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The real price of health- experiences of out-of-pocket costs in Australia: protocol for a systematic review

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Title: The real price of health- experiences of out-of-pocket costs in Australia: protocol for a systematic review

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Term	Definition	Author initials
Conceptualization	Ideas; formulation or evolution of overarching research goals and aims	JD, AP
Methodology	Development or design of methodology; creation of models	SW, JD, AP, SDL, DB
Software	Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components	N/A
Validation	Verification, whether as a part of the activity or separate, of the overall replication/ reproducibility of results/experiments and other research outputs	SW, AP
Formal analysis	Application of statistical, mathematical, computational, or other formal techniques to analyse or synthesize study data	N/A
Investigation	Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection	SW
Resources	Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools	N/A
Data Curation	Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later reuse	N/A
Writing - Original Draft	Preparation, creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation)	SW
Writing - Review & Editing	Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre-or post-publication stages	SW, JD, AP, DB, VF
Visualization	Preparation, creation and/or presentation of the published work, specifically visualization/ data presentation	SW
Supervision	Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team	JD
Project administration	Management and coordination responsibility for the research activity planning and execution	SW, JD
Funding acquisition	Acquisition of the financial support for the project leading to this publication	JD

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Keywords:

Out-of-pocket costs, expenses, chronic disease, multimorbidity

Conflict of Interest Statement

The authors declare that they have no competing interests

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ABSTRACT

Introduction

Australians have substantial out-of-pocket (OOP) health costs compared to other developed nations, even with universal health insurance coverage. This can significantly affect access to care and subsequent wellbeing, especially for priority populations including those on lower incomes or with multimorbidity and chronic illness. While it is known that high OOP healthcare costs may contribute to poorer health outcomes, it is not clear exactly how these expenses are experienced by people with chronic illnesses. Understanding this may provide critical insights into the burden of OOP costs among people with chronic illnesses and may highlight policy gaps.

Method and analysis

A systematic review of qualitative studies will be conducted across Pubmed, CINAHL Complete (EBSCO), Cochrane Library, PsycINFO (Ovid) and EconLit from date of inception to June 2022. Primary outcomes will include people's experiences of out-of-pocket costs such as their preferences, priorities, trade-offs and other decision-making considerations. Study selection will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines and methodological appraisal of included studies will be assessed using the Critical Appraisal Skills Programme (CASP). A narrative synthesis will be conducted for all included studies.

Ethics and dissemination

Ethics approval was not required given this is a systematic review that does not include human recruitment or participation. This review is part of "The Real Price of Health: Experiences of Out-of-Pocket Costs in Australia" project, funded by an Australian Research Council Discovery Early Career Researcher Award (Grant ID: DE220100663) and the Australian National University.

Prospero registration number CRD42022337538

Strength and limitations of this study

- This systematic review protocol follows guidelines from the Preferred Reporting Items for Systematic Review and Meta-Analysis and Cochrane handbook.
- The systematic review addresses a gap in the literature through investigating how out of pocket costs affects the subjective experience of patients with chronic diseases.
- Limitations may include scarcity of studies or low-quality evidence exploring the qualitative experience of out-of-pocket costs in Australians with chronic diseases
- The data analysed may not be representative of the general Australian population due to detection, selection and publication bias or limited studies.
- This systematic review will be limited to Australian studies published in English.

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INTRODUCTION

Even with Medicare, a universal healthcare insurance coverage, Australians have significant out-of-pocket (OOP) health costs compared to other countries with similar economies(1-3). The impact of these expenses can be substantial and disproportionally affect the wellbeing of priority populations, including those with chronic illnesses and disabilities(4-7). Yet while OOP healthcare costs affect a significant portion of Australians, including those with chronic diseases, little is known about their experiences with these costs including any variations between income groups; for example, what trade-offs do people make to pay for health care and medicines? Understanding this is crucial to the provision of equitable healthcare and addressing potential policy gaps.

OOP health costs are the most direct way in which the financial impact of a medical condition is felt. Australia has consistently high OOP costs for individuals compared to similar economies, with figures between 18% and 22%(1, 2, 8, 9) of healthcare spending. In comparison the Organisation for Economic Co-operation and Development (OECD) median is 15.8%(3). This proportion is unlikely to decrease given the National Health and Hospitals Reform Commission has recommended maintenance of the balance in spending through taxation, private health insurance and OOP contribution(10). In fact, rather than decreasing, historical data indicates OOP health costs have been increasing since 1984(11). A research group examined OOP health expenditure at two timepoints – one at 2009-10 and the second at 2015-16 and found OOP household healthcare expenditure was consistently greater than total household expenditure and OOP as a fraction of household expenditure increased by over 25% between 2009-10 and 2015-16(8, 12). This growth has been largely attributed to rising private health insurance expenses(12, 13).

The burden of OOP health costs is not distributed equitably. People with chronic illnesses tend to be older, have lower incomes, higher healthcare costs and spend a greater proportion of their incomes on healthcare (8, 13-15). Moreover, chronic conditions compound existing levels of financial stress(14) with the literature showing each additional chronic ailment increases the likelihood of severe financial burden by almost 50%(15). These high costs are the product of rising co-payments, private medical consultations and inadequately subsidised health support associated with chronic diseases(7, 16).

These financial burdens have enduring individual and systemic effects. Both Australian(17) and international studies associate a pattern of decreased adherence to medications with increased OOP costs (18-20) and the opposite with reduced OOP costs(21). Australian research suggests that up to 14% of the population and 24% of those with chronic health concerns forgo recommended healthcare due to cost(22); this is consistent with international studies(23-25). These statistics highlight the need to further stratify and understand why certain populations are disproportionally affected by OOP healthcare costs.

Of note, while the literature has associated cost related non-adherence with increased hospitalisations (26), comorbidities(27) and significant systemic economic burden(28, 29) these have been disputed. Some studies suggest that safety net schemes from Medicare, a publicly funded universal health care insurance in Australia, are ineffective due to the need for recipients to pay beyond an annual OOP threshold and its limited coverage of medical items(30, 31), while others suggest only certain aspects of care are vulnerable to OOP costs with bulkbilling practises mitigating financial burden as a barrier to receiving primary health care (32, 33).

We aim to elucidate how OOP costs of healthcare and medicines are experienced by Australians with chronic illnesses and their preferences in managing these costs. Exploring these experiences will provide critical insights into decision making amongst Australians with chronic disease and highlight important policy gaps.

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METHODS AND ANALYSIS

Protocol development

This study protocol is based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) and the Cochrane Handbook for Systematic Reviews as described elsewhere(36, 37). The protocol for this review is registered with the PROSPERO International Prospective Register of Systematic Reviews (CRD42022337538)

Search strategy

In the interest of maintaining reproducibility and transparency, this search strategy was developed in accordance with the PRISMA-P checklist(36). Search terms followed a CHIP (context, how, issues, population) framework as described elsewhere(38). Five databases including Pubmed, CINAHL Complete (EBSCO), Cochrane Library, PsycINFO (Ovid) and EconLit will be systematically searched from their inception to (June 2022) for the primary source of literature. In addition, the reference lists of selected studies and review articles will be searched.

Search terms were developed in a CHIP design and combined using Boolean operators “AND” and “OR”. An initial exploratory search was performed on all databases mentioned previously and Proquest. The search strategy was updated based on search results and Proquest was removed as excessive studies were mined.

The final search term is as follows: ((Interview*) OR (survey*) OR (qualitative)) AND (("out of pocket") OR ("out-of-pocket") OR ("financial burden*") OR ("financial hardship*") OR ("health expenditure*") OR ("high cost*") OR ("financial toxicity")) AND ((experience*) OR (perception*) OR (attitude*) OR (view*)) AND (Australia*). The following limits were applied where stratification tools were available: English language, geographic subset of Australia or New Zealand, human studies, research articles, scholarly journals. In Cochrane Library, only trials were considered. No restriction was placed for the date.

The final search string that will be used for the literature search conducted on the 29th of June is documented in Table 1.

Table 1. Search string conducted on CINAHL Complete (EBSCO)

Restrictions: Boolean/phrase, Also search within the full text of the articles, Full text available, English language, research article, Scholarly (peer reviewed journals), Human, Geographic subset - Australia& NZ, Publication type: all

Search number	Query	Search Details
1	Interview*	Interview, interviews, interviewing, interviewed
2	Survey*	Survey, surveys
3	Qualitative	Qualitative
4	“out of pocket"	out of pocket
5	“out-of-pocket"	out-of-pocket
6	“financial burden*"	financial burden, financial burdens
7	"financial hardship*"	financial hardship, financial hardships

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8	"health expenditure*"	Health expenditure, health expenditures
9	"high cost*"	High cost, high costs, high costing, high costed
10	("financial toxicity"))	Financial toxicity
11	AND ((experience*) OR	Experience, experiences, experienced, experiencing
12	(perception*	Perception, perceptions
13	(attitude*) OR	Attitude, attitudes
14	(view*))	View, views, viewing, viewed
15	(Australia*)	Australia, Australian
16	#1 OR #2 OR # 3	Interview OR interviews OR interviewing, interviewed OR survey OR surveys OR qualitative
17	#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10	out of pocket OR out-of-pocket OR financial burden OR financial burdens OR financial hardship OR financial hardships OR health expenditure OR health expenditures OR high cost OR high costs OR high costing OR high costed OR financial toxicity
18	#11 or #12 OR #13 OR #14	Experience OR experiences OR experienced OR experiencing OR perception OR perceptions OR attitude OR attitudes OR view OR views OR viewing OR viewed OR viewership OR viewer
11	#16 AND #17 AND #18 AND #15	(Interview OR interviews OR interviewing, interviewed OR survey OR surveys OR qualitative) AND (out of pocket OR out-of-pocket OR financial burden OR financial burdens OR financial hardship OR financial hardships OR health expenditure OR health expenditures OR high cost OR high costs OR high costing OR high costed OR financial toxicity) AND (experience OR experiences OR experienced OR experiencing OR perception OR perceptions OR attitude OR attitudes OR view OR views OR viewing OR viewed OR viewership OR viewer) AND (Australia, Australian)

Study selection

Search results will be uploaded to and managed from Covidence, a workflow platform which allows for collaborators to review uploaded studies while limiting bias (39).

The criterion for selecting studies is described in table 2. A broader search strategy will be implemented without the term ‘chronic diseases’ as including the term may limit the strength of the search and its findings. Data allowing, this search will be narrowed to only include studies referring to populations with chronic illness. All studies describing how OOP costs affect individuals with chronic diseases, regardless of

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the pathology type, will be selected. The exclusion criteria will be review articles, studies written in language other than English or those describing populations outside Australia.

Table 2: The inclusion criteria as described in a CHIP format, and the exclusion criteria.

	Inclusion criteria	Exclusion criteria
Context	Australian public health systems	-
How	Qualitative studies	-
Issues	Experiences of out-of-pocket costs	-
Populations	Adults living in Australian who have or are managing one or more chronic diseases.	-
Study design		Review articles, commentaries, letters, issue briefs, editorials, poster presentations or conference papers
Language	English	-
Setting	Australia	-
Timing	From database inception to 29 June 2022	-

The planned selection process is illustrated in Figure 1. Three members of the research team (SW, AP, JD) will independently review the studies to determine their inclusion in the review. A preliminary screening will be based on the study title and abstract. The full text of studies included from this stage will then be screened. Conflicts will be resolved through consensus between the three reviewers. If a study is excluded in the selection phase, the reason for exclusion will be recorded. During this process, no reviewers will be blinded to the study types, journals, and authors.

Data extraction

A data extraction table will be developed and piloted. Two independent reviewers will extract data from five studies each and compare their results to establish agreement and the validity of the extraction tool.

Data items to be extracted include:

1. Identification of the study (article title, journal, authors, year, citation, host institution (research center/university/hospital/organization), conflict of interest, funding/sponsorship),
2. Methodological description (study purpose, study design, demographics of participant including chronic illness and socio-economic status or income, recruitment process, inclusion, exclusion criteria, statistical analysis),
3. Main findings (people's experiences of out-of-pocket costs including their preferences, priorities, trade-offs and other decision-making considerations.).

If a study's outcome is unclear, the authors will be contacted for interpretation or clarification. Any disagreements will be resolved through discussion and consensus between the three reviewers.

Quality appraisal

Risk of bias will be assessed using the Critical Appraisal Skills Programme (CASP) checklist(40) by two independent reviewers (SW and JD). CASP is a standardized appraisal tool which provides a systematic

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assessment of the reliability and validity of published papers(40). Discrepancies will be resolved in discussion with a third reviewer (AP).

Data synthesis and meta-analysis

Interpretation of the data will be discussed amongst the study team. A narrative approach will be taken to synthesizing data using the Centre for Reviews and Dissemination guidelines(41). This will include detailed, written commentary on extracted data related to outcomes listed in table 2. Doing so will further our understanding of how people with chronic disease experience and manage the OOP costs of health care.

Any significant changes made to this protocol will be documented and published with the findings of the systematic review.

Patient and public involvement

The research team includes health services researchers, with backgrounds in nursing, medicine, sociology, public health and epidemiology. The team also includes two people living with chronic disease, who will be involved in the interpretation of findings and study write up.

Ethics and dissemination

Ethics approval was not required given this is a systematic review that does not include human recruitment or participation. The study's findings will be published in peer-review journals, conferences and symposia and shared to consumers, policy makes and service providers.

AUTHOR CONTRIBUTIONS

SW prepared the study protocol and drafted the manuscript. JD and AP supervised the procedure of developing the study protocol. HDL, DB and VF reviewed the study protocol.

All authors were involved in discussions related to the study design and concept. The manuscript was revised by all authors.

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Funding officials are not involved in any part of the review including protocol development, data selection, synthesis, reporting and publishing of the results.

Competing interests

None declared.

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FIGURE

Figure 1. The planned selection process. Duplicates will be removed in endnote prior to importing references into Covidence for screening and selection.

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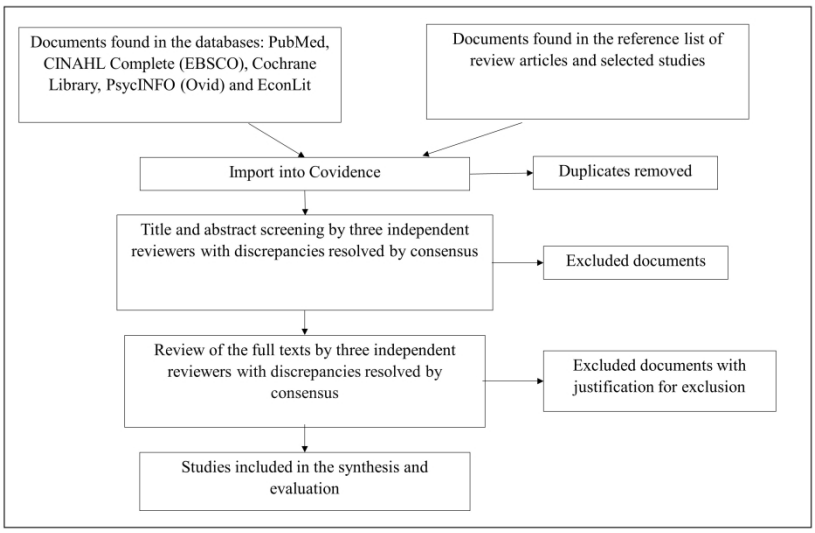

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Section and topic	Item No	Checklist item	Presence and location
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Yes, preceding abstract
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Yes, under the subheading 'Protocol development' of the methods.
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Yes, in the title page
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Yes, under the subheading 'Author contributions'
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Yes, under the subheading 'data synthesis' of the methods.
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Yes, under the subheading 'Funding'
Sponsor	5b	Provide name for the review funder and/or sponsor	Yes, under the subheading 'Funding'
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Yes, under the subheading 'Funding'
INTRODUCTION			

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Rationale	6	Describe the rationale for the review in the context of what is already known	Yes, in the introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Yes, have done this in the form of CHIP (context, how, issues, population)
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Yes, under the subheading 'study selection'
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Yes, under the subheading 'search strategy'
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Yes, under the subheading 'search strategy' and in Table 1.
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Yes, under the subheading 'study selection'
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Yes, under the subheading 'study selection'
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Yes, under the subheading 'data extraction'
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Yes, under the subheading 'data extraction'
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Yes, under the subheading 'data extraction'
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Yes, under the subheading 'quality appraisal'

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Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A – study data may not be suitable for quantitative synthesis.
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I², Kendall's τ)	N/A- data likely not suitable for quantitative synthesis.
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Yes, under the subheading 'data synthesis'
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Yes, under the subheading 'data synthesis'
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Yes, under the subheading 'quality appraisal'
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Yes, at the top of the page
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Yes, in the introduction paragraph 1-5)
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Yes, in the introduction paragraph 6)
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Yes, in table 2 and under the subheading 'Study Selection' of the Methods
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Yes, under the subheading 'Search Strategy' of the methods.
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Yes, under the subheading 'Search Strategy' of the methods.
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Yes, under the subheading 'Study selection' of the methods.
Data collection	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the	Yes, under the

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
process		process.	subheading 'Study selection of the methods' and 'Data extraction'.
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Yes, under the subheading 'Data extraction' of the methods.
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Yes, under the subheading 'Data extraction' of the methods.
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Yes, under the subheading 'Quality appraisal' of the methods.
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Outcomes are under the subheading 'Data extraction' of the methods. The effect measures are not stated yet as data collection has not begun.
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Yes, under the subheading 'Data synthesis and meta-

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
			analysis' of the methods.
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Yes, under the subheading 'Data synthesis and meta-analysis' of the methods.
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A.
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Yes, under the subheading 'Data synthesis and meta-analysis' of the methods.
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A.
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Yes, under the subheading 'quality appraisal' of the methods.
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Yes, under the subheading 'quality appraisal' of the methods.
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	N/A
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	N/A
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	N/A

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	N/A
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N/A
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	N/A
	23b	Discuss any limitations of the evidence included in the review.	N/A
	23c	Discuss any limitations of the review processes used.	N/A
	23d	Discuss implications of the results for practice, policy, and future research.	N/A
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Yes, under the subheading 'Protocol development' of the methods
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	N/A
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	N/A
Competing interests	26	Declare any competing interests of review authors.	Yes, under the subheading 'Competing interests'
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

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The real price of health- experiences of out-of-pocket costs in Australia: protocol for a systematic review

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Title: The real price of health- experiences of out-of-pocket costs in Australia: protocol for a systematic review

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ABSTRACT

Introduction

Australians have substantial out-of-pocket (OOP) health costs compared to other developed nations, even with universal health insurance coverage. This can significantly affect access to care and subsequent wellbeing, especially for priority populations including those on lower incomes or with multimorbidity and chronic illness. While it is known that high OOP healthcare costs may contribute to poorer health outcomes, it is not clear exactly how these expenses are experienced by people with chronic illnesses. Understanding this may provide critical insights into the burden of OOP costs amongst this population group and may highlight policy gaps.

Method and analysis

A systematic review of qualitative studies will be conducted using Pubmed, CINAHL Complete (EBSCO), Cochrane Library, PsycINFO (Ovid) and EconLit from date of inception to June 2022. Primary outcomes will include people's experiences of OOP costs such as their preferences, priorities, trade-offs, and other decision-making considerations. Study selection will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and methodological appraisal of included studies will be assessed using the Critical Appraisal Skills Programme (CASP). A narrative synthesis will be conducted for all included studies.

Ethics and dissemination

Ethics approval was not required given this is a systematic review that does not include human recruitment or participation. The study's findings will be disseminated through conferences and symposia and shared with consumers, policy makers and service providers, and published in a peer reviewed journal.

Prospero registration number CRD42022337538

Strength and limitations of this study

- This systematic review protocol follows guidelines from the Preferred Reporting Items for Systematic Review and Meta-Analysis and Cochrane handbook.
- The systematic review addresses a gap in the literature through investigating how out-of-pocket costs affects the subjective experience of people with chronic diseases.
- Limitations may include a scarcity of studies or low-quality evidence exploring the qualitative experience of out-of-pocket costs in Australians with chronic diseases
- The data analysed may not be representative of the general Australian population due to detection, selection and publication bias or limited studies.
- This systematic review will be limited to Australian studies published in English.

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INTRODUCTION

Even with Medicare, a universal healthcare insurance coverage, Australians have significant out-of-pocket (OOP) health costs compared to other countries with similar economies(1-3). The impact of these expenses can be substantial and disproportionally affect the wellbeing of priority populations, including those with chronic illnesses and disabilities(4-7). Yet while OOP healthcare costs affect a significant portion of Australians, including those with chronic diseases, little is known about their experiences with these costs, including any variations between income groups; for example, what trade-offs do people make to pay for health care and medicines? Understanding this is crucial to the provision of equitable healthcare and addressing potential policy gaps.

OOP health costs are the most direct way in which the financial impact of a medical condition is felt. Australia has consistently high OOP costs for individuals compared to similar economies. Australia's OOP expenditure as a proportion of health spending is ranked 16th highest amongst the 34 high income OECD members at 14.9%(8). This is substantially greater than countries such as the United States (9.9%), United Kingdom (12.3%), Canada (12.6%) and New Zealand (12.9%)(8).

The impact of these OOP costs is likely to only grow in significance given historical data indicates that OOP health costs in Australia have been increasing since 1984(9). More recently, from 2009-10 to 2015-16OOP household healthcare expenditure increased at a greater rate than total household expenditure at 3.8% per annum and 2.4% per annum respectively(10).. This growth in OOP expenditure has been largely attributed to rising private health insurance premiums, which make up the largest proportion of household OOP expenses (40.6%), followed by co-payments towards health professionals (28.3%) and therapeutic products including subsidised medicines (20.4%) (10). The impact of these increasing costs is unclear but may include households foregoing health insurance as demonstrated elsewhere in the world(11). In 2009, the National Health and Hospitals Reform Commission recommended maintaining existing balances in Australian healthcare spending derived from taxation, private health insurance and OOP contribution(12). *Exploring how OOP health costs impact vulnerable populations, including those living with chronic health conditions or from lower socioeconomic backgrounds, will help us better understand the implications of such recommendations and possibly encourage amendments*.

The burden of OOP health costs is not distributed equitably. People with chronic illnesses tend to be older, have lower incomes, higher healthcare costs and spend a greater proportion of their incomes on healthcare (13-16). Moreover, chronic conditions compound existing levels of financial stress(13) with the literature indicating that each additional chronic ailment increases the likelihood of severe financial burden by almost 50%(14). These high costs are the product of rising co-payments, private medical consultations and inadequately subsidised health support associated with chronic diseases(7, 17).

Such financial burdens have enduring individual and systemic effects. Both Australian(18) and international studies associate a pattern of decreased adherence to medications with increased OOP costs (19-21) and the opposite with reduced OOP costs(22). Australian research suggests that up to 14% of the population and 24% of those with chronic health concerns forgo recommended healthcare due to cost(23); this is consistent with international studies(24-26). These statistics highlight the need to further stratify and understand why certain populations are disproportionally affected by OOP healthcare costs.

Of note, while the literature has associated high OOP costs with treatment non-adherence and increased hospitalisations (27), comorbidities(28) and significant systemic economic burden(29, 30), the aspect of care most affected by OOP costs has been disputed. Some studies suggest that safety net schemes from Medicare, Australia's publicly funded universal health care insurance scheme, are ineffective due to the need for recipients to pay beyond an annual OOP threshold and the limited coverage of medical items(31, 32). Under these safety net schemes, Australians are divided into two key groups, concession card holders, which includes pensioners and low-income populations, and general patients. Each medication costs up to

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$6.80 for concession card holders and $42.50 for general patients until they meet a threshold of $244.80 and $1, 457.10 respectively, following which concession card holders receive fully subsided medications while general patients pay a reduced cost of $6.80 per prescription(33). Other studies suggest only certain aspects of care are vulnerable to OOP costs with bulkbilling practises mitigating financial burden as a barrier to receiving primary health care (34, 35).

We aim to elucidate how OOP costs of healthcare and medicines are experienced by Australians with chronic illnesses and their preferences in managing these costs. Exploring these experiences will provide critical insights into decision making amongst Australians with chronic disease and highlight important policy gaps.

METHODS AND ANALYSIS

Protocol development

This study protocol is based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) and the Cochrane Handbook for Systematic Reviews as described elsewhere(36, 37). The protocol for this review is registered with the PROSPERO International Prospective Register of Systematic Reviews (CRD42022337538)

Search strategy

In the interest of maintaining reproducibility and transparency, this search strategy was developed in accordance with the PRISMA-P checklist (see Supplementary file) (36). Search terms followed a CHIP (context, how, issues, population) framework as described elsewhere(38). Five databases including Pubmed, CINAHL Complete (EBSCO), Cochrane Library, PsycINFO (Ovid) and EconLit will be systematically searched from their inception to 29th June 2022 for the primary source of literature. In addition, the reference lists of selected studies and review articles will be searched.

The search strategy was developed in collaboration with team members using an iterative approach. Search terms were developed using the CHIP framework and combined using Boolean operators “AND” and “OR.” An initial exploratory search was performed on all databases mentioned previously plus Proquest. The returned results demonstrated that some relevant papers that were disease specific (e.g. cancer) did not include the term “chronic disease” and that including this as a search term would limit results and exclude relevant literature. Proquest returned an unmanageable amount of results of which many were irrelevant following a check of the initial 100 results, and relevant studies were identified in the other databases. The search strategy was updated based on our exploratory search results - “chronic disease” was removed as a search term and Proquest was excluded as a database.

The final search terms are as follows: ((Interview*) OR (survey*) OR (qualitative)) AND (("out of pocket") OR ("out-of-pocket") OR ("financial burden*") OR ("financial hardship*") OR ("health expenditure*") OR ("high cost*") OR ("financial toxicity")) AND ((experience*) OR (perception*) OR (attitude*) OR (view*)) AND (Australia*). The following limits were applied where stratification tools were available: English language, geographic subset of Australia or New Zealand (it was not possible to select only Australia), human studies, research articles, scholarly journals. In Cochrane Library, only trials were considered. No restriction was placed for the date.

The final search string that will be used for the literature search to be conducted on the 29th of June 2022 is documented in Table 1.

Table 1. Search string conducted on CINAHL Complete (EBSCO)

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Restrictions: Boolean/phrase, Also search within the full text of the articles, Full text available, English language, research article, Scholarly (peer reviewed journals), Human, Geographic subset - Australia& NZ, Publication type: all		
Search number	Query	Search Details
1	Interview*	Interview, interviews, interviewing, interviewed
2	Survey*	Survey, surveys
3	Qualitative	Qualitative
4	“out of pocket"	out of pocket
5	“out-of-pocket"	out-of-pocket
6	“financial burden*"	financial burden, financial burdens
7	"financial hardship*"	financial hardship, financial hardships
8	"health expenditure*"	Health expenditure, health expenditures
9	"high cost*"	High cost, high costs, high costing, high costed
10	("financial toxicity"))	Financial toxicity
11	AND ((experience*) OR	Experience, experiences, experienced, experiencing
12	(perception*	Perception, perceptions
13	(attitude*) OR	Attitude, attitudes
14	(view*))	View, views, viewing, viewed
15	(Australia*)	Australia, Australian
16	#1 OR #2 OR # 3	Interview OR interviews OR interviewing, interviewed OR survey OR surveys OR qualitative
17	#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10	out of pocket OR out-of-pocket OR financial burden OR financial burdens OR financial hardship OR financial hardships OR health expenditure OR health expenditures OR high cost OR high costs OR high costing OR high costed OR financial toxicity
18	#11 or #12 OR #13 OR #14	Experience OR experiences OR experienced OR experiencing OR perception OR perceptions OR attitude OR attitudes OR view OR views OR viewing OR viewed OR viewership OR viewer
11	#16 AND #17 AND #18 AND #15	(Interview OR interviews OR interviewing, interviewed OR survey OR surveys OR qualitative) AND (out of pocket OR out-of-pocket OR financial burden OR financial burdens OR financial hardship

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		OR financial hardships OR health expenditure OR health expenditures OR high cost OR high costs OR high costing OR high costed OR financial toxicity) AND (experience OR experiences OR experienced OR experiencing OR perception OR perceptions OR attitude OR attitudes OR view OR views OR viewing OR viewed OR viewership OR viewer) AND (Australia, Australian)

Study selection

Search results will be uploaded to, and managed from, Covidence, a workflow platform which allows for collaborators to review uploaded studies while limiting bias (39).

The criterion for selecting studies is described in table 2. As described earlier, a broader search strategy will be implemented that excludes the term 'chronic disease' as it was determined that including the term may limit the strength of the search and its findings. Data allowing, this search will be narrowed to only include studies referring to populations with chronic illness. All studies describing how OOP costs affect individuals with chronic diseases, regardless of the pathology type, will be selected. The exclusion criteria will be review articles, studies written in language other than English or those describing populations outside Australia.

Table 2: The inclusion criteria as described in a CHIP format, and the exclusion criteria.

	Inclusion criteria	Exclusion criteria
Context	Australian public health systems	-
How	Qualitative studies	-
Issues	Experiences of out-of-pocket costs	-
Populations	Adults living in Australian who have or are managing one or more chronic diseases.	-
Study design		Review articles, commentaries, letters, issue briefs, editorials, poster presentations or conference papers
Language	English	-
Setting	Australia	-
Timing	From database inception to 29 June 2022	-

The planned selection process is illustrated in Figure 1. Three members of the research team (SW, AP, JD) will independently review the studies to determine their inclusion in the review. A preliminary screening will be based on the study title and abstract. The full text of studies included from this stage will then be screened. Conflicts will be resolved through consensus between the three reviewers. If a study is excluded in the selection phase, the reason for exclusion will be recorded. During this process, no reviewers will be blinded to the study types, journals, and authors.

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Data extraction

A data extraction table will be developed and piloted. Two independent reviewers will extract data from five studies each and compare their results to establish agreement and the validity of the extraction tool.

Data items to be extracted will include:

1. Identification of the study (article title, journal, authors, year, citation, host institution (research center/university/hospital/organization), conflict of interest, funding/sponsorship),
2. Methodological description (study purpose, study design, demographics of participant including chronic illness and socio-economic status or income, recruitment process, inclusion, exclusion criteria, statistical analysis),
3. Main findings (people's experiences of out-of-pocket costs including their preferences, priorities, trade-offs, and other decision-making considerations.).

If the outcome of a study is unclear, the authors will be contacted for interpretation or clarification. Any disagreements will be resolved through discussion and consensus between the three reviewers.

Quality appraisal

Risk of bias will be assessed using the Critical Appraisal Skills Programme (CASP) checklist(40) by two independent reviewers (SW and JD). CASP is a standardised appraisal tool which provides a systematic assessment of the reliability and validity of published papers(40). Discrepancies will be resolved in discussion with a third reviewer (AP).

Data synthesis and meta-analysis

Interpretation of the data will be discussed amongst the study team. A narrative approach will be taken to synthesising data using the Centre for Reviews and Dissemination guidelines(41). This will include a detailed, written commentary on extracted data related to outcomes as listed in table 2. Doing so will further our understanding of how people with chronic disease experience and manage the OOP costs of health care.

Any significant changes made to this protocol will be documented and published with the findings of the systematic review.

Patient and public involvement

We follow a co-production approach in all our work. The research team includes health services researchers, with backgrounds in nursing, medicine, sociology, public health, and epidemiology. The team also includes two people who are not academics and are living with chronic disease, (one of whom is a co-author on this protocol), and who will be involved in the interpretation and analysis of findings and study write up.

Ethics and dissemination

Ethical approval is not required given this is a systematic review that does not include human recruitment or participation. The study's findings will be disseminated through conferences and symposia and shared with consumer groups, policy makers and service providers, and published in a peer-reviewed journal,

AUTHOR CONTRIBUTIONS

SW prepared the study protocol and drafted the manuscript. JD and AP supervised the procedure of developing the study protocol. HDL, DB and VF reviewed the study protocol.

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All authors were involved in discussions related to the study design and concept. The manuscript was revised by all authors.

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Funding officials are not involved in any part of the review including protocol development, data selection, synthesis, reporting and publishing of the results.

Competing interests

None declared.

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Figure legend

Figure 1. The planned selection process.

*Duplicates will be removed in Endnote prior to importing references into Covidence for screening and selection.

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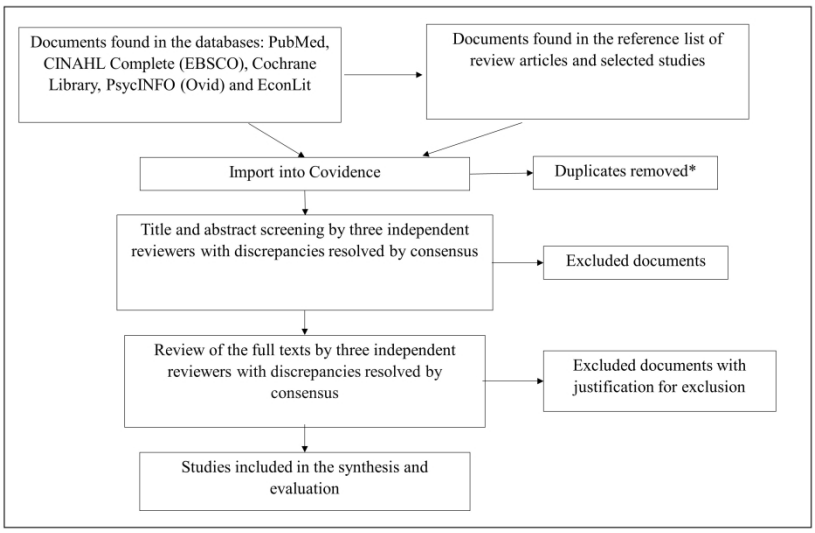

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Presence and location
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Yes, preceding abstract
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Yes, under the subheading 'Protocol development' of the methods.
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Yes, in the title page
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Yes, under the subheading 'Author contributions'
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Yes, under the subheading 'data synthesis' of the methods.
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Yes, under the subheading 'Funding'
Sponsor	5b	Provide name for the review funder and/or sponsor	Yes, under the subheading 'Funding'
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Yes, under the subheading 'Funding'
INTRODUCTION			

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Rationale	6	Describe the rationale for the review in the context of what is already known	Yes, in the introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Yes, have done this in the form of CHIP (context, how, issues, population)
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Yes, under the subheading 'study selection'
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Yes, under the subheading 'search strategy'
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Yes, under the subheading 'search strategy' and in Table 1.
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Yes, under the subheading 'study selection'
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Yes, under the subheading 'study selection'
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Yes, under the subheading 'data extraction'
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Yes, under the subheading 'data extraction'
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Yes, under the subheading 'data extraction'
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Yes, under the subheading 'quality appraisal'

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Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A – study data may not be suitable for quantitative synthesis.
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I², Kendall's τ)	N/A- data likely not suitable for quantitative synthesis.
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Yes, under the subheading 'data synthesis'
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Yes, under the subheading 'data synthesis'
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Yes, under the subheading 'quality appraisal'
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Yes, under the subheading 'quality appraisal'

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Yes, in the title page
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Yes, under the subheading 'Author contributions'
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Yes, under the subheading 'data synthesis' of the methods.
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