

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>info.bmjopen@bmj.com</u>

BMJ Open

Self-efficacy instruments for individuals with coronary artery disease: a systematic review protocol

Journal:	BMJ Open	
Manuscript ID	bmjopen-2022-062794	
Article Type:	Protocol	
Date Submitted by the Author:	15-Mar-2022	
Complete List of Authors:	Almeida, Jose Alexandre; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Florêncio, Rêncio; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Lemos, Darllane; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Leite, Jéssica; Universidade Federal do Rio Grande do Norte, Physical Therapy Graduate Program Monteiro, Karolinne; Universidade Federal do Rio Grande do Norte, Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program Peroni Gualdi, Lucien; Universidade Federal do Rio Grande do Norte, Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program	
Keywords:	CARDIOLOGY, Coronary heart disease < CARDIOLOGY, Ischaemic heart disease < CARDIOLOGY, Myocardial infarction < CARDIOLOGY	



Title: Self-efficacy instruments for individuals with coronary artery disease: a systematic review protocol.

Authors: José Alexandre Barbosa de Almeida¹, Rêncio Bento Florêncio², Darllane Azevedo Lemos³, Jéssica Costa Leite⁴, Karolinne Souza Monteiro⁵, Lucien Peroni Gualdi⁶.

Affiliation: ^{1,2,3} Master students, Rehabilitation Sciences Graduate Program, Federal University of Rio Grande do Norte, Santa Cruz, RN – Brazil;⁴ Ph.D. Physical Therapy Graduate Program, Federal University of Rio Grande do Norte, Natal, RN – Brazil; ^{5,6} Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program, Federal University of Rio Grande do Norte, Santa Cruz, RN – Brazil.

Corresponding author: Lucien Peroni Gualdi – Programa de Pós Graduação em Ciências da Reabilitação, Faculdade de Ciências da Saúde do Trairi, Rua Vila do Trairi S/N, CEP: 59200-000, Santa Cruz, RN – Brazil. E-mail address: lugualdi@hotmail.com, Telephone: +55(84) 99480 6888.

Financial support: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

iez oni

Word count: 1.155.

ABSTRACT

Introduction: Self-efficacy is associated with management of diseases, psychological well-being, improved quality of life, and rehabilitation adherence. Several instruments related to behavior or specific disease (e.g., coronary artery disease [CAD]) assess self-efficacy. The evaluation of cardiac self-efficacy in individuals with CAD will support healthcare professionals to improve self-efficacy in interventions; therefore, a suitable instrument is crucial. This systematic review aims to assess measurement properties, methodological quality, and content of outcome measures of cardiac self-efficacy instruments for individuals with CAD.

Methods and analysis: The study will be developed according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol (PRISMA-P) and Consensus Norms for Selection of Health Measuring Instruments (COSMIN). Search strategy will be performed in the following databases: MEDLINE (ovid), Web of Science, EMBASE, and PsycINFO. Studies assessing measurement properties of cardiac self-efficacy instruments for individuals with CAD and without language or date restrictions will be included. Two independent authors will be responsible for eligibility of studies. Methodological quality of studies will be assessed using the COSMIN RoB Checklist, whereas the Classification of Recommendations, Assessment, Development and Assessment (GRADE) will assess quality of each study. Another two authors will independently evaluate the content and link to the International Classification of Functioning, Disability, and Health.

Ethics and Dissemination: This study does not require ethics committee approval since it is based on previously published data. Evidence from this systematic review will be disseminated through publication in peer-reviewed journals of high scientific impact.

PROSPERO registration number: CRD42021262613.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- First systematic review evaluating instruments to assess cardiac self-efficacy in individuals with CAD.
- The review will use updated standards based on consensus (e.g., COSMIN) to select measurement instruments and report measurement properties of multiple validation studies.
- The review will allow researchers and healthcare professionals to choose validated patient-reported outcome measures according to measurement properties to improve assessment and rehabilitation programs.

- Published studies without language and date restrictions will be included to consider the maximum number of relevant studies.
 - The extracted content from eligible measurement instruments will be compared to ICF core sets.

INTRODUCTION

Self-efficacy is defined as the belief of individuals about their ability to organize and perform a certain activity. It consists of elements of awareness, planning, and motivation, which can reflect on self-responsibility throughout the disease process;[1] thus, it is important for health promotion and management of chronic diseases.[1-3] Moreover, self-efficacy is associated with psychological well-being, improved quality of life, and better rehabilitation adherence.[4,5]

Measurement instruments of self-efficacy can be general[6], for specific health conditions (e.g., feeding behavior, physical activity, and medication adherence),[7-9] or specific diseases (e.g., asthma, stroke, and coronary artery disease [CAD]).[10-13] Although many scales and questionnaires are available for self-efficacy, literature lacks methodological rigor and choice of instrument for individuals in pulmonary, metabolic, and cardiovascular rehabilitation programs.

CAD is characterized as reduced coronary artery lumen due to atherosclerotic plaques and may lead to chest pain, pressure or tightness sensation at different degrees of exertion, and dyspnea.[14, 15] Conventional treatment implies cardiovascular rehabilitation and changes in daily habits. The admission of individuals to cardiovascular rehabilitation programs aims to delay and prevent complications and improve physical fitness through aerobic and strength training.[16]

Therefore, instruments assessing self-efficacy are needed to prevent complications and increase treatment adherence.[1, 3] In this context, the assessment of cardiac self-efficacy instruments for individuals with CAD will support healthcare professionals in individual interventions and improve self-efficacy of patients. This systematic review aims to identify instruments developed to assess cardiac self-efficacy in individuals with CAD and evaluate methodological quality and measurement properties. We also aim to

link the content of instruments to the International Classification of Functioning, Disability, and Health (ICF). Based on this, the review will facilitate identifying discrepancies in measurement instruments and guide further research.

METHODS

Study method

This systematic review will be developed according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P)[17] and the Consensusbased Standards for the Selection of Health Measurement Instruments (COSMIN).[18, 19]

Protocol registration

The protocol was registered in the international prospective register of systematic reviews (PROSPERO registration number CRD42021262613). Relevant changes in the systematic review will be documented in the PROSPERO and published in the final study.

Inclusion and exclusion criteria

Studies on the development of assessment of measurement properties of cardiac selfefficacy instruments for individuals with CAD will be included without language and date restrictions. Clinical trials or validation studies using self-reported or proxyreported measurements and those published as abstracts will be excluded.

Search strategy

The search strategy will be conducted from inception to date in MEDLINE (ovid), Web of Science, EMBASE and PsycINFO databases considering the following: (1) construct of interest (cardiac self-efficacy); (2) target population (individuals with CAD); (3) type of instrument (questionnaire or scale); and (4) measurement properties; the latter will be assessed using search filters validated for measurement studies and already applied in previous reviews. Additional searches for relevant studies will be manually performed in reference lists of primary studies and review articles. Searches will be performed

again before final analysis to verify new studies. The Supplementary file 1 show the search strategies we developed for the databases search. The study will follow COSMIN recommendations.[20]

Screening and selection of studies

An online survey will be imported into a Mendeley reference manager list (https://www.mendeley.com). Duplicates will be deleted before selections, and the reference list exported to the Rayyan Qatar Computing Research Institute systematic review platform (https://rayyan.qcri.org).[21] The detailed selection process will be presented in the PRISMA-P flowchart.

Two independent authors (JABA and DAL) will select studies using titles and abstracts, conduct a complete reading of potentially eligible studies, and identify and record reasons for excluding those ineligible. In the case of disagreement, a virtual meeting will be held for discussion and consultation with a third reviewer (LPG).

Data extraction

Two authors (JABA and DAL) will extract data following the Cochrane Collaboration and PRISMA guidelines. Other authors will independently review data to verify inclusion and exclusion criteria. The extracted information will include first author, year of publication, general characteristics of the instrument (construct, subscales, number of items, and version), study design, sample size, characteristics of individuals (e.g., age, sex, location, country, language, methods for selecting participants, and response rate), and results of measurement properties (i.e., internal consistency, reliability, measurement error, content validity [including face validity], construct validity [subdivided into structural validity, hypothesis testing, and cross-cultural validity], validity of criterion, responsiveness, and interpretability [not a measurement property, but necessary to adapt a research instrument or clinical practice]).

Data quality

Methodological quality of studies will be assessed by two independent authors (RBF and JCL) using COSMIN RoB Checklist.[18, 19] This tool considers ten measurement properties and contains nine boxes with 3 to 35 items. Each box assigns a methodological quality score for instrument development: (1) content validity, (2)

structural validity, (3) internal consistency, (4) cross-cultural validity and measurement invariance, (5) reliability, (6) measurement error, (7) criterion validity, (8) hypothesis testing for construct validity, and (9) responsiveness. Each item has four response options: inadequate, doubtful, adequate, and very good.[22] Disagreements will be solved by a third author (KSM).

The content extracted from measurement instruments will be compared using the ICF framework.[23–25] Two independent authors (JABA and RBF) will evaluate the content and link items of questionnaires to ICF standards. After, a third author (JCL) will review the content.

Data synthesis

A narrative synthesis of results will be provided. Results and findings from different studies will be summarized if measurement properties are from the same instrument. A combination of measurement properties will determine the overall evidence of the instrument. Studies will be grouped according to similarity in terms of language, instrument version, study population, and application form.

Results will be evaluated in clusters or summarized against the criteria for good measurement properties to determine whether they are sufficient (+), insufficient (-), inconsistent (+/-), or indeterminate (?). Furthermore, a modified Classification of Recommendations, Assessment, Development, and *Evaluation* (GRADE) will determine study quality.[26, 27]

Afterward, instruments will be categorized and justified according to COSMIN recommendations:[28] (A) instrument is recommended for use and results are reliable; (B) when it may be recommended but requires further research to assess quality of these instruments; and (C) instrument should not be recommended.

Patient and public involvement

The design of this protocol does not involve individuals or the public.

Ethics and Dissemination

The study does not require ethics committee approval since it is based on published data. Evidence from this systematic review will be disseminated through publication of

 results in peer-reviewed journals of high scientific impact and submitted to scientific conferences.

DISCUSSION

This study is the first systematic review assessing measurement instruments for cardiac self-efficacy in individuals with CAD. The study will provide scientific evidence of existing tools through measurement analysis. Thus, results will highlight current gaps, guide future research, allow healthcare professionals and researchers to choose the best instrument for assessment, and facilitate referral of individuals to rehabilitation.

However, potential challenges may arise even following COSMIN guidelines and the PRISMA-P protocol since studies only report some psychometric properties.

Contributors: Authors made substantial contributions to the study design, developed inclusion criteria, and search strategies. JABA developed the protocol, RBF, DAL, JCL, KSM, and LPG provided critical insights and reviewed the protocol. JABA registered the protocol in the PROSPERO database. All authors read and approved the final version of the protocol.

Funding Statement: The study will be financied by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) – Brazil. JABA, DAL and RBF received grant from CAPES by Finance Code 001.

Competing interests: None declared.

Patients consent for publication: Not applicable.

Provenance and peer review: Not commissioned, externally peer-reviewed.

Open access: This is an open-access article distributed by the Creative Commons Attribution Non-Commercial (CC BY-NC 4.0) license, which allows distribution, remix, adapt, build upon this study non-commercially, and license the derivative studies on different terms. Original study must be cited, given appropriate credit, any changes must be indicated, and the use is non-commercial. See http://creativecommons.org/licenses/by-nc/4.0/.

ORCIDS iDs:

José Alexandre Barbosa de Almeida https://orcid.org/0000-0002-0876-6794 Rêncio Bento Florêncio https://orcid.org/0000-0003-2853-7988 Darllane Azevedo Lemos https://orcid.org/0000-0003-2020-3940 Jéssica Costa Leite https://orcid.org/0000-0002-4726-9416 Karolinne Souza Monteiro https://orcid.org/0000-0003-2254-8723 Lucien Peroni Gualdi https://orcid.org/0000-0002-6907-7335

REFERENCES

- 1 Bandura A. Health promotion by social cognitive means. *Health Educ Behav* 2004;31:143–64.doi:10.1177/1090198104263660.
- 2 Roest AM, Martens EJ, Denollet J, et al. Prognostic association of anxiety post myocardial infarction with mortality and new cardiac events: A metaanalysis. *Psychosom Med* 2010;72:563–9 doi:10.1097/PSY.0b013e3181dbff97
- 3 Bandura, A. Self-efficacy. In V. S. Ramachaudran, *Encyclopedia of human behavior*. New York: Academic Press. 1994.
- Joekes K, Van Elderen T, Schreurs K. Self-efficacy and overprotection are related to quality of life, psychological well-being and self-management in cardiac patients. *J Health Psychol* 2007;12:4–16. doi:10.1177/1359105306069096.
- Katch H. The role of self-efficacy in cardiovascular disease selfmanagement: a review of effective programs. *Patient Intell* 2010;2:33-44.doi:10.2147/PI.S12624

6	Luszczynska A, Scholz U, Schwarzer R. The general self-efficacy scale: Multicultural validation studies. <i>J Psychol</i> 2005;139:439- 57.doi:10.3200/JRLP.139.5.439-457.
7	Birkett NJ, Hotz SB. A self-efficacy scale for heart-healthy eating. <i>Can J Public Health</i> 1994;85:201-4. PMID: 7922967.
8	Wong EML, Leung DYP, Sit JWH, <i>et al.</i> Prospective Validation of the Chinese Version of the Self-Efficacy for Exercise Scale among Middle- Aged Patients with Coronary Heart Disease. <i>Rehabil Nurs</i> 2020;45:74– 9.doi:10.1097/RNJ.00000000000156.
9	Saffari M, Zeidi IM, Fridlund B, <i>et al.</i> A Persian Adaptation of Medication Adherence Self-Efficacy Scale (MASES) in Hypertensive Patients: Psychometric Properties and Factor Structure. <i>High Blood Press</i> <i>Cardiovasc Prev</i> 2015;22:247–55.doi:10.1007/s40292-015-0101-8.
10	Holley S, Knibb R, Latter S, <i>et al.</i> Development and validation of the Adolescent Asthma Self-Efficacy Questionnaire (AASEQ). <i>Eur Respir J</i> 2019;54:1–10.doi:10.1183/13993003.01375-2018.
11	Topçu S, Oguz S. Translation and validation study for the stroke self - efficacy questionnaire in stroke survivors. <i>Int J Nurs Pract</i> 2018:24:1– 8.doi:10.1111/ijn.12646.
12	Sullivan MD, Lacroix AZ, Russo J, <i>et al.</i> Self-efficacy and self-reported functional status in coronary heart disease: A six-month prospective study. <i>Psychosom Med</i> 1998;60:473–8.doi:10.1097/00006842-199807000-00014.
13	Fors A, Ulin K, Cliffordson C, <i>et al.</i> The Cardiac Self-Efficacy Scale, a useful tool with potential to evaluate person-centred care. <i>Eur J Cardiovasc Nurs</i> 2015;14:536–43.doi:10.1177/1474515114548622.
14	Li H, Sun K, Zhao R, <i>et al.</i> Inflammatory biomarkers of coronary heart disease. <i>Front Biosci (Schol Ed)</i> 2018;10:185–96.doi:10.2741/s508.

15	Cagle SD, Cooperstein N. Coronary Artery Disease: Diagnosis and
	Management. Prim Care 2018;45:45-61.doi:10.1016/j.pop.2017.10.001
16	Carvalho T, Milani M, Ferraz AS, et al. Brazilian Cardiovascular
	Rehabilitation Guideline – 2020. Arq Bras Cardiol 2020;114:943–
	87.doi:10.36660/abc.20200407.
17	Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for
	systematic review and meta-analysis protocols (prisma-p) 2015:
	Elaboration and explanation. <i>BMJ</i> 2015;349:1–25.doi:10.1136/bmj.g7647.
18	Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for
	assessing the methodological quality of studies on measurement properties
	of health status measurement instruments: an international Delphi study.
	Qual Life Res 2010;19:539–49.doi:10.1007/s11136-010-9606-8.
19	Mokkink LB, Terwee CB, Knol DL, et al. The COSMIN checklist for
	evaluating the methodological quality of studies on measurement
	properties: a clarification of its content. BMC Med Res Methodol.
	2010;10:22.doi:10.1186/1471-2288-10-22.
20	Terwee CB, Jansma EP, Riphagen II, et al. Development of a
	methodological PubMed search filter for finding studies on measurement
	properties of measurement instruments. Qual Life Res 2009;18:1115-
	23.doi:10.1007/s11136-009-9528-5.
21	Ouzzani M, Hammady H, Fedorowicz Z, et al. Rayyan-a web and mobile
	app for systematic reviews. Syst Rev 2016;5:1-10.doi:10.1186/s13643-
	016-0384-4.
22	Mokkink LB, de Vet HCW, Prinsen CAC, et al. COSMIN Risk of Bias
	checklist for systematic reviews of Patient-Reported Outcome Measures.
	Qual Life Res. 2018;27:1171-9.doi:10.1007/s11136-017-1765-4.
23	Cieza A, Geyh S, Chatterji S, et al. ICF linking rules: An update based on
	lessons learned. J Rehabil Med 2005;37:212-
	8.doi:10.1080/16501970510040263.

1		
2		
4	24	Cieza A, Brockow T, Ewert T, <i>et al.</i> Linking health-status measurements
5		to the International Classification of Functioning, Disability and Health. J
6		Rehabil Med 2002:34:205-10 doi:10 1080/165019702760279189
/		10.401.1000/1000/1000/1000/1000/1000/100
9	25	Contra CC Contanada I. da Anadi EC. et al Afaniaño da famaionalidade em
10	25	Castro SS, Castaneda L, de Arauj ES, <i>et al</i> . Alerição de funcionalidade em
11		inquéritos de saúde no Brasil: Discussão sobre instrumentos baseados na
12		Classificação Internacional de Funcionalidade Incapacidade e Saúde
14		$(CUE) D \qquad E : l : l = 0.016 l = 0.07 l : l = 1.000/1000$
15		(CIF). Rev Bras Epidemiol 2016;19:6/9–8/.doi:10.1590/1980-
16		5497201600030018.
17		
19	26	Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going
20		from avidence to recommondations. The significance and presentation of
21		from evidence to recommendations. The significance and presentation of
22		recommendations. J Clinl Epidemiol 2013;66:719–
24		25.doi:10.1016/i.iclinepi.2012.03.013.
25		
26	27	Andrews IC Schünemann HI Oxman AD <i>et al.</i> GRADE guidelines: 15
28	21	Tindrews Se, Sendremann His, Oxinan Trib, et al. Ortribli guidennes. 15.
29		Going from evidence to recommendation - Determinants of a
30 31		recommendation's direction and strength. J Clin Epidemiol 2013;66:726-
32		35.doi:10.1016/i.iclinepi.2013.02.003.
33		
34	28	Mokkink LB Prinsen CAC Patrick DL et al COSMIN methodology for
36	20	
37		systematic reviews of Patient-Reported Outcome Measures (PROMs) -
38		user manual Netherlands: COSMIN, 2018.
40		Available:https://www.cosmin.nl/wp-content/uploads/COSMIN-syst-
41		raview for PROMs manual version 1 feb 2018 1 pdf pdf [A coassed 20
42		Teview-for-1 Rolvis-manual_version-1_feb-2018-1.pdf.pdf [Accessed 20
44		Dez 2021].
45		
46		
47 48		
49		
50		
51		
52		
55		
55		
56		
57 58		
59		

SUPPLEMENTARY FILE 1

Search strategy for MEDLINE (Ovid)

- 1. exp Self Efficacy/
- 2. self-efficacy.mp.
- 3. 1 or 2

- 4. exp Coronary Artery Disease/
- 5. Coronary Artery Disease.mp.
- 6. coronary heart disease.mp.
- 7. exp Coronary Disease/
- 8. exp Acute Coronary Syndrome/
- 9. Heart disease.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 10. exp heart diseases/
- 11. exp myocardial ischemia/
- 12. exp Cardiovascular Diseases/
- 13. Cardiovascular Disease.mp.
- 14. exp Heart Failure/
- 15. heart failure.mp.
- 16. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
- 17. instrument*.mp.
- 18. instruments*.mp.
- 19. measure*.mp.
- 20. measures*.mp.
- 21. questionnaire*.mp.
- 22. exp "Surveys and Questionnaires"/
- 23. questionnaires*.mp.
- 24. scale*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 25. scales*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 26. tool*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 27. tools*.mp.
- 28. survey*.mp.
- 29. test*.mp.
- 30. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29
- 31. 3 and 16 and 30
 - 32. (instrumentation or methods).fs.
 - 33. (Validation Studies or Comparative Study).pt.

Page 13 of 19

1

2	
3	34. exp Psychometrics/
4	35. psychometr*.ti,ab.
5	36. (clinimetr* or clinometr*).tw.
6 7	37. outcome assessment.ti.ab.
/ 2	38 outcome measure* tw
9	39 exp Observer Variation/
10	40 observer variation ti ab
11	40. observer variation.tt, ab.
12	41. exp ficatili Status indicators/
13	42. exp Reproducionity of Results/
14	43. reproducio*.ti,ab.
15	44. exp Discriminant Analysis/
16	45. (reliab* or unreliab* or valid* or coefficient or homogeneity or homogeneous or
17	internal consistency).ti,ab.
18	46. (cronbach* and (alpha or alphas)).ti,ab.
19	47. (item and (correlation* or selection* or reduction*)).ti,ab.
20	48. (agreement or precision or imprecision or precise values or test-retest).ti, ab.
21	49. (test and retest).ti.ab.
22	50. (reliab* and (test or retest)).ti.ab.
23	51 ((replicab* or repeated) and (measure or measures or findings or result or results or
25	test or tests)) ti ah
26	52 (generaliza* or generaliza* or concordance) ti ab
27	52. (generaliza of generalisa of concordance).(1,a).
28	55. (Intractass and correlation ^{**}).u,ao.
29	54. (discriminative or known group or factor analysis or factor analyses or dimension*
30	or subscale*).ti,ab.
31	55. (multitrait and scaling and (analysis or analyses)).ti,ab.
32	56. (item discriminant or interscale correlation* or error or errors or individual
33	variability).ti,ab.
34	57. (variability and (analysis or values)).ti,ab.
35	58. (uncertainty and (measurement or measuring)).ti,ab.
37 37	59. (standard error of measurement or sensitiv* or responsive*).ti,ab.
38	60. ((minimal or minimally or clinical or clinically) and (important or significant or
39	detectable) and (change or difference)).ti.ab.
40	61. (small* and (real or detectable) and (change or difference)).ti.ab.
41	62 (meaningful change or ceiling effect or floor effect or Item response model or IRT
42	or Rasch or Differential item functioning or DIE or computer adaptive testing or item
43	bank or cross cultural acuivalance) ti ab
44	62 over Depreducibility of Decults/
45	65. exp Reproducibility of Results/
46	64. cross-cultural equivalence.ti,ab.
47	65. development.ti,ab.
48	66. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46
49	or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or
50	61 or 62 or 63 or 64 or 65
51 52	67. 31 and 66
53	
55	
55	
56	
57	
58	
59	

Search strategy for Web of Science

n	Search terms		
#1	Search: TS=(Self-Efficacy*) OR TS=(Self Efficacy*)		
#2	Search: TS=(Coronary Artery Disease*) OR TS=(Coronary Disease*) OR TS=(Coronary Heart Disease*) OR TS=(Acute Coronary Syndrome) OR TS=(Heart disease*) OR TS=(Cardiovascular disease*) OR TS=(Heart failure) OR TS=(Myocardial ischemia)		
#3	Search: TS=(Instrument*) OR TS=(instruments*) OR TS=(measure*) OR TS=(measures*) OR TS=(questionnaire*) OR TS=(questionnaires*) OR TS=(scale*) OR TS=(scale*) OR TS=(tool*) OR TS=(tool*) OR TS=(tool*) OR TS=(survey*) OR TS=(test*)		
#4	Search: TS=(instrumentation) OR TS=(methods) OR TS=("validation stud*") OR TS=("comparative stud*") OR TS=(psychometrics) OR TS=(psychometr*) OR ALL=(clinimetr*) OR ALL=(clinimetr*) OR TS=("observer variation") OR TS=("observer variation") OR TS=("cobserver variation") OR TS=("cofficient of variation") OR TS=(coefficient) OR TS=(unreliab*) OR TS=((valid*) OR TS=("coefficient of variation") OR TS=(coefficient) OR TS=(lomogeneity) OR TS=(nomogeneous) OR TS=("internal consistency") OR ((TS=(alpha) OR TS=(alphas)) AND TS=(cronbach*)) OR ((TS=(correlation*) OR TS=(selection*) OR TS=(internater)) OR TS=(internater) OR TS=(internater) OR TS=(inter-extenter) OR TS=(intra-exter) OR TS=(inter-exter) OR TS=(inter-exter) OR TS=(intra-exter) OR TS=(intra-exter) OR TS=(inter-exter) OR TS=(inter-exter) OR TS=(inter-exter) OR TS=(intra-exter) OR TS=(intra-exter) OR TS=(inter-exter) OR TS=(inter-exter) OR TS=(intra-exter) OR TS=(intra-individual) OR TS=(inter-individual) OR TS=(inter-individual) OR TS=(inter) OR TS=(intra-individual) OR TS=(inter) OR TS=(intra-individual) OR TS=(inter) OR TS=(intra-individual) OR TS=(inter) OR TS=(inter) OR TS=(intra-individual) OR TS=(inter) OR TS=(inter) OR TS=(intra-individual) OR TS=(inter) OR TS=(inter) OR TS=(intra-intiv) OR TS=(intra-intiv) OR TS=(inter) OR TS=(intra-intiv) OR TS=(in		

#5 #1 AND #2 AND #3 AND #4

1
2
2
2
4
5
6
7
8
0
9
10
11
12
13
14
15
15
16
17
18
19
20
20
21
22
23
24
25
25
20
27
28
29
30
31
27
52
33
34
35
36
37
20
20
39
40
41
42
43
11
44
45
46
47
48
49
-12
50
51
52
53
54
55
55
56
57
58

Search strategy for Embase and PsycoINFO

n	Search terms			
#1	("Self-Efficacy*" OR "Self Efficacy*")			
#2	("Coronary Artery Disease*" OR "Coronary Disease*" OR "Coronary Heart Disease*" OR "Acute Coronary Syndrome" OR "Heart disease*" OR "Cardiovascular disease*" OR "Heart failure" OR "Myocardial ischemia")			
#3	("Instrument*" OR "Instruments*" OR "measure*" OR "measures*" OR "questionnaire*" OR "questionnaires" OR "scale*" OR "scales*" OR "tool*" OR "tools*" OR "survey*" OR "test*")			
#4	("instrumentation" OR "methods" OR "Validation Studies" OR "Comparative Study" OR "psychometrics" OR "psychometr*" OR "clinimetr*" OR "clinometr*" OR "outcome assessment (health care)" OR "outcome assessment" OR "outcome measure*" OR "observer variation" OR "observer variation" OR "Health Status Indicators" OR "reproducibility of results" OR "reproducib*" OR "discriminant analysis" OR "reliab*" OR "unreliab*" OR "valid*" OR "coefficient of variation" OR "coefficient" OR "homogeneity" OR "homogeneous" OR "internal consistency" OR ("cronbach*" AND "alpha" OR "alphas") OR ("item" AND ("correlation*" OR "selection*" OR "reduction*")) OR "agreement" OR "precision" OR "imprecision" OR "inter-test" OR "inter-test" OR ("test" AND "retest") OR ("reliab*" AND ("test" OR "inter-test")) OR "inter-test" OR "inter-tester" OR "intra-tester" OR "intra-tester" OR "inter-tester" OR "inter-tobserver" OR "intra-tester" OR "intra-tester" OR "inter-tester" OR "inter-tester" OR "intra-technician" OR "inter-tester" OR "inter-tester" OR "intra-examiner" OR "intra-assay" OR "intraassay" OR "intra-assay" OR "interindividual" OR "inter-assay" OR "intraassay" OR "intra-assay" OR "interparticipant" OR "inter-assay" OR "repeatab*" OR (("ceplicab*" OR "repeated") AND ("measure" OR "measures" OR "factor structure" OR "factor analysis" OR "factor analysis" OR "factor structure" OR "factor structures" OR "interdiation") OR "inter- discriminative" OR "known group" OR "factor analysis" OR "factor analysis" OR "interale correlation*" OR "error" OR "interalester" OR "interdiation") OR "intersale correlation" OR "reter variability" AND ("eraibility" AND ("eaalysis" OR "values")) OR ("uncertainty" AND ("measurement" OR "interpatab*" OR "intersale correlation "OR "error" OR "indersation") OR "intersale correlation "OR "error" OR "indersation") OR "intersale correlation" OR "terporability" AND ("correlation") OR "intersale correlation" OR "terporability" AND ("analysis" OR "values")) OR ("uncertainty" AND ("measurement" OR "significant" OR "intaniant" O			
#5	#1 AND #2 AND #3 AND #4			

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title		L.	
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	1
Registration			
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors			
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1, 10
Contribution	<u>#3b</u> For p	Describe contributions of protocol authors and identify the guarantor of the review beer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	9

1 2	Amendments			
3 4 5 6 7 8 9		<u>#4</u>	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	n/a
10 11	Support			
12 13	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	10
14 15 16	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	n/a
17 18 19	Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
20 21 22	Introduction			
23 24 25 26	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	1,3
27 28 29 30 31	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
32 33	Methods			
34 35 36 37 38 39 40	Eligibility criteria	<u>#8</u>	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	3
41 42	Information	<u>#9</u>	Describe all intended information sources (such as electronic	4
43 44 45	sources		databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	
40 47 48 49 50 51	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file 1
52 53	Study records -	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records	4,5
54 55	data management		and data throughout the review	
56 57	Study records -	<u>#11b</u>	State the process that will be used for selecting studies (such as	4,5
58 59	selection process		two independent reviewers) through each phase of the review	
60For peer review only - http://bmjopen.bmj.com/site/about/guidelines.		eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml		

		(that is, screening, eligibility and inclusion in meta-analysis)	
Study records - data collection process	<u>#11c</u>	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	4
Data items	<u>#12</u>	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	3-5
Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	3-5
Risk of bias in individual studies	<u>#14</u>	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	6
Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	5
Data synthesis	<u>#15b</u>	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)	5
Data synthesis	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	5
Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type of summary planned	5
Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	5
Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	5
Notes:			
• 10: Supplemen	ntary file	1 The PRISMA-P elaboration and explanation paper is distributed un	der the terms

Page 18 of 19

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

of the Creative Commons Attribution License CC-BY. This checklist was completed on 09. March 2022

Page 19 of	19	BMJ Open
$1 \\ 2 \\ 3 \\ 4 \\ 5 \\ 6 \\ 7 \\ 8 \\ 9 \\ 10 \\ 11 \\ 12 \\ 13 \\ 14 \\ 15 \\ 16 \\ 17 \\ 18 \\ 19 \\ 20 \\ 12 \\ 23 \\ 24 \\ 25 \\ 27 \\ 28 \\ 29 \\ 30 \\ 31 \\ 32 \\ 33 \\ 4 \\ 35 \\ 36 \\ 37 \\ 38 \\ 9 \\ 40 \\ 14 \\ 23 \\ 44 \\ 45 \\ 46 \\ 7 \\ 48 \\ 9 \\ 51 \\ 52 \\ 35 \\ 55 \\ 57 \\ 56 \\ 57 \\ 57$	using https://www.goodreports.org/, a too Penelope.ai	al made by the <u>EQUATOR Network</u> in collaboration with

BMJ Open

Self-efficacy instruments for individuals with coronary artery disease: a systematic review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-062794.R1
Article Type:	Protocol
Date Submitted by the Author:	11-Jun-2022
Complete List of Authors:	Almeida, Jose Alexandre; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Florêncio, Rêncio; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Lemos, Darllane; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Leite, Jéssica; Universidade Federal do Rio Grande do Norte, Physical Therapy Graduate Program Monteiro, Karolinne; Universidade Federal do Rio Grande do Norte, Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program Peroni Gualdi, Lucien; Universidade Federal do Rio Grande do Norte, Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program
Primary Subject Heading :	Cardiovascular medicine
Secondary Subject Heading:	Communication
Keywords:	CARDIOLOGY, Coronary heart disease < CARDIOLOGY, Ischaemic heart disease < CARDIOLOGY, Myocardial infarction < CARDIOLOGY



Title: Self-efficacy instruments for individuals with coronary artery disease: a systematic review protocol.

Authors: José Alexandre Barbosa de Almeida¹, Rêncio Bento Florêncio¹, Darllane Azevedo Lemos¹, Jéssica Costa Leite², Karolinne Souza Monteiro³, Lucien Peroni Gualdi³.

Affiliation: ¹ Master students, Rehabilitation Sciences Graduate Program, Federal University of Rio Grande do Norte, Santa Cruz, RN – Brazil;² Ph.D. Physical Therapy Graduate Program, Federal University of Rio Grande do Norte, Natal, RN – Brazil; ³ Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program, Federal University of Rio Grande do Norte, Santa Cruz, RN – Brazil.

Corresponding author: Lucien Peroni Gualdi – Programa de Pós Graduação em Ciências da Reabilitação, Faculdade de Ciências da Saúde do Trairi, Rua Vila do Trairi S/N, CEP: 59200-000, Santa Cruz, RN – Brazil. E-mail address: lugualdi@hotmail.com, Telephone: +55(84) 99480 6888.

Word count: 1.217.

ABSTRACT

Introduction: Self-efficacy is associated with management of diseases, psychological well-being, improved quality of life, and rehabilitation adherence. Several instruments related to behavior or specific disease (e.g., coronary artery disease [CAD]) assess self-efficacy. The evaluation of cardiac self-efficacy in individuals with CAD will support healthcare professionals to improve self-efficacy in interventions; therefore, a suitable instrument is crucial. This systematic review aims to assess measurement properties, methodological quality, and content of outcome measures of cardiac self-efficacy instruments for individuals with CAD.

Methods and analysis: The study will be developed according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol (PRISMA-P) and Consensus Norms for Selection of Health Measuring Instruments (COSMIN). Search strategy will be performed in the following databases: MEDLINE (ovid), Web of Science, EMBASE, and PsycINFO. Studies assessing measurement properties of cardiac self-efficacy instruments for individuals with CAD and without language or date restrictions will be included. Two independent authors will be responsible for eligibility of studies. Methodological quality of studies will be assessed using the COSMIN RoB Checklist, whereas the Classification of Recommendations, Assessment, Development and Assessment (GRADE) will assess quality of each study. Another two authors will independently evaluate the content and link to the International Classification of Functioning, Disability, and Health.

Ethics and Dissemination: This study does not require ethics committee approval since it is based on previously published data. Evidence from this systematic review will be disseminated through publication in peer-reviewed journals and submitted to scientific conferences .

PROSPERO registration number: CRD42021262613.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This systematic review protocol is designed according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P) and the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN).
- No language and date restrictions will be included to consider the maximum number of relevant studies.
- The protocol will allow peer review reducing the possibility of duplicates or bias.

- The study will not include studies of instruments that have self-efficacy in their construct (eg, self-management, self-care), limiting only to self-efficacy instruments for coronary patients.
- This protocol may be limited due to the lack of patients and public involvement.

INTRODUCTION

Self-efficacy is defined as the belief of individuals about their ability to organize and perform a certain activity. It consists of elements of awareness, planning, and motivation, which can reflect on self-responsibility throughout the disease process;[1] thus, it is important for health promotion and management of chronic diseases.[1-3] Moreover, self-efficacy is associated with psychological well-being, improved quality of life, and better rehabilitation adherence.[4,5]

Measurement instruments of self-efficacy can be general[6], for specific health conditions (e.g., feeding behavior, physical activity, and medication adherence),[7-9] or specific diseases (e.g., asthma, stroke, and coronary artery disease [CAD]).[10-13] Although many scales and questionnaires are available for self-efficacy, literature lacks methodological rigor and choice of instrument for individuals in pulmonary, metabolic, and cardiovascular rehabilitation programs.

CAD is characterized as reduced coronary artery lumen due to atherosclerotic plaques and may lead to chest pain, pressure or tightness sensation at different degrees of exertion, and dyspnea.[14, 15] Conventional treatment implies cardiovascular rehabilitation and changes in daily habits. The admission of individuals to cardiovascular rehabilitation programs aims to delay and prevent complications and improve physical fitness through aerobic and strength training.[16]

Therefore, instruments assessing self-efficacy are needed to prevent complications and increase treatment adherence.[1, 3] In this context, the assessment of cardiac self-efficacy instruments for individuals with CAD will support healthcare professionals in individual interventions and improve self-efficacy of patients. This systematic review aims to identify instruments developed to assess cardiac self-efficacy in individuals with CAD and evaluate methodological quality and measurement properties. We also aim to link the content of instruments to the International Classification of Functioning,

Disability, and Health (ICF). Based on this, the review will facilitate identifying discrepancies in measurement instruments and guide further research.

METHODS AND ANALYSIS

Study methods

 This protocol was developed according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P)[17] and the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN).[18, 19]

Protocol registration

The protocol was registered in the international prospective register of systematic reviews (PROSPERO registration number CRD42021262613). Relevant changes in the systematic review will be documented in the PROSPERO and published in the final study.

Inclusion and exclusion criteria

Studies on the development of assessment of measurement properties of cardiac selfefficacy instruments for individuals with CAD will be included without language and date restrictions. Clinical trials or validation studies using self-reported or proxyreported measurements and those published as abstracts. Moreover, studies of instruments that have self-efficacy in their construct (eg, self-management, self-care) will also be excluded, limiting to self-efficacy instruments for coronary patients.

Search strategy

The search strategy will be conducted from inception to date in MEDLINE (ovid), Web of Science, EMBASE and PsycINFO databases considering the following: (1) construct of interest (cardiac self-efficacy); (2) target population (individuals with CAD); (3) type of instrument (questionnaire or scale); and (4) measurement properties; the latter will be assessed using search filters validated for measurement studies and already applied in previous reviews. Additional searches for relevant studies will be manually performed in reference lists of primary studies and review articles. Searches will be performed again before final analysis to verify new studies. The Supplementary file 1 show the

search strategies we developed for the databases search. The study will follow COSMIN recommendations.[20]

Screening and selection of studies

An online survey will be imported into a Mendeley reference manager list (https://www.mendeley.com). Duplicates will be deleted before selections, and the reference list exported to the Rayyan Qatar Computing Research Institute systematic review platform (https://rayyan.qcri.org).[21] The detailed selection process will be presented in the PRISMA-P flowchart.

Two independent authors (JABA and DAL) will select studies using titles and abstracts, conduct a complete reading of potentially eligible studies, and identify and record reasons for excluding those ineligible. In the case of disagreement, a virtual meeting will be held for discussion and consultation with a third reviewer (LPG).

Data extraction

Two authors (JABA and DAL) will extract data following the Cochrane Collaboration and PRISMA guidelines. Other authors will independently review data to verify inclusion and exclusion criteria. The extracted information will include first author, year of publication, general characteristics of the instrument (construct, subscales, number of items, and version), study design, sample size, characteristics of individuals (e.g., age, sex, location, country, language, methods for selecting participants, and response rate), and results of measurement properties (i.e., internal consistency, reliability, measurement error, content validity [including face validity], construct validity [subdivided into structural validity, hypothesis testing, and cross-cultural validity], validity of criterion, responsiveness, and interpretability [not a measurement property, but necessary to adapt a research instrument or clinical practice]).

Data quality

Methodological quality of studies will be assessed by two independent authors (RBF and JCL) using COSMIN RoB Checklist.[18, 19] This tool considers ten measurement properties and contains nine boxes with 3 to 35 items. Each box assigns a methodological quality score for instrument development: (1) content validity, (2) structural validity, (3) internal consistency, (4) cross-cultural validity and measurement

invariance, (5) reliability, (6) measurement error, (7) criterion validity, (8) hypothesis testing for construct validity, and (9) responsiveness. Each item has four response options: inadequate, doubtful, adequate, and very good.[22] Disagreements will be solved by a third author (KSM).

The content extracted from measurement instruments will be compared using the ICF framework.[23–25] Two independent authors (JABA and RBF) will evaluate the content and link items of questionnaires to ICF standards. After, a third author (JCL) will review the content.

Data synthesis

A narrative synthesis of results will be provided. In the possibility of validation studies of the same instrument for different populations, methodological and psychometric properties quality of such studies will be addressed as a unique instrument but discussing the particularity of each version. A combination of measurement properties will determine the overall evidence of the instrument. Studies will be grouped according to similarity in terms of language, instrument version, study population, and application form.

Results will be evaluated in clusters or summarized against the criteria for good measurement properties to determine whether they are sufficient (+), insufficient (-), inconsistent (+/-), or indeterminate (?). Furthermore, a modified Classification of Recommendations, Assessment, Development, and *Evaluation* (GRADE) will determine study quality.[26, 27]

Afterward, instruments will be categorized and justified according to COSMIN recommendations:[28] (A) instrument is recommended for use and results are reliable; (B) when it may be recommended but requires further research to assess quality of these instruments; and (C) instrument should not be recommended.

Patient and public involvement

No patient or public involvement.

Ethics and Dissemination

 The study does not require ethics committee approval since it is based on published data. Evidence from this systematic review will be disseminated through publication of results in peer-reviewed journals and submitted to scientific conferences.

Contributors: Authors made substantial contributions to the study design, developed inclusion criteria, and search strategies. JABA developed the protocol, RBF, DAL, JCL, KSM, and LPG provided critical insights and reviewed the protocol. JABA registered the protocol in the PROSPERO database. All authors read and approved the final version of the protocol.

Funding Statement: The study will be financed by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) – Brazil. JABA, DAL and RBF received grant from CAPES by Finance Code 001.

Competing interests: None declared.

Patients consent for publication: Not applicable.

Provenance and peer review: Not commissioned, externally peer-reviewed.

Open access: This is an open-access article distributed by the Creative Commons Attribution Non-Commercial (CC BY-NC 4.0) license, which allows distribution, remix, adapt, build upon this study non-commercially, and license the derivative studies on different terms. Original study must be cited, given appropriate credit, any changes must be indicated, and the use is non-commercial. See http://creativecommons.org/licenses/by-nc/4.0/.

ORCIDS iDs:

José Alexandre Barbosa de Almeida https://orcid.org/0000-0002-0876-6794 Rêncio Bento Florêncio https://orcid.org/0000-0003-2853-7988 Darllane Azevedo Lemos https://orcid.org/0000-0003-2020-3940 Jéssica Costa Leite https://orcid.org/0000-0002-4726-9416 Karolinne Souza Monteiro https://orcid.org/0000-0003-2254-8723 Lucien Peroni Gualdi https://orcid.org/0000-0002-6907-7335

REFERENCES

1 Bandura A. Health promotion by social cognitive means. *Health Educ Behav* 2004;31:143–64.doi:10.1177/1090198104263660.

2 Roest AM, Martens EJ, Denollet J, *et al.* Prognostic association of anxiety post myocardial infarction with mortality and new cardiac events: A meta-analysis. *Psychosom Med* 2010;72:563–9 doi:10.1097/PSY.0b013e3181dbff97

3 Bandura, A. Self-efficacy. In V. S. Ramachaudran, *Encyclopedia of human behavior*. New York: Academic Press. 1994.

Joekes K, Van Elderen T, Schreurs K. Self-efficacy and overprotection are related to quality of life, psychological well-being and self-management in cardiac patients. *J Health Psychol* 2007;12:4–16. doi:10.1177/1359105306069096.

5 Katch H. The role of self-efficacy in cardiovascular disease self-management: a review of effective programs. *Patient Intell* 2010;2:33-44.doi:10.2147/PI.S12624

Luszczynska A, Scholz U, Schwarzer R. The general self-efficacy scale:
Multicultural validation studies. *J Psychol* 2005;139:43957.doi:10.3200/JRLP.139.5.439-457.

7 Birkett NJ, Hotz SB. A self-efficacy scale for heart-healthy eating. *Can J Public Health* 1994;85:201-4. PMID: 7922967.

8 Wong EML, Leung DYP, Sit JWH, *et al.* Prospective Validation of the Chinese Version of the Self-Efficacy for Exercise Scale among Middle-Aged Patients with Coronary Heart Disease. *Rehabil Nurs* 2020;45:74– 9.doi:10.1097/RNJ.00000000000156.

9 Saffari M, Zeidi IM, Fridlund B, *et al.* A Persian Adaptation of Medication Adherence Self-Efficacy Scale (MASES) in Hypertensive Patients: Psychometric Properties and Factor Structure. *High Blood Press Cardiovasc Prev* 2015;22:247– 55.doi:10.1007/s40292-015-0101-8.

BMJ Open

Holley S, Knibb R, Latter S, *et al.* Development and validation of the
Adolescent Asthma Self-Efficacy Questionnaire (AASEQ). *Eur Respir J* 2019;54:1–
10.doi:10.1183/13993003.01375-2018.

11 Topçu S, Oguz S. Translation and validation study for the stroke self - efficacy questionnaire in stroke survivors. *Int J Nurs Pract* 2018:24:1–8.doi:10.1111/ijn.12646.

12 Sullivan MD, Lacroix AZ, Russo J, *et al.* Self-efficacy and self-reported functional status in coronary heart disease: A six-month prospective study. *Psychosom Med* 1998;60:473–8.doi:10.1097/00006842-199807000-00014.

13 Fors A, Ulin K, Cliffordson C, *et al.* The Cardiac Self-Efficacy Scale, a useful tool with potential to evaluate person-centred care. *Eur J Cardiovasc Nurs* 2015;14:536–43.doi:10.1177/1474515114548622.

14 Li H, Sun K, Zhao R, *et al.* Inflammatory biomarkers of coronary heart disease. *Front Biosci (Schol Ed)* 2018;10:185–96.doi:10.2741/s508.

15 Cagle SD, Cooperstein N. Coronary Artery Disease: Diagnosis and Management. *Prim Care* 2018;45:45–61.doi:10.1016/j.pop.2017.10.001

16 Carvalho T, Milani M, Ferraz AS, *et al.* Brazilian Cardiovascular Rehabilitation Guideline – 2020. *Arq Bras Cardiol* 2020;114:943–87.doi:10.36660/abc.20200407.

17 Shamseer L, Moher D, Clarke M, *et al.* Preferred reporting items for systematic review and meta-analysis protocols (prisma-p) 2015: Elaboration and explanation. *BMJ* 2015;349:1–25.doi:10.1136/bmj.g7647.

18 Mokkink LB, Terwee CB, Patrick DL, *et al.* The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res* 2010;19:539–49.doi:10.1007/s11136-010-9606-8.

19 Mokkink LB, Terwee CB, Knol DL, *et al.* The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. *BMC Med Res Methodol.* 2010;10:22.doi:10.1186/1471-2288-10-22. 20 Terwee CB, Jansma EP, Riphagen II, *et al.* Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments. *Qual Life Res* 2009;18:1115–23.doi:10.1007/s11136-009-9528-5.

21 Ouzzani M, Hammady H, Fedorowicz Z, *et al.* Rayyan-a web and mobile app for systematic reviews. *Syst Rev* 2016;5:1–10.doi:10.1186/s13643-016-0384-4.

22 Mokkink LB, de Vet HCW, Prinsen CAC, *et al.* COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. *Qual Life Res.* 2018;27:1171-9.doi:10.1007/s11136-017-1765-4.

23 Cieza A, Geyh S, Chatterji S, *et al.* ICF linking rules: An update based on lessons learned. *J Rehabil Med* 2005;37:212–8.doi:10.1080/16501970510040263.

24 Cieza A, Brockow T, Ewert T, *et al.* Linking health-status measurements to the International Classification of Functioning, Disability and Health. *J Rehabil Med* 2002;34:205–10.doi:10.1080/165019702760279189.

25 Castro SS, Castaneda L, de Araúj ES, *et al.* Aferição de funcionalidade em inquéritos de saúde no Brasil: Discussão sobre instrumentos baseados na Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF). *Rev Bras Epidemiol* 2016;19:679–87.doi:10.1590/1980-5497201600030018.

Andrews J, Guyatt G, Oxman AD, *et al.* GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clinl Epidemiol* 2013;66:719–25.doi:10.1016/j.jclinepi.2012.03.013.

Andrews JC, Schünemann HJ, Oxman AD, *et al.* GRADE guidelines: 15. Going from evidence to recommendation - Determinants of a recommendation's direction and strength. *J Clin Epidemiol* 2013;66:726–35.doi:10.1016/j.jclinepi.2013.02.003.

28 Mokkink LB, Prinsen CAC, Patrick DL, et al. COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) - user manual Netherlands: COSMIN, 2018. Available:https://www.cosmin.nl/wpcontent/uploads/COSMIN-syst-review-for-PROMs-manual_version-1_feb-2018-1.pdf.pdf [Accessed 20 Dez 2021].

SUPPLEMENTARY FILE 1

Search strategy for MEDLINE (Ovid)

- 1. exp Self Efficacy/
- 2. self-efficacy.mp.
- 3. 1 or 2
- 4. exp Coronary Artery Disease/
- 5. Coronary Artery Disease.mp.
- 6. coronary heart disease.mp.
- 7. exp Coronary Disease/
- 8. exp Acute Coronary Syndrome/
- 9. Heart disease.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 10. exp heart diseases/
- 11. exp myocardial ischemia/
- 12. exp Cardiovascular Diseases/
- 13. Cardiovascular Disease.mp.
- 14. exp Heart Failure/
- 15. heart failure.mp.
- 16. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
- 17. instrument*.mp.
- 18. instruments*.mp.
- 19. measure*.mp.
- 20. measures*.mp.
- 21. questionnaire*.mp.
- 22. exp "Surveys and Questionnaires"/
- 23. questionnaires*.mp.
- 24. scale*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 25. scales*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 26. tool*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 27. tools*.mp.
- 28. survey*.mp.
- 29. test*.mp.
- 30. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29
- 31. 3 and 16 and 30
 - 32. (instrumentation or methods).fs.
 - 33. (Validation Studies or Comparative Study).pt.

- 34. exp Psychometrics/
- 35. psychometr*.ti,ab.

- 36. (clinimetr* or clinometr*).tw.
- 37. outcome assessment.ti,ab.
- 38. outcome measure*.tw.
- 39. exp Observer Variation/
- 40. observer variation.ti,ab.
- 41. exp Health Status Indicators/
- 42. exp Reproducibility of Results/
- 43. reproducib*.ti,ab.
- 44. exp Discriminant Analysis/
- 45. (reliab* or unreliab* or valid* or coefficient or homogeneity or homogeneous or internal consistency).ti,ab.
- 46. (cronbach* and (alpha or alphas)).ti,ab.
- 47. (item and (correlation* or selection* or reduction*)).ti,ab.
- 48. (agreement or precision or imprecision or precise values or test-retest).ti,ab.
- 49. (test and retest).ti,ab.
- 50. (reliab* and (test or retest)).ti,ab.
- 51. ((replicab* or repeated) and (measure or measures or findings or result or results or test or tests)).ti,ab.
- 52. (generaliza* or generalisa* or concordance).ti,ab.
- 53. (intraclass and correlation*).ti,ab.
- 54. (discriminative or known group or factor analysis or factor analyses or dimension* or subscale*).ti,ab.
- 55. (multitrait and scaling and (analysis or analyses)).ti,ab.
- 56. (item discriminant or interscale correlation* or error or errors or individual variability).ti,ab.
- 57. (variability and (analysis or values)).ti,ab.
- 58. (uncertainty and (measurement or measuring)).ti,ab.
- 59. (standard error of measurement or sensitiv* or responsive*).ti,ab.
- 60. ((minimal or minimally or clinical or clinically) and (important or significant or detectable) and (change or difference)).ti,ab.
- 61. (small* and (real or detectable) and (change or difference)).ti,ab.
- 62. (meaningful change or ceiling effect or floor effect or Item response model or IRT or Rasch or Differential item functioning or DIF or computer adaptive testing or item bank or cross-cultural equivalence).ti,ab.
- 63. exp Reproducibility of Results/
- 64. cross-cultural equivalence.ti,ab.
- 65. development.ti,ab.
- 66. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65
- 67. 31 and 66

Search strategy for Web of Science

n	Search terms						
#1	Search: TS=(Self-Efficacy*) OR TS=(Self Efficacy*)						
#2	Search: TS=(Coronary Artery Disease*) OR TS=(Coronary Disease*) OR TS=(Coronary Heart Disease*) OR TS=(Acute Coronary Syndrome) OR TS=(Heart disease*) OR TS=(Cardiovascular disease*) OR TS=(Heart failure) OR TS=(Myocardial ischemia)						
#3	Search: TS=(Instrument*) OR TS=(instruments*) OR TS=(measure*) OR TS=(measures*) OR TS=(questionnaire*) OR TS=(questionnaires*) OR TS=(scale*) OR TS=(scales*) OR TS=(tool*) OR TS=(tools*) OR TS=(survey*) OR TS=(test*)						
#4	Search: TS=(instrumentation) OR TS=(methods) OR TS=("validation stud*") OR TS=("comparative stud*") OR TS=(psychometries) OR TS=(psychometr*) OR ALL=(clinimetr*) OR ALL=(clinometr*) OR TS=("observer variation") OR TS=("observer variation") OR TS=("health status indicators") OR TS=(valid*) OR TS=("discriminant analysis") OR TS=(clial*) OR TS=(unreliab*) OR TS=(valid*) OR TS=("coefficient of variation") OR TS=(coefficient) OR TS=(homogeneity) OR TS=(mongeneous) OR TS=("internal consistency") OR ((TS=(alpha) OR TS=(alphas)) AND TS=(crombach*)) OR ((TS=(correlation*) OR TS=(selection*) OR TS=(internal*)) AND TS=(internal consistency") OR (TS=(stability) OR TS=(internater) OR TS=(inter- section*) OR TS=(stability) OR TS=(interater) OR TS=(inter- section*) OR TS=(intra-rater) OR TS=(interater) OR TS=(inter- section*) OR TS=(intra-rater) OR TS=(interater) OR TS=(inter- section*) OR TS=(intra-tsector) OR TS=(interater) OR TS=(inter- section*) OR TS=(intra-tsector) OR TS=(intera-examiner) OR TS=(intra-observer) OR TS=(intra-examiner) OR TS=(inter- technician) OR TS=(intra-assay) OR TS=(intra-examiner) OR TS=(inter-assay) OR TS=(intra-assay) OR TS=(inter-individual) OR TS=(inter-assay) OR TS=(intra-assay) OR TS=(intra-intra-individual) OR TS=(inter-assay) OR TS=(intra-assay) OR TS=(intra-intra-individual) OR TS=(inter-assay) OR TS=(intra-intra-inter) OR TS=(intra-intra-individual) OR TS=(inter-individual) OR TS=(intra-assay) OR TS=(intra-individual) OR TS=(inter-individual) OR TS=(intra-assay) OR TS=(intra-individual) OR TS=(inter-individual) OR TS=(intra-assay) OR TS=(intra-individual) OR TS=(inter-individual) OR TS=(intra-inter) OR TS=(intra-inter) OR ((ALL=(replicab*) OR ALL=(result) OR ALL=(results) OR ALL=(results) OR ALL=(results) OR TS=(in						

#5 #1 AND #2 AND #3 AND #4

2
3
1
-
5
6
/
8
9
10
11
12
13
14
15
16
10
1/
18
19
20
21
22
23
24
27
25
20
2/
28
29
30
31
32
33
34
25
22
30
37
38
39
40
41
42
<u>4</u> 3
11
44
45
46
4/
48
49
50
51
52
53
54
55
55
20
5/
58
59

1

Search strategy for Embase and PsycoINFO

n	Search terms							
#1	("Self-Efficacy*" OR "Self Efficacy*")							
#2	("Coronary Artery Disease*" OR "Coronary Disease*" OR "Coronary Heart Disease*" OR "Acute Coronary Syndrome" OR "Heart disease*" OR "Cardiovascular disease*" OR "Heart failure" OR "Myocardial ischemia")							
#3	("Instrument*" OR "Instruments*" OR "measure*" OR "measures*" OR "questionnaire*" OR "questionnaires" OR "scale*" OR "scales*" OR "tool*" OR "tools*" OR "survey*" OR "test*")							
#4	("instrumentation" OR "methods" OR "Validation Studies" OR "Comparative Study" OR "psychometries" OR "psychometr*" OR "clinometr*" OR "clinometr*" OR "outcome assessment (health care)" OR "outcome assessment" OR "outcome measure*" OR "observer variation" OR "observer variation" OR "Health Status Indicators" OR "reproducibility of results" OR "reproducib*" OR "discriminant analysis" OR "reliab*" OR "unreliab*" OR "walid*" OR "internal consistency" OR ("cronbach*" AND "alpha" OR "alphas") OR ("item" AND ("correlation*" OR "selection*" OR "retest") OR "reterest" OR "internater" OR "inter-tester" OR "inter-tester" OR "intra-tester" OR "intra-tester" OR "inter-tester" OR "inter-tester" OR "in							

#5 #1 AND #2 AND #3 AND #4

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

	Reporting Item	Page Number
	4	
<u>#1a</u>	Identify the report as a protocol of a systematic review	1
<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	1
<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1, 10
<u>#3b</u> For r	Describe contributions of protocol authors and identify the guarantor of the review	9
	#1a #1b #2 #3a #3b	Reporting Item #1a Identify the report as a protocol of a systematic review #1b If the protocol is for an update of a previous systematic review, identify as such #2 If registered, provide the name of the registry (such as PROSPERO) and registration number #3a Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author #3b Describe contributions of protocol authors and identify the guarantor of the review For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2	Amendments			
2 3 4 5 6 7 8		<u>#4</u>	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	n/a
9 10 11	Support			
12 13	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	10
14 15 16	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	n/a
17 18 19 20	Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
21 22	Introduction			
23 24 25 26	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	1,3
27 28 29 30 31	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
32 33	Methods			
34 35 36 37 38 39 40	Eligibility criteria	<u>#8</u>	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	3
41 42	Information	<u>#9</u>	Describe all intended information sources (such as electronic	4
43 44 45	sources		databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	
46 47 48 49 50 51	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file 1
52 53	Study records -	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records	4,5
54 55	data management		and data throughout the review	
56 57	Study records -	<u>#11b</u>	State the process that will be used for selecting studies (such as	4,5
58 59	selection process		two independent reviewers) through each phase of the review	
60	6 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml			

1			(that is, screening, eligibility and inclusion in meta-analysis)	
2 3 4 5 6 7 8 9 10 11	Study records - data collection process	<u>#11c</u>	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	4
	Data items	<u>#12</u>	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	3-5
13 14 15 16 17	Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	3-5
18 19 20 21 22 23 24	Risk of bias in individual studies	<u>#14</u>	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	6
25 26 27 28	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	5
29 30 31 32 33 34	Data synthesis	<u>#15b</u>	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)	5
35 36 37 38	Data synthesis	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	5
 39 40 41 42 43 44 45 46 47 	Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type of summary planned	5
	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	5
48 49 50 51 52 53	Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	5
54 55	Notes:			
56 57 58 59 60	• 10: Supplement of the Creative	ary file Commo For p	1 The PRISMA-P elaboration and explanation paper is distributed under the terr ons Attribution License CC-BY. This checklist was completed on 09. March 2022 eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	ns 2

using <u>https://www.goodreports.org/</u>, a tool made by the <u>EQUATOR Network</u> in collaboration with <u>Penelope.ai</u>

For peer terien only

BMJ Open

Self-efficacy instruments for individuals with coronary artery disease: a systematic review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-062794.R2
Article Type:	Protocol
Date Submitted by the Author:	13-Jul-2022
Complete List of Authors:	Almeida, Jose Alexandre; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Florêncio, Rêncio; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Lemos, Darllane; Universidade Federal do Rio Grande do Norte, Rehabilitation Sciences Graduate Program Leite, Jéssica; Universidade Federal do Rio Grande do Norte, Physical Therapy Graduate Program Monteiro, Karolinne; Universidade Federal do Rio Grande do Norte, Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program Peroni Gualdi, Lucien; Universidade Federal do Rio Grande do Norte, Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program
Primary Subject Heading :	Cardiovascular medicine
Secondary Subject Heading:	Communication
Keywords:	CARDIOLOGY, Coronary heart disease < CARDIOLOGY, Ischaemic heart disease < CARDIOLOGY, Myocardial infarction < CARDIOLOGY



Self-efficacy instruments for individuals with coronary artery disease: a systematic review protocol

José Alexandre Barbosa de Almeida¹, Rêncio Bento Florêncio¹, Darllane Azevedo Lemos¹, Jéssica Costa Leite², Karolinne Souza Monteiro³, Lucien Peroni Gualdi³.

Affiliations: ¹ Master students, Rehabilitation Sciences Graduate Program, Federal University of Rio Grande do Norte, Santa Cruz, RN – Brazil;² Ph.D. Physical Therapy Graduate Program, Federal University of Rio Grande do Norte, Natal, RN – Brazil; ³ Professor of department of Physical Therapy and Rehabilitation Sciences Graduate Program, Federal University of Rio Grande do Norte, Santa Cruz, RN – Brazil.

Correspondence to: Lucien Peroni Gualdi – Programa de Pós Graduação em Ciências da Reabilitação, Faculdade de Ciências da Saúde do Trairi, Rua Vila do Trairi S/N, CEP: 59200-000, Santa Cruz, RN – Brazil. E-mail address: lugualdi@hotmail.com

ABSTRACT

Introduction: Self-efficacy is associated with management of diseases, psychological well-being, improved quality of life, and rehabilitation adherence. Several instruments related to behavior or specific disease (e.g., coronary artery disease [CAD]) assess selfefficacy. The evaluation of cardiac self-efficacy in individuals with CAD will support healthcare professionals to improve self-efficacy via interventions; therefore, a suitable instrument is crucial. This systematic review aims to assess measurement properties, methodological quality, and content of outcome measures of cardiac self-efficacy instruments for individuals with CAD.

Methods and analysis: The study has been developed according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol (PRISMA-P) and Consensus Norms for Selection of Health Measuring Instruments (COSMIN). The following databases will be searched: MEDLINE (ovid), Web of Science, EMBASE, and PsycINFO. Studies assessing measurement properties of cardiac self-efficacy instruments for individuals with CAD will be included. No date or language restrictions will be applied to the search. Two independent authors will be responsible for assessing the eligibility of studies. Methodological quality of studies will be assessed using the COSMIN RoB Checklist, and the Grading of Recommendations, Assessment, Development and Assessment (GRADE) will be used to assess the quality of each study. Two authors will independently evaluate the content of instruments and link this to the International Classification of Functioning, Disability, and Health.

Ethics and dissemination: This study does not require ethics committee approval since it is based on previously published data. Evidence from this systematic review will be disseminated through publication in peer-reviewed journals and presentation at scientific conferences.
PROSPERO registration number: CRD42021262613.

Strengths and limitations of this study

- This systematic review protocol is designed according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P) and the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN).
- No language and date restrictions will be used, to include the maximum number of relevant studies.
- The publication of this protocol will ensure use of a preplanned methodology, helping to reduce the risk of biased reporting and avoid duplication of effort.

- The review will not include studies of instruments that have self-efficacy in their construct (eg, self-management, self-care), limiting only to self-efficacy instruments for coronary patients.
 - This protocol may be limited by the lack of patient and public involvement in its development.

INTRODUCTION

Self-efficacy is defined as the belief of individuals about their ability to organize and perform a certain activity. It consists of elements of awareness, planning, and motivation, which can reflect on self-responsibility throughout the disease process;[1] thus, it is important for health promotion and management of chronic diseases.[1-3] Moreover, self-efficacy is associated with psychological well-being, improved quality of life, and better rehabilitation adherence.[4,5]

Measurement instruments of self-efficacy can be general[6], for specific health conditions (e.g., feeding behavior, physical activity, and medication adherence),[7-9] or specific diseases (e.g., asthma, stroke, and coronary artery disease [CAD]).[10-13] Although many scales and questionnaires are available for self-efficacy, literature lacks methodological rigor and choice of instrument for individuals in pulmonary, metabolic, and cardiovascular rehabilitation programs.

CAD is characterized as reduced coronary artery lumen due to atherosclerotic plaques and may lead to chest pain, pressure or tightness sensation at different degrees of exertion, and dyspnea.[14, 15] Conventional treatment implies cardiovascular rehabilitation and changes in daily habits. The admission of individuals to cardiovascular rehabilitation programs aims to delay and prevent complications and improve physical fitness through aerobic and strength training.[16]

Therefore, instruments assessing self-efficacy are needed to prevent complications and increase treatment adherence.[1, 3] In this context, the assessment of cardiac self-efficacy instruments for individuals with CAD will support healthcare professionals in individual interventions and improve self-efficacy of patients. This systematic review aims to identify instruments developed to assess cardiac self-efficacy in individuals with CAD and evaluate methodological quality and measurement properties. We also aim to link the content of instruments to the International Classification of Functioning,

Disability, and Health (ICF). Based on this, the review will facilitate identifying discrepancies in measurement instruments and guide further research.

METHODS AND ANALYSIS

Study design and registration

This protocol was developed according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P)[17] and the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN).[18, 19] The protocol was registered in the international prospective register of systematic reviews (PROSPERO registration number CRD42021262613). Relevant changes in the systematic review will be documented in the PROSPERO and published in the final study report.

Inclusion and exclusion criteria

Studies on the development of assessment of measurement properties of cardiac selfefficacy instruments for individuals with CAD will be included without language and date restrictions. Translation of other languages will be performed by language experts. Clinical trials or validation studies using self-reported or proxy-reported measurements and those published as abstracts will be excluded. Moreover, studies of instruments that have self-efficacy in their construct (eg, self-management, self-care) will also be excluded, limiting to self-efficacy instruments for coronary patients.

Search strategy

The search strategy will be conducted from database inception to the date of the final searches in MEDLINE (ovid), Web of Science, EMBASE and PsycINFO databases considering the following: (1) construct of interest (cardiac self-efficacy); (2) target population (individuals with CAD); (3) type of instrument (questionnaire or scale); and (4) measurement properties; the latter will be assessed using search filters validated for measurement studies and already applied in previous reviews. Additional searches for relevant studies will be manually performed in reference lists of primary studies and review articles. Searches will be repeated before the final analysis to check for new studies. Supplementary file 1 show the search strategies we developed for the databases search. The study will follow COSMIN recommendations.[20]

Page 5 of 18

Screening and selection of studies

The search results will be imported into the reference list management tool Mendeley (https://www.mendeley.com). Duplicates will be deleted before selections, and the reference list exported to the Rayyan Qatar Computing Research Institute systematic review platform (https://rayyan.qcri.org).[21] The detailed selection process will be presented in the PRISMA-P flowchart.

Two independent authors (JABA and DAL) will select studies using titles and abstracts, conduct a complete reading of potentially eligible studies, and identify and record reasons for excluding those ineligible. In the case of disagreement, a virtual meeting will be held for discussion and consultation with a third reviewer (LPG).

Data extraction

Two authors (JABA and DAL) will extract data following the Cochrane Collaboration and PRISMA guidelines. Other authors will independently review data to verify inclusion and exclusion criteria. The extracted information will include first author, year of publication, general characteristics of the instrument (construct, subscales, number of items, and version), study design, sample size, characteristics of individuals (e.g., age, sex, location, country, language, methods for selecting participants, and response rate), and results of measurement properties (i.e., internal consistency, reliability, measurement error, content validity [including face validity], construct validity [subdivided into structural validity, hypothesis testing, and cross-cultural validity], validity of criterion, responsiveness, and interpretability [not a measurement property, but necessary to adapt a research instrument or clinical practice]).

Data quality

Methodological quality of studies will be assessed by two independent authors (RBF and JCL) using COSMIN RoB Checklist.[18, 19] This tool considers ten measurement properties and contains nine boxes with 3 to 35 items. Each box assigns a methodological quality score for instrument development: (1) content validity, (2) structural validity, (3) internal consistency, (4) cross-cultural validity and measurement invariance, (5) reliability, (6) measurement error, (7) criterion validity, (8) hypothesis testing for construct validity, and (9) responsiveness. Each item has four response

options: inadequate, doubtful, adequate, and very good.[22] Disagreements will be solved by a third author (KSM).

The content extracted from measurement instruments will be compared using the ICF framework.[23–25] Two independent authors (JABA and RBF) will evaluate the content and link items of questionnaires to ICF standards. After, a third author (JCL) will review the content.

Data synthesis

A narrative synthesis of results will be provided. In the possibility of validation studies of the same instrument for different populations, methodological and psychometric properties quality of such studies will be addressed as a unique instrument but discussing the particularity of each version. A combination of measurement properties will determine the overall evidence of the instrument. Studies will be grouped according to similarity in terms of language, instrument version, study population, and application form.

Results will be evaluated in clusters or summarized against the criteria for good measurement properties to determine whether they are sufficient (+), insufficient (-), inconsistent (+/-), or indeterminate (?). Furthermore, a modified Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) will determine study quality.[26, 27]

Afterward, instruments will be categorized and justified according to COSMIN recommendations:[28] (A) instrument is recommended for use and results are reliable; (B) when it may be recommended but requires further research to assess quality of these instruments; and (C) instrument should not be recommended.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The study does not require ethics committee approval since it is based on published data. Evidence from this systematic review will be disseminated through publication of results in peer-reviewed journals and presentation at scientific conferences.

Contributors: Authors made substantial contributions to the study design, developed inclusion criteria, and search strategies. JABA developed the protocol, RBF, DAL, JCL, KSM, and LPG provided critical insights and reviewed the protocol. JABA registered the protocol in the PROSPERO database. All authors read and approved the final version of the protocol.

Funding: The study will be financed by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) – Brazil. JABA, DAL and RBF received grant from CAPES by Finance Code 001.

Competing interests: None declared.

Patients consent for publication: Not applicable.

Provenance and peer review: Not commissioned, externally peer-reviewed.

Open access: This is an open-access article distributed by the Creative Commons Attribution Non-Commercial (CC BY-NC 4.0) license, which allows distribution, remix, adapt, build upon this study non-commercially, and license the derivative studies on different terms. Original study must be cited, given appropriate credit, any changes must be indicated, and the use is non-commercial. See http://creativecommons.org/licenses/by-nc/4.0/.

ORCIDS iDs:

José Alexandre Barbosa de Almeida https://orcid.org/0000-0002-0876-6794 Rêncio Bento Florêncio https://orcid.org/0000-0003-2853-7988 Darllane Azevedo Lemos https://orcid.org/0000-0003-2020-3940 Jéssica Costa Leite https://orcid.org/0000-0002-4726-9416 Karolinne Souza Monteiro https://orcid.org/0000-0003-2254-8723 Lucien Peroni Gualdi https://orcid.org/0000-0002-6907-7335

REFERENCES

1 Bandura A. Health promotion by social cognitive means. *Health Educ Behav* 2004;31:143–64.doi:10.1177/1090198104263660.

2 Roest AM, Martens EJ, Denollet J, *et al.* Prognostic association of anxiety post myocardial infarction with mortality and new cardiac events: A meta-analysis. *Psychosom Med* 2010;72:563–9 doi:10.1097/PSY.0b013e3181dbff97.

3 Bandura, A. Self-efficacy. In V. S. Ramachaudran, *Encyclopedia of human behavior*. New York: Academic Press. 1994.

Joekes K, Van Elderen T, Schreurs K. Self-efficacy and overprotection are related to quality of life, psychological well-being and self-management in cardiac patients. *J Health Psychol* 2007;12:4–16. doi:10.1177/1359105306069096.

5 Katch H. The role of self-efficacy in cardiovascular disease self-management: a review of effective programs. *Patient Intell* 2010;2:33-44.doi:10.2147/PI.S12624.

6 Luszczynska A, Scholz U, Schwarzer R. The general self-efficacy scale: Multicultural validation studies. *J Psychol* 2005;139:439-57.doi:10.3200/JRLP.139.5.439-457.

7 Birkett NJ, Hotz SB. A self-efficacy scale for heart-healthy eating. *Can J Public Health* 1994;85:201-4. PMID: 7922967.

8 Wong EML, Leung DYP, Sit JWH, *et al.* Prospective Validation of the Chinese Version of the Self-Efficacy for Exercise Scale among Middle-Aged Patients with Coronary Heart Disease. *Rehabil Nurs* 2020;45:74– 9.doi:10.1097/RNJ.00000000000156.

9 Saffari M, Zeidi IM, Fridlund B, *et al.* A Persian Adaptation of Medication Adherence Self-Efficacy Scale (MASES) in Hypertensive Patients: Psychometric Properties and Factor Structure. *High Blood Press Cardiovasc Prev* 2015;22:247– 55.doi:10.1007/s40292-015-0101-8.

Holley S, Knibb R, Latter S, *et al.* Development and validation of the
Adolescent Asthma Self-Efficacy Questionnaire (AASEQ). *Eur Respir J* 2019;54:1–
10.doi:10.1183/13993003.01375-2018.

He V C C C C C C 9.4 9.4 9.4

BMJ Open

11 Topçu S, Oguz S. Translation and validation study for the stroke self - efficacy questionnaire in stroke survivors. *Int J Nurs Pract* 2018:24:1–8.doi:10.1111/ijn.12646.

12 Sullivan MD, Lacroix AZ, Russo J, *et al.* Self-efficacy and self-reported functional status in coronary heart disease: A six-month prospective study. *Psychosom Med* 1998;60:473–8.doi:10.1097/00006842-199807000-00014.

Fors A, Ulin K, Cliffordson C, *et al.* The Cardiac Self-Efficacy Scale, a useful tool with potential to evaluate person-centred care. *Eur J Cardiovasc Nurs* 2015;14:536–43.doi:10.1177/1474515114548622.

14 Li H, Sun K, Zhao R, *et al.* Inflammatory biomarkers of coronary heart disease. *Front Biosci (Schol Ed)* 2018;10:185–96.doi:10.2741/s508.

15 Cagle SD, Cooperstein N. Coronary Artery Disease: Diagnosis and Management. *Prim Care* 2018;45:45–61.doi:10.1016/j.pop.2017.10.001.

16 Carvalho T, Milani M, Ferraz AS, *et al.* Brazilian Cardiovascular Rehabilitation Guideline – 2020. *Arq Bras Cardiol* 2020;114:943–87.doi:10.36660/abc.20200407.

17 Shamseer L, Moher D, Clarke M, *et al.* Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: Elaboration and explanation. *BMJ* 2015;349:1–25.doi:10.1136/bmj.g7647.

18 Mokkink LB, Terwee CB, Patrick DL, *et al.* The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res* 2010;19:539–49.doi:10.1007/s11136-010-9606-8.

19 Mokkink LB, Terwee CB, Knol DL, *et al.* The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. *BMC Med Res Methodol.* 2010;10:22.doi:10.1186/1471-2288-10-22.

20 Terwee CB, Jansma EP, Riphagen II, *et al.* Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments. *Qual Life Res* 2009;18:1115–23.doi:10.1007/s11136-009-9528-5. 21 Ouzzani M, Hammady H, Fedorowicz Z, *et al.* Rayyan-a web and mobile app for systematic reviews. *Syst Rev* 2016;5:1–10.doi:10.1186/s13643-016-0384-4.

22 Mokkink LB, de Vet HCW, Prinsen CAC, *et al.* COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. *Qual Life Res.* 2018;27:1171-9.doi:10.1007/s11136-017-1765-4.

23 Cieza A, Geyh S, Chatterji S, *et al.* ICF linking rules: An update based on lessons learned. *J Rehabil Med* 2005;37:212–8.doi:10.1080/16501970510040263.

Cieza A, Brockow T, Ewert T, *et al.* Linking health-status measurements to the International Classification of Functioning, Disability and Health. *J Rehabil Med* 2002;34:205–10.doi:10.1080/165019702760279189.

25 Castro SS, Castaneda L, de Araújo ES, *et al.* Aferição de funcionalidade em inquéritos de saúde no Brasil: Discussão sobre instrumentos baseados na Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF). *Rev Bras Epidemiol* 2016;19:679–87.doi:10.1590/1980-5497201600030018.

Andrews J, Guyatt G, Oxman AD, *et al.* GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clinl Epidemiol* 2013;66:719–25.doi:10.1016/j.jclinepi.2012.03.013.

Andrews JC, Schünemann HJ, Oxman AD, *et al.* GRADE guidelines: 15. Going from evidence to recommendation - Determinants of a recommendation's direction and strength. *J Clin Epidemiol* 2013;66:726–35.doi:10.1016/j.jclinepi.2013.02.003.

28 Mokkink LB, Prinsen CAC, Patrick DL, et al. COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs) - user manual Netherlands: COSMIN, 2018. https://www.cosmin.nl/wp-content/uploads/COSMINsyst-review-for-PROMs-manual_version-1_feb-2018-1.pdf [accessed 20 Dec 2021].

SUPPLEMENTARY FILE 1

Search strategy for MEDLINE (Ovid)

- 1. exp Self Efficacy/
- 2. self-efficacy.mp.
- 3. 1 or 2
- 4. exp Coronary Artery Disease/
- 5. Coronary Artery Disease.mp.
- 6. coronary heart disease.mp.
- 7. exp Coronary Disease/
- 8. exp Acute Coronary Syndrome/
- 9. Heart disease.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 10. exp heart diseases/
- 11. exp myocardial ischemia/
- 12. exp Cardiovascular Diseases/
- 13. Cardiovascular Disease.mp.
- 14. exp Heart Failure/
- 15. heart failure.mp.
- 16. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
- 17. instrument*.mp.
- 18. instruments*.mp.
- 19. measure*.mp.
- 20. measures*.mp.
- 21. questionnaire*.mp.
- 22. exp "Surveys and Questionnaires"/
- 23. questionnaires*.mp.
- 24. scale*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 25. scales*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 26. tool*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 27. tools*.mp.
- 28. survey*.mp.
- 29. test*.mp.
- 30. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29
- 31. 3 and 16 and 30
 - 32. (instrumentation or methods).fs.
 - 33. (Validation Studies or Comparative Study).pt.

34. exp Psychometrics/

- 35. psychometr*.ti,ab.
- 36. (clinimetr* or clinometr*).tw.
- 37. outcome assessment.ti,ab.
- 38. outcome measure*.tw.
- 39. exp Observer Variation/
- 40. observer variation.ti,ab.
- 41. exp Health Status Indicators/
- 42. exp Reproducibility of Results/
- 43. reproducib*.ti,ab.
- 44. exp Discriminant Analysis/
- 45. (reliab* or unreliab* or valid* or coefficient or homogeneity or homogeneous or internal consistency).ti,ab.
- 46. (cronbach* and (alpha or alphas)).ti,ab.
- 47. (item and (correlation* or selection* or reduction*)).ti,ab.
- 48. (agreement or precision or imprecision or precise values or test-retest).ti,ab.
- 49. (test and retest).ti,ab.
- 50. (reliab* and (test or retest)).ti,ab.
- 51. ((replicab* or repeated) and (measure or measures or findings or result or results or test or tests)).ti,ab.
- 52. (generaliza* or generalisa* or concordance).ti,ab.
- 53. (intraclass and correlation*).ti,ab.
- 54. (discriminative or known group or factor analysis or factor analyses or dimension* or subscale*).ti,ab.
- 55. (multitrait and scaling and (analysis or analyses)).ti,ab.
- 56. (item discriminant or interscale correlation* or error or errors or individual variability).ti,ab.
- 57. (variability and (analysis or values)).ti,ab.
- 58. (uncertainty and (measurement or measuring)).ti,ab.
- 59. (standard error of measurement or sensitiv* or responsive*).ti,ab.
- 60. ((minimal or minimally or clinical or clinically) and (important or significant or detectable) and (change or difference)).ti,ab.
- 61. (small* and (real or detectable) and (change or difference)).ti,ab.
- 62. (meaningful change or ceiling effect or floor effect or Item response model or IRT or Rasch or Differential item functioning or DIF or computer adaptive testing or item bank or cross-cultural equivalence).ti,ab.
- 63. exp Reproducibility of Results/
- 64. cross-cultural equivalence.ti,ab.
- 65. development.ti,ab.
- 66. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65
- 67. 31 and 66

Search strategy for Web of Science

n	Search terms						
#1	Search: TS=(Self-Efficacy*) OR TS=(Self Efficacy*)						
#2	Search: TS=(Coronary Artery Disease*) OR TS=(Coronary Disease*) OR TS=(Coronary Heart Disease*) OR TS=(Acute Coronary Syndrome) OR TS=(Heart disease*) OR TS=(Cardiovascular disease*) OR TS=(Heart failure) OR TS=(Myocardial ischemia)						
#3	Search: TS=(Instrument*) OR TS=(instruments*) OR TS=(measure*) OR TS=(measures*) OR TS=(questionnaire*) OR TS=(questionnaires*) OR TS=(scale*) OR TS=(scales*) OR TS=(tool*) OR TS=(tools*) OR TS=(survey*) OR TS=(test*)						
#4	Search: TS=(instrumentation) OR TS=(methods) OR TS=("validation stud*") OR TS=("comparative stud*") OR TS=(psychometries) OR TS=(psychometr*) OR ALL=(clinimetr*) OR ALL=(clinometr*) OR TS=("observer variation") OR TS=("observer variation") OR TS=("health status indicators") OR TS=(valid*) OR TS=("discriminant analysis") OR TS=(clial*) OR TS=(unreliab*) OR TS=(valid*) OR TS=("coefficient of variation") OR TS=(coefficient) OR TS=(homogeneity) OR TS=(mongeneous) OR TS=("internal consistency") OR ((TS=(alpha) OR TS=(alphas)) AND TS=(crombach*)) OR ((TS=(correlation*) OR TS=(selection*) OR TS=(internal*)) AND TS=(internal consistency") OR (TS=(test) AND TS=(retext)) OR ((TS=(test) OR TS=(inter- selection*) OR TS=(intra-rater) OR TS=(interater) OR TS=(inter- test) OR (TS=(intra-rater) OR TS=(interater) OR TS=(inter-tester) OR TS=(intrarater) OR TS=(intra-tester) OR TS=(inter-tester) OR TS=(intra-tester) OR TS=(intra-tester) OR TS=(inter-tester) OR TS=(intra-casany) OR TS=(intra-assay) OR TS=(inter-tester) OR TS=(inter-examiner) OR TS=(intra-assay) OR TS=(inter-tester) OR TS=(inter-assay) OR TS=(intra-assay) OR TS=(inter-assay) OR TS=(inter-assay) OR TS=(intra-assay) OR TS=(inter-individual) OR TS=(inter-assay) OR TS=(intra-assay) OR TS=(intra-individual) OR TS=(inter-assay) OR TS=(intra-assay) OR TS=(intra-individual) OR TS=(inter-assay) OR TS=(intra-intra-individual) OR TS=(intra-intra-individual) OR TS=(inter-assay) OR						

#5 #1 AND #2 AND #3 AND #4

2
3
1
-
5
6
/
8
9
10
11
12
13
14
15
16
10
1/
18
19
20
21
22
23
24
27
25
20
2/
28
29
30
31
32
33
34
25
22
30
37
38
39
40
41
42
<u>4</u> 3
11
44
45
46
4/
48
49
50
51
52
53
54
55
55
20
5/
58
59

1

Search strategy for Embase and PsycoINFO

n	Search terms							
#1	("Self-Efficacy*" OR "Self Efficacy*")							
#2	("Coronary Artery Disease*" OR "Coronary Disease*" OR "Coronary Heart Disease*" OR "Acute Coronary Syndrome" OR "Heart disease*" OR "Cardiovascular disease*" OR "Heart failure" OR "Myocardial ischemia")							
#3	("Instrument*" OR "Instruments*" OR "measure*" OR "measures*" OR "questionnaire*" OR "questionnaires" OR "scale*" OR "scales*" OR "tool*" OR "tools*" OR "survey*" OR "test*")							
#4	("instrumentation" OR "methods" OR "Validation Studies" OR "Comparative Study" OR "psychometrics" OR "psychometr*" OR "clinometr*" OR "clinometr*" OR "outcome assessment (health care)" OR "outcome assessment" OR "outcome masure*" OR "observer variation" OR "health Status Indicators" OR "reproducibility of results" OR "cepficient of variation" OR "coefficient" OR "homogeneity" OR "walid*" OR "cefficient of variation" OR "cefficient" OR "homogeneity" OR "homogeneous" OR "internal consistency" OR ("cronbach*" AND "alpha" OR "alphas") OR ("iter" AND ("correlation*" OR "selection*" OR "retest") OR ("tertiab*" OR "internal consistency" OR ("cronbach*" AND "alpha" OR "alphas") OR ("iter" AND ("correlation*" OR "selection*" OR "retest") OR ("tertiab*" OR "inter-retest" OR ("test" AND "retest") OR ("terliab*" AND ("test" OR "inter-retest" OR "inter-tester" OR "intra-technician" OR "intra-technician" OR "inter-tester" OR "intra-technician" OR "inter-tester" OR "intra-technician" OR "intra-technician" OR "inter-tester" OR "intra-assay" OR "interindividual" OR "inter-assay" OR "interandicipant" OR "inter-assay" OR "interindividual" OR "intra-assay" OR "intra-assay" OR "interadicipant" OR "inter-assay" OR "interindividual" OR "intra-assay" OR "intra-assay" OR "interadicipant" OR "intra-assay" OR "interindividual" OR "intra-assay" OR "interadicipant" OR "inter-assay" OR "interadicipant" OR "inter-assay" OR "interadicipant" OR "intra-assay" OR "interadicipant" OR "intra-assay" OR "interadicipant" OR "inte							

#5 #1 AND #2 AND #3 AND #4

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

	Reporting Item	Page Number
	4	
<u>#1a</u>	Identify the report as a protocol of a systematic review	1
<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	1
<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1, 10
<u>#3b</u> For r	Describe contributions of protocol authors and identify the guarantor of the review	9
	#1a #1b #2 #3a #3b	Reporting Item #1a Identify the report as a protocol of a systematic review #1b If the protocol is for an update of a previous systematic review, identify as such #2 If registered, provide the name of the registry (such as PROSPERO) and registration number #3a Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author #3b Describe contributions of protocol authors and identify the guarantor of the review For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2	Amendments			
2 3 4 5 6 7 8		<u>#4</u>	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	n/a
9 10 11	Support			
12 13	Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	10
14 15 16	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	n/a
17 18 19 20	Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
21 22	Introduction			
23 24 25 26	Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	1,3
27 28 29 30 31	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
32 33	Methods			
34 35 36 37 38 39 40	Eligibility criteria	<u>#8</u>	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	3
41 42	Information	<u>#9</u>	Describe all intended information sources (such as electronic	4
43 44 45	sources		databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	
46 47 48 49 50 51	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file 1
52 53	Study records -	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records	4,5
54 55	data management		and data throughout the review	
56 57	Study records -	<u>#11b</u>	State the process that will be used for selecting studies (such as	4,5
58 59	selection process		two independent reviewers) through each phase of the review	
60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml			

1			(that is, screening, eligibility and inclusion in meta-analysis)			
2 3 4 5 6 7 8 9 10 11	Study records - data collection process	<u>#11c</u>	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	4		
	Data items	<u>#12</u>	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	3-5		
13 14 15 16 17	Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	3-5		
 18 19 20 21 22 23 24 25 26 27 28 	Risk of bias in individual studies	<u>#14</u>	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	6		
	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	5		
29 30 31 32 33 34	Data synthesis	<u>#15b</u>	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)	5		
35 36 37 38	Data synthesis	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	5		
39 40 41 42	Data synthesis	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type of summary planned	5		
43 44 45 46 47	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	5		
48 49 50 51 52 53	Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	5		
54 55	Notes:					
56 57 58 59 60	 10: Supplementary file 1 The PRISMA-P elaboration and explanation paper is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist was completed on 09. March 2022 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml 					

using <u>https://www.goodreports.org/</u>, a tool made by the <u>EQUATOR Network</u> in collaboration with <u>Penelope.ai</u>

For peer terien only