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Psychological distress and quality of life following provision of vascular imaging results of the coronary and carotid arteries to asymptomatic adults: a scoping review protocol

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STUDY PROTOCOL

REVISED Psychological distress and quality of life following provision of vascular imaging results of the coronary and carotid arteries to asymptomatic adults: a scoping review protocol [version 3; peer review: 2 approved]

Previously titled: Mental distress and quality of life following provision of vascular imaging results of the coronary and carotid arteries to asymptomatic adults: a scoping review protocol

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Abstract

Background: Non-invasive screening for atherosclerosis or asymptomatic cardiovascular disease of the coronary and carotid arteries is commonly undertaken, and research has been focussed on how results from these screenings lead to behaviour change. However, no review has focused on the effects of these results on psychological distress and health-related quality of life (HRQoL). This protocol will outline how a scoping review will be conducted to map all available evidence on psychological distress and/or HRQoL outcomes following the provision of vascular imaging results of the coronary and carotid arteries.

Methods: Arksey and O'Malley's (2005) framework subsequently enhanced by Levac et al. (2010) and Peters et al (2015, 2017) will guide the scoping review. Databases such as MEDLINE (Clarivate), APA

Open Peer Review

Approval Status ✓ ✓

	1	2
version 3 (revision) 09 Nov 2021		✓ view
version 2 (revision) 28 May 2021	✓ view	? view
version 1 26 Nov 2020	✗ view	

1. **Md Mahbub Hossain**, Texas A&M

PsychINFO, EMBASE, Social Work Abstracts, Psychology and Behavioural Sciences Collection, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) will be searched using MeSH terms such as "Coronary stenosis", "Carotid Stenosis", "Psychological Distress" and "Quality of Life" and related terms. Two investigators will screen title and abstract and all articles meeting inclusion criteria will be extracted. Data on authors, publication year, country of origin, aims/purpose, methodology, intervention, outcome measures as well as key findings that relate to the scoping review questions will be extracted for each included study. The findings will be presented using tables and thematic narrative synthesis. The scoping review will not produce a pooled estimate of the impact of vascular imaging results on psychological distress and HRQoL but will present information from the included studies related to psychological distress and HRQoL.

Conclusion: The review will highlight and address gaps in knowledge and provide direction for future investigations.

Keywords
Psychological distress, Quality of life, Non-invasive vascular imaging, Asymptomatic adults, Scoping review

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REVISED **Amendments from Version 2**

There will be no critical appraisal and risk of bias assessment for this review and therefore the quality appraisal section in the protocol has been removed.

Any further responses from the reviewers can be found at the end of the article

Introduction

Cardiovascular disease (CVD) refers to diseases of the blood vessels, and in particular the heart, brain and peripheral vasculature[1]. CVDs due to atherosclerosis include cerebrovascular events such as stroke, ischaemic heart disease events such as heart attacks, and peripheral arterial diseases causing peripheral claudication[1]. CVD is the leading cause of death and disability globally[1,2] with an estimated 17.9 million people dying from CVDs in 2016, representing 31% of all global deaths. Of these CVD-related deaths, 85% were due to heart attack and stroke or their sequelae[2]. By 2030, it is estimated that more than 22.2 million people will die annually from CVDs[3].

Atherosclerosis before clinical events, or "asymptomatic CVD", can be easily visualised using a range of imaging methods, with the most common being computed tomography of the coronary arteries to calculate coronary artery calcification (CAC) or carotid ultrasound to identify carotid plaques and assess intimal medial thickness[4]. Imaging of the arteries to identify asymptomatic CVD is becoming commonplace in medical practice[5], and provides asymptomatic individuals with a visible and tangible illustration of an otherwise hidden disease process, even before distinctive symptoms appear[6]. Such information can improve an individual's knowledge of the disease which may enable them to increase control over, and improve their health[7]. Increased knowledge may also lead to personal and social benefits, such as enabling effective community action and contributing to developing one's social capital[8,9]. However, diagnostic information or results related to a disease (depending on how the situation is evaluated) may also affect an individual's sense of well-being[10] or lead to psychological distress[6,11,12]. For example, previous studies have reported that women who undergo mammography screening may be susceptible to psychological distress following the provision of results[13–21].

Psychological distress, often referred to as mental distress, refers to the unique discomforting emotional state an individual experiences in response to a particular demand or stressor that causes temporary or permanent harm to them[22]. Psychological distress often manifests through attributes including: (a) discomfort (e.g., anguish, misery, suffering); (b) perceived inability to effectively cope (e.g., inability to solve problems); (c) communication of discomfort (e.g. facial expressions); (d) loss of independence and confidence (e.g. dependency, decreased self-esteem);and/or (e) changes in emotional status (e.g. change from stable emotional state to one of depression, self-depreciation, amotivation, dysregulated motivation or maladaptive motivation, aggressiveness, irritability, nervousness, and anxiety)[23–33]. Quality of Life (QOL) encompasses a person's psychological state, appraisals of physical health, personal beliefs as well as social relationships[34]. It is often measured in research using physical and mental health summary scores[35]. This review focuses on health-related quality of life (HRQoL), which refers to a multidimensional construct encompassing appraisals of physical and emotional health, wellness or illness[36–38]. HRQoL is generally considered as the most suitable variant of quality of life when one is investigating medical conditions or disease related outcomes[39]. HRQoL and psychological distress have been extensively studied in health research[40–46]. Reported impaired HRQoL (e.g., illness , role limitations due to physical or emotional/psychological problems), improved HRQoL (e.g., wellness, improved physical or mental health) and psychological distress (e.g., anxiety, depression, worry) following screening are the outcomes of interest for this scoping review. Psychological outcomes will be reported under HRQoL domain in this scoping review if they were categorised as QoL/HRQoL in the included studies (e.g., measured using validated QoL/HRQoL instrument and reported as impaired/improved QoL/HRQoL). Psychological outcomes will also be reported under psychological distress domain in this scoping review if they were measured and reported as a single psychosocial variable (e.g., depression, self-esteem, anxiety).

The scoping review was informed by Witte's[47] extended parallel process model (EPPM) and cognitive stress appraisal theory[48]. Based on the constructs of the EPPM[47], the provision of information—in particular, negative information—about a person's coronary artery calcium and carotid plaque (and the potential implications of this condition) is likely to stimulate subjective 'threat' appraisals (i.e., perceived susceptibility to, and severity of, CVD)[49]. Depending on interactions between that threat appraisal and individuals' efficacy appraisals, individuals may react to screening information by (a) adopting danger control responses (including attitudes, beliefs, behavioural intentions, and/or behaviours) that align with message recommendations, or (b) adopting fear control processes (such as denial, reactance, and avoidance) intended to reduce fear rather than take protective action[50]. Behavioural intentions and/or behaviours such as increasing physical activity, health responsibility, good nutrition, and stress management could impact health outcomes[51]. Behavioural intentions and/or behaviours are also associated with lifestyle related disease burden such as CVD[52] which could undermine HRQoL[53]. Cognitive stress appraisal theory[48] also proposes that individuals primarily evaluate circumstances/situations as 'challenging' (i.e., threat that can be overcome or met) or 'threatening' (i.e., anticipated loss/harm)[48]. Positive cognitive stress appraisal (i.e. appraising a situation as a challenge to be resolved and setting goals to achieve that) may contribute to prevention of depression and improved HRQoL[54]. Negative appraisals of stress—viewing an issue such as detected atherosclerotic plaque in the arteries as a threat and believing that resolving it is beyond one's abilities—may, however, lead to psychological distress[55–57].

Based on the EPPM and cognitive stress appraisal frameworks, we therefore hypothesized that; (a) population screening

to detect atherosclerotic plaque in the coronary or carotid arteries can influence HRQoL, and (b) population screening to detect atherosclerotic plaque in the coronary or carotid arteries can cause psychological distress. To date, however, the available evidence that may support (or refute) these hypotheses has not been scrutinised or reported in any coherent manner. Hence, there is a need for a scoping review to synthesize the state of scientific literature on this subject.

Scoping reviews aim to map key concepts, main sources and types of evidence available in a research area and can be undertaken where an area is complex or has not been comprehensively reviewed before[58]. Previous reviews reported very little evidence relating to HRQoL or psychological distress following provision of vascular imaging results to asymptomatic adults[7,59–62]. It is important, therefore, to collate evidence relating to the findings available in this field, how studies in this field have been conducted, the key characteristics of studies, and important knowledge gaps. As such, this scoping review will comprehensively map the evidence on psychological distress and HRQoL outcomes following provision of vascular imaging results of the coronary or carotid arteries to asymptomatic adults. We will also report other details of included studies that we deem important in this scoping review (e.g., the information provided during counselling and whether the counselling could reduce distress, or any information included in the results that shaped the nature of the response).

Study rationale and guiding question

There is great interest (and value) in providing people with vascular imaging results of the coronary and carotid arteries to prompt healthful behaviour change and better management of CVD[7,60]. However, the provision of the imaging results may produce markedly different emotions—and as a result, downstream behaviours—depending upon the way in which they are received and appraised. Also, the uncertainty about a possible future threat (due to coronary artery calcium and carotid plaque) may cause anxiety[63]. There is theoretical justification to anticipate that information aimed at prompting healthful behaviour change and better management of CVD may stimulate negative psychosocial outcomes or psychological distress such as anxiety or depression impairing HRQoL. Accordingly, it is important to identify which research questions have and have not been addressed in this area. Also, by highlighting the extent of findings on distress and/or HRQoL, a scoping review could support the development of strategies designed to mitigate or prevent distress during and following such screening exercises.

The aim of this review is to map all available evidence on psychological distress and HRQoL outcomes among participants who were screened for atherosclerosis by non-invasive methods and provided with their own coronary or carotid artery vascular imaging results. This scoping review will address this research question:

1. What is the state of scientific literature on psychological distress and HRQoL related to the provision of vascular imaging results of the coronary and carotid arteries, and what are the gaps in that literature?

Table 1 further clarifies the core elements of the questions guiding the conduct of this scoping review.

Protocol

Methods

Study design. The framework initially developed by Arksey and O'Malley[64] and subsequently enhanced by Levac *et al.*[65] and Peters *et al.*[66–68] will be used for this scoping review. The framework involves stages such as: (1) identifying, clarifying, defining and linking the purpose of the study and the research question; (2) identifying relevant studies, balancing comprehensiveness and breadth with feasibility; (3) developing and aligning inclusion criteria with study questions and objectives; (4) using an iterative approach to study selection and data extraction; (5) using a planned approach to searching evidence, study selection, extracting data, and evidence presentation; (6) incorporating qualitative thematic analysis and numerical summary to collating, summarizing and reporting the results; and (7) Summarizing the evidence in relation to the aims of the review, making conclusions and identifying any implications for practice, policy or research. The reporting of this scoping review will also be guided by the PRISMA extension for scoping review reporting checklist[69].

Identifying relevant studies

Information sources and search strategy. The main purpose of a scoping review is to comprehensively identify primary studies (published and unpublished) and reviews suitable for answering the review questions. To achieve this, databases such as MEDLINE (Clarivate), APA PsychINFO, EMBASE, Social Work Abstracts, Psychology and Behavioural Sciences Collection, and Cumulative Index to Nursing and Allied Health Literature (CINAHL), will be searched for articles of relevance. Further manual searching of reference lists in identified articles will be undertaken to include other studies of relevance. We will also search relevant grey literature databases such as Open Grey and Open Access Theses and Dissertations (OATD) to identify relevant studies.

Approach to developing search strategy. Different sources (e.g. MeSH headings and thesaurus) will be used to identify terms and synonyms to comprehensively cover the research questions as much as possible[70–73]. The proposed search strategy was developed in consultation with an academic librarian (Table 2) for MEDLINE using MeSH terms such as "Coronary stenosis", "Carotid Stenosis", "Psychological Distress" and "Quality of Life". We also used Boolean operators "AND" to narrow search results to include only relevant results containing required keywords and "OR" to expand search results and combine synonyms. Other keywords such as behaviour, lifestyle, motivation, risk perception, medication adherence and smoking cessation were included to capture all relevant studies as mental health and HRQoL outcomes are unlikely to be primary or secondary outcomes and thus reported in the title or abstract. This search strategy will be modified for use in other databases. Due to the exploratory nature of scoping reviews and the need to ensure a comprehensive search of relevant literature, an iterative approach to search strategies will be employed[64]. This implies that the search strategy will be

Table 1. An overview of core elements of scoping review questions. HRQoL, health-related quality of life

CORE ELEMENTS	EXPLANATION
SCOPE OF THE REVIEW	Global
SETTING	Community and/or clinical settings
POPULATION	Adult participants who have been screened for coronary artery calcium/calcification or carotid plaque/ stenosis
INTERVENTION	Screening for atherosclerosis in the coronary or carotid arteries using non-invasive imaging techniques
COMPARISON	1. Reported psychological distress and/or HRQoL in sub-groups provided with results of detected atherosclerotic plaque after screening and those without 2. Reported psychological distress and/or HRQoL in sub-groups within different risk categories (e.g. no risk/normal, low risk, mild risk, moderate risk and high risk groups) 3. Reported psychological distress and/or HRQoL in sub-groups with knowledge of test results and those without 4. Reported psychological distress and/or HRQoL in sub-groups screened and provided results and non-screening group 5. Reported psychological distress and/or HRQoL in populations before and after provision of results
EVALUATION	Reported changes/no changes or differences/no differences in psychological distress and/or HRQoL following the provision of vascular imaging results of an individual's carotid or coronary arteries; how studies were conducted and important knowledge gaps.

Table 2. Proposed search strategy. MeSH, Medical Subject Headings; CAC, Coronary Artery Calcium.

"coronary stenosis"[MeSH Terms] OR Coronary Stenosis [Text Word] OR Coronary artery stenosis OR "Carotid Stenosis"[MeSH] OR Carotid plaques OR Carotid ultrasound OR Coronary artery calc* OR Coronary calc* OR CAC score* OR Coronary artery calcium score OR Calcium score
AND
Mental* OR "Psychological Distress"[MeSH] OR Psych* OR "Quality of Life"[MeSH] OR "Anxiety"[MeSH] OR Anx* OR "Depression"[MeSH] OR Dep* OR mood OR Worr* OR alarm OR Lifestyle change OR Behaviour change OR Behaviour OR Lifestyle OR Motivation OR Risk perception OR Risk perception* OR Medication adherence OR smoking cessation

updated as we discover new terms as we work through the review.

These terms will be searched as keywords in the title and abstract headings and no date limits will be applied. Search results will be downloaded, imported and saved as Microsoft Word and PDF documents. Database outputs will be compared to check for the existence of any duplicates.

Study selection

Databases and records will be screened using the eligibility criteria (see below) and studies not meeting the criteria will be excluded. The process for identification, screening, eligibility and studies to be included is displayed in Figure 1. The process of searching and selection will be reported in the main review using a PRISMA flowchart[74].

The screening will begin with title and abstract screening by two investigators (RA and JRL) who will independently screen the titles and abstracts for all retrieved records for inclusion and to agree on exclusions. This process will be piloted using a sample of abstracts to ensure that this approach will be efficient enough to capture all relevant articles. Any articles that meet the inclusion criteria or that cannot be excluded will be retained for full text review. For the second stage, two investigators (RA and JRL) will each independently screen the full text of articles to determine if they meet the inclusion criteria and conflicts will be resolved by an independent reviewer (LCB) and data from included studies will be extracted.

Inclusion criteria

The following inclusion criteria will apply:

a) Study characteristics

Studies must be of adults who are 18 years and over and asymptomatic (not screened due to clinical symptoms such as chest pain or angina) and without pre-existing CVD (e.g., stroke, myocardial infarction, peripheral arterial disease or transient

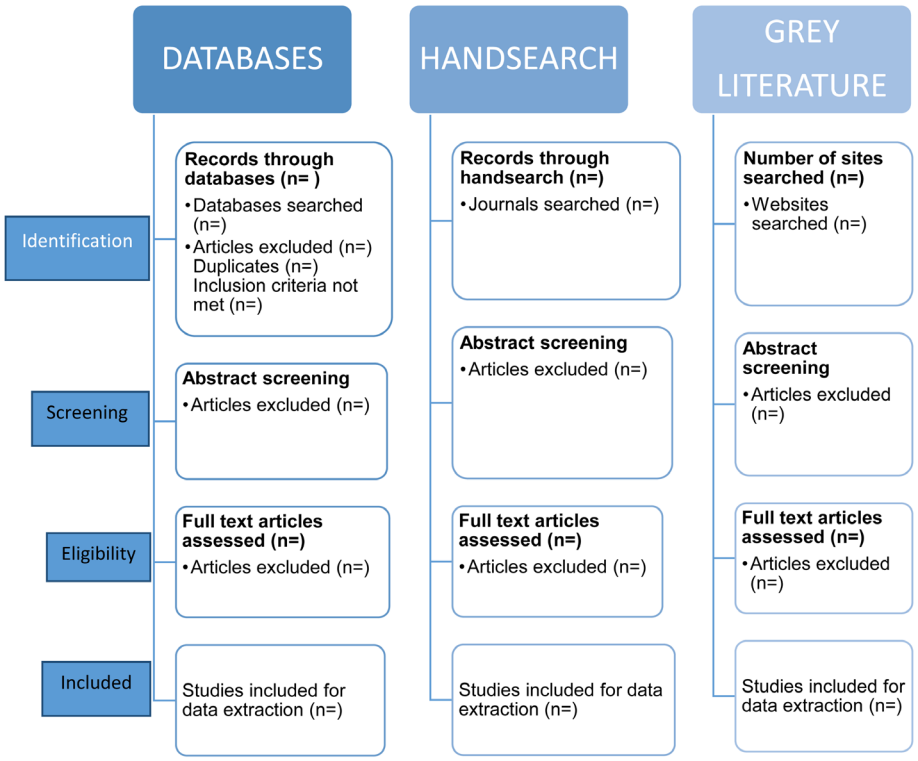

Figure 1. Selection process chart.

ischemic attack). Studies may report follow-up assessment and outcomes such as psychological distress and/or HRQoL after participants received information related to their own coronary artery calcification or carotid stenosis/plaque.

b) Study types

Study types that will be included for this scoping review are empirical studies of any type. No year of publication and language restrictions will be applied.

Concepts

i) Imaging results

Information regarding the state of arteries, extent of stenosis, extent of coronary artery calcification, or carotid/atherosclerotic plaques, coronary calcium score, arterial wall irregularities or obstructive artery walls conveyed to study participants.

ii) Psychological distress and HRQoL

An article may report psychological distress (e.g., anxiety, depression, impulsivity, worry, psychoticism, impulsivity, aggression, obsession-compulsion, or interpersonal sensitivity) and/or QoL/HRQoL (i.e., an individual's self-perceived health status) as an outcome or include QoL/HRQoL measure using a standard instrument to be included in this review.

c) Context

This scoping review will include studies conducted in any geographical location among any racial/ethnic group and gender. Studies will be included irrespective of their settings.

Exclusion criteria

a) Study types, participants, and imaging methods

Studies in symptomatic patients undergoing invasive imaging for diagnostic purposes will be excluded. Other studies that will be excluded are studies providing imaging results of other vascular diseases/conditions such as Aneurysm or Endoleak; Angiodysplasia; Angioedema; Angiomatosis (Bacillary Angiomatosis, Klippel-Trenaunay-Weber Syndrome, Sturge-Weber Syndrome, von Hippel-Lindau Disease); Arteriovenous Malformations; Capillary Leak Syndrome; Ischemic Colitis; Compartment Syndromes; Diabetic Angiopathies; Hand-Arm Vibration Syndrome; Hemorrhoids; Hemostatic Disorders; Hyperemia; Hepatic Veno-Occlusive Disease; Hypotension; Peliosis Hepatis; Ischemic Optic Neuropathy; Pulmonary Veno-Occlusive Disease; Scimitar Syndrome; Retinal Vein Occlusion;Pulmonary Vein Stenosis; Splenic Infarction; Superior Vena Cava Syndrome; Telangiectasis; Varicocele; Thoracic Outlet Syndrome; Varicose Veins; Vascular Fistula; Vascular Neoplasms; Vascular System Injuries; Vasculitis as well as Vasoplegia and Venous Insufficiency.

b) Outcomes

Studies without outcomes considered as psychological distress and/or QoL/HRQoL will be excluded. We will also exclude studies where psychological distress/psychiatric and/or QoL/HRQoL assessments were performed only before vascular imaging procedure and not after provision of imaging results.

Charting the data
A draft data extraction chart will be developed and piloted with a selection of identified studies. The diagrammatic or tabular form of presentation or charting will be used for this study. The potential chart categories may consist of authors information (names, year of publication, study location), participant characteristics (age, gender), research design, methods, instruments/techniques/clinical assessments used to gather data on coronary artery calcification, carotid plaque/stenosis, psychological distress, HRQoL and aims/purpose of the extracted studies (Table 3). We will also extract data on how vascular imaging results were provided and whether there was additional counselling or support mechanisms.

EndNote X9 will be used as a reference management tool and to avoid duplications. Microsoft Excel and Word will be used to manage data within the review team.

Collating, summarizing and reporting the results
This review will employ thematic and numeric approaches to summarise studies. A thematic approach will be used to summarise the main and sub-themes that will emerge after the scoping exercise. A numeric approach will also be used to summarise results of the scoping review by presenting the quantity of each emerging concept (e.g., worry was used interchangeably with anxiety (n=2) or most of the studies (n=25) measured depression using the Center for Epidemiological Studies Depression (C-ESD) instrument). The scoping review will not produce a pooled estimate of the impact of vascular imaging results on psychological distress and/or HRQoL as we aim to preliminary assess the potential size, scope and gaps in available literature.

Results on the state of scientific literature will be reported and the gaps in the literature will be identified. There will be further discussion on the implications of the results for practice and future research.

Study findings and dissemination
The findings from this review will be submitted to peer-reviewed journals to be considered for publication and may be presented at scientific conferences. Also, we aim to share our results with key stakeholders to influence policy and practice.

Study status
Start date of search: August 2020; anticipated date of completing review: July, 2021

Current study status:
Preliminary searches: Yes

Piloting search strategy: Yes

Pilot screening of search results: Yes

Study selection process piloting: Yes

Formal screening of search results against eligibility criteria: Started

Data extraction: Started

Data analysis and interpretation: Started

Conclusion
The purpose of this protocol is to describe the methodological considerations that will guide the completion of a scoping review that will summarise the extent, range and nature of studies on psychological distress and/or HRQoL outcomes reported among asymptomatic adults following the provision of vascular imaging results. This comprehensive review will help advance knowledge about potential negative effects of screening for asymptomatic CVD to elicit healthful behaviour changes. It could also possibly enable the development of strategies to prevent distress. The results of this review will help advance knowledge in this field and will be useful for future medical practice when providing vascular imaging

Table 3. Summary of data extraction items. HRQoL, health-related quality of life.

RECORD DETAILS	Last name of first author, publication year, journal
STUDY	Study purpose
SETTING	Study location
POPULATION	Age of participants, gender of participants, sample
INTERVENTION	Imaging technique used, results provision details, follow-up period after baseline screening, psychological distress and HRQoL outcome assessment instruments, counselling/additional support for study participants
STUDY DESIGN/ TYPE	As reported by authors or as defined by review team
OUTCOMES	Key psychological distress and/or HRQoL outcomes reported by authors

results to patients, cardiovascular research, and future clinical trials providing vascular imaging results to participants. This scoping review will be limited to studies reporting coronary or carotid artery plaque screening only as these are the commonly used structural vascular imaging modalities for large screening initiatives of asymptomatic individuals.

Ethics approval and consent to participate

There will be no formal ethical application and ethical review as no primary data will be collected.

Data availability

No data are associated with this article.

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 3

Reviewer Report 05 January 2022

https://doi.org/10.5256/f1000research.78990.r99576

✔ **Aaron Conway**
Peter Munk Cardiac Centre, Toronto, Canada

The authors have addressed my comments from the initial version.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I have published many systematic reviews in the area of cardiovascular care.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 2

Reviewer Report 06 October 2021

https://doi.org/10.5256/f1000research.56954.r93685

? **Aaron Conway**
Peter Munk Cardiac Centre, Toronto, Canada

This protocol for a scoping review is well-written and provides adequate detail about the proposed methods. In general, the methods seem well-justified given the research design. My one suggestion is to re-consider the intended use of Cochrane risk of bias assessment tools. Most up to date guidance for scoping reviews include recommendations that critical appraisal and risk of

bias assessment is not consistent with the aims of this systematic review design. For example: Peters *et al.* (2020[1]).

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Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I have published many systematic reviews in the area of cardiovascular care.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 01 Nov 2021

Reindolf Anokye, Edith Cowan University, Australia

We would like to thank the reviewer for his time reviewing the manuscript. We have considered the suggestion, other recommendations such as *PRISMA* extension for scoping reviews (2018), and the outcomes that will be reported in this scoping review and have decided not to include any critical appraisal and risk of bias assessment for this review.

Competing Interests: No competing interests were disclosed.

Reviewer Report 16 July 2021

https://doi.org/10.5256/f1000research.56954.r86346

Md Mahbub Hossain
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The updated version of the protocol addressed all major concerns that were mentioned in the prior peer-review comments.

Is the rationale for, and objectives of, the study clearly described?
Not applicable

Is the study design appropriate for the research question?
Not applicable

Are sufficient details of the methods provided to allow replication by others?
Not applicable

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Psychosocial Epidemiology; Evidence-based Mental Health; Mental Health Policies and Systems

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 08 March 2021

https://doi.org/10.5256/f1000research.30316.r77059

Md Mahbub Hossain

Department of Health Promotion and Community Health Sciences, School of Public Health, Texas A&M University, College Station, USA

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Samia Tasnim

Department of Health Promotion and Community Health Sciences, School of Public Health, Texas A&M University, College Station, USA

We want to express our gratitude to the authors who have chosen to work on such an important area of health science. With the growing burden of cardiovascular diseases, it is necessary to understand how such diagnoses may impact mental health and overall wellbeing in affected individuals. This prospective scoping review is likely to add great value; however, there are a few concerns that require to be addressed before the review protocol is indexed, and more importantly before the review is conducted.

First, the authors planned to use the framework by Arksey and O'Malley, which is one of the most widely used frameworks for scoping reviews. However, this framework has undergone further improvements by Levac et al. (2010)[1] and Peters et al. (2015, 2017)[2,3,4]. The authors may consider using the updated frameworks or give the rationale for using the current one over the more recent versions.

Second, in Table 1, the authors mentioned adults and international within core elements such as "perspective" and "setting," respectively. A researcher and/or a practitioner may wish to know where the population belonged to in the primary studies, which can be local/global as well as community/clinical settings. I'd suggest using "population" for adults and expanding the concept of "setting" to the community and/or clinical settings while keeping the search terms and the scope of the review as global. This would bring more clarity and might make more sense from a systematic assessment perspective on the evidence.

Third, the authors must explain what "mental distress" and "quality of life" are. These concepts have varying definitions from different disciplines. It may not be feasible to do another review to summarize what they mean; however, it would be useful to have at least a working definition of these concepts that refers to some of the leading articles explaining these terms. Such explanations would be helpful to present and discuss the findings of the review in the future. However, the protocol must mention these clearly before the review begins.

Lastly, in the concepts section, the authors mentioned that "studies must report" mental distress and quality of life. The use of "must" in both concepts creates a dilemma that is they will recruit articles if they (must) include both these concepts. We found this idea less practical. Rather, an article may report either "mental distress" or "quality of life," and the authors may present both as the summarized evidence, which would provide a better "map" of the evidence landscape. We would humbly request the authors to make necessary changes that reflect the true objective of the review, as they feel appropriate.

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Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Psychosocial Epidemiology; Evidence-based Mental Health; Mental Health Policies and Systems

We confirm that we have read this submission and believe that we have an appropriate level of expertise to state that we do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 17 May 2021

Reindolf Anokye, Edith Cowan University, Australia

We want to express our gratitude to the authors who have chosen to work on such an important area of health science. With the growing burden of cardiovascular diseases, it is necessary to understand how such diagnoses may impact mental health and overall wellbeing in affected individuals. This prospective scoping review is likely to add great value; however, there are a few concerns that require to be addressed before the review protocol is indexed, and more importantly before the review is conducted.

Response:

We would like to thank the reviewers for their time and valuable comments when reviewing the manuscript. We have extensively revised the manuscript to address the comments and feedback.

First, the authors planned to use the framework by Arksey and O'Malley, which is one of the most widely used frameworks for scoping reviews. However, this framework has undergone further improvements by Levac et al. (2010) and Peters et al. (2015, 2017). The authors may consider using the updated frameworks or give the rationale for using the current one over the more

recent versions.

Response:

We agree that the updated framework would better suit this study and provide a better approach to the design of the study including collating, summarizing and reporting the results. The framework has been updated in the manuscript. Please see the study design section for details of the updated framework.

Second, in Table 1, the authors mentioned adults and international within core elements such as "perspective" and "setting," respectively. A researcher and/or a practitioner may wish to know where the population belonged to in the primary studies, which can be local/global as well as community/clinical settings. I'd suggest using "population" for adults and expanding the concept of "setting" to the community and/or clinical settings while keeping the search terms and the scope of the review as global. This would bring more clarity and might make more sense from a systematic assessment perspective on the evidence.

Response:

Table 1 has been updated as per comments under 'study rationale and guiding question' section of the manuscript. We have now expanded the concept of "setting" to include community and/or clinical settings and also using "population" for adults while keeping the scope of the review global.

Third, the authors must explain what "mental distress" and "quality of life" are. These concepts have varying definitions from different disciplines. It may not be feasible to do another review to summarize what they mean; however, it would be useful to have at least a working definition of these concepts that refers to some of the leading articles explaining these terms. Such explanations would be helpful to present and discuss the findings of the review in the future. However, the protocol must mention these clearly before the review begins.

Response:

We agree that "mental distress" and "quality of life" could have been explained better in the manuscript. We have replaced mental distress with psychological distress in the manuscript even though articles using mental distress will still be included in the review. Although mental distress and psychological distress are often used interchangeably, psychological distress is well defined in the literature and is perhaps more easily understood. We have also expanded our definition of quality of life and indicated that our focus is on health-related quality of life. The explanation or definition for psychological distress and health-related quality of life can be found in the third paragraph of the introduction section of the manuscript.

Lastly, in the concepts section, the authors mentioned that "studies must report" mental distress and quality of life. The use of "must" in both concepts creates a dilemma that is they will recruit articles if they (must) include both these concepts. We found this idea less practical. Rather, an article may report either "mental distress" or "quality of life," and the authors may present both as the summarized evidence, which would provide a better "map" of the evidence landscape. We would humbly request the authors to make necessary changes that reflect the true objective of the review, as they feel appropriate.

Response:

We have replaced "studies must report" with "an article may report" psychological distress

and/or quality of life/health-related quality of life for inclusion in the review. This can be found in the concepts section of the manuscript.

Competing Interests: None