OBJN
Online Brazilian Journal of Nursing
ISSN: 1676 - 4285 | www.objnursing.uff.br

Submission: 09-Aug-2024
Approved: 20-Mar-2025

HELMET THERAPY IN NON-INVASIVE VENTILATORY SUPPORT FOR ADULT PATIENTS: A SCOPING REVIEW PROTOCOL

ELMOTERAPIA NO SUPORTE VENTILATÓRIO NÃO INVASIVO EM PACIENTES ADULTOS: PROTOCOLO DE REVISÃO DE ESCOPO

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How to cite: Sousa VTS, Martins LVC, Nocrato CRO, Batista MJNS, Vasconcelos PF, Freire VECS, et al. Helmet therapy in non-invasive ventilatory support for adult patients: a scoping review protocol. Online Braz J Nurs. 2025;24(Suppl 1):e20256824. http://doi.org/10.17665/1676-4285.20256824

RESUMO

Objetivo: Mapear a utilização da elmoterapia como modalidade de suporte ventilatório em pacientes adultos no cenário hospitalar durante a pandemia de COVID-19. **Método:** Este protocolo de revisão de escopo é baseado na metodologia do Joanna Briggs Institute e nas recomendações do Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews. A revisão será conduzida em cinco etapas: 1) identificação da questão de pesquisa; 2) identificação de estudos relevantes que permitam a amplitude e abrangência dos propósitos da revisão; 3) seleção de estudos, de acordo com critérios predefinidos; 4) mapeamento dos dados; e 5) apresentação dos resultados. Serão consultadas as bases de dados MEDLINE, LILACS, Web of Science, Scopus, IBECS e Biblioteca Digital Brasileira de Teses e Dissertações. Os resultados da revisão de escopo serão apresentados por meio de diagrama de fluxo, quadros e descrição textual. Adicionalmente, serão discutidos e analisados, visando identificar limitações e potencialidades da temática abordada.

Descritores: Adulto; Hipóxia; Oxigenoterapia Hiperbárica; Ventilação não Invasiva.

ABSTRACT

Objective: To map the utilization of helmet therapy as a modality of ventilatory support in adult patients within the hospital setting during the COVID-19 pandemic. **Method:** This scoping review protocol is based on the Joanna Briggs Institute methodology and the recommendations of the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews. The review will be conducted in five stages: 1) identification of the research question; 2) identification of relevant studies that allow for the breadth and scope of the review's purposes; 3) selection of studies, according to predefined criteria; 4) data mapping; and 5) presentation of results. The MEDLINE, LILACS, Web of Science, Scopus, IBECS, and Brazilian Digital Library of Theses and Dissertations databases will be consulted. The results of the scoping review will be presented through a flow diagram, tables, and textual description. Additionally, they will be discussed and analyzed, aiming to identify limitations and potential of the addressed theme.

Descriptors: Adult; Hipoxia; Hyperbaric Oxygenation; Noninvasive Ventilation.

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INTRODUCTION

Respiratory support is a fundamental aspect of healthcare delivery to hospitalized patients. During the COVID-19 pandemic, approximately 15% to 20% of hospitalized adult patients developed hypoxemic respiratory failure, requiring oxygen supplementation[1]. The global health crisis highlighted the critical need for non-invasive respiratory support modalities that offer low risk, mitigate the adverse progression of moderate cases, and enhance survival rates in severe cases[2].

In response to this challenge, a therapeutic innovation emerged in Ceará, Brazil, gaining global recognition as a respiratory support modality for patients with Severe Acute Respiratory Syndrome – the Elmo 1.0 helmet. Helmet therapy was first implemented during clinical trials at Leonardo da Vinci Hospital, in Ceará. The first patient to benefit from this treatment used the device in July 2020 and recovered from the illness[3]. This technological innovation represented a significant advancement, addressing the scarcity of pulmonary ventilators and Intensive Care Unit (ICU) beds, reducing the need for hospitalizations by up to 60%[4]. However, the introduction of Elmo necessitated the training of healthcare professionals on the device's operational mechanisms, clinical indications, and usage protocols.

Elmo is a safe modality of Non-Invasive Ventilation (NIV), designed to deliver oxygen under controlled pressure around the patient's face, thereby improving blood oxygen levels. It can be utilized as a respiratory support modality outside of ICUs. Its development was led by a pulmonologist, in collaboration with a multidisciplinary team of healthcare professionals and clinical engineers[5]. This innovative helmet-shaped device is based on NIV, intended for use primarily without ventilators and outside of ICUs. The device provides high-flow continuous positive airway pressure (CPAP) and inspiratory oxygen fraction (FiO2) up to 100%, indicated for the treatment of acute hypoxemic respiratory failure[5-6].

NIV is a ventilatory support modality that aims to promote adequate ventilation, reduce respiratory workload, improve gas exchange, increase alveolar ventilation, and prevent respiratory fatigue. The primary goal is to avoid intubation and, in some cases, facilitate early extubation. An additional advantage is the elimination of the need for an orotracheal tube (OTT) or tracheostomy[7].

Patients with acute respiratory failure (ARF) exhibiting moderate hypoxemia can significantly benefit from positive pressure therapy, which demonstrates greater efficacy in optimizing gas exchange and is simpler to use and implement in clinical practice compared to invasive techniques requiring mechanical ventilation. Furthermore, CPAP has lower costs and a reduced incidence of complications compared to facial masks, making it a safe and effective option for patients requiring prolonged treatment. CPAP application can maintain and improve oxygenation without the need for additional pressure support, highlighting its potential in ARF management[8].

The exploration of novel NIV modalities is crucial in the context of healthcare delivery, particularly in situations such as the COVID-19 pandemic. The pursuit of technological innovations, exemplified by the Elmo 1.0 helmet, represents a significant advancement in providing adequate oxygenation and improving hypoxemia in patients. Therefore, the continuous investigation and adoption of new NIV modalities are fundamental steps in the evolution of clinical practice and the management of emerging healthcare challenges[9].

Helmet therapy emerges as an innovative approach to mitigate the challenges associated with invasive mechanical ventilation, exploring the potential therapeutic benefits derived from natural environments. This approach aims not only to improve pulmonary oxygenation but also to reduce oxidative stress and stimulate a more robust immune response in hospitalized adult patients[2].

In a context of continuous pursuit for more sustainable treatment methods, investigating the efficacy and applicability of helmet therapy as an NIV modality becomes imperative. Understanding how this technique can be integrated into clinical practice has the potential to transform intensive care and open new perspectives for the management of complex respiratory conditions, contributing to the optimization of clinical outcomes and patient quality of life.

This protocol will enable the development and completion of this scoping review, which aims to map the utilization of helmet therapy as a ventilatory support modality in adult patients within the hospital setting during the COVID-19 pandemic.

METHOD

This protocol delineates a scoping literature review, developed based on the methodology proposed by the Joanna Briggs Institute (JBI)[10] and the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR)[11]. The review will be conducted in five stages: 1) identification of the research question; 2) identification of relevant studies that enable the breadth and scope of the review's purposes; 3) selection of studies according to predefined criteria; 4) data mapping; and 5) presentation of results[10,12-13].

Protocol and registration

In addition to being developed in accordance with the references mentioned before, this protocol was registered on the Open Science Framework (OSF) platform under registration https://osf.io/b3572/ and DOI: 10.17605/OSF.IO/B3572.

Research question

To determine the research question, the PCC mnemonic was employed, which refers to Population (Adults), Concept (Helmet therapy), and Context (Hospital setting; COVID-19 pandemic). From this, the following research question was established: How has helmet therapy been used in the ventilatory support of adult patients in the hospital setting during the COVID-19 pandemic?

Inclusion criteria

Population

Studies involving adults, defined as individuals aged between 20 and 59 years, will be included. The Ministry of Health and the World Health Organization do not delineate the age range corresponding to "adult"; however, adolescents are considered those up to 19 years, 11 months, and 29

days[14], and elderly individuals as those aged 60 or more[15], with adults being those within the interval between these classifications.

Concept

Studies must focus on helmet therapy, i.e., therapy based on the use of the Elmo helmet.

Context

This review will be contextualized in the hospital setting, with patients hospitalized during the COVID-19 pandemic, a period from March 11, 2020, to May 5, 2023[16].

Types of evidence source

Regarding study type, primary research published from 2020 onwards (the start of the COVID-19 pandemic), with any design or methodology and without language restrictions, will be eligible for inclusion. Duplicated studies or those unrelated to the research question will be excluded from the sample.

Search strategy

Based on the PCC mnemonic, search strategies will be constructed using Health Sciences Descriptors (DeCS), Medical Subject Headings (MeSH) terms, and uncontrolled terms identified in the searches, in Portuguese and English. Figure 1 provides an example of how the search strategy will be systematized.

Search sources

The following databases will be included: 1) Medical Literature Analysis and Retrieval System Online (MEDLINE) via PubMed, 2) MEDLINE via Virtual Health Library (VHL), 3) Latin American and Caribbean Health Sciences Literature (LILACS), 4) Web of Science, 5) Scopus, and 6) Spanish Bibliographic Index in Health Sciences (IBECS). Gray literature will be consulted through the Brazilian Digital Library of Theses and Dissertations (BDTD).

Study selection

Following the execution of the search strategy, the results identified in the search sources will be exported in formats compatible with the Rayyan reference manager, which will be used to remove duplicate studies, retaining only one copy of each. Subsequently, the sample will be exported in formats compatible with Microsoft Excel, where the selection of eligible studies will be operationalized through spreadsheets. Two independent and blinded reviewers will participate, as recommended by JBI[10], and a third reviewer will be consulted to resolve discrepancies, if necessary.

Objective	To map the utilization of helmet therapy as a modality of ventilatory support in adult patients within the hospital setting during the COVID-19 pandemic		
	P (Population)	C (Concept)	C (Context)
Extraction	Adult	Helmet therapy	Hospital setting; COVID-19 pandemic
Combination	“adulto”, “adultos”, “adult”, “adults”	"capacete elmo", “CPAP”, “elmo”, "elmo CPAP", “elmoterapia”, “elmotherapy”	“hospital”, “hospitais”, "contexto hospitalar", “hospitals”, "hospital context" “COVID”, "COVID-19"
Construction	"capacete elmo" OR CPAP OR elmo OR "elmo CPAP" OR elmoterapia OR CPAP OR elmotherapy	adulto OR adultos OR adult OR adults	hospital OR hospitais OR "contexto hospitalar" OR hospitals OR "hospital context" COVID OR "COVID-19"
Aplication	(("capacete elmo" OR CPAP OR elmo OR "elmo CPAP" OR elmoterapia OR CPAP OR elmotherapy) AND (adulto OR adultos OR adult OR adults) AND (hospital OR hospitais OR "contexto hospitalar" OR hospitals OR "hospital context") AND (COVID OR "COVID-19"))		

Figure 1 - Systematization of the search strategy. Redenção, CE, Brazil, 2024

The first selection stage involves the reading of titles and abstracts. In this phase, the reviewers will select 20% of the sample, and from their results, Cohen's Kappa Coefficient statistical test will be performed to verify agreement between the authors[17].

For the calculation, the following classification will be considered: none - 0-0.20; minimal - 0.21-0.39; weak - 0.40-0.59; moderate - 0.60-0.79; strong - 0.80-0.90; and almost perfect >90[18]. At this point, Jamovi software will be employed for statistical processing. For the process to continue, the results must be equal to or greater than 0.80, and if there is no agreement, training will be conducted among the evaluators to increase the reliability of the process and achieve the expected value.

Following this, the reading of the remaining titles and abstracts will proceed. The second selection stage will involve the full-text assessment of the studies to identify compliance with the proposed objective, also performed by two independent and blinded reviewers. As an additional strategy, the references of the primary studies will be consulted

to identify additional studies that may address the guiding question.

Data extraction

Studies that meet all eligibility criteria will be read in full and will undergo a data extraction stage. Relevant data will be extracted into a Microsoft Excel spreadsheet, to be developed by the authors of this review protocol.

Again, in the data extraction process, two independent reviewers and a third will be employed, and any discrepancies and doubts that arise will be resolved through discussions until consensus is reached among the reviewers.

The mapping of information will be carried out based on the JBI instrument[10], which allows for the characterization of production. At this point, the descriptive method described by Arksey and O'Malley[12] will be used, including: title; authorship; year of publication; country of origin; publication journal; objectives; methods; level of evidence; data collection period; research subjects; sample size; details related to the intervention under consideration (helmet therapy); main findings; study implications and limitations.

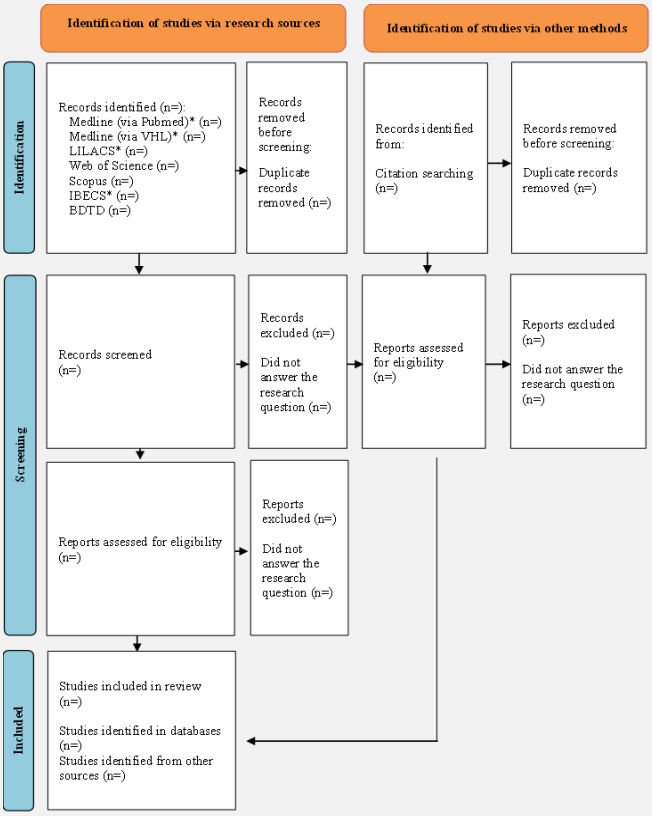
Results presentation

The selection process will be documented in accordance with the PRISMA-ScR checklist and presented in a flowchart format in the Results section, as illustrated below (Figure 2).

The main characteristics of the analyzed studies will be synthesized through a summary table. Subsequently, a descriptive presentation of the review results will be conducted, providing a comprehensive overview of the studies included in the scoping review. To enhance the rigor of the analysis process and the reliability of the results, meetings will be held among the authors to discuss the analysis and finalize the review. Discrepancies will be resolved through discussions among the authors.

Ethical considerations

This study will not be submitted for evaluation by a Research Ethics Committee, as it is a scoping review that will only use scientific texts. However, all ethical aspects related to copyright will be respected, and these will be duly referenced.



Note: *Medline: Medical Literature Analysis and Retrieval System Online; VHL: Virtual Health Library; LILACS: Latin American and Caribbean Health Sciences Literature; IBECS: Spanish Bibliographic Index in Health Sciences; BDTD: Brazilian Digital Library of Theses and Dissertations.
Source: PRISMA-ScR flowchart adapted from Peters et al., 2020.

Figure 2 – PRISMA Extension for Scoping Reviews flowchart of study selection and inclusion. Redenção, CE, Brazil. 2024.

CONFLICT OF INTERESTS

The authors have declared that there is no conflict of interests.

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Final approval of the version to be published: Sousa VTS, Martins LVC, Nocrato CRO, Batista MJNS, Vasconcelos PF, Freire VECS, Barros LM.
Responsibility for the text in ensuring the accuracy and completeness of any part of the paper: Sousa VTS, Martins LVC, Nocrato CRO, Batista MJNS, Vasconcelos PF, Freire VECS, Barros LM.