BMJ Open

Opioid consumption pattern: Protocol for a systematic review of validated assessment tools

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-021948
Article Type:	Protocol
Date Submitted by the Author:	30-Jan-2018
Complete List of Authors:	Galindo, Sheila; Universidade Federal de Pernambuco, Neuropsychiatry Silva, Tatiana ; Universidade Federal de Pernambuco, neuropsiquiatria Marinho, Manoel; Universidade de Pernambuco Ribeiro, Carlos Eduardo; Universidade Federal de Pernambuco, Neuropsychiatry Lima, Murilo; Universidade Federal de Pernambuco Vasconcelos, Selene; Federal University of Pernambuco, Neuropsychiatry and behavior sciences
Keywords:	opioids, drug users, systematic reviews, validation studies, MENTAL HEALTH

Opioid consumption pattern: Protocol for a systematic review of validated assessment tools

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1468 words

Abstract

Introduction: Recent data show that the use, abuse and adverse consequences of opioids, including death, have increased. Evidence reveals that, despite the drastic reduction in prescriptions, there has not been a reduction in opioid-related deaths. This paradox may be explained by therapeutic but excessive and/or abusive use on the part of individuals who suffer from chronic pain. Thus, managing the opioid consumption pattern demonstrates has proven to be a protection factor as well as an important tool for health professionals who offer care to this type of patient. The aim is to evaluate validated tools for measuring opioid use patterns and determine the psychometric properties of these instruments in different age groups. **Methods and analysis:** The review process will be based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols. The Consensus-Based Standards for the Selection of Health Measurement Instruments will be used for the analysis of the assessment tools. Two independent reviewers will the literature search and analysis procedures. Searches will be performed in the Pubmed, Web of Science, Cochrane, PsycINFO, SCOPUS and CINAHL databases and the "snowball" strategy will be employed. The inclusion criteria will be 1) validation studies, 2) assessment tools designed exclusively for measuring opioid consumption patterns and 3) assessment tools designed for the evaluation of individuals with chronic pain. The titles and abstracts of the studies retrieved from the databases will be analyzed for the pre-selection of articles, which will be submitted to a full-text analysis for the definition of the final sample. Divergences of opinion between the two reviewers will be resolved by consulting a third reviewer. **Ethics and dissemination:** The review will offer an overview of assessment tools available for the evaluation of opioid consumption patterns, which is relevant to reducing the risk of deaths due to abusive consumption and for the clinical management of patients with chronic pain.

Systematic review registration: CRD42018081577

Keywords: Opioids; Drug users; Systematic review; Validation studies; Mental health.

Strengths and limitations of this study:

- Broadens understanding regarding the opioid consumption patterns of individuals with chronic pain.

- Provides an overview of assessment tools for evaluating the opioid consumption pattern of individuals with chronic pain.
- Provides evidence of the best assessment tools for measuring this health phenomenon to assist in decision-making processes for health professionals who offer care to such patients.
- Assists in the development of therapeutic guidelines for the management of opioid consumption by individuals with chronic pain.
- Limitations may be related to the subjectivity of the researchers with regard to delineating evidence focused on specific gaps in knowledge in the field of interest.

Introduction

Recent data show that the use, abuse and adverse consequences of opioids, including death, have increased at an alarming rate since the 1990s. Evidence reveals that, despite the drastic reduction in prescriptions, there has not been a reduction in opioid-related deaths. This paradox may be explained by therapeutic but excessive and/or abusive use on the part of individuals who suffer from chronic pain.[1-3] Indeed, there have been increasing reports of deaths related to the improper use and/or abuse of controlled substances.[4-7] The United States, for instance, which correspond to 4.6% of the world's population, accounted for approximately 69% of the global supply of opioids in 2014,[8,9] including 99.7% of hydrocodone, 51.2% of morphine, 73.1% of oxycodone and 53% of hydromorphone, and improper use and/or abuse rates have gone from 4 to 26%.[10,11] Thus, managing opioid consumption patterns is an important monitoring and intervention tool for health professionals who work with such patients and can be used as a care management mechanism at healthcare centers, contributing significantly to the reduction in morbidity and mortality rates.

The proposed systematic review has considerable clinical implications with regard to assisting health professionals in the choice of assessment tools that are appropriate to the profile of their patients, since an understanding of opioid consumption patterns can assist in decision making and the adequate management of patients with a diagnosis of chronic pain. Thus, the following research question was posed to guide the analysis of the evidence: What are the available assessment tools designed to measure opioid consumption patterns and what are their most robust psychometric properties for use in

different age groups? The proposed study will involve a systematic review of the literature on validated quantitative assessment tools for measuring opioid consumption patterns and the psychometric properties of these instruments in different age groups.

Methods/Design

Design and registration of the study

The present review protocol is registered with the International Prospective Registry of Systematic Reviews (PROSPERO). The protocol was designed considering the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P).[12] This review will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement,[13] and consists of acquiring, extracting and assessing the data.

Inclusion of articles

The following will be the inclusion criteria for the selection of articles: a) validation studies; b) assessment tools designed for the quantitative evaluation of consumption patterns; c) assessment tools designed for the evaluation of individuals with chronic non-oncological pain; d) assessment tools designed for different age groups (children, adolescents, adults and older adults); e) assessment tools designed for the quantitative evaluation of consumption patterns based on self-reported information from the patient; f) articles describing the psychometric properties of the opioid consumption assessment tools. No restrictions will be imposed with regard to language or year of publication. Systematic reviews will be excluded.

Search strategy

The search strategy will be based on the Population Intervention Comparator Outcome Setting (PICOS)[14] method to make the research question, the title, and choice the keywords. The Pubmed, PsycINFO, Web of Science, Cochrane, SCOPUS and CINAHL databases will be searched and the “snowball” strategy will also be employed.

The keywords indexed in the Mesh Terms and their crosses will be used The descriptors indexed in the Mesh Terms and their crosses will be used: "sickle cell disease", opioid, “validation studies”, "substance-related disorders", instrument.

To minimize the risk of bias of the individual studies, two independent reviewers will perform analyses of the titles, abstracts and full texts based on the eligibility criteria. In

cases of divergence of opinion regarding the inclusion of a given study, a third reviewer will be consulted. Descriptive analyses will be performed of the characteristics of the studies, participants, psychometric properties and clinical usefulness of the assessment tools.

Screening, data extraction and comparative content analysis

All results of the database searching will be filed to record the initial search strategy and subsequent modifications. Duplicated articles will only be counted once. Authors will be contacted for further information, when necessary.

Data extraction will involve the use of a chart specifically designed for the proposed study to organize the following data:

1- Information and general characteristics: Authors, year of publication, country and sample characteristics;
2- Description of assessment tool: Acronym for the measure, domains, number of items, scores and application format.

The data will subsequently be tabulated in a databank created exclusively for the proposed study.

The contents will be compared through meetings between the two reviewers. Divergences of opinion will be resolved by a third reviewer to extract complete information from all manuscripts. A study selection file will be kept to record the references for all studies excluded and the reasons for exclusion. A flowchart will be created showing the article selection process. All relevant data from the studies will be summarized in tables.

Appraisal of methodological quality of selected articles

The Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN checklist) will be used for the appraisal of the methodological quality of the articles. This checklist has four domains: reliability, validity, responsiveness and interpretability. Only those articles considered adequate based on this checklist will be included in the systematic review.[15-18]

Evaluation of clinical usefulness of assessment tools

The appraisal of the clinical usefulness of the assessment tools will follow the criteria proposed by Tyson and Brown (2014)[19] related to interpretability and viability, with the aim of quantifying the practical aspects of the measures based on factors that could

influence the decision-making process of health professionals in clinical practice [20]. These criteria are listed below:

- Total time required for the administration, analysis and interpretation of the data obtained using the assessment tool: < 10 min (3 points); 10-30 min (2 points); 30-60 min (1 point) and > 1 h (0 points).
- Cost involved in the acquisition and use of the assessment tool: < £ 100 (3 points); £ 100-500 (2 points); £ 500-1000 (1 point); £ 1000 (zero).
- Need for training and calibration for use of the assessment tool: none (2 points); yes, but simple and clinically viable (1 point); yes and not clinically viable/unknown (zero).
- Portability of tool (can it be taken to the patient?): yes, easily (fits in pocket) (2 points); yes (fits in a carrying case) (1 point); no or very difficult (zero).
- Accessibility of tool (are detailed instructions for use available?): yes (complete operating procedure/instruction manual can be obtained in article or site) (2 points); no, but the operation can be performed simply based on the description in the article (1 point); no available instructions for use (zero).

Data synthesis

The systematic review report shall be in accordance with the PRISMA recommendations[13] and the certainty of the evidence will be analyzed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE).[21] For the proposed review, assessment tools with the following qualities will be considered adequate:

- Those with a methodology considered "good" or "excellent" based on the COSMIN checklist;[15-18]
- Those with a score of 10 or more points on the clinical usefulness evaluation scale proposed by Tyson and Brown (2014).[19]

Ethics and dissemination

The general aim of the review is to provide a discussion on the strong points and limitations of different assessment tools used to measure opioid consumption patterns through an analysis of the general characteristics, psychometric properties and clinical

usefulness of the measures as well as the methodological quality of the studies included in the review.

Thus, to contribute of the health professionals to determine which measures are the most appropriate based on the characteristics of their patients, and to assist in decision-making processes and the determination of the most adequate care management for patients with a diagnosis of chronic pain. The use of valid and reliable instruments is fundamental for the reliability of the evidence produced about a health phenomenon.[21]

In conclusion, the proposed review will offer relevant data that can be used to reduce the risk of death due to the abusive consumption of opioids as well as the clinical management of patients with chronic pain.

The results will be released according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA) and will be submitted to a peer-reviewed journal. The protocol and the systematic review will be included in a doctoral thesis.

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Authors' contributions

All authors made substantial contributions to the conception and design of the study and participated in the drafting of the submission request. SRG[1], TPSS[2] and SCV[6] conceived of the study, developed the criteria, performed the literature search and selection of the studies and wrote the present systematic review protocol study. MHNM[3], CESLR[4] and MDCL[5] served as advisers throughout all phases of this systematic review protocol study and performed a critical revision of the manuscript. All authors read and approved the final version.

Funding statement

'This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors'.

Competing interests statement.

The authors declare that they have no conflicts of interest.

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

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review (YES)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number CRD42018081577
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author(OK)
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review(OK)
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments (Not applicable)
Support:		
Sources	5a	Indicate sources of financial or other support for the review(Not applicable)
Sponsor	5b	Provide name for the review funder and/or sponsor(Not applicable)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol(Not applicable)
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known (YES)
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) (YES)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review (YES)
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage (YES)
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated(YES)
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review(YES)

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) (YES)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators(YES)
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications(YES)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale(YES)
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis(YES)
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised(YES)
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ) (YES, according to COSMIN)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) (YES)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned(Not applicable)
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) (YES, according to COSMIN)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) (YES, according to COSMIN)

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

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

BMJ Open

Risk of behavior suggestive of opioid abuse: Protocol for a systematic review of validated assessment tools

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-021948.R1
Article Type:	Protocol
Date Submitted by the Author:	04-Apr-2018
Complete List of Authors:	Galindo, Sheila; Universidade Federal de Pernambuco, Neuropsychiatry Silva, Tatiana ; Universidade Federal de Pernambuco, neuropsiquiatria Marinho, Manoel; Universidade de Pernambuco Ribeiro, Carlos Eduardo; Universidade Federal de Pernambuco, Neuropsychiatry Lima, Murilo; Universidade Federal de Pernambuco Vasconcelos, Selene; Federal University of Pernambuco, Neuropsychiatry and behavior sciences
Primary Subject Heading:	Addiction
Secondary Subject Heading:	Mental health, Research methods
Keywords:	opioids, drug users, systematic reviews, validation studies, MENTAL HEALTH

Risk of behavior suggestive of opioid abuse: **Protocol for a systematic review of validated assessment tools**

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1656 words

Abstract

Introduction: Opioid use patterns by individuals with non-oncological pain are influenced by the behavioral dynamics of the patient in managing and properly following the prescription. The use of assessment tools for measuring the risk of behavior suggestive of the opioid abuse is important for health professionals who provide care to individuals with non-oncological pain. The aim of the proposed review is to analyze validated tools for measuring the risk of behavior suggestive of the abuse of opioids. **Methods and analysis:** The review process will be based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols. The Consensus-Based Standards for the Selection of Health Measurement Instruments will be used for the analysis of the assessment tools. Two independent reviewers will perform the literature search and analysis procedures. Searches will be performed in the PubMed, Web of Science, Cochrane, SCOPUS and CINAHL databases and the "snowball" strategy will be employed. The inclusion criteria will be 1) validation studies, 2) assessment tools designed exclusively for measuring the risk of behavior suggestive of opioid abuse and 3) assessment tools designed for the evaluation of adults with chronic non-oncological pain. The titles and abstracts of the studies retrieved from the databases will be analyzed for the pre-selection of articles, which will be submitted to a full-text analysis for the definition of the final sample. Divergences of opinion between the two reviewers will be resolved by consulting a third reviewer. **Ethics and dissemination:** The review will offer an overview of assessment tools available for measuring the risk of behavior suggestive of opioid abuse, which is relevant to reducing the risk of deaths due to abusive consumption and for the clinical management of patients with chronic non-oncological pain.

Systematic review registration: CRD42018081577

Keywords: Opioids; Drug users; Systematic review; Validation studies; Mental health.

Strengths and limitations of this study:

- Broadens understanding regarding the risk of behavior suggestive of opioid abuse among adults with chronic non-oncological pain.
- Provides an overview of assessment tools for evaluating the opioid consumption pattern of adults with chronic non-oncological pain.

- Provides evidence of the best assessment tools for measuring this health phenomenon to assist in decision-making processes for health professionals who provide care to such patients.
- Assists in the development of therapeutic guidelines for the management of opioid consumption by adults with chronic non-oncological pain.
- Limitations may be related to the subjectivity of the researchers with regard to delineating evidence focused on specific gaps in knowledge in the field of interest.

Introduction

The consumption of opioids and the risk of improper use in populations with chronic non-oncological pain have generated considerable discussion in recent years. The improper use of opioids can result in serious consequences to one's health, contributing to the development of dependency on these drugs.[1] It is estimated that up to 60% of patients with chronic pain who take opioids are susceptible to abusive use, commonly in the form of excessive consumption.[2] Another study reports that 61.8% of patients had chronic pain prior to their first diagnosis of an opioid use disorder.[3]

The risk of behavior suggestive of opioid abuse constitutes a predictor of the development of a substance use disorder, which is a real possibility for individuals with chronic non-oncological pain and a considerable concern for health professionals.[4] Opioid use patterns by individuals with non-oncological pain are influenced by the behavioral dynamics of the patient in managing and properly following the prescription as well as the skills of health professionals regarding the identification of risk and protection factors of opioid abuse by these individuals.[5]

Physical, psychological, social, cultural, spiritual, genetic and behavioral factors can all contribute to an individual's attitude toward chronic pain.[6] Different strategies have been used for monitoring opioid use by individuals with chronic non-oncological pain, such as electronic health records,[7] the signing of a "narcotic contract" or "opioid treatment agreement",[8] and prescription drug monitoring programs.[9]

Sickle cell anemia is a chronic condition with diverse clinical manifestations that can lead to recurring hospitalization and death. Adequate health care with a specialized multidisciplinary team and social support can contribute to a reduction in the number of hospitalizations and an improvement in the quality of life of affected individuals.[10] Patients with sickle cell anemia experience chronic pain that is treated with opioids,

making them a vulnerable population. Therefore, the use of a valid, reliable assessment tool for measuring the risk of behavior suggestive of opioid abuse is an important monitoring strategy that can help guide health professionals in the management of these patients. Moreover, evidence produced from such investigations can be used to help professionals at healthcare services also monitor other type of patients.

The proposed systematic review has considerable clinical implications with regard to assisting health professionals in the choice of assessment tools that are appropriate to the profile of their patients, since an understanding the risk of behavior suggestive of opioid abuse can assist in decision making and the adequate management of adult patients with a diagnosis of chronic non-oncological pain. Thus, the following research question was posed to guide the analysis of the evidence: What are the available assessment tools designed to measure the risk of behavior suggestive of opioid abuse in individuals with chronic non-oncological pain and what are the psychometric properties of these instruments in different age groups? The proposed study will involve a systematic review of the literature on validated quantitative assessment tools for measuring the risk of behavior suggestive of opioid abuse and the psychometric properties of these instruments in adult groups.

Methods/Design

Design and registration of the study

The present review protocol is registered with the International Prospective Registry of Systematic Reviews (PROSPERO). The report of the methods for the review protocol was drafted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA- P).[11] The report of the methods for the systematic review article will follow the PRISMA guidelines.[12]

Patient and Public Involvement

It is a systematic review protocol article, we do not work with patients or their companions.

Inclusion of articles

The following will be the inclusion criteria for the selection of articles: a) validation studies; b) assessment tools designed for the quantitative evaluation of the risk of behavior suggestive of opioid abuse; c) assessment tools designed for the evaluation of individuals with chronic non-oncological pain; d) assessment tools designed for adult groups; e) assessment tools designed for the quantitative evaluation of the risk of

behavior suggestive of opioid abuse based on self-reported information from the patient; f) articles describing the psychometric properties of the tools. No restrictions will be imposed with regard to language or year of publication. Systematic reviews will be excluded.

Search strategy

The search strategy will be based on the Population Intervention Comparator Outcome Setting (PICOS)[13] method to form the research question, determine the title, and choose the keywords. The PubMed, Web of Science, Cochrane, SCOPUS and CINAHL databases will be searched and the "snowball" strategy will also be employed.

The following keywords indexed in the Mesh Terms and combinations will be used: "sickle cell disease", "opioid", "validation studies", "opioid related disorders", "chronic pain", and "instrument". The term "sickle cell disease" was included to locate instruments developed specifically for adults with this disease due to the high incidence of chronic pain and opioid abuse in this population.

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2- Description of assessment tool: Acronym for the measure, domains, number of items, scores and application format.

The data will subsequently be tabulated in a databank created exclusively for the proposed study.

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information from all manuscripts. A study selection file will be kept to record the references for all studies excluded and the reasons for exclusion. A flowchart will be created showing the article selection process. All relevant data from the studies will be summarized in tables.

Appraisal of methodological quality of selected articles

The Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN checklist) will be used for the appraisal of the methodological quality of the articles. This checklist has four domains: reliability, validity, responsiveness and interpretability. Only those articles considered adequate based on this checklist will be included in the systematic review.[14-17]

Evaluation of clinical usefulness of assessment tools

For an assessment tool that measures a health phenomenon based on the self-report of adult patients to be adopted by health professionals, it needs to be analyzed with regard to its interpretability and viability, which are factors that could influence the decision-making of health professionals in clinical practice.[18] Therefore, the systematic review article will include an evaluation of these assessment tools based on the criteria proposed by Tyson and Brown (2014)[19] listed below:

- Total time required for the administration, analysis and interpretation of the data obtained using the assessment tool: < 10 min (3 points); 10-30 min (2 points); 30-60 min (1 point) and > 1 h (0 points).
- Cost involved in the acquisition and use of the assessment tool: < £ 100 (3 points); £ 100-500 (2 points); £ 500-1000 (1 point); £ 1000 (zero).
- Need for training and calibration for use of the assessment tool: none (2 points); yes, but simple and clinically viable (1 point); yes and not clinically viable/unknown (zero).
- Portability of tool (can it be taken to the patient?): yes, easily (fits in pocket) (2 points); yes (fits in a carrying case) (1 point); no or very difficult (zero).
- Accessibility of tool (are detailed instructions for use available?): yes (complete operating procedure/instruction manual can be obtained in article or site) (2 points); no, but the operation can be performed simply based on the description in the article (1 point); no available instructions for use (zero).

Data synthesis

The systematic review report will be drafted in accordance with the PRISMA recommendations[12] and the certainty of the evidence will be analyzed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE).[20] For the proposed review, assessment tools with the following qualities will be considered adequate:

- Those with a methodology considered "good" or "excellent" based on the COSMIN checklist;[14-17]
- Those with a score of 10 or more points on the clinical usefulness evaluation scale proposed by Tyson and Brown (2014).[19]

Ethics and dissemination

The general aim of the review is to provide a discussion on the strong points and limitations of different assessment tools used for measuring the risk of behavior suggestive of opioid abuse through an analysis of the general characteristics, psychometric properties and clinical usefulness of the measures as well as the methodological quality of the studies included in the review. This is expected to assist health professionals in the determination of what measures are more appropriate based on the characteristics of their patients as well as assist in decision-making processes and the determination of the most adequate care management for patients with a diagnosis of chronic non-oncological pain. The use of valid and reliable instruments is fundamental to the reliability of the evidence produced on a health phenomenon.[21]

In conclusion, the proposed systematic review will provide relevant clinical evidence on assessment tools designed to measure the risk of behavior suggestive of opioid abuse that health professionals can use in the clinical management of patients with chronic non-oncological pain.

The report of the methods of the systematic review article will follow the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA) and will be submitted to a peer-reviewed journal. This protocol and the proposed systematic review are activities of the main researcher related to the obtainment of her doctoral degree and her doctoral theses fulfilled all these ethical issues.

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Authors' contributions

All authors made substantial contributions to the conception and design of the study and participated in the drafting of the submission request. SRG[1], TPSS[2] and SCV[6] conceived of the study, developed the criteria, performed the literature search and selection of the studies and wrote the present systematic review protocol study. MHNM[3], CESLR[4] and MDCL[5] served as advisers throughout all phases of this systematic review protocol study and performed a critical revision of the manuscript. All authors read and approved the final version.

Funding statement

'This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors'.

Competing interests statement.

The authors declare that they have no conflicts of interest.

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

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review (YES)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number CRD42018081577
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author(OK)
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review(OK)
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments (Not applicable)
Support:		
Sources	5a	Indicate sources of financial or other support for the review(Not applicable)
Sponsor	5b	Provide name for the review funder and/or sponsor(Not applicable)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol(Not applicable)
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known (YES)
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) (YES)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review (YES)
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage (YES)
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated(YES)
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review(YES)

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) (YES)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators(YES)
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications(YES)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale(YES)
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis(YES)
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised(YES)
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ) (YES, according to COSMIN)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) (YES)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned(Not applicable)
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) (YES, according to COSMIN)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) (YES, according to COSMIN)

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

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

BMJ Open

Risk of behavior suggestive of opioid abuse: Protocol for a systematic review of validated assessment tools

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-021948.R2
Article Type:	Protocol
Date Submitted by the Author:	03-Jul-2018
Complete List of Authors:	Galindo, Sheila; Universidade Federal de Pernambuco, Neuropsychiatry Silva, Tatiana ; Universidade Federal de Pernambuco, neuropsiquiatria Marinho, Manoel; Universidade de Pernambuco Ribeiro, Carlos Eduardo; Consultório Particular Lima, Murilo; Universidade Federal de Pernambuco Vasconcelos, Selene; Federal University of Pernambuco, Neuropsychiatry and behavior sciences
Primary Subject Heading:	Addiction
Secondary Subject Heading:	Mental health, Research methods
Keywords:	opioids, drug users, systematic reviews, validation studies, MENTAL HEALTH

Risk of behavior suggestive of opioid abuse: Protocol for a systematic review of validated assessment tools

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1837 words

Abstract

Introduction: Opioid use patterns by individuals with non-cancer pain are influenced by the behavioral dynamics of the patient in managing and properly following the prescription. The use of assessment tools for measuring the risk of behavior suggestive of the opioid abuse is important for health professionals who provide care to individuals with non-cancer pain. The aim of the proposed review is to analyze on the psychometric properties of tools for measuring the risk of behavior suggestive of opioid abuse in adult with non-cancer pain. **Methods and analysis:** The review process will be based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols. The Consensus-Based Standards for the Selection of Health Measurement Instruments will be used for the analysis of the assessment tools. Two independent reviewers will perform the literature search and analysis procedures. Searches will be performed in the PubMed, Web of Science, Cochrane, SCOPUS and CINAHL databases and the "snowball" strategy will be employed. The inclusion criteria will be 1) validation studies, 2) assessment tools designed exclusively for measuring the risk of behavior suggestive of opioid abuse and 3) assessment tools designed for the evaluation of adults with chronic non-cancer pain. The titles and abstracts of the studies retrieved from the databases will be analyzed for the pre-selection of articles, which will be submitted to a full-text analysis for the definition of the final sample. Divergences of opinion between the two reviewers will be resolved by consulting a third reviewer. **Ethics and dissemination:** The review will offer an overview of assessment tools available for measuring the risk of behavior suggestive of opioid abuse, which is relevant to reducing the risk of deaths due to abusive consumption and for the clinical management of adult with chronic non-cancer pain.

Systematic review registration: CRD42018081577

Keywords: Opioids; Drug users; Systematic review; Validation studies; Mental health.

Strengths and limitations of this study:

- Broadens understanding regarding the risk of behavior suggestive of opioid abuse among adults with chronic non-cancer pain.
- Provides an overview of assessment tools for evaluating the opioid consumption pattern of adults with chronic non-cancer pain.

- Provides evidence of the best assessment tools for measuring this health phenomenon to assist in decision-making processes for health professionals who provide care to such patients.
- Assists in the development of therapeutic guidelines for the management of opioid consumption by adults with chronic non-cancer pain.
- Limitations may be related to the subjectivity of the researchers with regard to delineating evidence focused on specific gaps in knowledge in the field of interest.

Introduction

The consumption of opioids and the risk of improper use in populations with chronic non-cancer pain have generated considerable discussion in recent years. The improper use of opioids can result in serious consequences to one's health, contributing to the development of dependency on these drugs.[1] It is estimated that up to 60% of patients with chronic pain who take opioids are susceptible to abusive use, commonly in the form of excessive consumption.[2] Another study reports that 61.8% of patients had chronic pain prior to their first diagnosis of an opioid use disorder.[3]

The risk of behavior suggestive of opioid abuse constitutes a predictor of the development of a substance use disorder, which is a real possibility for individuals with chronic non-cancer pain and a considerable concern for health professionals.[4] Opioid use patterns by individuals with non-cancer pain are influenced by the behavioral dynamics of the patient in managing and properly following the prescription as well as the skills of health professionals regarding the identification of risk and protection factors of opioid abuse by these individuals.[5]

In this context, stands out the sickle cell anemia is a chronic condition with diverse clinical manifestations that can lead to recurring hospitalization and death. Adequate health care with a specialized multidisciplinary team and social support can contribute to a reduction in the number of hospitalizations and an improvement in the quality of life of affected individuals.[6] Patients with sickle cell anemia experience chronic pain that is treated with opioids, making them a vulnerable population.[7]

Therefore, the use of a valid, reliable assessment tool for measuring the risk of behavior suggestive of opioid abuse is an important monitoring strategy that can help guide health professionals in the management of these patients. Moreover, evidence produced

from such investigations can be used to help professionals at healthcare services also monitor other type of patients.

Although two systematic reviews have been found on the evaluation of instruments to measure the risk of opioid abuse,[8,9] the current proposal for a systematic review differs in important methodological aspects, namely: a) search more comprehensive, in other databases and use of reverse search strategy, with no time limit and no language; b) only methodological studies of primary data were included; c) proposes a rigorous evaluation of the psychometric properties of COSMIN, besides including aspects related to the clinical application of these instruments.

In this context, the proposed systematic review has considerable clinical implications with regard to assisting health professionals in the choice of assessment tools that are appropriate to the profile of their patients, since an understanding the risk of behavior suggestive of opioid abuse can assist in decision making and the adequate management of adult patients with a diagnosis of chronic non-cancer pain. Thus, the following research question was posed to guide the analysis of the evidence: Do the instruments for measuring the risk of behavior suggestive of opioid abuse of adults have adequate psychometric properties? The proposed study will involve a systematic review of the literature on the psychometric properties of tools for measuring the risk of behavior suggestive of opioid abuse in adult with non-cancer pain.

Methods/Design

Design and registration of the study

The present review protocol is registered with the International Prospective Registry of Systematic Reviews (PROSPERO). The report of the methods for the review protocol was drafted in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P).[10] The report of the methods for the systematic review article will follow the PRISMA guidelines.[11]

Patient and Public Involvement

It is a systematic review protocol article, we do not work with patients or their companions.

Inclusion of articles

The following will be the inclusion criteria for the selection of articles: a) validation studies; b) assessment tools designed for the quantitative evaluation of the risk of behavior suggestive of opioid abuse; c) assessment tools designed for the evaluation of adult with chronic non-cancer pain; d) assessment tools designed for adult groups; e)

assessment tools designed for the quantitative evaluation of the risk of behavior suggestive of opioid abuse based on self-reported information from the patient; f) articles describing the psychometric properties of the tools. No restrictions will be imposed with regard to language or year of publication. Systematic reviews will be excluded.

Search strategy

The search strategy will be based on the Population Intervention Comparator Outcome Setting (PICOS)[12] method to form the research question, determine the title, and choose the keywords. The PubMed, Web of Science, Cochrane, SCOPUS and CINAHL databases will be searched and the "snowball" strategy will also be employed.

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The Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN checklist) will be used for the appraisal of the psychometric properties of the selected instruments. This checklist has four domains: reliability, validity, responsiveness and interpretability.[13-16]

Evaluation of clinical usefulness of assessment tools

For an assessment tool that measures a health phenomenon based on the self-report of adult patients to be adopted by health professionals, it needs to be analyzed with regard to its interpretability and viability, which are factors that could influence the decision-making of health professionals in clinical practice.[17] Therefore, the systematic review article will include an evaluation of these assessment tools based on the criteria proposed by Tyson and Brown (2014)[18] listed below:

- Total time required for the administration, analysis and interpretation of the data obtained using the assessment tool: < 10 min (3 points); 10-30 min (2 points); 30-60 min (1 point) and > 1 h (0 points).
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Ethics and dissemination

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In conclusion, the proposed systematic review will provide relevant clinical evidence on assessment tools designed to measure the risk of behavior suggestive of opioid abuse that health professionals can use in the clinical management of patients with chronic noncancer pain.

The report of the methods of the systematic review article will follow the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA) and will be submitted to a peer-reviewed journal. This protocol and the proposed systematic review are activities of the main researcher related to the obtainment of her doctoral degree and her doctoral theses fulfilled all these ethical issues.

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Authors' contributions

All authors made substantial contributions to the conception and design of the study and participated in the drafting of the submission request. SRG[1], TPSS[2] and SCV[6] conceived of the study, developed the criteria, performed the literature search and selection of the studies and wrote the present systematic review protocol study. MHNM[3], CESLR[4] and MDCL[5] served as advisers throughout all phases of this systematic review protocol study and performed a critical revision of the manuscript. All authors read and approved the final version.

Funding statement

'This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors'.

Competing interests statement.

The authors declare that they have no conflicts of interest.

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

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review (YES)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number CRD42018081577
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author(OK)
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review(OK)
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments (Not applicable)
Support:		
Sources	5a	Indicate sources of financial or other support for the review(Not applicable)
Sponsor	5b	Provide name for the review funder and/or sponsor(Not applicable)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol(Not applicable)
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known (YES)
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) (YES)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review (YES)
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage (YES)
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated(YES)
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review(YES)

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) (YES)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators(YES)
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications(YES)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale(YES)
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis(YES)
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised(YES)
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ) (YES, according to COSMIN)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) (YES)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned(Not applicable)
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) (YES, according to COSMIN)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) (YES, according to COSMIN)

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

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