PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH
A Global Journal of Clinical Research

Study Design

Protective Effect of Surgical Masks *versus* N95 Respirator in Prevention of SARS-CoV-2 Contamination in Healthcare Professionals: Systematic Review Protocol

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Received: 07/07/2021; accepted: 08/04/2022; published: 12/01/2022.

ABSTRACT:

Introduction: Even though more than two years have passed since the beginning of the pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), it does not seem clear if the healthcare professional can choose between the surgical mask and the N95 respirator to avoid being contaminated by SARS-CoV-2. Objective: To assess scientific evidence that compared the protective effect of surgical masks versus N95 respirators in preventing COVID-19 in healthcare professionals.

Methods: Systematic review. The primary outcome will be a comparison between surgical masks versus N95 respirators in preventing COVID-19 in healthcare professionals. The secondary outcome will be comparing the time that the surgical mask and the N95 respirator can be used without the need to change. Clinical trials, prospective and retrospective cohort studies, and case-control studies published between 2020 and 2022 in English, Portuguese, and Spanish will be included. Databases searched will be MedLine via PubMed, Latin American and Caribbean Literature on Health Sciences (LILACS), Cochrane Library, Excerpta Medica dataBASE (Embase), manual search, and gray literature. Studies that do not pertain to the research questions, incomplete articles, abstracts, review articles, editorials, expert opinions, books, academic articles, dissertations, theses, and proceedings of scientific events will be excluded. The risk of bias and methodological quality of the included studies will be analyzed by the Cochrane tool Rob 2 for clinical trials and the Joanna Briggs Institute critical assessment for observational studies. The study protocol was registered with PROSPERO CRD42021216568.

Expected results: Expand existing evidence with greater strength of recommendation.

Keywords: Surgical masks; Respirator N95; SARS-CoV-2; Prevention

Academic Editor: Felipe Fregni
Peer-reviewers: Nicolas Rincon; Mustafa Jaber; Livia Liberata; Julia De Conti.

DOI: http://dx.doi.org/10.21801/ppcrj.2022.83.4

Introduction

Protecting healthcare professionals from contamination with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been a worldwide challenge since the beginning of the pandemic (Suzuki et al., 2021; Wang et al., 2020). Healthcare workers are at high risk of COVID-19 infection due to close contact with infected patients in a relatively closed environment. Knowledge about the transmission of the SARS-CoV-2 virus evolves as new evidence accumulates, but it has already been demonstrated that COVID-19 is primarily a respiratory disease. In this way, SARS-CoV-2 might spread through aerosols from respiratory droplets (Chu et al., 2020).

According to available evidence, SARS-CoV-2 spreads between people, mainly when an infected person is in close contact with another person. The transmissibility of the virus depends on factors such as the amount of viable virus shed by a person (Chu et al., 2020), the type of contact between the infected person and the other, the scenario, and the individual protection measures in place. When the infected person coughs, sneezes, sings, breathes heavily, or talks, the virus can be spread through the mouth or nose in small liquid particles. These liquid particles are of different sizes, ranging from larger 'respiratory droplets' to smaller 'aerosols'. There is consensus that SARS-CoV-2 spreads primarily through large droplets and contact. However, although there is debate about the role of aerosol, if another person is within a short distance (usually within 1 meter), this can result in inhalation or inoculation of the virus through mouth, nose, or eyes (Kirkner, 2020). In this way, the risk of infection is highly dependent on the distance from the infected individual and the type of face mask and eye protection used.

To protect healthcare workers from contamination when working in the care of infected patients, the World Health Organization (WHO) has recommended using medical masks (WHO, 2020). Masks are part of a comprehensive package of prevention and control measures that can limit the spread of certain respiratory viral diseases, including COVID-19 (WHO, 2022). It is also recommended that the maximum period of use of the same mask be for up to 6 uninterrupted hours, without removing them, without storing them for a defined period, without replacing them, and without reuse. There is little evidence about how long the mask can be used. According to the WHO, this depends on manufacturers' specifications, information that is not always available. However, globally, regarding the type of mask and how long the mask can be used, there are still conflicting recommendations. While the Center for Disease Control and Prevention (CDC) and European Center for Disease and Prevention (ECDC) recommend the N95 respirator for Routine care of COVID-19 patients, the WHO and the Public Health Agency of Canada recommend surgical masks (Centers for Disease Control and Prevention, 2020; European Centre for Disease Prevention and Control. An agency of the European Union, 2020).

The optimum use of medical face masks in health-care settings, which have been used for decades for infection prevention, is facing challenges amid personal protective equipment shortages. Despite the recommendation of medical masks by health professionals, issues regarding the cost and the lack of availability in some places, have limited their use. In addition, differences in the infection control protocols of each institution or even low adherence to recommendations by health professionals have caused differences in use. Evidence shows that many health professionals have been and continue to be contaminated by COVID-19, despite the use of medical masks. Some studies have been conducted to analyze the surgical mask and the N95 as a measure of protection from contamination by SARS-cOV-2 in health professionals (Bartoszko et al., 2020; Chu et al., 2020). Despite this, recommendations are still conflicting and epidemiological data are limited. Any recommendations about the use of face masks should be based on the best available evidence.

Therefore, this systematic review protocol aims to synthesize the scientific evidence to answer the following research question: "is the protective effect of surgical masks and the N95 respirator in the prevention of COVID-19 in healthcare professionals the same?"

Materials and Methods

Protocol Registration

The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) under the number CRD42021216568.

Ethical Considerations

There is no conflict of interest in this study.

Study Design and Research Question

This is a systematic review study protocol that followed the methodological recommendations of the Cochrane Collaboration Handbook (Higgins et al., 2022) and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement (Page et al., 2021).

The acronym Population, Intervention or Exposure, comparator, and Outcome (PICO/PECO) was used to describe all components related to the identified problem and to structure the research question: "is the protective effect of surgical masks and the N95 respirator in the prevention of COVID-19 in healthcare professionals the same?" The acronym was defined as P: Health professionals; I/E: surgical masks and/or the N95 respirator; O: prevention of SARS-CoV-2 infection or COVID-19 (**Box 1**).

Eligibility criteria

Box 1. Inclusion criteria

Study Design

- Clinical trials,
- Prospective cohort studies,
- Retrospective cohort studies,
- Case-control observational studies.

Participants (P)

- Health professionals.

Intervention (I) or Exposure (E)

- Surgical masks and/or the N95 respirator

Primary Outcome (O)

- To compare surgical masks and N95 respirators in preventing COVID-19 in healthcare professionals

Secondary Outcome

- Compare how long the surgical mask and N95 respirator can be used before replacement.

Inclusion Criteria

Clinical trials, prospective and retrospective cohorts, and case-control studies, published between 2020 and 2022 in English, Portuguese, and Spanish will be included. We will endeavor to include all studies that meet the inclusion and exclusion criteria, including contacting authors for unavailable studies.

Exclusion Criteria

Studies that do not address the research question, incomplete articles, abstracts, review articles, expert opinion, editorials, books, academic works, dissertations, theses, annals of scientific events, articles not available online, and studies performed on animals.

Outcomes

Primary Outcome

The primary outcome will be a comparison between surgical masks versus N95 respirators in preventing COVID-19 in healthcare professionals.

Secondary Outcome

The secondary outcome will be the comparison between the time that the surgical mask and the N95 respirator can be used without the need to change.

Search Strategy and Information Sources

The search process will be conducted in MedLine databases via PubMed, LILACS, Embase, manual search, gray literature, and Cochrane Library through descriptors and correlates found in the Medical Subject Heading (MeSH) and descriptors in Health Sciences (DeCS): Health Personnel, Allied Health Personnel, Coronavirus Infections, Beta coronavirus, Respiratory Protective Devices, Masks, Personal Protection, Time, Efficacy, Safety. We will also use the non-MeSH term severe acute respiratory syndrome coronavirus 2 to search on PubMed which accepts these terms. Terms will be combined using the Boolean operator "AND" and "OR", according to the search strategy of PubMed, LILACS, Cochrane Library and Embase, according to **Table 1**. Whenever possible, the following filters will be used: Language: English, Portuguese, and Spanish; type of studies: only in humans; and time of publication: from 2020 to 2022.

The flowchart in **Figure 1** presents the details of each research phase according to the PRISMA method.

Identification

The study selection process will be carried out by two health reviewers independently and divided into three phases: Identification, Screening, Eligibility, and Selection. Phase 1 (Identification) will search the database through descriptors and filters. After the identification of studies, duplicates will be removed. Phase 2 (Screening) will select studies after reading the titles and abstracts. If necessary, the study will be read in full to resolve doubts. Phase 3 (Eligibility) will consist of selecting studies after the complete reading of the

PUBMED	((("Health Personnel"[Mesh] OR (Personnel, Health) OR (Health Care Providers) OR (Health Care Provider) OR (Provider, Health Care) OR (Providers, Health Care) OR (Healthcare Providers) OR (Healthcare Provider) OR (Provider, Healthcare) OR (Providers, Healthcare) OR (Healthcare Workers) OR (Healthcare Worker) OR "Allied Health Personnel"[Mesh] OR (Health Personnel, Allied) OR (Personnel, Allied Health) OR (Allied Health Professional) OR (Allied Health Professionals) OR (Health Professional, Allied) OR (Health Professionals, Allied) OR (Professional, Allied Health) OR (Professionals, Allied Health) OR (Healthcare Assistants) OR (Assistant, Healthcare) OR (Assistants, Healthcare) OR (Healthcare Assistant) OR (Healthcare Support Workers) OR (Healthcare Support Worker) OR (Support Worker, Healthcare) OR (Support Workers, Healthcare) OR (Worker, Healthcare Support) OR (Workers, Healthcare Support) OR Paramedics OR Paramedic OR (Paramedical Personnel) OR (Personnel, Paramedical) OR (Population Program Specialists) OR (Population Program Specialist) OR (Program Specialist, Population) OR (Program Specialists, Population) OR (Specialist, Population Program) OR (Specialists, Population Program)) AND ("Coronavirus Infections"[Mesh] OR (Coronavirus Infection) OR (Infection, Coronavirus) OR (Infections, Coronavirus) OR "Betacoronavirus"[Mesh] OR Betacoronaviruses OR "severe acute respiratory syndrome coronavirus 2" [Supplementary Concept] OR 2019-nCoV OR (Wuhan coronavirus) OR SARS-CoV-2 OR (2019 novel coronavirus) OR (COVID-19 virus) OR (coronavirus disease 2019 virus) OR (COVID19 virus) OR (Wuhan seafood market pneumonia virus))) AND ("Respiratory Protective Devices"[Mesh] OR (Device, Respiratory Protective) OR (Devices, Respiratory Protective) OR (Protective Device, Respiratory) OR (Protective Devices, Respiratory) OR (Respiratory Protective Device) OR (Respirators, Industrial) OR (Industrial Respirators) OR (Industrial Respirator) OR (Respirator, Industrial) OR (Gas Masks) OR (Gas Mask) OR (Mask, Gas) OR (Masks, Gas) OR (Respirators, AirPurifying) OR (Air-Purifying Respirator) OR (Air-Purifying Respirators) OR (Respirator, Air-Purifying) OR (Respirators, Air Purifying) OR "Masks"[Mesh] OR Mask)) AND ("Personal Protective Equipment"[Mesh] OR (Equipment, Personal Protective) OR (Protective Equipment, Personal) OR "Time"[Mesh] OR (Longterm Effects) OR (Effects, Longterm) OR (Effect, Longterm) OR (Longterm Effect) OR (Long-Term Effects) OR (Long Term Effects) OR (Effects, Long-Term) OR (Effect, Long-Term) OR (Effects, Long Term) OR (Long-Term Effect) OR "Self Efficacy"[Mesh] OR (Efficacy, Self) OR "Safety"[Mesh] OR Safeties)
LILACS	(MH:"Pessoal de Saúde" OR MH:"HealthPersonnel" OR MH:"Personal de Salud" OR (Prestadores de Cuidados de Saúde) OR (Profissionais da Saúde) OR (Profissionais de Saúde) OR (Profissional da Saúde) OR (Profissional de Saúde) OR (Trabalhador da Saúde) OR (Trabalhador de Saúde) OR (Trabalhadores da Saúde) OR (Trabalhadores de Saúde) OR MH:M01.526.485$ OR MH:N02.360$ OR MH:SH1.030.020.020.010$ OR MH:VS3.004.001$) OR (MH:"Pessoal Técnico de Saúde" OR MH:"Allied Health Personnel" OR MH:"TécnicosMediosenSalud" OR (Auxiliares em Cuidados de Saúde) OR Paramédico OR Paramédicos OR (Pessoal Paramédico) OR (Profissionais Aliados de Saúde) OR (Profissionais de Apoio aos Cuidados de Saúde) OR MH:M01.526.485.067$ OR MH:N02.360.067$ OR MH:SH1.030.020.020.020$) AND (MH:"Infecções por coronavirus" OR MH:"CoronavirusInfections" OR MH:"Infecciones por coronavirus" OR COVID-19 OR (Doença pelo Novo Coronavírus (2019-nCoV)) OR (Doença por Coronavírus 2019-nCoV) OR (Doença por Novo Coronavírus (2019-nCoV)) OR (Epidemia de Pneumonia por Coronavirus de Wuhan) OR (Epidemia de Pneumonia por Coronavírus de Wuhan)

	OR (Epidemia de Pneumonia por Coronavírus de Wuhan de 2019-2020) OR (Epidemia de Pneumonia por Coronavírus em Wuhan) OR (Epidemia de Pneumonia por Coronavírus em Wuhan de 2019-2020) OR (Epidemia de Pneumonia por Novo Coronavírus de 2019-2020) OR (Epidemia pelo Coronavírus de Wuhan) OR (Epidemia pelo Coronavírus em Wuhan) OR (Epidemia pelo Novo Coronavírus (2019-nCoV)) OR (Epidemia pelo Novo Coronavírus 2019) OR (Epidemia por 2019-nCoV) OR (Epidemia por Coronavírus de Wuhan) OR (Epidemia por Coronavírus em Wuhan) OR (Epidemia por Novo Coronavírus (2019-nCoV)) OR (Epidemia por Novo Coronavírus 2019) OR (Febre de Pneumonia por Coronavírus de Wuhan) OR (Infecção pelo Coronavírus 2019-nCoV) OR (Infecção pelo Coronavírus de Wuhan) OR (Infecção por Coronavirus 2019-nCoV) OR (Infecção por Coronavírus 2019- nCoV) OR (Infecção por Coronavírus de Wuhan) OR (Infecções por Coronavírus) OR (Pneumonia do Mercado de Frutos do Mar de Wuhan) OR (Pneumonia no Mercado de Frutos do Mar de Wuhan) OR (Pneumonia por Coronavírus de Wuhan) OR (Pneumonia por Novo Coronavírus de 2019-2020) OR (Surto de Coronavírus de Wuhan) OR (Surto de Pneumonia da China 2019-2020) OR (Surto de Pneumonia na China 2019-2020) OR (Surto pelo Coronavírus 2019-nCoV) OR (Surto pelo Coronavírus de Wuhan) OR (Surto pelo Coronavírus de Wuhan de 2019-2020) OR (Surto pelo Novo Coronavírus (2019-nCoV)) OR 30 (Surto pelo Novo Coronavírus 2019) OR (Surto por 2019-nCoV) OR (Surto por Coronavírus 2019-nCoV) OR (Surto por Coronavírus de Wuhan) OR (Surto por Coronavírus de Wuhan de 2019-2020) OR (Surto por Novo Coronavírus (2019-nCoV)) OR (Surto por Novo Coronavírus 2019) OR MH:C01.925.782.600.550.200$) OR (MH:"Betacoronavírus" OR MH:"Betacoronavirus" OR MH:"Betacoronavirus" OR (2019-nCoV) OR (Coronavirus HKU1 Humano) OR (Coronavirus Humano HKU1) OR (Coronavírus da Síndrome Respiratória Aguda Grave 2) OR (Coronavírus de Wuhan) OR (HCoV-HKU1) OR (Novo Coronavírus (2019-nCoV) OR (Novo coronavírus (2019-nCoV) OR (SARS-CoV-2) OR (Vírus de Pneumonia no Mercado de Frutos do Mar de Wuhan) OR (Wuhan coronavirus) OR MH:B04.820.504.540.150.113$) AND (MH:"Dispositivos de proteção respiratória" OR MH:"RespiratoryProtective Devices" OR MH:"Dispositivos de protección respiratória" OR (Máscaras de Gás) OR (Respiradores Industriais) OR (Respiradores de Ar Purificado) OR MH:E07.700.700$ OR MH:J01.637.708.560.937$) OR (MH:"Tempo" OR MH:"Time" OR MH:"Tiempo" OR (Efeito a Longo Prazo) OR (Efeitos a Longo Prazo) OR Futuro OR MH:G01.910$) OR (MH:"Eficácia" OR MH:"Efficacy" OR MH:"Eficacia" OR MH:SP5.001.047.153$) OR (MH:"Segurança" OR MH:"Safety" OR MH:"Seguridad" OR (Segurança Pública) OR MH:N06.850.135.060.075$ OR MH:VS4.002.001.001.007$)
COCHRANE	Date Run: 15/10/2020 18:14:20 ID Search Hits #21 MeSHdescriptor: [Health Personnel] explode alltrees 8826 #22 MeSHdescriptor: [Allied Health Personnel] explode alltrees 1168 #23 MeSHdescriptor: [CoronavirusInfections] explode alltrees 454 #24 MeSHdescriptor: [Betacoronavirus] explode alltrees 87 #25 MeSHdescriptor: [RespiratoryProtective Devices] explode alltrees71 #26 MeSHdescriptor: [Masks] explode alltrees 1549 #27 MeSHdescriptor: [Time] explode alltrees 69519 #28 MeSHdescriptor: [Self Efficacy] explode alltrees 3118 #29 MeSHdescriptor: [Safety] explode alltrees 3912 #30 (Healthcare Worker) OR (Providers, Healthcare) OR (Providers, Health Care) OR (Healthcare Providers) OR (Health Care Providers) OR (Healthcare Provider) OR (Provider, Healthcare) OR (Healthcare Workers) OR (Health Care Provider) OR (Provider, Health Care) OR (Personnel, Health) OR (Healthcare Assistants) OR (Healthcare Assistant) OR (Healthcare Support Worker) OR (Worker, Healthcare Support) OR (Assistants, Healthcare) OR (Workers,

	Healthcare Support) OR (Support Worker, Healthcare) OR (Assistant, Healthcare) OR (Support Workers, Healthcare) OR (Healthcare Support Workers) OR (Program Specialist, Population) OR (Specialists, Population Program) OR (Program Specialists, Population) OR (Population Program Specialist) OR (Population Program Specialists) OR (Specialist, Population Program) OR (Health Professional, Allied) OR (Health Personnel, Allied) OR (Personnel, Allied Health) OR (Allied Health Professional) OR (Professionals, Allied Health) OR (Allied Health Professionals) OR (Professional, Allied Health) OR (Health Professionals, Allied) OR (Personnel, Paramedical) OR Paramedics OR Paramedic OR (Paramedical Personnel) 27499 32 #31 (Infection, Coronavirus) OR (Infections, Coronavirus) OR (Coronavirus Infection) OR (Human coronavirus HKU1) OR HCoV-HKU1 OR Betacoronaviruses 1136 #32 (Devices, Respiratory Protective) OR (Device, Respiratory Protective) OR (Protective Device, Respiratory) OR (Respiratory Protective Device) OR (Protective Devices, Respiratory) OR (Masks, Gas) OR (Gas Masks) OR (Mask, Gas) OR (Gas Mask) OR (AirPurifying Respirator) OR (Respirator, Air-Purifying) OR (Air-Purifying Respirators) OR (Respirators, Air Purifying) OR (Respirators, Air-Purifying) OR (Respirators, Industrial) OR (Industrial Respirator) OR (Respirator, Industrial) OR (Industrial Respirators) OR Mask 10684 #33 (Longterm Effect) OR (Effects, Long Term) OR (Effect, Longterm) OR (Long Term Effects) OR (Effects, Longterm) OR (Longterm Effects) OR (Effects, Long-Term) OR (Effect, Long-Term) OR (Long-Term Effect) OR (Long-Term Effects) OR (Efficacy, Self) OR Safeties 92459 #34 #21 OR #22 OR #30 33496 #35 #23 OR #24 OR #31 1161 #36 #25 OR #26 OR #32 10836 #37 #27 OR #28 OR #29 OR #33 158004 #38 #34 AND #35 AND #36 AND #37 18
EMBASE	('health care personnel'/exp OR (health AND care AND practitioner) OR (health AND care AND professional) OR (health AND care AND provider) OR (health AND care AND worker) OR (health AND personnel) OR (health AND profession AND personnel) OR (health AND worker) OR (healthcare AND personnel) OR (healthcare AND practitioner) OR (healthcare AND professional) OR (healthcare AND provider) OR (healthcare AND worker) OR (home AND health AND aides) OR (personnel, AND health) OR (public AND health AND officer) OR 'paramedical personnel'/exp OR (allied AND health AND personnel) OR (ophthalmic AND assistants) OR (para AND medical AND personnel) OR (paramedical AND assistant) OR (paramedical AND manpower) OR (paramedical AND professional) OR (paramedical AND staff) OR (psychiatric AND aides)) AND ('coronavirus infection'/exp OR (coronavirus AND infections) OR 'betacoronavirus'/exp OR (beta AND coronavirus) OR 'severe acute respiratory syndrome coronavirus 2'/exp OR (2019 AND new AND coronavirus) OR (2019 AND novel AND coronavirus) OR '2019 ncov' OR 'hcov 19' OR (human AND coronavirus AND 2019) OR 'ncov 2019' OR (novel AND 2019 AND coronavirus) OR (novel AND coronavirus AND 2019) OR (sars AND coronavirus AND 2) OR 'sarscov 2' OR (sars2 AND virus) OR (wuhan AND coronavirus) OR (wuhan AND seafood AND market AND pneumonia AND virus)) AND ('gas mask'/exp OR gasmask OR (respiratory AND protective AND devices) OR 'mask'/exp OR masks) AND ('protective equipment'/exp OR (personal AND protective AND equipment) OR (protective AND devices) OR (protective AND product) OR (protective AND products) OR 'time'/exp OR 'efficacy'/exp OR 'safety'/exp OR (safety AND management) OR (safety AND precaution) OR (safety AND protection) OR (safety AND regulation))

Table 1. Search Strategies. Fonte: os autores (2022).

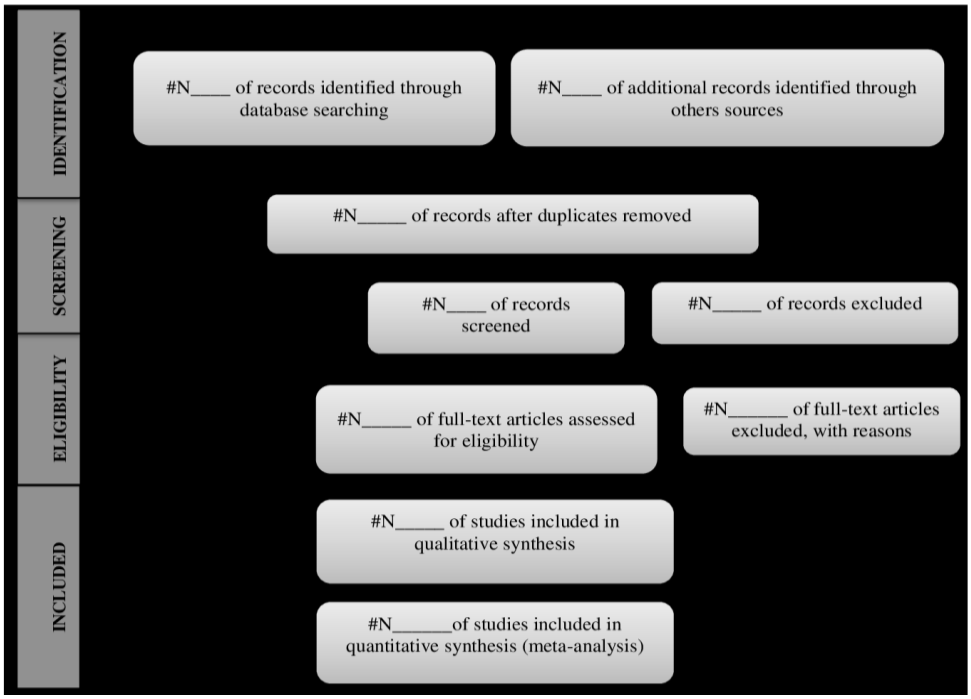

Figure 1. Flow of information in the different phases f the systematic review. Moher, D., et al. The PRISMA Group. (2009).

texts, based on the inclusion/exclusion criteria. Differences of opinion will be discussed until a consensus is reached; the opinion of a third reviewer will be sought when necessary. Excluded articles will be presented together with the reasons for exclusion. The following characteristics of each article will be described: authors, year, journal, study type, sample number, objective, the main outcome, and conclusion.

Data Management

Rayyan software from the Qatar Computing Research Institute (QCRI) will be used to remove duplicates during data analysis (Ouzzani et al., 2016).

For the management of bibliographic references, the Mendeley Desktop software, version 1.19.8 (Glyph, 2020), will be used.

Risk of Bias

The Revised Cochrane risk-of-bias tool for randomized trials (Rob 2) (Sterne et al., 2019), will be used to assess the risk of bias in randomized clinical trials. Rob 2 has five domains: Risk of bias due to the randomization process; Risk of bias due to deviations from the intended interventions, which quantify the attribution and adherence to the interventions; Missing result data; Risk of bias in measuring the result and Risk of bias in the selection of the reported result.

The risk of bias in observational studies will be assessed by the Joanna Briggs Institute (JBI) (Joanna Briggs Institute, 2014) standardized critical assessment checklist, determining the extent to which a study addressed the possibility of selection and information bias in its design, conduction, analysis, and confusion.

Statistical analysis

Meta-analysis

After selecting the studies and identifying the outcome variables, a software review Manager (RevMan)(Deeks & Higgins, 2020), version 5.4.1, will be used for statistical analysis, with a 95% confidence interval, heterogeneity (Cochran's Q test, Higgins and Thompson's I^2) and total effect size (Z), with a significant p-value <0.05.

If it is possible to perform a meta-analysis of the results of clinical trials that compared those not contaminated by COVID-19 among health professionals who used a surgical mask or used an N95 respirator, measures of central tendency will be used, depending on the normality or not of the distribution of the disease. Sample by the Shapiro-Wilk test. Statistical analyzes will be performed using Student's T test for parametric distribution or the Mann-Whitney test for non-parametric distribution.

Observational studies

To analyze observational studies, we will compare the associations between mask use and the incidence of COVID-19 using the Spearman correlation or the Pearson correlation. The results of the studies will be presented descriptively with mean and standard deviation for numerical variables with normal distribution and median and interquartile ranges for those with non-normal distribution.

The results related to the secondary, exploratory outcome will be presented descriptively, showing the measures of central tendency, according to the sample distribution, in tables. If it is possible to statistically analyze the difference in the time of use of each of the masks without the need for replacement, analyses like those described for the primary outcome will be performed, analyzing the distribution of variables, and choosing the best comparison test.

The level of statistical significance considered for the value will be $p<0.05$, with a confidence interval of 95% (CI 95%).

Quality Analysis, report, and recommendations

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) (Guyatt et al., 2008) system will be used to evaluate randomized clinical trials and observational studies, which grades the quality of evidence and the strength of health recommendations. Its classification is based on categories: high, moderate, low, and very low quality. The study design, methodological limitations (risk of bias), inconsistency, indirect evidence, imprecision, publication bias, the magnitude of effect, dose-response gradient, and residual confounding factors are analyzed to determine the level of evidence.

The JBI standardized critical assessment checklist (Tufanaru et al., 2020) will assess the quality of observational studies. The JBI tool presents eight questions which are: (1) Were the criteria for inclusion in the sample clearly defined? (2) Were the study subjects and the setting described in detail? (3) Was the exposure measured in a valid and reliable way? (4) Were objective, standard criteria used for measurement of the condition? (5) Were the confounding factors identified? (6) Were strategies to deal with confounding factors stated? (7) Were the outcomes measured in a valid and reliable way? (8) Was appropriate statistical analysis used? The studies were categorized according to the percentage of positive responses to the questions in the assessment instrument. The risk of bias was considered high when the study obtained below 49% of responses classified as "yes"; moderate when the study achieved 50% to 69%, and low when the study achieved more than 70% of a "yes" score.

Studies based on assessing the risk of bias and methodological quality will not be excluded. However, these analyses will determine confidence in the synthesis findings as part of the GRADE-CERQual (Grading of Recommendations Assessment, Development, and Evaluation - Confidence in Evidence of Qualitative Research Assessments) approach (Lewin et al., 2018).

The CASP tool presents ten questions which are: (1) Was there a clear statement of the aims of the research? (2) Is a qualitative methodology appropriate? (3) Was the research design appropriate to address the aims of the research? (4) Was the recruitment strategy appropriate to the aims of the research? (5) Was the data collected in a way that addressed the research issue? (6) Has the relationship between researcher and participants been adequately considered? (7) Have ethical issues been taken into consideration? (8) Was the data analysis sufficiently rigorous? (9) Is there a clear statement of findings? (10) How valuable is the research?

The **Box 2** summarizes the strengths and limitations of this study.

Box 2. Strengths and limitations of this study

Strengths

- The result of this review will expand knowledge about the protection offered by surgical masks and N95 respirators to protect against COVID-19.
- Rigorous application of the methodological evaluation of the included studies, which increases the level of confidence in the results.
- The results of this study are relevant to healthcare providers and healthcare professionals.

Limitations

- The inclusion of studies only in the English, Spanish, and Portuguese lines may be a limitation of this review.

Funding: This research received no external funding.

Conflicts of Interest: The authors declare no conflict of interest.

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