and Hardon 1988). Considerando que o uso de medicamentos sem prescrição também foi relacionado com o perfil sociodemográfico, é necessário que estudos semelhantes sejam conduzidos em diferentes tipos de serviço para avaliar a prevalência destes fatores e o comportamento de outras variáveis. Para melhor desenvolvimento das estratégias de prevenção e educação da população, recomenda-se também avaliar as principais fontes de informação utilizadas em relação ao uso de medicamentos sem prescrição.

A discussão sobre a classificação de risco dos medicamentos utilizados durante a gestação vem se tornando cada vez mais ampla. Com a mudança da classificação de risco da FDA, a indicação de medicamentos para gestantes tem levado em consideração o risco e benefício de exposição ao tratamento e possíveis consequências caso determinada doença ou sintoma não seja tratada (FDA 2019, FDA 2020).

Considerando o conceito do uso racional de medicamentos, em que a medicação deve atender às necessidades individuais do paciente (WHO 2002) estima-se que será cada vez menos frequente a criação de classificações universais e que será cada vez mais necessário a participação da equipe multidisciplinar no cuidado ao paciente, o que deve ser encarado como uma ótima oportunidade para o profissional farmacêutico.

Diferentes estudos mostraram que a participação do farmacêutico na equipe de saúde contribui na segurança do paciente, principalmente por reduzir erros de prescrição e por aumentar a adesão ao tratamento (Moriel, Carnevale et al. 2011, Ferracini, Rodrigues et al. 2017). Além dos benefícios mensurados, o farmacêutico tem se tornado cada vez mais essencial na equipe de saúde e sua atuação vem sendo reconhecida por diferentes profissionais e especialidades, incluindo a ginecologia e obstetrícia (Forinash, Chamness et al. 2016). Para que isso possa continuar acontecendo, é importante que o profissional farmacêutico busque capacitação para prestar os serviços previstos, garantindo ainda mais um acesso seguro aos serviços de saúde.

O trabalho realizado apresenta algumas limitações. Por conta da possibilidade de viés, a população de estudantes e profissionais da saúde foi excluída da revisão de literatura, não sendo possível comparar a prática da automedicação entre essas populações. Os resultados

apresentados na revisão de literatura tiveram como base o número absoluto da prevalência da automedicação e para análises mais abrangentes, é necessário empregar diferentes metodologias estatísticas.

Em relação ao estudo transversal, a prevalência da automedicação na gestação foi avaliada de forma qualitativa, sem mensurar o número de doses utilizadas para cada um dos medicamentos mencionados. Considerando que o risco de má formação fetal está associado a fatores como frequência de exposição ao medicamento, não foi possível estimar as possíveis consequências ao feto. Sendo assim, novas pesquisas são necessárias para avaliar a relação da frequência da automedicação com outras variáveis e risco de má formação fetal.

O trabalho apresentado possibilitou a compreensão do cenário atual da automedicação na gestação e em outras fases da vida, bem como observar seus pontos em comum. As variáveis associadas à prática da automedicação podem auxiliar na elaboração da estratégia de prevenção da automedicação na gestação, bem como diferentes ideias para a exploração sobre o tema.

5 CONCLUSÕES

A prática da automedicação durante a gestação é frequente em diferentes países, inclusive no Brasil. Os medicamentos utilizados sem prescrição e os sintomas tratados através da automedicação são semelhantes entre os estudos disponíveis na literatura e são comparáveis aos utilizados pela população geral. Os fatores motivacionais relacionados à automedicação na gestação estão ligados ao perfil sociodemográfico e às questões maternas, como trimestre gestacional e número de gestações prévias. Avaliar os fatores relacionados à prática da automedicação na gestação é fundamental para elaborar as estratégias de prevenção adequadas, garantido uma gestação segura e saudável.

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7 ANEXOS

7.1 Parecer do Comitê de Ética em Pesquisa (CEP)



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação da prática da automedicação e acompanhamento farmacoterapêutico na gestação.

Pesquisador: Priscila Gava Mazzola

Área Temática:

Versão: 2

CAAE: 04012118.7.0000.5404

Instituição Proponente: Hospital da Mulher Prof. Dr. José Aristodemo Pinotti - CAISM

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.146.397

Apresentação do Projeto:

A Organização Mundial de Saúde (OMS) define a automedicação como "seleção e uso de medicamentos (incluindo plantas medicinais) por indivíduos para tratar doenças ou sintomas autoconhecidos" (WHO, 1998) e sua prática pode trazer sérios problemas à saúde, como reações alérgicas, intoxicação e principalmente retardo no diagnóstico e cura de uma patologia importante (Castro, Santos et al. 2013) e sua prática é motivada por fatores como baixa qualidade do sistema de saúde, indicação de familiares e amigos e fatores socioeconômicos como baixa escolaridade (Ebrahimi, Atashsokhan et al. 2017). De acordo com Abasiubong et al. (2012), gestantes de países em desenvolvimento possuem maior probabilidade de praticar a automedicação durante a gestação. Um estudo realizado por Ebrahimi et al. (2017) no Irã comparou a prevalência da automedicação entre 384 mulheres antes e durante a gestação, sendo 63,9% e 43,5%, respectivamente. Embora a automedicação tenha sido menor durante a gestação, o resultado é significativo e mostra a necessidade da realização de medidas educativas como forma de prevenção à automedicação. Por conta das alterações fisiológicas e bioquímicas que acometem as gestantes, quase todas as mulheres estão sujeitas a utilizar algum tipo de medicamento durante a gravidez e amamentação seja por prescrição ou automedicação. Porém, poucos medicamentos são testados quanto à eficácia e segurança nesta população devido a questões éticas, fazendo com que muitos medicamentos sejam aprovados sem informação sobre seu potencial teratogênico (Wannmacher).

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2010). A classificação mais utilizada em relação ao uso de medicamentos durante a gestação é a elaborada pela Food and Drug Administration (FDA) que categoriza os riscos associados de acordo com a indução de defeitos congênitos no feto com base em dados científicos, sendo dividido em 5 categorias: A, B, C, D e X, onde A, através de estudos em animais não representa risco ao feto e X, sendo contraindicado na gestação por estar relacionado a anomalias fetais (Wannmacher 2010, Hilal-Dandan and Brunton 2015).

Durante a pesquisa, espera-se encontrar gestantes em uso de suplementos de acordo com o recomendado pela OMS, sendo os principais suplementos o ácido fólico (AF) e sulfato ferroso (SF) (WHO 2016). Em relação a outros tipos de medicamentos utilizados pelas gestantes, os mesmos serão abordados durante a escrita do trabalho, uma vez que a abordagem depende dos casos incluídos na pesquisa.

O acompanhamento farmacoterapêutico está entre os componentes da atenção farmacêutica e pode ser definido como "um processo no qual o farmacêutico se responsabiliza pelas necessidades do usuário relacionadas ao medicamento, por meio da detecção, prevenção e resolução de Problemas Relacionados a Medicamentos (PRM)" cujo objetivo é alcançar resultados definitivos como cura, controle ou retardo de uma enfermidade (Bisson 2007).

São sete os PRMs e podem ser divididos em quatro categorias: necessidade (terapia medicamentosa desnecessária e necessidade de terapia adicional), efetividade (medicamento ineficaz e baixa dosagem), segurança (reação adversa ao medicamento e alta dosagem) e adesão (falta de adesão a terapia medicamentosa) e interferem no sucesso da terapia contribuindo com o aparecimento de morbidades e aumento da mortalidade relacionada a medicamentos (Cipolle, Strand et al. 2006, Rovers and Currie 2010). O ciclo da atenção farmacêutica consiste em identificar o problema do paciente para então estabelecer e criar um plano de tratamento seguido pelo monitoramento e acompanhamento dos resultados tendo como principal objetivo a identificação e resolução de PRM como fator de proteção ao paciente (Cipolle, Strand et al. 2006, Rovers and Currie 2010, Correr, Otuki et al. 2011). Até o momento não foram encontrados estudos publicados em relação ao acompanhamento farmacoterapêutico na gestação. Porém estudos realizados com outras populações (hipertensos, pacientes HIV positivo, diabéticos, idosos etc) mostram resultados satisfatórios alcançados através da prática da atenção farmacêutica (Souza, Yugar-Toledo et al. 2007, Moriel, Carnevale et al. 2011). São bons os resultados alcançados com a prática do cuidado farmacêutico e seu benefício deve ser estendido a toda população, incluindo as gestantes, que estão sujeitas a ações desconhecidas de alguns medicamentos.

De modo geral, o crescimento do mercado de medicamentos que não necessitam de prescrição e a

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• Avaliar o grau de conhecimento das gestantes em relação ao uso de medicamentos no início e no final do acompanhamento.

Avaliação dos Riscos e Benefícios:

De acordo com as pesquisadoras, a pesquisa não modifica a conduta médica indicada pelo protocolo do serviço para seu caso e não apresenta riscos potenciais, individuais ou coletivos, oferecendo o máximo de benefícios e o mínimo de riscos. Em relação aos benefícios, os resultados obtidos através da aplicação dos questionários da avaliação da automedicação, adesão ao tratamento e conhecimento sobre a terapia medicamentosa irá permitir que o pesquisador responsável preste orientações às gestantes atendidas, melhorando os resultados do tratamento realizado. Os resultados também servirão de apoio para a realização de medidas educativas contínuas em relação ao uso seguro de medicamentos, não só na gestação como em todas as fases da vida.

Comentários e Considerações sobre a Pesquisa:

Este protocolo se refere aos Projeto de Pesquisa intitulado "Avaliação da prática da automedicação e acompanhamento farmacoterapêutico na gestação", cuja Pesquisadora Responsável é a Profa. Dra. Priscila Gava Mazzola, docente da Faculdade de Ciências Farmacêuticas da UNICAMP, orientadora do projeto de Mestrado da aluna Gabriela Pereira, e a co-orientação está sob responsabilidade da Profª. Drª Fernanda Garanhani de Castro Surita do Departamento de Tocoginecologia da FCM/UNICAMP. A Instituição Proponente do estudo é o Ambulatório do Pré-natal do Hospital da Mulher "Prof. Dr. José Aristodemo Pinotti – CAISM-UNICAMP.

Esta pesquisa será conduzida em dois modelos distintos de estudo. Para a avaliação da automedicação será realizado um estudo observacional transversal. As gestantes que preencherem os critérios de inclusão para o acompanhamento farmacoterapêutico serão incluídas numa segunda etapa da pesquisa, que será realizada através de um estudo observacional coorte. O estudo será realizado nos ambulatórios de pré-natal do hospital Prof. Dr. José de Aristodemo Pinotti – Centro de Atenção Integral à Saúde da Mulher – CAISM / UNICAMP. A amostra será composta por amostra de n=382 gestantes, considerada representativa para estimar a prevalência de automedicação. Para o cálculo do tamanho amostral para estimar a prevalência de adesão farmacoterapêutica em gestantes (um dos objetivos dentro do acompanhamento farmacoterapêutico), estimou-se que uma amostra de n=163 gestantes, totalizando 545 participantes. Dados como altura, peso, IMC, prescrição médica atual e futuros atendimentos serão coletados através do prontuário eletrônico

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Continuação do Parecer: 3.146.397

de cada participante. Dados sociodemográficos, como grau de escolaridade e renda mensal familiar serão obtidos através da participante, no momento de inclusão no estudo.

As pesquisadoras esclarecem que inicialmente, toda gestante incluída no acompanhamento farmacoterapêutico terá passado pela avaliação da automedicação. Logo, o número TOTAL de indivíduos a serem abordados será no máximo 382. Com a divisão dos grupos, o sistema não aceitou o número 382 como referente a abordagem total possivelmente por entender que o grupo de acompanhamento farmacoterapêutico seria composto por outras participantes que não foram abordadas na etapa anterior, somando um total de 545, inserido no campo solicitado. Porém, o NÚMERO REAL DE PARTICIPANTES A SEREM ABORDADAS SERÁ DE 382 MULHERES.

Para a coleta dos dados, serão utilizados diversos instrumentos, conforme descrito:

a) o acompanhamento farmacoterapêutico das gestantes será realizado de acordo com o método Pharmacist Workup Drug Therapy (PWDT) de acompanhamento farmacoterapêutico (Strand, Cipolle et al. 1988). Todos os medicamentos utilizados pelas gestantes (prescritos ou não) serão classificados de acordo com a classificação Anatomic Therapeutic Chemical Code (ATC), que classifica os medicamentos utilizados de acordo com o órgão e sistema que atuam (WHOC 2012). No acompanhamento farmacoterapêutico os medicamentos prescritos, serão analisados quanto a presença de erros de prescrição através da classificação da National Coordinating Council for Medication Error and Reporting (NCCMERP 2001). Será considerado para o acompanhamento farmacoterapêutico qualquer medicamento prescrito de uso contínuo, incluindo suplementação para fins de profilaxia ou tratamento. A prescrição será analisada em relação à presença de problemas relacionados a medicamentos seguindo a classificação de Cipolle et al. (2006) e as intervenções farmacêuticas serão realizadas junto à equipe médica e às gestantes, de acordo com a classificação de Leape et al. (1999).

b) As interações medicamentosas serão avaliadas através da base de dados Micromedex®, onde será adicionado (em inglês) o nome de cada medicamento que compõe a prescrição médica. As interações aparecem classificadas por ordem de gravidade (contraindicada, importante, moderada e secundária) em conjunto com seu provável mecanismo, condutas a serem realizadas e referências bibliográficas. É possível verificar interações medicamento-medicamento, medicamento-alimento, medicamento-exames, medicamento-gravidez e medicamento-lactação (Micromedex 2011).

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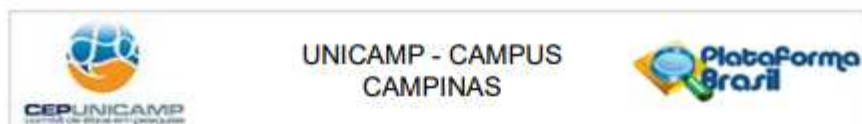
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c)- Teste para avaliação da automedicação: Não há instrumento validado para o português para a avaliação da automedicação. A mesma será realizada baseada em métodos descritos na literatura e irá conter duas perguntas adicionais que irão auxiliar na participação da segunda etapa do estudo. O questionário avalia a automedicação nos últimos 7, 30 e 60 dias e contém as seguintes perguntas: nome do medicamento e concentração, dose, duração do tratamento, propósito, eficácia, indicação (familiar, amigos, vizinhos etc.) e fatores motivacionais (falta de acesso ao serviço de saúde, praticidade, considera um problema de saúde simples e outros) e reaparecimento da queixa após o tratamento. O questionário será aplicado na primeira etapa do estudo e durante o acompanhamento farmacoterapêutico (neste caso, será utilizada uma versão adaptada do questionário inicial, incluindo apenas a automedicação realizada no intervalo das visitas de acompanhamento (30 dias +/- 10). (Souza 2016).

d)- Folha para coleta de dados gerais: Será preenchida na data de inclusão da gestante para avaliação da automedicação. Nela irá conter nome da paciente, número de matrícula interna do hospital, número de controle no estudo, data da inclusão, idade, peso (kg), altura (cm), IMC e classificação, estado civil, procedência, cor, escolaridade (analfabeta, ensino fundamental incompleto ou cursando, ensino médio incompleto ou cursando e ensino superior, incompleto, cursando ou concluído), profissão, renda familiar em salário mínimo (SM). A ficha também irá incluir dados da gestação e história de parto da gestante (idade gestacional, número de fetos, número de gestações, partos, cesárea e aborto) e filhos vivos. A utilização de método contraceptivo antes da gestação também será avaliada. Caso a resposta seja positiva para "em uso de método contraceptivo antes da gestação?" "Será questionado qual método e há quanto tempo era utilizado (menos de 6 meses, mais de 6 meses, 1 ano, de 1 a 2 anos e mais de 2 anos). Será questionado se a gestação foi planejada, se a gestante sabe o que é planejamento familiar e se já participou de algum programa. Por último, os hábitos das gestantes serão avaliados, como prática de atividade física (qual atividade e frequência em minutos por semana), uso de substância ilícitas, uso de álcool (qual frequência), uso de cigarro (quantidade de maços por dia) e ingestão de café.

e)- Ficha de consulta farmacêutica: O modelo utilizado será baseado na literatura e será preenchido na data de inclusão da gestante para o acompanhamento farmacoterapêutico (anexo V). Objetiva avaliar a história médica da gestante, comorbidades, uso de medicamentos prescritos, presença e resolução de PRM (Rovers and Currie 2010).

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f)- Avaliação da adesão ao tratamento: Será realizada pelo método Morisky, Green e Levine (MGL) (anexo VI) padrão ouro na avaliação da adesão ao tratamento. O questionário será aplicado durante as 3 visitas de acompanhamento farmacoterapêutico, para cada medicamento prescrito em uso e é composto por quatro perguntas: "você, alguma vez, esqueceu de tomar o seu remédio?" (sim = 0 ponto e não = 1 ponto), "você, as vezes, é descuidado quanto ao horário de tomar o seu remédio?" (sim = 0 ponto e não = 1 ponto), "quando você se sente bem, algumas vezes, você deixa de tomar seu remédio?" (sim = 0 ponto e não = 1 ponto), "quando você se sente mal, as vezes, você deixa de toma-lo?" (sim = 0 ponto e não = 1 ponto). A soma dos pontos vai de 0 a 4, sendo baixa e alta adesão respectivamente (Morisky, Green et al. 1986).

g)- Avaliação do grau de conhecimento da farmacoterapia: O questionário "MedTake Test" original é na língua inglesa, não estando disponível para o português. Para a validação do questionário, será utilizado a referência proposta por Beaton et al. (2007), que inclui as etapas de tradução para a língua portuguesa, síntese das traduções, retrotradução para a língua original (inglês), síntese da retrotradução, avaliação por uma comissão de juízes, pré-teste (que será realizado durante o estudo piloto) e documentos para os autores do questionário original para avaliação. O questionário é composto por quatro questões (dose da medicação, indicação para tomar o medicamento, ingestão do medicamento com água ou alimentos e regime de medicamentos e horários) que visam avaliar o grau de conhecimento do paciente em relação a terapia medicamentosa. As respostas são classificadas como: totalmente incorreto (0 pontos), maior parte incorreto (+5 pontos), um pouco incorreto (+10 pontos), um pouco correto (+15 pontos), maior parte correto (+20 pontos) e totalmente correto (+25 pontos). A soma dos scores vai de 0 a 100 (0= nenhum conhecimento sobre a farmacoterapia e 100= conhecimento total da farmacoterapia) e o questionário é aplicado para cada medicamento utilizado durante as três visitas de acompanhamento farmacoterapêutico (Raehl, Bond et al. 2002, Souza 2016).

h)- Material educativo: Para a educação das gestantes em relação a automedicação na gestação será utilizado um folheto informativo, que está em fase de elaboração. O modelo se encontra no anexo VIII e está sujeito a alterações de cor, fonte, imagens e informações.

Os documentos apresentados não informam detalhadamente qual será o tempo destinado para aplicação de cada instrumento, possibilitando a participante estimar o tempo que será dedicado à

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sua participação na pesquisa. Há menção no documento "Projeto" acerca da realização de um estudo piloto para a testagem dos instrumentos, possibilitando realizar alterações de acordo com as necessidades observadas durante os atendimentos. Para a análise, os dados serão preenchidos no papel e serão tabulados posteriormente para planilhas específicas no Microsoft Office Excel. Os dados serão analisados através do pacote estatístico R para microcomputadores (Kirby et al., 2013). O nível de significância assumido, após devidas correções, será de 5% ($p < 0,05$ e intervalos de confiança de 95%). As principais análises a serem realizadas serão: média, mediana, desvio padrão, teste de KR 20 (para avaliação da homogeneidade necessária na validação do questionário MedTake Test) e teste de Qui-quadrado.

De acordo com o documento "informações Básicas do Projeto", o financiamento da pesquisa será realizado pelas próprias pesquisadoras, perfazendo um total de R\$ 300,00 (trezentos reais). O cronograma apresentado apenas apresenta as etapas iniciais do estudo em março de 2019 e a previsão de concluir a pesquisa em março de 2021.

Considerações sobre os Termos de apresentação obrigatória:

Foram analisados os seguintes documentos de apresentação obrigatória abaixo listados.

Conclusões ou Pendências e Lista de Inadequações:

Após a análise dos documentos apresentados verificou-se que todas as pendências foram equacionadas e o protocolo de pesquisa pode ser considerado APROVADO.

Considerações Finais a critério do CEP:

- O participante da pesquisa deve receber uma via do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado (quando aplicável).
- O participante da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (quando aplicável).
- O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado. Se o

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pesquisador considerar a descontinuação do estudo, esta deve ser justificada e somente ser realizada após análise das razões da descontinuidade pelo CEP que o aprovou. O pesquisador deve aguardar o parecer do CEP quanto à descontinuação, exceto quando perceber risco ou dano não previsto ao participante ou quando constatar a superioridade de uma estratégia diagnóstica ou terapêutica oferecida a um dos grupos da pesquisa, isto é, somente em caso de necessidade de ação imediata com intuito de proteger os participantes.

- O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo. É papel do pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.

- Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas e aguardando a aprovação do CEP para continuidade da pesquisa. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprovatório do CEP, para serem juntadas ao protocolo inicial.

- Relatórios parciais e final devem ser apresentados ao CEP, inicialmente seis meses após a data deste parecer de aprovação e ao término do estudo.

- Lembramos que segundo a Resolução 466/2012, Item XI.2 letra e, "cabe ao pesquisador apresentar dados solicitados pelo CEP ou pela CONEP a qualquer momento".

- O pesquisador deve manter os dados da pesquisa em arquivo, físico ou digital, sob sua guarda e responsabilidade, por um período de 5 anos após o término da pesquisa.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1266369.pdf	23/01/2019 15:59:36		Aceito

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Recurso Anexado pelo Pesquisador	Carta_resposta_CEP.pdf	23/01/2019 15:57:04	Priscila Gava Mazzola	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Mestrado_Gabriela_Pereira.pdf	23/01/2019 15:54:36	Priscila Gava Mazzola	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Gabriela_Pereira.pdf	23/01/2019 15:51:21	Priscila Gava Mazzola	Aceito
Outros	parecer_circunstanciado.pdf	04/12/2018 16:36:20	Priscila Gava Mazzola	Aceito
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8 MATERIAL SUPPLEMENTAR

Material supplementar 1. Self-medication (SM) practice among the General Population Group (GPG).

Author, Year, Country	Sample size	Study aims	Exposure period	SM Prevalence n (%)	Medications used n (%)	Related Symptoms n (%)	Comments and general Conclusion
Afridi MI et al, 2015; Pakistan (Afridi <i>et al.</i> , 2015)	500 participants, both genders ,18 years or more	Understand the phenomena of SM in local contest in terms of frequency, pattern and gender	Information was not clear	- (84.8)	Painkillers - (28.6), antipyretic (20), cough syrups (14.0), anti-allergy (5.8) and others (32.2), including homeopathy, HM and MP	Headache and pain - (-), sore throat/ cough, fever, skin and hair problems, diarrhea, allergy and others	SM is highly prevalent (84.8%). The main reasons for its use were headache and fever
Akram A et al, 2019; Pakistan (Akram <i>et al.</i> , 2019)	786 participants, 18 to 50 years	Study the reasons of SM in rural and urban population	At the moment of the study	746 (95)	Analgesics 629 (84.3), antipyretics 539 (72.3), antibiotics 363 (48.7) vitamin 250 (33.5) expectorants 215 (28.8) others 227 (30.4)	Headache 644 (86.3), fever 598 (80.2), flu 432 (57.9), body ache 432 (57.9), allergy 254 (34.0) and others 290 (38.9)	The practice was found to be very high in both urban and rural people
Alghanim SA, 2011; Saudi Arabia (Alghanim, 2011)	500 participants, 18 to 65 years	Mainly: to determine the prevalence of SM and identify factors associated	Last 2 weeks	177 (35.4)	-	-	Considerable rate of SM. The findings will encourage studies of the role of SM in health
Alzahrani M et al, 2015; Saudi Arabia (Alzahrani <i>et al.</i> , 2015)	380 participants, 18 to 83 years	Determine the frequency of using non-prescribed medication	At the moment of the study	363 (93.1)	Antibiotics - (-), painkillers and antipyretics	Fever - (-), pain and headache	High use of SM. Men used non-prescribed medications more than did women
Amaha MH et al, 2019; Ethiopia (Amaha <i>et al.</i> , 2019)	547 participants, 18 to > 45 years	Determine the magnitude and factors associated with SM practice	Information was not clear	205 (37.5)	Antibiotics 84 (41.0), analgesics 56 (27.3), ant-helments 28 (13.7), antacids 25 (12.2)	Gastrointestinal disease 60 (29.3), fever 40 (19.5), eye and skin infection 27 (31.2), UTI 25 (12.2) and others 20	More than one thirds of the participants practiced SM. High income was one of factors associated
Annadurai K et al, 2017;	335 participants, adults, 18 to >66	Evaluating SM practice and its	Last 6 months	179 (53.4) Allopathy: -	Paracetamol 152(84.91%) pain killer 88(49.16%) cough	Fever 100 (55.8), headache 86 (48.0),	High prevalence of SM. Only half of the study

India (Annadurai <i>et al.</i> , 2017)	years	determinants among rural population		(99.4) Homeopathy: (0.5)	syrup 65(36.31%) antacids 35(19.55%) and others 68 (37.9)	musculoskeletal pain 76 (42.4), cough 65 (36.3) and others 118 (65.8)	population opined that it was harmful
Barrenberg E <i>et al.</i> , 2018; Germany (Barrenberg <i>et al.</i> , 2018)	7091 participants, 18 to 79 years	Estimate the OTC drug use among adults and to identify factors related	Last 7 days	- (40.2)	-	-	High prevalence of OTC drug use. Female gender, and poor health status were factors related to OTC drug use
Bhambhani G <i>et al.</i> , 2015; India (Bhambhani <i>et al.</i> , 2015)	300 participants, older than 18 years	Assess SM practice related awareness for correct usage and association with demographic factors	Last 6 months	- (37.8)	Acetaminophen - (-)	Cough and cold - (33), fever (35), body ache (28) and others (6.5)	SM practice was common. Knowledge about appropriate usage of medication is inadequate
Chang J <i>et al.</i> , 2017; China (Chang <i>et al.</i> , 2017)	23699 participants, 45 to >70 years	Evaluate SM with OTC and POM	Last 4 weeks	OTC: - (32.6) POMs: (15.0)	-	-	SM was prevalent. Lower income tended to rely more on SM with POMs
Chatziathanas iou D <i>et al.</i> , 2017; Greece (Chatziathanas iou <i>et al.</i> , 2017)	138 participants, elderly older than 65 years, both gender	Evaluate whether beliefs about OTC drugs correlate with the intention of the person to SM or not	Information was not clear	Purchasing frequency: Not often (31.6), quite often (31.6), often (22.7), very often (14.1)	Analgesics - (44.0), OTC for myalgia (5.0), dermatological (14.0), OTC for flu and cold (24.0), missing (7.0), ophthalmic (6.0).	-	SM with OTC is more likely when necessity regarding their use outweigh the concerns arising from their use
Dawood OT <i>et al.</i> , 2017; Malaysia (Dawood <i>et al.</i> , 2017)	888 participants, from 18 to >64 years	Mainly: Evaluate the first action for seeking medical assistance and assess the prevalence of SM	General / in the last 3 months	480 (54.1) General Once: 429 (-), twice: 161, 3 times or more: 132 Last 3 months	-	-	SM was quite significant. Health professionals should work to increase the awareness of the negative effects of SM
de Oliveira MA <i>et al.</i> , 2012; Brazil (De Oliveira <i>et al.</i> , 2012)	1515 participants, elderly, 60 years and more	Evaluate the prevalence, factors associated and the main drugs consumed in SM by elderly	Last 3 days	106 (8.9)	Metamizole - (25.7), ASA (15.9), diclofenac (13.0), acetaminophen (8.8) and others: (7.8). Homeopathy: (6.0), HM: (13.0)	-	Low prevalence of SM. Metamizole, ASA, diclofenac, Ginkgo biloba and paracetamol were the most used in SM
de Oliveira SBV <i>et al.</i> ,	170 participants, elderly, older than	Determine the profile of drugs used by the	At the moment of study	137 (80.6)	Musculoskeletal system 96 (36.1), nervous system 94	-	The practice of SM was frequent. Central action

2018; Brazil (Oliveira <i>et al.</i> , 2018)	60 years	elderly population for SM			(35.3), digestive tract and metabolism 34 (12.8) and others 50 (14.6)		muscle relaxant and analgesics were the most drugs used
Domingues PHF <i>et al.</i> , 2017; Brazil (Domingues <i>et al.</i> , 2017)	1820 participants, 18 to 65 years	Estimate the prevalence and associated factors of adult SM	Last 7 days	271 (14.9)	Nervous system 68 (46.9), digestive system and metabolism 21 (14.5), cardiovascular system 16 (11.0) and others 40 (27.6)	-	Low prevalence of SM. Young adults and people with problem to do daily activities are more probably to practice SM
El-Nimr NA <i>et al.</i> , 2015; Egypt (El-Nimr <i>et al.</i> , 2015)	1100 participants, 18 to 85 years	Estimate the prevalence of SM with drugs and CAMs and describe the medication use	Information was not clear	950 (86.4) Allopathy and CAM: (77.0) Allopathy: (18.1) CAM: (4.4)	Analgesics - (96.7), cough and cold (81.9), vitamins (63.2), antibiotics (53.9), GI drugs (51.4), and others (36.7)	Allopathy: GI problems - (95.9), headache/body aches (89.5), flu/ cold and cough (86.6) and others (23.9)	Large proportion of adults use drugs and CAM for SM. There is a need for education of the public regarding SM
Eticha T <i>et al.</i> , 2014; Ethiopia (Eticha e Mesfin, 2014)	270 participants, <25 to >35 years	Evaluate the practices of SM and to identify factors associated	At the moment of study	270 (100)	Analgesics/antipyretics - (20.8), GI drugs (17.5), respiratory drugs (14.9), ORS (14.2), vitamins (11.1) and others (13)	Headache and fever - (20.7), GI disease (17.3), respiratory tract infection (15.9) and others (46.0)	Non-seriousness of the illness, prior experience and less expensive were cited to be the major reasons for SM
Foroutan B <i>et al.</i> , 2014; Iran (Foroutan e Foroutan, 2014)	500 participants, 20 to >50 years	Investigate the frequency and determinants of SM	Last 3 months	268 (53.6)	Analgesics 159 (59.3), cold remedies 31 (11.6), antibiotics 26 (9.7) and others 27 (10.1). HM: 25 (9.3)	-	High prevalence of SM was also noted, especially those who were less well educated
Garofalo L <i>et al.</i> , 2015; Italy (Garofalo <i>et al.</i> , 2015)	672 participants, <40 to >49	Assess the prevalence SM and to investigate the determinants and reasons associated	Last year	334 (71.8)	NSAIDS - (83.5), antibiotics (26.7), antacids (4.2), and corticosteroids (3.4)	-	SM was high within this community, mainly in female, younger, and more educated groups
Gazibara T <i>et al.</i> , 2013; Serbia (Gazibara <i>et al.</i> , 2013)	354 participants, older than 65 years	Assess the prevalence and factors associated with OTC drug use in elderly	Last month	202 (57.0)	Analgesics - (41.1), vitamins (35), oligoelements (17.8), antiagregation drugs (15.3) and others (26.8). HM (6.0)	-	Multiple chronic conditions are correlated with multiple OTC drug use
Gonzalez-López JR <i>et al.</i> , 2012;	190 participants, adults, 25 to 44 years	Estimate the prevalence of drug consumption without	Last 6 months	147 (77.4)	Anti-inflammatories (58.8), analgesics (54.1) and antibiotics (21.6). MP (47.3)	-	High consumption of nonprescription pharmaceuticals

Spain (González-López <i>et al.</i> , 2012)		medical prescription					
Ha TV et al 2019; Papua New Guinea (Ha <i>et al.</i> , 2019)	1000 participants, 18 to >60 years	Describe the prevalence of SM and determine factors associated	Last 12 months	833 (83.3)	-	-	High prevalence of SM. Gender, ethnicity and employment were factors associated
Hassali MA et al, 2011; Malaysia (Hassali <i>et al.</i> , 2011)	314 participants, 21 to >60 years	Assess the prevalence of and to identify characteristics associated	Last week	197 (62.7) HM or supplements: 87 (27.7)	Cough and cold preparations 210 (66.9), pain medication 183 (57.6), diarrhea 138 (43.9), allergy and/or rashes 111 (35.4), constipation 105 (33.4) others 163 (52.0)	-	SM was prevalent at various socio-demographic levels. There was a lack of awareness about the interaction of medications
Heidari, M. et al, 2018; Iran (Heidari <i>et al.</i> , 2018)	300 participants, elderly, 60 to >80 years	Evaluate the awareness, attitude and practice toward SM	At the moment of study	228 (76.0)	-	Musculoskeletal 51 (16.0), headache 48 (17.0), GI 43 (14.3), joint disease 41 (13.6 and others 117 (38.8)	SM rate was high among the elderly. Therefore, more attention should be paid to medical education
Jafari F et al, 2015; Iran (Jafari <i>et al.</i> , 2015)	272 participants, older 60 years	Investigate SM practice and its related factors among elderly	Last 3 months	225 (83.0)	Analgesics - (92.0), cold tablets (74.0), and vitamins (61.0)	-	High prevalence of SM. Women were significantly more likely to practice SM
Jember E et al, 2019; Ethiopia (Jember <i>et al.</i> , 2019)	632 participants, <30 to >45 years	Assess SM practices and associated factors among households	Last 6 months	317 (50.2)	-	Headache 200 (63.1), GI infection 122 (38.5), cold and flu 98 (30.9), fever 79 (18.9) and others 98 (30.9)	SM among who had access to pharmacy were higher compared with who had no access
Kamran A et al, 2015; Iran (Kamran <i>et al.</i> , 2015)	924 participants, older than 18 years	Investigate the relationship between health literacy and SM	Last 3 months	- (61.6)	Antibiotics - (40.0), sedatives (54.4) and HM (59.1)	-	SM had a high prevalence and significant relationship with health literacy and health status
Kassie AD et al, 2018; Ethiopia	722 participants, 18 to >55 years	Assess the prevalence of SM practice and associated factors	Last one month	259 (35.9)	-	Headache/ fever 217 (30.1), respiratory infections 122 (16.8),	SM was common. Being unmarried and presence of medication

(Kassie <i>et al.</i> , 2018)		among adult household				joint pain 78 (10.8) and others 294 (40.6)	at home were predictors to SM
Kazaura MR, 2017; Tanzania (Kazaura, 2017)	474 participants, older than 18 years	Estimate SM with OTC, reasons for use and perceived outcomes after SM	Last 3 months	236 (64.8)	Antipyretics 167 (58.2), analgesics 162 (56.4), antimalarials 118 (41.1), antibiotics 51 (17.8) and others - (31)	Pain 155 (54.0), fever 117 (61.7), cold 90 (31.4), cough 75 (26.1) and others 97 (39.9)	High prevalence of SM associated with sex, education and occupation status
Kim HJ et al, 2018; Korea (Kim <i>et al.</i> , 2018)	345 participants, from <45 to >75 years	Examine the use patterns of OTC and assess patients' perceptions regarding OTC use	Information was not clear	224 (64.9)	Antipyretics, analgesics and anti-inflammatory 150 (43.5), antihistamines 89 (25.8), digestives 62 (18.0), expectorants 47 (13.6) and others 150 (43.4)	Cold 97 (28.1), dyspepsia 78 (22.6), pain 67 (19.4), heartburn 34 (9.9), fatigue 28 (8.1) and others 71 (20.5)	High prevalence of OTC use. The awareness level DRPs such as ADRs resulting from the use of OTC medications was relatively low
Klemenc-Ketis Z et al, 2011; Slovenia (Klemenc-Ketis e Kersnik, 2011)	410 participants, from 18 to >64 years	Mainly: assess the reasons for SM and the opinions about the safety of SM	Last year	389 (94.9)	-	-	SM was common. Doctors should ask about SM and aware patients about SM
Klemenc-Ketis Z et al, 2017; Slovenia (Klemenc-Ketis e Mitrovic, 2017)	371 participants, older than 18 years	Determine the prevalence of SM and detect factors associated	One year (2013)	300 (80.9)	HM/ MP 299 (80.6), OTC 253 (68.2), vitamins 251 (67.7), POMs 139 (37.5) and homeopathy 30 (8.1)	-	SM was high. Most people reported that SM was safe only with the appropriate information
Lawan UM et al, 2013; Nigeria (Lawan <i>et al.</i> , 2013)	380 participants, from 18 to >63	Determine the pattern, awareness and perceptions of the adult about SM	Last 6 months	300 (78.9)	Antimalarials 136 (42.1), analgesics 131 (40.6), antibiotics 95 (29.4), cough mixtures 43 (13.3) and others 19 (5.9)	-	Despite participants perceived that SM could be hazardous, the prevalence of SM was high
Lei X et al, 2018; China	258 participants, from 18 to >60	Assess SM behavior and its associated	Last 2 weeks	- (45.4)	-	Cold and cough (55.1), cardiovascular (18.2),	45% of the participants would select SM if they

(Lei <i>et al.</i> , 2018)	years	factors				GI (15.7), bruises (5.5) and others (5.5)	felt sick. Regulate OTC is required
Machado-Alba JE et al, 2014; Colombia (Machado-Alba <i>et al.</i> , 2014)	414 participants, older than 18 years	Determine the prevalence of SM and the actors associated	At least once in life / in the previous 30 days	321 (77.5) / 132 (31.9)	30 days: Analgesics, home remedies, anti-inflammatory drugs, antacids and Influenza	Flu 274 (-), headache 242, fever 196, insomnia 189, muscle pain 143, diarrhea 140 and others 246	High rate of SM. As well as the sociocultural and economic factors associated
Mamo S et al, 2018; Ethiopia (Mamo <i>et al.</i> , 2018)	356 participants, from 18 to >34 years	Assess SM practices and perspectives toward role of community pharmacy	At the moment of	356 (100)	Analgesic / antipyretics 156 (42.2) respiratory drugs 115 (31.1) GI drugs 72 (19.5) antimicrobials 11 (3.0) and others 16 (4.3)	Headache 112 (30.3), respiratory disorders 109 (29.5), GI disorders 100 (27.0) and others 49 (13.2)	Experience with drugs, diseases and affordability were frequently reported reasons for SM
Mensah BN et al, 2019; Ghana (Mensah <i>et al.</i> , 2019)	361 participants, from 18 to >55 years	Assess SM among people of a rural setting	Last 3 months	361 (100)	Antibiotics 116 (32.1), analgesics 76 (21), anti-diabetics 75 (20.8), antacids 39 (10.8), antimalarials 36 (10), anti-hypertensives 19 (5.3)	-	Family members, cost-saving, minimal severity of illness, and bureaucracy of health system were factors associated with SM
Motavali ZS et al, 2016; Iran (Motavali <i>et al.</i> , 2016)	350 participants, from 65 to 90 years	Evaluate SM and its effective modifiable factors among the elderly	Last 6 months	- (87.6)	HM - (47.1), analgesics (40.2), antibiotics (29.0), cold tablets (10.0), iron (5.7), tranquilizers (4.8), and vitamins (1.4)	-	High prevalence of SM. There is a need of a training program to change the knowledge of the elderly about SM
Ouédraogo DD, 2015; Africa (Ouédraogo <i>et al.</i> , 2015)	203 participants, from 18 to 75 years	Describe the prevalence of and factors associated with SM in patients from rheumatology	Information was not clear	146 (71.9) General diseases 99 (48.8) Rheumatology symptoms	Acetaminophen 60 (60.6) Ibuprofen 57 (57.5) Diclofenac 54 (54.5) Tramadol 6 (6.0) and others 15 (15.1)	-	SM for rheumatologic were less common. SM were associated with male gender and high education level
Panda A et al, 2016; India (Panda <i>et al.</i> , 2016)	1100 participants, from 20 to >60 years	Describe the nature of DRPs associated with SM and non- SM	At the moment of the study	206 (18.7)	Anti-inflammatory 79 (38.0), antimicrobials 21 (10.0), GI drugs 32 (16.0), cough remedies 28 (14.0) and others 46 (21.5)	Fever 46 (22.3), pain 33 (16.0), GI disorder 32 (15.3), respiratory symptoms 28 (13.5) and others 67 (32.0)	SM is associated with a higher risk of DRPs. Drug information can bring down the DRPs associated with SM
Pons ED et al, 2017; Brazil	31573 participants, older than 20 years	Understand factors that lead to SM and	Last 15 days	- (18.3)	-	-	SM was frequent, more prevalent in women and

(Pons <i>et al.</i> , 2017)		the factors associated with it				people with low self-assessment of health	
Prado MAMB <i>et al.</i> , 2016; Brazil (Prado <i>et al.</i> , 2016)	1063 participants, men, from 20 to >60 years	Identify the main pharmaceuticals consumed through SM and the reason for this use among adult men	Last 3 days	80 (11.2)	Metamizole or combination 80 (29.5), acetaminophen or combination 16 (23.5), ASA or combination 14 (18.2), diclofenac 9 (12.3) and others 21 (16.5)	Cephalea, flu, migraine 20 (29.5), cephalea, flu, migraine, myalgia and cold 16 (23.5) and others 44 (47)	For those who reported SM, a higher chance of use was found to be among those who complained of frequent headaches/migraines
Sánchez J, 2014; USA (Sánchez, 2014)	278 participants, adults, older than 18 years	Assess the prevalence of SM among Latino immigrants and examining SM related behaviors	Last 12 months	- (-)	OTC - (-), prescription drugs and MP	OTC: Allergies - (91.2) respiratory infection (88.6), other infections (77.3), pain (75.2), and others. Prescription: allergies (76.4), antibiotics (66.2) and others	Lack of access to health care system contribute to the high prevalence of SM that can have harmful consequences
Santos TRA <i>et al.</i> , 2013; Brazil (Santos <i>et al.</i> , 2013)	934 participants, from 60 to >80 years	Analyze medicine use patterns in the elderly and socio-economic aspects and self-rated health	Information was not clear	- (35.7)	Painkillers, muscle relaxant 142 (30.8), anti-hypertensives 68 (14.8), HM 36 (7.8) anti-inflammatory 31 (6.7) and others 184 (39.9)	-	SM were within national average and was associated with lower levels of education and worse self-rated health
Secoli SR <i>et al.</i> , 2018; Brazil (Secoli <i>et al.</i> , 2018)	2006: 1413 participants, from >60 years; 2010: 990 participants, from >65. Elderly, both gender	Examine the trends in the practice of SM among the elderly population between 2006 and 2010	At the moment of the study	2006: 525 (42.3) 2010: 172 (18.2)	2006 <i>n</i> (%) / 2010 <i>n</i> (%) Dipyron 54 (16.2) /46 (16.0), multivitamins 29 (8.7) /32 (11.1), diclofenac 21 (6.3) /17 (5.9), dexchlorfeniramine 18 (5.4) /07 (2.4), bisacodyl 16 (4.8) /25 (8.7) and others 93 (27.9) / 69 (24.0)	-	The prevalence of SM decreased from 2006 to 2010, but the use of medicines that offer risks to health was still reported
Schmid B <i>et al.</i> , 2010; Brazil (Schmid <i>et al.</i> , 2010)	2921 participants, from 40 to 95 years	Estimate the prevalence of SM and identify associated factors	Last 15 days	562 (29.9)	-	-	Free access to medicines was shown to be a protective factor for SM
Shafie M <i>et al.</i> , 2018; Ethiopia (Shafie <i>et al.</i> , 2018)	604 participants, from 18 to 84 years	Determine the prevalence and determinants of SM in households	Last 2 months	456 (75.5) Allopathy: - (66.9), MP: (16.0), both (17.1)	Paracetamol 91 (20.0), MP 73 (16.0), diclofenac 45 (9.9), amoxicillin 30 (6.6), metronidazole 20 (4.4), anti-acids 12 (2.6) and others 185	Headache 117 (25.7), abdominal pain 59 (12.9), cough 54 (11.8), diarrhea 43 (9.4), toothache 39 (8.6) and	High prevalence of SM. Mildness of illness, previous knowledge about the drug, and emergencies were

					(40.6)	others 144 (32.0)	reasons for SM practice
Sridhar SB et al, 2018; UAE (Sridhar <i>et al.</i> , 2018)	413 participants from 18 to >65 years	Identify the association of some of the factors with SM practice	Sometimes	215 (52.1)	-	Headache 155 (37.5), fever 119 (28.8), cough/cold 89 (21.5), gastric problem 65 (15.7) and others 161 (38.9)	High prevalence of SM. Younger age group and occupation status (homemaker) were significantly associated with SM
Tesfamariam S et al, 2019; Eritrea (Tesfamariam <i>et al.</i> , 2019)	587 participants, from 18 to 95 years	Assess the practice of SM with OTC drugs, prevalence of risk practice and its associated factors	Information was not clear	- (93.7)	Analgesic - (34.3), antipyretic (15.7), cough (14.2), antacid (10.2), antidiarrhea drugs (9.9) and others (15.7)	-	Educational level, religion, occupation, and knowledge were identified as risk factors for inappropriate OTC use
Vanhaesebrouck A et al, 2018; France (Vanhaesebrouck <i>et al.</i> , 2018)	3023 participants, from 18 to >60 years	Assess the frequency of SM among adults, factors and behaviors associated	Last 4 weeks	1602 (55.3)	-	-	SM is a frequent practice. Some factors were found to be associated with SM such as age or gender
Wijesinghe PR et al, 2012; Sri Lanka (Wijesinghe <i>et al.</i> , 2012)	1709 participants, both genders, from 18 to 89 years	Determine the prevalence of medicines use and predictors of SM	Last 2 weeks	Rural - (35.3), urban (33.9)	-	-	SM at comparatively low rates, exists with an urban-rural differential

SM: Self-medication; OTC: Over-the-counter; - : Missing information; MP: Medicinal Plants; HM: Herbal Medicines; UTI: Urinary Tract Infection; POM: Prescribed Only Medicines; CAM: Complementary Alternative Medicines; GI: Gastrointestinal; ORS: Oral Rehydration Solution; ASA: Acetylsalicylic Acid; DRPs: Drug Related Problems; ADRs: Adverse Drug Reactions; All studies have a cross-sectional design, except Sánchez J and Secoli SR et al.