

Economic evaluations of health care interventions in Oropharyngeal Dysphagia after Stroke: Protocol for a Systematic Review.

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Protocol

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Abstract

Background and purpose: Oropharyngeal Dysphagia (OD) affects 40-81% of patients after stroke.

A recent systematic review on the costs of OD and its main complications showed higher acute and long-term costs for those patients who developed OD, malnutrition and pneumonia after stroke. These results suggest that appropriate management of post-stroke OD could lead to reduction of clinical complications and significant cost savings. The purpose of this systematic review is to assess the available literature exploring the efficiency or cost-effectiveness of available healthcare interventions on the appropriate management of OD.

Methods: A systematic review on economic evaluations of health care interventions on post-stroke patients with OD following PRISMA recommendations will be performed. MEDLINE, Embase, the National Health Service Economic Evaluation Database and the Cost-Effectiveness Analysis Registry Database will be searched and a subsequent reference check will be done. English and Spanish literature will be included without date restrictions. Studies will be included if they refer to economic evaluations or studies in which cost savings were reported in post-stroke patients suffering OD. Studies will be excluded if they are partial economic evaluation studies, if they refer to esophageal dysphagia, or if OD is caused by causes different from stroke. Evidence will be presented and synthesized with a narrative method and using tables. Quality evaluation will be done using Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement.

Discussion: The protocol for this systematic review is the first step to assess the cost-effectiveness of the healthcare interventions that have been described as potential treatments for post-stroke OD. This systematic review will summarize the current evidence on the relation between cost and benefits associated with the appropriate management of OD in post-stroke patients.

Systematic review registration: PROSPERO CRD42020136245

Introduction

Oropharyngeal dysphagia (OD) is a common complication in patients who have suffered from stroke; its prevalence in this population varies from 40% to 81% depending on the study selected.¹ It has been associated with the development of severe complications such as dehydration, malnutrition, respiratory infections including aspiration pneumonia, and hospital readmissions.¹⁻³ We previously showed that OD is an independent risk factor for prolonged hospital stay and institutionalization after discharge, poorer functional capacity and increased mortality.² In addition, according to our previous systematic review, OD after stroke is associated to higher costs than in those stroke patients who did not develop OD.⁴ This systematic review showed that incremental hospitalization cost of OD after stroke is up to 15,000€ (approx. 16,900 USD) and the cost of an episode of pneumonia of 24,000€ (approx. 27,600 USD) based on studies performed in France, Switzerland, Argentina, Brazil, Taiwan and the United States.⁵ Appropriate

management and treatment of post-stroke OD is required to avoid clinical complications, improve patients' quality of life and to save healthcare resources.³ Current treatment for post-stroke OD is not standardized and includes a series of strategies that can go from compensation measures, including fluid thickening and texture-modified foods (classical treatment)⁶, to more innovative neurorehabilitation approaches including peripheral stimulation treatments (electrical and pharmacologic studies) and non-invasive brain stimulation techniques (NIBS).⁷ Compensatory strategies are the most used ones and can include from adaptation of fluids and diets with thickeners and texture-modified food respectively, to the use of postures and manoeuvres compensating biomechanical deficits during deglutition;⁸ however, these strategies do not improve swallowing physiology.⁷ On the other hand, new strategies are based on the recovery of swallowing function and include peripheral stimulation treatments (transcutaneous and intrapharyngeal electrical stimulation and pharmacological TRP stimulants) and central stimulation treatments such as chemical or electrical stimulation and transcranial direct current stimulation (tDCS) or repetitive transcranial magnetic stimulation (rTMS), respectively.^{7,9,10}

Although the application of an appropriate treatment for OD in post-stroke patients should be mandatory in the neurology wards and also during the follow-up due to the high clinical, psychological and economic impact of OD,^{2,5,11,12} currently, the cost-effectiveness of the mentioned strategies is not well known. Thus, the aim of this study is to develop a protocol for a systematic review to assess and summarise the current evidence on the efficiency or cost-effectiveness of available healthcare interventions on the appropriate management of OD.

Methods

Protocol and registration

A systematic review on the economic evaluations of healthcare interventions on OD in patients who suffered a stroke will be performed. This systematic review will follow the recommendations stated by the Preferred Reporting Items for Systematic Reviews and Meta-analysis.¹³ This protocol for a systematic review has been designed following the recommendations stated by PRISMA protocols annex (PRISMA-P).¹⁴ The protocol for this systematic review was registered on the international prospective register of systematic reviews of the Center for Reviews and Dissemination (PROSPERO) (registration number: CRD42020136245).¹⁵ The main outcome of interest will be the costs and the associated health benefits of available sanitary/healthcare interventions on the appropriate management of post-stroke OD.

Literature search

We will search MEDLINE using Pubmed, Embase using Ovid, the National Health Service Economic Evaluation Database using the Center for Reviews and Dissemination Database of the University of York and the Cost-Effectiveness Analysis Registry database of the Center for the Evaluation of Value and Risk in Health. These Databases will be searched up to 31th December 2020. A publication date restriction will not be imposed. English and Spanish literature will be included. This systematic review will not include

posters, abstracts, book chapters or unpublished literature. Search strategy (combined MeSH and search terms used) applied at Pubmed is described in Table 1. A similar strategy will be used in the other databases.

Table 1
Search terms and MeSH terms used in the bibliographic search

Terms related to Oropharyngeal Dysphagia and connected among themselves by "OR"	Terms related to Stroke and connected among themselves by "OR"	Terms related to Economic Evaluations and connected among themselves by "OR"
1. "Deglutition"[Mesh]	17."Stroke"[Mesh]	41."Economics"[Mesh]
2. "Deglutition Disorders"[Mesh]	18."Stroke Rehabilitation" [Mesh]	42."Economics" [Subheading]
3. "Oropharynx/abnormalities"[Mesh]	19. "Brain Ischemia/ complications"[Mesh]	43."Models, Economic" [Mesh]
4."Oropharynx/diagnosis"[Mesh]	20. "Cerebral Infarction"[Mesh]	44. Health Resources" [Mesh]
5."Oropharynx/diagnostic imaging"[Mesh]	21." Cerebral Hemorrhage"[Mesh]	45. "Tertiary Care Centers/economics" [Mesh]
6."Oropharynx/pathology"[Mesh]	22."Intracranial Embolism and Thrombosis"[Mesh]	46. "Rehabilitation Centers/economics" [Mesh]
7."Oropharynx/pharmacology"[Mesh]	23. "Intracranial Hemorrhages"[Mesh]	47."Length of Stay/ economics"[Mesh]
8."Oropharynx/physiopathology"[Mesh]	24."Intracranial Arteriosclerosis"[Mesh]	48. "Medicare/economics" [Mesh]
9."Oropharynx/therapy"[Mesh]	25."Cerebrovascular Disorders"[Mesh]	49. "Physical Therapy Modalities/economics" [Mesh]
10.Enteral tube feed*/	26.Stroke[ti/abs]	50. "Emergency Medical Services/economics" [Mesh]
11.Swallow[ti/abs]	27.Post stroke[ti/abs]	51. "Food, Formulated/ economics"[Mesh]
12.Dysphag*[ti/abs]	28.Poststroke[ti/abs]	52. "Cerebrovascular Disorders/ economics" [Mesh]
13.Deglut*[ti/abs]	29.Post-stroke[ti/abs]	53.Cost effectiveness analysis
14.Dysphagia[tw]	30.Cerebral Ischaemia[ti/abs]	54.Cost utility analysis
15.Dysphag*/	31.Brain Ischaemia[ti/abs]	55.Cost minimization analysis
16.Dysphagia therapy/	32.Brain infarct[ti/abs]	
	33.Intracranial hemorrhage[ti/abs]	
	34.Intracranial haemorrhage[ti/abs]	
	35.Cerebral Hemorrhage[ti/abs]	
Terms, detailed in the three columns above, related to Oropharyngeal Dysphagia, Stroke and Health Economics will be connected using "AND".		

Terms related to Oropharyngeal Dysphagia and connected among themselves by "OR"	Terms related to Stroke and connected among themselves by "OR"	Terms related to Economic Evaluations and connected among themselves by "OR"
	36.Cerebral Haemorrhage[ti/abs] 37.Brain Hemorrhage[ti/abs] 38.Brain Haemorrhage[ti/abs] 39.Stroke discharge/ 40.Post-stroke/	56.Cost benefit analysis 57.Cost[tw] 58.Costs[tw] 59.Quality-adjusted life years/ 60.Cost utility[ti/abs] 61.Cost-utility[ti/abs] 62.Cost benefit[ti/abs] 63. Cost-benefit[ti/abs] 64.Cost minimization[ti/abs] 65-Cost-minimization[ti/abs] 66.Cost effectiveness[ti/abs] 67.Cost-effectiveness[ti/abs]
Terms, detailed in the three columns above, related to Oropharyngeal Dysphagia, Stroke and Health Economics will be connected using "AND".		

Selection Process Including Eligibility Criteria

Studies will be identified through literature search and will be selected using a double-phase process. In the first phase one reviewer will assess the title and abstract of the identified articles. These articles will be excluded if they do not contain at least minimal relevant information about: "stroke" or "cerebral infarction" or "cerebral hemorrhage" or "brain ischemia", "dysphagia" or "deglutition" or "swallowing assessment" or "swallowing disorders" and, "economic evaluation" or "economics" or "economic models" or "costs" on their abstracts or titles. A second reviewer will check the excluded articles using the same criteria. In the second phase, articles will be selected according to eligibility criteria. We will include articles if they had economic evaluations in which the intervention effect was quantified by effectiveness results or other measures of effect on healthcare (cost minimization studies, cost-utility studies, cost-effectiveness studies, cost-benefit analysis) or studies in which costs saving applying interventions in OD management were assessed (for instance, studies in which potential savings in post-stroke patients to

whom interventions were different to the usual management were applied) and provided information on post-stroke adult patients (≥ 18 years) with OD. Studies will be excluded if they had only partial economic evaluation studies (cost of illness studies, cost-description studies, costs analysis or cost-consequence analysis among others), if they referred to esophageal dysphagia, OD caused by causes different from stroke or if there were duplicate publications from the same study (in that case only one will be considered). Two independent reviewers will perform this process independently. Subsequently, the results will be compared and a third reviewer will make a decision for disagreements.

Data Collection

One reviewer will extract all data from included studies in a specific data sheet. Total articles will be divided in three groups and each of the other three reviewers will extract data from one group using the same datasheet. The extracted data will be compared and, in case of disagreement, a third reviewer will participate in order to reach a final agreed decision. We will gather data related to the design, the participants, the quality and the results of each study. All study data will be transferred from the data collection form to a specific datasheet for each study. We will gather this data from each study: a) Study identification: first author, title, journal and year of publication; b) Main study characteristics: aim, type of economic evaluation (cost minimization, cost-utility, cost-effectiveness, cost-benefit, cost savings), intervention/s assessed, eligibility criteria, retrospective or prospective data gathering, data source, time horizon, economic perspective (patient, hospital, payer, healthcare system or societal), country, year, currency, use of a temporary discount rate (yes/no), presence of a sensitivity analysis (yes/no), data source, location/setting; c) Study sample characteristics (if applicable, studies could use an economic model of the disease): sample size, sociodemographic data (age, average and range; gender), stroke type, mean value of National Institutes of Health Stroke Scale (NIHSS) or Canadian Neurologic Scale (if available on admission, hospitalization or discharge); d) Description of the Healthcare intervention assessed; e) Elements of cost considered, all of them (yes/no): direct healthcare costs (hospitalization: emergency room, hospitalization ward, intensive care unit; long-term care: nursing home, social and health center, hospitalization at home; primary care, medication, ambulance, special diets, tube-feeding, percutaneous endoscopic gastrostomy (PEG) insertion, outpatient visits: nutritionist, physical therapist, speech therapist, nurse; complication related costs: pneumonia, malnutrition), direct non-healthcare costs (social services, time, transportation) and, indirect costs (loss of productivity or time off from work, morbidity, mortality and/or impairment); f) Specific data depending on the type of economic evaluation: for cost minimization studies the data related to the equivalence of interventions, for cost-utility studies the data on the quality-adjusted life years (QALYs) and/or the disability-adjusted life years (DALYs) applied, for cost-effectiveness studies the effect units applied and for cost-benefit studies the measured benefits; and g) Results of studies depending on the type of economic evaluation: for cost minimization studies the economic savings by applying the most efficient intervention, for cost-utility studies the incremental cost-utility ratio (ICUR), for cost-effectiveness studies the incremental cost-effectiveness ratio (ICER) and for cost-benefit studies the cost-benefit ratio. These data will be reported on their original format. If necessary, we will contact study authors of eligible articles to answer questions about unreported information or to clarify possible misunderstandings. Data obtained from study authors that

is not available in the original articles will be clearly identified. We will not plan any calculation based on study data nor any assumption resulting from lost or unavailable information. Moreover, any assumption resulting from lost or unavailable information will be reported.

Quality Assessment

A specific tool to assess the internal validity and the reporting key factors of economic evaluation studies will be used. We will apply the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement.¹⁶ A set of items that apply to a critical appraisal of economic evaluation studies is provided in this checklist. Each item represents a study aspect that we will rate as “Yes, partly, no or not applicable”. For each study, the total amount of items will be rated as “yes (1 point)” and partly (0.5 points) and then it will be divided between the total applicable items. This total score will be expressed as a percentage; a higher score will represent a lower risk of bias. We will consider a score of 100% as a very low risk of bias study. As we want to assess the current state of the literature on this topic and not to create a final sum of the evidence, we did not exclude from this review any study based on its quality assessment score.

Data Presentation And Data Synthesis

We will use two different strategies to synthesize the information of this systematic review. A narrative method will be used to describe main study characteristics, characteristics of the study sample, cost elements considered and specific data depending on the type of economic evaluation. Identification of studies, results and global score on quality assessment will be presented on a Table. Finally, a meta-narrative synthesis of the extracted information will be performed. In this meta-narrative synthesis we will describe both the assessed evidence on the efficiency/cost effectiveness of different clinical interventions for post-stroke OD together with some of the key aspects of quality assessment evaluation. We will report if studies identified, measured and assessed the complete form of all the important costs for each assessed alternative, if the study structure (study approach, data source) was performed in the most appropriate way to answer the study question and if the most important factors to understand these economic evaluations were properly reported. Finally, the possibility of creating an economic model of the disease will be studied and we will evaluate which pharmacoeconomic studies are still pending to be carried out in order to understand the cost-effectiveness of the adequate management of post-stroke OD.

Discussion

The appropriate management of OD in post-stroke patients is imperative during acute stroke hospitalization and during patients' rehabilitation beyond acute care due to the potential clinical severity of its complications and also due to the high health-economic costs of these events. From the clinical perspective, we previously found prevalence of post-stroke OD during admission in a general hospital was of 45% and that OD after stroke was an independent risk factor for prolonged hospital stay ($P = .049$; $\beta = 0.938$) and institutionalization after discharge ($OR = 0.47$; $CI = 0.24-0.92$); OD was an independent risk

factor for poorer functional capacity (OR = 3.00; CI = 1.58–5.68) and increased mortality (HR = 6.90; CI = 1.57–30.34) 3 months after stroke.² Post-stroke OD prevalence on admission and at 3-month follow-up remained very high in the population of this study.² Post-stroke OD is a dynamic condition and, although some spontaneous recoveries can be observed in patients with an optimal functional status, new signs/symptoms can appear beyond acute stroke hospitalization in those patients with poorer functionality.^{17,18}

In addition to its clinical impact, post-stroke OD and its main complications, malnutrition and pneumonia, have been associated with independent direct sanitary costs during acute hospitalization and at long-term follow-up phases, direct non-sanitary costs and indirect costs associated with patients' productivity losses.⁴ Some health economic data on the cost and on sanitary resource consumption of post-stroke OD and its main complications have also been reported.^{5,19} This shows an independent increase in costs associated with OD after stroke during hospitalization that can increase exponentially with the development of its main complications (malnutrition and respiratory infections) during long-term follow-up. In a recent study, we found the 1-year cost of a post-stroke patient with OD, malnutrition and at least one episode of respiratory infection is $19,817.58 \pm 13,724.83$ vs. $7,242.8 \pm 7,402.6$ euros, the latter of a post-stroke patient without OD, clearly showing the economic burden of post-stroke OD from both the Hospital and the Health Care System Perspectives. However, there is a lack of literature on the cost-effectiveness of the appropriate management of OD. A summary of the available literature on this field could help as a point of departure for future investigations aimed to study the cost-effectiveness of these interventions and to create an economic model of the disease. Considering that OD and its main complications malnutrition and pneumonia, have been associated with high costs after stroke, the massive screening and specialized management of post-stroke patients with OD not only could significantly improve patients' clinical outcomes and quality of life (QoL) but also bring significant cost savings. This systematic review will be the second part of a research project created to evaluate the specific burden of OD in the health and social costs after stroke and the cost-effectiveness of the appropriate management and treatment of this condition.

The complete management of post-stroke OD comprises the early and systematic evaluation of these patients' deglutition (screening and assessment) and the management of the impairments on safety of swallow that can cause aspiration and aspiration pneumonia, the impaired efficacy of swallow that can lead to dehydration and malnutrition and subsequent impaired immunity and frailty. Finally, poor oral hygiene is prevalent among these patients and it is associated with oral colonisation by respiratory pathogens. Diagnosis of post-stroke OD includes the assessment of impaired biomechanics of swallowing function and the characterization of dysfunctional sensorimotor integration processes involved in deglutition, and the paradigm of treatment is changing from compensatory strategies to the promotion of brain plasticity aiming at the recovery of both impaired swallow and brain-related swallowing dysfunction.^{7,20} We believe that these two strong tendencies and the results of new randomized control trials will induce, in the near future, a lot of changes in the management of post-stroke OD, and future treatment for stroke will be very different from how it is today. With regard to the

management, there is evidence showing that by increasing the levels of viscosity the risk of airway penetration and aspiration is reduced, and recent studies with gum-based thickeners showed the specific range of viscosity values providing this therapeutic effect on safety of swallow.⁶ Long-term studies showing the clinical impact of fluid thickening in post-stroke patients are clearly required. This minimal and massive intervention that has been proved to be useful and effective in elderly people with OD can be done with fluid and food texture adaptations, nutritional support and oral hygiene.²¹

Innovative strategies that aim to restore the swallowing function have emerged during recent years. Those strategies include pharmacological and electrical peripheral (transcutaneous and intrapharyngeal stimulation) and central stimulation treatments along with tDCS and rTMS strategies.⁷ Transcutaneous electrical stimulation (TES) is a safe and effective therapy for chronic post-stroke OD patients. A recent randomized study with a one-year follow-up reported that the biomechanical effect of both sensory (SES) and motor (MES) electrical stimulation strategies improves the safety of swallow in post-stroke OD patients and reduces the need of fluid thickening without any major adverse event.²² Moreover, recent data show that strategies aiming to neurostimulate the sensory pathway cause an immediate improvement of the excitability of the motor cortex (pharmacological modulation with capsaicin and intra-pharyngeal electrical stimulation) and of the pharyngeal sensory conduction (rTMS).²³ These interventions are safe, simple, cost-effective and are based on the best scientific evidence collected over decades and might change the paradigm of treatment of post-stroke dysphagic patients.¹⁰

List Of Abbreviations

CHEERS: Consolidated Health Economic Evaluation Reporting Standards; DALYs: disability-adjusted life years; EMBASE: Excerpta Medica Database; ICER: incremental cost-effectiveness ratio; ICUR: incremental cost-utility ratio; MES: motor electrical stimulation; MeSH: Medical Subject Heading; NIBS: non-invasive brain stimulation techniques; NIHSS: National Institutes of Health Stroke Scale; OD: Oropharyngeal dysphagia; PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-analysis-Protocols; PROSPERO: International Prospective Register of Systematic Reviews; QoL: quality of life QUALYs: quality-adjusted life years; rTMS: repetitive transcranial magnetic stimulation; SES: sensory electrical stimulation; TES: Transcutaneous electrical stimulation; tDCS: transcranial direct current stimulation

Declarations

Ethics approval and consent to participate Not applicable

Consent for publication Not applicable

Availability of data and materials Not applicable

Competing interests The authors declare that they have no competing interests

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Authors' contributions SM is the guarantor. SM and OO drafted the first version of this article. All authors contributed with the PROSPERO registration. All authors contributed with the development of this protocol. All authors reviewed the full content of this manuscript and approved the publication of this protocol.

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Figures

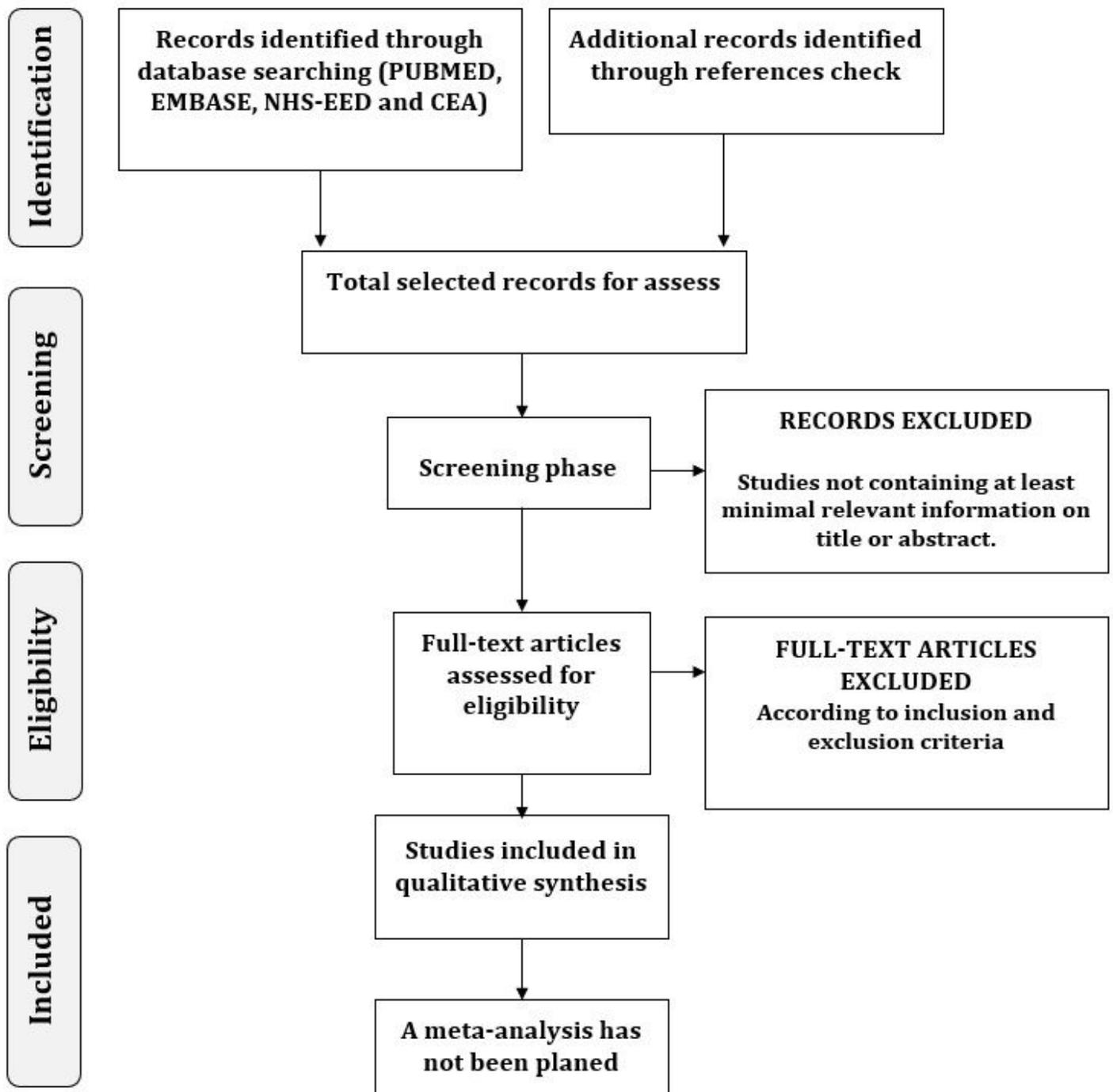


Figure 1

Selection process, flow diagram