BMJ Open Health insurance awareness and its uptake in India: a systematic review protocol

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ABSTRACT:

Introduction Health insurance is one of the important approaches that can help in boosting universal healthcare coverage through improved healthcare utilisation and financial protection. This objectives of this review are to identify various interventions implemented in India to promote awareness of health insurance, and to provide evidence for the effectiveness of such interventions on the awareness and uptake of health insurance by the resident Indian population.

Methods and analysis A systematic review will be carried out based on the Cochrane handbook for systematic reviews of interventions. The review will include experimental and analytical observational studies that have included adult population (>18 years) in India. We will include any intervention, policy or programme that directly or indirectly affects awareness or uptake of health insurance. The following outcomes will be eligible to be included: awareness or health insurance literacy, attitude such as readiness to buy health insurance or decision making, uptake of health insurance, demand-side and supply-side factors for awareness of health insurance, and awareness as a factor for uptake and re-enrolment in health insurance. Databases such as MEDLINE (PubMed), Web of Science, Scopus, 3ie impact evaluation repository and Social Science Research Network will be searched from January 2010 to 15 July 2020. Additionally, important government websites and references of the included studies will be scanned to identify potential records. Three authors, independently, will carry out screening and data extraction. Studies will be categorised into quantitative and qualitative, and mixed-methods synthesis will be employed to analyse the findings.

Ethics and dissemination This review will be based on published studies and will not recruit human participants directly, therefore, ethical clearance is not applicable. We will disseminate the final review findings in a national or international conference and publish in a peer-reviewed journal.

INTRODUCTION

Low-income and middle-income countries (LMICs) contribute to around 84% of the world population and 90% of the global burden of disease.¹ People living in the LMICs rely majorly on out-of-pocket payments as the prime source for managing healthcare

Strengths and limitations of this study

- This systematic review will use mixed-methods analysis involving findings from quantitative and qualitative studies conducted in India.
- We will comprehensively search the evidence in various databases, grey literature and reference and forward citations of included studies, however, the publications will be restricted to English.
- We anticipate heterogeneity owing to study designs of potentially included studies, however, to mitigate this challenge we have planned to conduct subgroup analysis based on PROGRESS-Plus framework.

expenses, that results in a massive demand for services and financial burden of households (usually catastrophic), which in turn leads to impoverishment.^{1–5} It is projected that every year approximately 150 million people experience financial catastrophe, by spending more than 40% on health expenses other than food.⁶ Families generally spend more than 10% of the household income on illness-related expenses, due to which other household expenses are affected.^{2,5} To make it worse, evidence suggests that per capita spending on healthcare in many LMICs is expected to increase in coming years.⁴ Additionally, the increased costs of seeking and receiving care can hinder the access to healthcare.⁷

The Universal Health Coverage (UHC) is embedded within the Sustainable Development Goals (SDGs) and aims ‘to ensure healthy lives and promote well-being for all at all ages by 2030’.⁸ It includes financial risk protection and equal access to quality essential healthcare services.^{8,9} In other terms, UHC encourages equitable healthcare² and nations across the world are committed to achieving SDGs through UHC.¹⁰

Health insurance is one of the important approaches that can help in boosting UHC through improved healthcare utilisation and

financial protection.^{7–9 11} There are multiple types of insurance in LMICs that differ with providers (government vs private sector), scales and types of beneficiaries.⁸ However, in many LMICs, due lack of acceptability and unwillingness to pay (WTP) premiums, health insurance coverage is limited.^{2 4} This increases the risk of excluding vulnerable and at-risk population, who cannot afford to pay health insurance premium.⁸ Additionally, the older adults, and the individuals with disability and chronic diseases, have less probability of enrolling in health insurance schemes or their specific needs may not be covered under the scheme.⁸

The coverage of health insurance policies or programmes in India is improving, however, the publicly funded health insurance schemes are mostly restricted to socioeconomically backward people or government employees.¹² India's first health insurance programme, launched in the 1950s, was limited to central government employees and certain low-income population.¹¹ Over the years, the private healthcare providers' dominance in quality healthcare service provision can be seen.¹¹ Nevertheless, many economically backward families are either deprived of healthcare or are pushed into poverty in the absence of financial protection.¹¹ In 2002, targeted health insurance programmes for low-income households were introduced by central and state governments in partnership with private sector and non-governmental organisations (NGO). Since 2002 (recommendations of National Health Policy 2002), more than 17 health insurance schemes have been launched by various governments in India.¹¹ The most recent one is 'Ayushman Bharat' or Pradhan Mantri Jan Arogya Yojana (PMJAY) (Prime minister's health assurance scheme) launched in 2018 to achieve UHC. PMJAY is fully financed by the government and seeks to cover 500 million citizens with an annual cover of approximately US\$7000 per household. The main aim of the PMJAY is to lessen the economic burden experienced by poor and vulnerable groups for access to healthcare facility.¹³

Despite the availability of multiple health insurance schemes, evidence suggests that the uptake of health insurance in India is poor. As per the recently concluded National Sample Survey Office data, there were as low as 14% rural and 18% urban residents of India having some form of health insurance.¹⁴ The low coverage of health insurance was evident in other literature, wherein it was reported to be less than 20%.^{5 12} Similarly, other LMICs have reported poor registrations in the national health insurance schemes.^{8 9 12 15}

There are multiple factors that are responsible for awareness and enrolment in health insurance schemes.^{2 4} These factors can be broadly divided into individual (age, gender, education, employment status, marital status),^{29 16} and household characteristics (wealth, size of family).^{19 17} Other factors are programme-related (premium amount, rules, regulation and procedures), social capital (trust, networks and group participation, social norms and solidarity and togetherness features of

the social organisation of the community), institutional factors (regulatory mechanisms, complaint handling systems and insurance education) and supply-side factors (quality of care and distance of house from the nearest health facility).² The aforementioned factors may also determine the consumer preference in selecting the health insurance.¹⁷ Inadequate claim returns, poor accountability and non-transparent operations hinders the uptake of health insurance.¹⁸

In Indian studies, a scant that is, 34% of the participants who did not have health insurance were willing to pay for any health insurance.⁵ Previous research in LMICs suggests that financial status of household is positively associated with WTP.^{2 4 9 18} Whereas level of education received contradictory findings, that is, a study conducted in Nigeria reported that education was negatively associated with WTP⁴ contrary to study conducted in Uganda,¹ Ghana¹⁶ and India.⁵ Family who had good perceived health had less probability of getting insurance as compared with those individuals who perceived their health as poor. Similarly, those individuals who had chronic diseases were more inclined to have health insurance than those who did not have chronic diseases.² Corruption and mistrust in the health insurance scheme^{15 18} and expensive plans^{5 18} were some of the reasons for non-WTP. Lack of information or health insurance illiteracy is another important reason for non-WTP.^{15 18}

Health insurance literacy is defined as 'the degree to which individuals have the knowledge, ability and confidence to find and evaluate information about health plans, select the best plan for their own (or their families) financial and health circumstances, and use the plan once enrolled.'¹ Lack of health insurance literacy or education hinders the uptake of health insurance and in many LMICs health insurance literacy is poor. A study conducted in Uganda reported that about 34% of the studied population were not aware of health insurance.¹ Whereas, proportion of people having inadequate knowledge about health insurance was found to be high in countries such as India (46%),⁵ Myanmar (66%)³ and Hispanic American in the USA (70%).¹⁹

Familiarity or awareness of the insurance schemes increases the utilisation of health insurance and subsequently help in healthcare uptake.^{12 19} Individuals usually enrol into health insurance because of their personal experiences, awareness or word-of-mouth advertisements.¹⁷ Mass media such as newspaper, radio and television play an important role in making people aware of health insurance schemes.¹ Friends, community meetings, school gatherings and health workers have an influence on increasing the health insurance awareness of the people.¹ Although, aforesaid factors help in increasing the awareness and enrolment in health insurance scheme, some enrollees may not pay premium on regular basis and might not get to know even after health insurance is lapsed.⁹ Women farmers, as compared with other occupations, had more odds of unawareness that their insurance was lapsed.⁹

It is evident from the above description that there is inadequate awareness of health insurance among general population in LMICs. Knowledge about health insurance can boost individuals' confidence and self-efficacy; thus, it is an important *a priori* factor that is required to get enrolled in health insurance scheme.¹⁹ Outreach programmes to increase general knowledge of health insurance and integrating health insurance education within health delivery systems may help to improve the uptake of health insurance.¹⁹ Globally, there are different methods available to promote and raise awareness about different health insurance schemes. However, India is a diverse country with a complex health system and numerous contextual factors. A 'one size fits all' approach for any policy or intervention is not suitable for the country. Therefore, it is imperative to understand the different approaches implemented to raise awareness about health insurance in the country. Additionally, due to increased population and a meagre public health spending on healthcare, it is important to understand if the resources are being used appropriately. To ensure this, understanding the effectiveness of such policies is essential, so that focus is directed towards the suitable interventions. 'Ayushman Bharat Scheme-PMJAY' is implemented to ensure increased utilisation of the healthcare facilities with financial protection of the beneficiaries. The evidence available on the effectiveness of the PMJAY scheme states no effect of the scheme on utilisation of healthcare and financial protection of enrolled beneficiaries,¹³ however, this evidence is limited. Therefore, in the Indian context, it is important to understand if awareness is a factor that has led to decreased utilisation of PMJAY or failure of the other schemes (*viz.* Rashtriya Swasthya Bima Yojana-RSBY) in securing financial protection of the beneficiaries.²⁰ Also, it is vital to understand the importance of awareness programmes for success of the health insurance schemes, which will be the focus of this review.

A systematic review will help in synthesising high-quality evidence in a systematic manner, for this important topic of interest. The proposed systematic review will, therefore, identify the different approaches and interventions for increasing health insurance awareness in India and will give information about the impact of these interventions. This review is planned to address the following research questions:

1. What are the various interventions implemented in India to promote awareness of health insurance?
2. What is the effectiveness of the above interventions on the awareness and uptake of health insurance by people of India?

METHODS AND ANALYSIS

Methodology for this systematic review will be based on the Cochrane handbook for systematic reviews of interventions²¹ and we have adhered to Preferred Reporting Items for Systematic Reviews and Meta-Analyses

(PRISMA)-Protocols guidelines for reporting this protocol.²²

Criteria for including studies in the review

Population: The review will include studies conducted in India that involve adult population (>18 years). We will consider the studies having household as a unit of analysis, if the head of the family (or the family member who was interviewed) is an adult.

Intervention/exposure: We will include any intervention, policy or programme that directly or indirectly affects awareness of health insurance. The health insurance scheme could be of any type, including but not limited to, public, private, for profit and not-for-profit. Contribution for premiums could be made by individual, NGO, employer or government. There is no restriction on focus of health insurance for example, hospital stay, surgery or critical illness.

Intervention/exposure could be educational, informative, training, technology and m-health or e-health related. The interventions could be focused on raising income threshold to be eligible for health insurance, such as, conditional or unconditional cash transfers that indirectly influences awareness of health insurance. Similarly, training and performance-based financing for healthcare staff or other groups will be eligible for inclusion. The intervention could be a modification of the enrolment procedure, changes in the premium or organisational changes in handling health insurance. Intervention could be directed on general population or targeted groups such as vulnerable population, indigenous groups, community leaders, employees, formal or informal groups and healthcare staff.

Comparison: This review will not restrict the studies based on comparison, as having a comparison group may not always be feasible.

Outcomes:

1. Awareness/health insurance literacy (refers to knowledge of the household head or household member on the presence of insurance schemes, its principles and significance. The outcome measure can be objective or subjective).
2. Attitude: Readiness to buy health insurance, decision making.
3. Uptake of health insurance.
4. Demand-side and supply-side factors for awareness of health insurance.
5. Awareness of health insurance as a factor for uptake or re-enrolment of health insurance.

Types of study designs: This review will include experimental studies that assessed the effect of intervention to promote awareness and uptake of health insurance. It is sometimes not practical to conduct randomised controlled trials (RCTs) to measure the effect of public health interventions, therefore, the review will also include other study designs. Studies with following designs will be included: RCTs, interrupted time-series studies, difference-in-difference, regression discontinuity

designs, statistical matching, quasi-randomised and non-randomised trials. Additionally, this review will include prospective, retrospective, analytical cross-sectional and studies related to process evaluation and policy analysis, if the studies have provided description of intervention or exposure of our interest. Qualitative studies are important source of information about barriers and enabling factors that can complement the findings, therefore, we will also include these types of studies. This review will exclude descriptive cross-sectional (prevalence) studies, commentaries, perspectives, editorials, reviews and conference abstracts. Policy papers that do not provide details of implementation of intervention will not be considered.

Searching and locating the studies

The electronic databases such as MEDLINE (PubMed), Web of Science and Scopus will be searched to identify potential records. Additionally, Sie impact evaluation repository and Social Science Research Network will be searched. Databases will be searched from January 2010 to 15 July 2020 and publications will be restricted to English language. Ministry of Health and Family Welfare, RSBY, Ayushman Bharat and other state health insurance websites will be searched for reports on the health insurance schemes. We will also scan through references of the included studies for any additional eligible records. After identifying the keywords, initial search will be carried out in PubMed, which will then be replicated in other databases. A designated information scientist will be responsible for conducting search. The preliminary search concepts and key terms are given in [table 1](#).

Applying eligibility and screening the studies

The results of search will be imported to Endnote X7 reference manager software and duplicates will be removed.

MS Excel spreadsheet will be used to screen the records. Based on inclusion and exclusion criteria, all the records will be subjected to two stage—title/abstract and full text (FT)—screening process, independently by three (SSP, ER and BTV) reviewers (in pairs). Any disagreements between the reviewers will be resolved by discussion, and senior reviewer will be involved in decision making in case of disagreements between the reviewers. The reasons for excluding FTs will be documented and the PRISMA flow diagram will be provided. A detailed screening protocol will be used as a back-up document to aid the screening process. [Table 2](#) gives detailed screening protocol.

Data extraction

Data will be extracted independently by three reviewers (SSP, ER and BTV). A predesigned data extraction form will be used for extraction of the data. The data extraction form will be subjected to pilot testing and will be revised as per the suggestions by the reviewers and the experts at this stage. Any disagreements during data extraction will be resolved by consensus supported by the senior reviewer. Data will be extracted based on the characteristics mentioned in the [table 3](#).

Critical appraisal of included studies

Effective Public Health Practice Project (EPHPP) tool²³ will be used to assess the methodological quality of quantitative studies (except observational studies) and Newcastle-Ottawa scale (NOS)²⁴ will be used for the observational studies. The EPHPP rates the study as 'strong', 'moderate' or 'weak' based on eight domains. These domains are selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity and analysis.²³ NOS rates the study based on three domains viz. selection, comparability

Table 1 Search concepts and key words

Concept	Key terms
Intervention or exposure	'Information Education Communication', 'Mass Media', 'Television', 'Leaflet', 'Brochure', 'Flyer', 'Radio', 'Television', 'Advertisement', 'Behavioural change communication', 'Awareness programme/ programme/ campaign/ initiatives/policy', 'Promotion', 'Marketing', 'Social media', 'E-health', 'M-health'.
Insurance names	'Community insurance', 'Health insurance', 'Health insurance programmes/programmes/schemes', 'Health finance /financing', 'Healthcare reform', 'Insurance coverage', 'National health insurance', 'National health insurance scheme', 'Medical insurance', 'Micro health insurance', 'Public health insurance', 'Social insurance', 'Social protection', 'Universal healthcare', 'Universal healthcare', 'Ayushman Bharat', 'Pradhan Mantri Jan Arogya Yojana', 'Mukhyamantri Swasthya Bima Yojana', 'Rashtriya Swasthya Bima Yojana', 'Aarogysri', 'Rajiv Arogyabhagya', 'Rajiv Arogyashree health insurance', 'Rajiv Gandhi Jeevandayee Arogya Yojana', 'Yesasvini health insurance', 'Yashshvini Community based health insurance programme', 'Vajpayee Arogyashree', 'Biju Krushak Kalyan', 'Kalinagar', 'CHIS', 'Employee State Insurance Scheme', 'Central Government Health Scheme', 'Mediclaime', 'Deen Dayal Swasthya Seva Yojana'.
Outcome	'Awareness of health insurance', 'Health insurance literacy', 'Uptake of health insurance', 'Utilisation of healthcare services', 'Enrolment under health insurance', 'Health insurance enrolment', 'Health insurance retention', 'Healthcare utilisation', 'Medical service utilisation', 'Readiness to buy health insurance', 'Decision making', 'Perceptions', 'Knowledge', 'Demand-side and supply-side factors', 'factors', 'barriers', 'enablers'.
Region	India

Table 2 Screening protocol

1 Title and abstract screening			
A	Is the study published in English? AND Is it published in the year 2000 or later?	If answer to both the components are 'yes', Go to B	If it is non-English or published before 2000 then exclude the study
B	Is it a study conducted in India?	1. If it is 'yes' OR 2. If it is not clearly stated, thus cannot decide, Go to C	If it is clearly stated that it is conducted elsewhere, but India, then exclude the study
C	Does study involve one of the following design or analysis: RCTs, interrupted time series studies, difference-in-difference, regression discontinuity designs, statistical matching, quasi-randomised and non-randomised trials, prospective, retrospective and analytical cross-sectional studies and studies related to process evaluation and policy analysis.	If answer is 'yes' OR it is not clearly stated in abstract, Go to D	If the study is descriptive cross-sectional (or prevalence study) having single group OR if the publication is a commentary, perspective, editorial, reviews, conference abstracts OR policy paper that does not provide details of implementation of intervention: exclude the study
D	Does the study describe the intervention for increasing awareness of and uptake of health insurance? (The intervention could be any intervention, policy or programme (eg, behavioural change communication or educational) that directly or indirectly affects awareness of health insurance. There is no restriction on mode of intervention, for example, mass media or group discussions. There is no restriction on who provides the intervention, for example, researcher, community-based workers or insurance agent. There is no restriction on duration and frequency of providing intervention. The health insurance scheme could be of any type, including but not limited to, public, private, for profit and not-for-profit. Contribution for premiums could be made by individual, non-governmental organisations, employer or government. There is no restriction on focus of health insurance, for example, hospital stay or surgery.)OR Does the study describe about the factors associated with awareness of health insurance? OR Does the study describe awareness as a factor for uptake or re-enrolment of health insurance?	If answer to one of the components is 'yes' OR if it is not clearly stated and you are in doubt, then Include the study for full-text screening If you are in doubt: flag for discussion	If no, exclude the study
2 Full-text screening			
E	Is it a study conducted in India?	If it is 'yes', Go to F	If no exclude the study
F	Did the study involve adult population?	If it is 'yes', Go to G	If no exclude the study
G	Does the study involve one of the following design or analysis: RCTs, interrupted time series studies, difference-in-difference, regression discontinuity designs, statistical matching, quasi-randomised and non-randomised trials, prospective, retrospective and analytical cross-sectional studies and studies related to process evaluation and policy analysis.	If answer is 'yes' Go to H OR If you are doubtful, then flag for discussion	If the study is descriptive cross-sectional (or prevalence study) having single group OR If the publication is a commentary, perspective, editorial, reviews, conference abstracts or policy paper that does not provide details of implementation of intervention: exclude the study

Continued

Table 2 Continued

1	Title and abstract screening		
H	<p>Does the study describe the intervention for increasing awareness of and uptake of health insurance? (The intervention could be any intervention, policy or programme (eg, behavioural change communication or educational) that directly or indirectly affects awareness of health insurance. There is no restriction on mode of intervention, for example, mass media or group discussions. There is no restriction on who provides the intervention, for example, researcher, community-based workers or insurance agent. There is no restriction on duration and frequency of providing intervention. The health insurance scheme could be of any type, including but not limited to, public, private, for profit and not-for-profit. Contribution for premiums could be made by individual, non-governmental organisations, employer or government. There is no restriction on focus of health insurance, for example, hospital stay or surgery.) OR Does the study describe about the factors associated with awareness of health insurance? OR Does the study describe awareness as a factor for uptake or re-enrolment of health insurance?</p>	<p>If answer to one of the components is 'yes' Go to I OR If you are in doubt, then flag for discussion</p>	<p>If no exclude the study</p>
I	<p>Did the study measure the outcomes of our interest?</p>	<p>If answer is 'yes' then include for data analysis</p>	<p>If no, exclude the study</p>

RCT, randomised controlled trial.

and outcome, and the final score ranges between 0 and 10.²⁴ Reviewers (BTV, ER and SSP), independently in pairs, will appraise the included studies. Any discrepancies between the decisions of reviewers will be resolved by discussion until consensus is achieved. If required, a senior reviewer will be involved as arbitrator and final decision maker to rate the study quality.

Data analysis

Study characteristics consisting of population, intervention/exposure, comparator, outcome, study design components across studies will be tabulated, which will help us to compare and analyse. Subsequently, studies will be categorised into quantitative and qualitative and will be analysed separately. This step will be followed by mixed methods synthesis as suggested by Panda *et al.*²⁵

Quantitative studies

Studies will be grouped based on study design, and type of data available (continuous or categorical). If possible, similar studies will be pooled to perform meta-analysis using random effect model. If data are continuous, standardised mean difference will be calculated with 95% CI.

For categorical data, OR or risk ratio will be calculated and reported with 95% CI. Meta-analysis will be visually represented with a forest plot. We assume possibility of heterogeneity owing to differences in study design or analysis, intervention, type of insurance and other contextual factors. If heterogeneity exists due to aforementioned components, we will not perform meta-analysis. After ruling out clinical or methodological heterogeneity, we will statistically measure heterogeneity by using I^2 test. If significant heterogeneity (>50%) persists for a particular outcome, meta-analysis will not be conducted. In this case, our focus would be on conducting narrative synthesis and undertaking a subgroup analysis. Key findings of the studies will be summarised in tables/figures or vote counting will be considered. Subgroups could be based on study design, intervention type, insurance type (such as private and public), region and other contextual factors (eg, urban/rural).

Qualitative synthesis

We will carry out thematic analysis as suggested by Thomas and Harden.²⁶ An iterative process of line-by-line coding

Table 3 Data extraction format

Publication details	First author's last name
	Year of publication
Publication type: report/ journal publication	
Population characteristics	Age Gender Religion/race/ethnicity No of participants included
Location/setting	State/district or other details of place where study was conducted Setting: hospital/community based Rural/urban
Study methodology/design	Study design: RCT, quasi-randomised trial, case-control study. Type of analysis
Intervention details	Type of intervention, mode of delivery, other details such as content/ frequency, who provided it. Start time and duration of intervention Details of comparison
Insurance details	Public/private/community-based insurance Start or launch date (month and year) of insurance Type of plan, for example, individual, family, senior citizen, critical illness. Benefits of health insurance, for example, cashless facility, hospitalisation, prehospitalisation and posthospitalisation, medical check-up, maternity benefits, childcare, critical illness.
Exposure details	List different factors or themes
Outcome details	List down outcome, variable type: continuous or categorical, type of analysis Effect measures with 95% CI (such as OR, risk ratio, HR) No of participants analysed, number lost to follow-up Details of subgroup analysis, if any. Themes and subthemes
Other details	
RCT, randomised controlled trial.	

will be undertaken as a first step, which will be followed by categorising the codes into code families. Subsequently, a code tree will be created, and themes and subthemes will be generated. Three reviewers (SSP, ER and BTV) will code the data independently and resolve the discrepancies by discussion until consensus is achieved.

Mixed-methods synthesis

The result from both, qualitative and quantitative synthesis will be merged for each outcome. Parallel synthesis will be carried out, and the findings will be summarised narratively.²⁵ To understand the influence of inequality in uptake of health insurance based on type of insurance, we will explore the possibility of conducting subgroup analysis based on some of the components of PROGRESS (Place of residence, Race/ethnicity/culture/language, Occupation, Gender, Religion, Education, Socio-economic status, Social capital)-Plus framework.²⁷

Grading the evidence

We will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to evaluate the certainty of evidence for each outcome.²¹ Using GRADE profiler software, we will present the main

findings of the systematic review in a summary of findings table.

Patient and public involvement

We did not involve patients or public while designing and writing this protocol.

Ethics and dissemination

This review will be based on published studies, therefore, an ethical clearance is not applicable. We have planned following activities to communicate and disseminate the findings of this review. We plan to make at least one national or international conference presentation. We will prepare policy brief to be shared with funder and to get a wider reader, we plan to submit the manuscript to a peer-reviewed journal. On journal publication, we intend to circulate the findings through our social media platform and website.

Twitter Shradha S Parsekar @ParsekarShrads

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Contributors RB is the guarantor of the review. RB, SSP, ER and BTV conceptualised the manuscript. SSP drafted the first manuscript, which was further edited by ER. RV developed the search strategy. All the authors (RB, BU, SSP, ER, RV and BTV) read, edited, provided feedback and approved the final manuscript.

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Disclaimer Funder did not have any role in writing this protocol and decision to submit it for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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