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Self-efficacy of alcohol and other drug users: systematic review protocol

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ABSTRACT

Introduction: The abuse of alcohol and other drugs is a worldwide problem and the treatment of users constitutes a challenge for the different care settings. Self-efficacy has been addressed as an important component of the treatment of this clientele and its

measurement has been considered an important scientific evidence. A wide range of instruments has been produced in recent years, which justifies the need to assess their psychometric properties and clinical applicability regardless of adherence to treatment. In this sense, the objectives of this systematic review were to examine the psychometric properties and applicability of the instruments developed to measure the self-efficacy of users of alcohol and other drugs to resist the desire to use these substances in high-risk situations. **Methods and analysis:** The elaboration of the article will follow the PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analyzes) and strategy PICOS (Population Intervention Comparator Outcome Setting). The electronic search will be conducted on the bases: Medline, Pubmed, SCOPUS and CINAHL, followed by the use of Snowball strategy. The inclusion criteria of the studies will be: 1) development and/or validation of instruments; 2) quantitative instrument; 3) created for adults; 4) based on self-report of the examinee; and 5) with descriptions of the psychometric properties. Two independent reviewers will examine the studies, evaluating all titles, abstracts and full texts according to the inclusion criteria and, in case of divergences, a third reviewer will evaluate the articles. A descriptive analysis will be carried out containing data on participants, characteristics, psychometric properties and clinical usefulness of the instruments. **Discussion:** This review will provide an overview of the available instruments, broadening the discussions on self-efficacy of users of alcohol and other drugs, contributing to the decision-making of clinicians and researchers working in this follow-up.
Registration number at PROSPERO: CRD42017068555

Background

The abuse and dependence of alcohol and other drugs are public health problems in the world[1], characterized by search behaviors for the consumption of these substances and the loss of pleasure for usual activities, changing the user's social, work and family relationships[2]. This consumption represents a source of immediate gratification, perceived as a way of solving their problems in difficult and/or conflicting situations[3]. Among the various harmful effects, there are cognitive and behavioral disorders[4-7], also affecting a person's self-efficacy[8].

Thus, self-efficacy has been approached as an important component in the treatment of drug users and their families, being related to the results and prognoses in the treatment of drug users, as well as to the recovery rates of problems arising from the consumption of these substances[9-10].

The systematic review will consider the concept of self-efficacy in Bandura (1977)[11], which focuses on personal confidence about one's own ability to perform a specific action necessary to obtain a particular result, favoring the planning and execution of a specific behavior. Thus, the person will identify that the severity of a particular situation

and its deleterious effects relate to his/her perception and understanding on this situation and his/her capacity to face it[11-12].

Therefore, the choice of validated instruments to measure a given phenomenon to guide health care interventions to users of alcohol and/or other drugs can contribute to the planning and implementation of strategies that are more adequate and to mitigate the damages resulting from the use of these substances[13-14]

The present systematic review may subsidize health professionals in the choice of instruments that are more appropriate to their clinical practice. Thus, the following research question arose: Are the instruments used to measure the self-efficacy of users of alcohol and/or other drugs adequate for psychometric properties?

Therefore, the purpose of this systematic review protocol article is to present a systematic review proposal to identify whether the instruments used to assess the self-efficacy of users of alcohol and/or other drugs have adequate psychometric properties.

Method/Design

Design and registration of the study

This systematic review was registered at the International Prospective Registry of Systematic Reviews (PROSPERO) on CRD 42017068555 (https://www.crd.york.ac.uk/PROSPERO/register_new_review.asp). The protocol was written and reported by using the PRISMA-P declaration[15].

Inclusion of the articles

This review will include all the methodological articles destined to the validation of instruments of quantitative approach developed for adult populations (≥18 years old), based on the self-report of the examinee and that describe the psychometric properties, of clinical utility to measure the self-efficacy of users of alcohol and other drugs to resist the urge to use these substances in high-risk situations. There will be no restriction on language and date of publication. Systematic review studies will be excluded.

Search strategy

The search strategy will be conducted according to the PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analyzes) and strategy PICOS (Population Intervention Comparator Outcome Setting). The electronic search will be conducted on the bases: Medline, Pubmed, SCOPUS and CINAHL, followed by the use of the Snowball strategy[16].

Two independent reviewers will examine the studies, who will evaluate all titles, abstracts and full texts according to the inclusion criteria. In case of divergences, a third reviewer will evaluate the articles. A descriptive analysis will be carried out containing data on participants, characteristics, psychometric properties and clinical usefulness of the instruments.

Tracking, data extraction, and content comparison analysis

All database search will be archived in order to record the initial search strategy and subsequent modifications. Duplicate articles in the databases will be counted only once. Authors will be contacted, when necessary, for additional information.

Two reviews will work independently on the development of the search strategy and the selection of studies. The studies will initially be selected by the analysis of titles and abstracts. Those considered eligible will be assessed by the complete reading, using the inclusion criteria, constituting the final sample. Disagreements will be resolved through discussion and consensus. If necessary, a third reviewer will be consulted. A study selection file will be maintained to record the references to the excluded studies and the reason for deleting them. Following the PRISMA-P guidelines[15], a diagram will be created to report the flow through the study. Relevant data from all included studies will be summarized in tables.

An overview of all self-reporting measures will be presented to measure the self-efficacy of users of alcohol and other drug to resist the desire to use these substances in high-risk situations, highlighting the areas that will be compared later.

Evaluation of the methodological quality of the included studies

The Census-Based Standards for the selection of the COSMIN checklist will be used to assess the methodological quality of the included studies. The following four domains are distinguished: reliability, validity, responsiveness and interpretability. Likewise, the quality criteria will be followed for the investigation of properties of measuring instruments of health phenomena, and only those studies that present a positive classification will be included[17-20].

Evaluation of the clinical usefulness of the instruments

The data on interpretability and clinical utility (viability) will comply with the original article. In addition, the clinical utility will be evaluated to quantify the practical aspects of the identified tool. Thus, previously recommended criteria will be applied, based on the following factors that could influence the decisions of physicians to use a measurement tool in their clinical practice[21].

- Time of administration, analysis and interpretation of measurements: <10 min (3 points); 10-30 min (2 points); 30-60 min (1 point) and> 1 h (0 point).
- Cost: 3 = <£ 100; 2 = £ 100-500; 1 = £ 500-1000; 0> 1000.

- Does the measuring tool need specialized equipment and training to use? 2 = no; 1 = yes, but simple and clinically feasible; 0 = yes and not clinically viable/unknown.
- Is the measuring tool portable? Can it be taken to the patient? 2 = yes, easily (can fit in the pocket); 1 = yes (can fit in a suitcase or cart); 0 = no or very difficult.
- Is the measuring tool accessible? Is there a detailed instruction for application? 2 = yes (the complete operating procedure/instruction manual can be obtained from the article or from the website); 1 = no, but the operation can simply be elaborated from a description in the article; 0 = no operating instructions available.
- The score on each criterion, as well as the total score (maximum of 12 points) will also be reported in a table. Tools with a total score <10 points will not be considered viable for clinical use and this criterion will be applied in the present study.

Synthesis of data

A systematic narrative synthesis will be provided in both text as table formats to summarize and discuss the general characteristics, psychometric properties, measurement or clinical utility of the included studies.

Discussion

The study will examine the psychometric properties of clinical utility for measuring the self-efficacy of users of alcohol and other drug to resist the desire to use these substances in high-risk situations.

The objective is to provide a discussion on the strengths and limitations of the different tools used to measure self-efficacy, analyzing the general characteristics, psychometric properties, methodological quality of the included studies, as well as the clinical utility of the identified instruments.

This review intends to be clear and specific regarding the follow-up and methodological rigor, employing a systematic and replicable approach in relation to the research, sorting, evaluation and extraction of data from the eligible electronic database.

The choice of validated instruments to measure certain phenomena such as self-efficacy corroborates the understanding of valid and reliable results, guiding professionals in their interventions in health care to drug users. It also contributes to the adoption of strategies that are more adequate to promote self-efficacy, mitigating the harm caused by the use of these substances.

Competing Interests

The authors declare that they have no conflicts of interest.

Authors' Contributions

All authors contributed substantially to the design and development of the study and participated in the elaboration of the request for submission. The authors SCV[1], TPSS[4] conceived the study, developed the criteria and carried out the search and selection of the studies and wrote the present article of protocol of systematic review. ISF[2], EBS[3], SLS[5] and MDCL[6] guided all phases of this systematic review protocol article as well as in the review of this manuscript. All authors have read and approved the final version.

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

Section and topic	Item No	Checklist item
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 CRD42017068555
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.

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Word count: 1936

ABSTRACT

Introduction: Introduction: The abuse of alcohol and other drugs is a problem throughout the world and the treatment of users is a challenge for healthcare professionals. Self-efficacy is considered an important component of the treatment process of such individuals and the measurement of this aspect constitutes important scientific evidence. A broad range of self-efficacy assessment tools have been produced and there is a need to evaluate the psychometric properties and clinical applicability of such tools. This document proposes the execution of a systematic review to examine the psychometric properties and applicability of assessment tools developed to measure self-efficacy in users of alcohol and other drugs with regard to resisting the urge to use such substances in high-risk situations. **Methods and Analysis:** Will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA statement). Will be used Medline, Pubmed, SCOPUS and CINAHL databases, followed by the use of the "snowball" strategy. The inclusion criteria will be: the development and/or validation of self-efficacy assessment tools; quantitative assessment tools; developed for adults; self-reported data from participants; studies involving a description of psychometric properties. The articles will be evaluated by two independent reviewers, who will analyze the titles, abstracts and full texts based on the inclusion criteria. Divergences of opinion will be resolved by a third reviewer. Moreover, the COSMIN checklist will be used for the appraisal of the methodological quality of the articles. Descriptive analysis will be performed of the data on the participants as well as the characteristics, psychometric properties and clinical usefulness of the assessment tools. **Discussion:** The proposed review will provide an overview of available assessment tools and broaden the discussion on self-efficacy in users of alcohol and other drugs, contributing to the decision-making process of clinicians and researchers who work with this population.

Strengths and limitations of this study:

- The publication provides details of the methods and psychometric properties of the instruments available for measuring the self-efficacy of alcohol and other drug users with regard to resistance to the desire to use these substances in high-risk situations;
- Use of methods to evaluate the strength of the evidences found;
- Presentation of the strengths and limitations of the different assessment tools used to measure self-efficacy;
- Study developed by a single research center;
- Reviewers not blind to the circumstances of the procedure, which may impair their application of scales.

Registration number at PROSPERO: CRD42017068555

Background

The abuse of alcohol and other drugs is a public health problem throughout the world[1] and is characterized by drug-seeking behavior and the loss of pleasure in habitual activities, with negative impacts on social, work and family relations.[2] Substance abuse represents a source of immediate gratification and is seen as a way to cope with problems in difficult or conflicting situations.[3] The harmful effects include cognitive and behavioral alterations[4-6] that substantially interfere with personal beliefs related to coping with dependence.[7] Such beliefs compose the concept of self-efficacy described by Bandura (1977),[8] which is centered on the personal confidence one has regarding one's ability to execute a specific action necessary to achieving a particular goal, thereby favoring the planning and execution of a specific behavior.[8,9]

Self-efficacy is considered a strong predictor of both abstinence and a reduction in the use of drugs, specifically, self-efficacy to resist the urge to consume drugs in high-risk situations.[10] This concept also seems to be important to the treatment of drug users and their families and is related to outcomes and prognoses as well as the recovery from problems stemming from the consumption of such substances.[11,12] Thus, there is a need to measure this construct at services that assist drug users and their families in an attempt to guide interventions and health care based on the understanding of the patient's degree of self-efficacy. This measure can also contribute to the planning and implementation of more adequate strategies aimed at minimizing the harm caused by substance abuse.[13,14]

The systematic review proposed herein can assist healthcare professionals in the choice of assessment tools that are adequate to their practice as a way of monitoring degrees of self-efficacy during the management of drug users. Thus, the following research question was formulated: What are the most adequate assessment tools for measuring self-efficacy with regard to resisting the urge to use drugs in high-risk situations?

Thus, the aim of the present study is to propose a protocol for a systematic review to identify the assessment tools used to measure the self-efficacy of users of alcohol and/or other drugs that have adequate psychometric properties.

Method/Design

Design and registration of the study

The systematic review is registered with the International Prospective Registry of Systematic Reviews (PROSPERO) on CRD 42017068555 (https://www.crd.york.ac.uk/PROSPERO/register_new_review.asp). The protocol was written in accordance with the PRISMA-P declaration.[15]

Inclusion of articles

All methodological articles developed for the validation of assessment tools with a quantitative approach for adult drug users (≥18 years of age) based on self-reported data and that describe psychometric properties, the clinical usefulness of which consists of the measurement of self-efficacy in users of alcohol and/or other drugs with regard to resisting the urge to use such substances in high-risk situations will be included. No restrictions will be imposed with regard to language or publication date. Review studies will be excluded.

Search strategy

The search strategy will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA statement) and the PICOS (Population - Intervention - Comparator - Outcome - Setting) framework. Electronic searches will be conducted in the Medline, Pubmed, SCOPUS and CINAHL databases, followed by the use of the "snowball" strategy.[16]

To evaluate and reduce the risk of bias of the individual studies, the manuscripts will be examined by two independent reviewers who will analyze the titles, abstracts and full texts based on the inclusion criteria. Divergences of opinion will be resolved by a third reviewer. Descriptive analysis will be performed of the data on the participants as well as the characteristics, psychometric properties and clinical usefulness of the assessment tools.

Tracking, data extraction, and content comparison analysis

The data from the selected studies will be organized in a data extraction chart designed specifically for the proposed review and will include the following:

- General characteristics of the study: Authors, year of publication, country of origin, sample size and main outcomes;

- Descriptive information on the assessment tools: name and acronym of the instrument, domains/dimensions, number of items, form of application, form of scoring responses and cutoff points.

The entire search process of the databases will be filed to register the initial search strategy and subsequent modifications. Duplicated articles will only be counted once. Authors of the articles selected for this review will be contacted, if necessary, for the acquisition of further information.

Two reviewers will work independently on the development of the search strategy and selection of articles. Articles will be preselected based on an analysis of the title and abstract. Those considered potentially eligible will be submitted to full-text analysis and those that meet the pre-established inclusion criteria will compose the final sample.

Divergences of opinion will be resolved by discussion until reaching a consensus. A third reviewer will be consulted if needed. A study selection file will be kept to record the references for the excluded studies and the reasons for exclusion. Following the PRISMA guidelines,[15] a flow diagram will be created illustrating the study selection process. The relevant data from all studies will be summarized in tables and/or charts.

An overview will be presented of all assessment tools for measuring the self-efficacy of users of alcohol and other drugs with regard to resisting the urge to use such substances in high-risk situations. The domains will be described and compared.

Appraisal of methodological quality of selected articles

The Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN checklist)[9] 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.[17-20]

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)[21] 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.[22] 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 of assessment tool: < £ 100 (3 points); £ 100-500 (2 points); £ 500-1000 (1 point); £ 1000 (zero).

- Need for specialized equipment and training for use: 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 data will be synthesized in accordance with the PRISMA recommendations[23] and the certainty of the evidence will be analyzed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE).[24] The assessment tools will be described in tables and/or charts highlighting the general characteristics, application contexts, applicability and information on the evaluation methods of the measures. At the end of the analyses, assessment tools with the following qualities will be considered adequate for measuring self-efficacy with regard to resisting the urge to consume drugs in high-risk situations:

- Those with a methodology considered "good" or "excellent" based on the COSMIN checklist;[17-20]

- Those with a score of 10 or more points on the clinical usefulness evaluation scale proposed by Tyson and Brown (2014).[21]

Discussion

The proposed study will examine the psychometric properties and clinical usefulness of assessment tools for measuring the self-efficacy of users of alcohol and other drugs with regard to resisting the urge to use such substances in high-risk situations.

The aim is to provide a discussion on the strong points and limitations of the different assessment tools used to measure self-efficacy, analyzing the general characteristics, psychometric properties, methodological quality of the studies and clinical usefulness of the assessment tools. The review will be clear and specific with regard to methodological rigor, employing a systematic, replicable approach in terms of the bibliographic survey, screening, evaluation and data extracted from studies retrieved from the electronic databases.

The choice of validated instruments for measuring given phenomena, such as self-efficacy, contributes to the understanding of valid, reliable results that can guide health professionals with regard to interventions for drug users and assists in the adoption of adequate strategies for the promotion of self-efficacy and the minimization of the harm caused by substance abuse.

Competing Interests

The authors declare that they have no conflicts of interest.

Authors' Contributions

All authors made substantial contributions to the concept and study design and participated in the drafting of the submission request. Authors SCV[1] and TPSS[5] conceived the study, developed the inclusion criteria, performed the search and selection of the studies and wrote the present systematic review protocol article. ISF[2], EBS[3], SLS[4] and MDCL[6] guided all phases of this systematic review protocol article and performed a critical review of the manuscript. All authors read and approved the final version.

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

Section and topic	Item No	Checklist item
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 CRD42017068555
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.

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Self-efficacy assessment tools for users of alcohol and other drugs: Protocol for a systematic review

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Assessment tools for the measurement of the self-efficacy of drug users: Protocol for a systematic review

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ABSTRACT

Introduction: The abuse of alcohol and other drugs is a worldwide problem, the treatment of which poses a challenge to healthcare workers. Self-efficacy is considered an important component of the treatment process. **Objective**: Present a proposal for a systematic review to analyze the psychometric properties of assessment tools developed to measure the self-efficacy of drug users with regard to resisting the urge to take drugs in high-risk situations. **Methods and Analysis:** The guiding question was based on PICOS (Population Intervention Comparator Outcome Setting) and the method will be in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols. Searches will be performed in the PsycINFO, Cochrane, Pubmed, Web of Science, SCOPUS and CINAHL databases, followed by the use of the "snowball" strategy. The inclusion criteria for the articles will be 1) assessment tool validation studies; 2) assessment tools developed to measure self-efficacy; 3) quantitative measures; 4) measures designed for use on adults; 5) data from self-reports of the participants; 6) studies involving a description of psychometric properties of the measures; and 7) studies that explain how the level of self-efficacy is scored. The search, selection and analysis will be performed by two independent reviewers. In cases of a divergence of opinion, a third reviewer will be consulted. The COSMIN checklist will be used for the appraisal of the methodological quality of the assessment tools and the certainty of the evidence in the articles (risk of bias) will be analyzed using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. **Discussion:** This protocol will offer a clear explanation of the method to be employed in the systematic review, which will give an overview of the available assessment tools and will recommend a gold standard for measuring the phenomenon in question.

Strengths and limitations of this study:

- The article will recommend a gold standard among existing assessment tools for the measurement of self-efficacy related to resisting the urge to take drugs in high-risk situations.

- The study will involve the use of quantitative methods for appraising the strength of the evidence encountered.

- This will be the first review on assessment tools for measuring self-efficacy related to resisting the urge to take drugs in high-risk situations.

- The study will be developed at a single research center.

- Grey literature will not be included.

Background

Dependence on alcohol and other drugs is characterized by behavior aimed at maintaining use as well as the loss of pleasure in habitual activities. It is a maladaptive way to cope with stressful situations and is considered a serious public health problem throughout the world.[1-3] Cognitive and behavioral alterations are among the harmful effects of substance abuse,[4-6] affecting personal, familial and social relations as well as compromising an individual's self-efficacy with regard to resisting the urge to take drugs in high-risk situations.[7]

Bandura (1977)[8] conceives self-efficacy as a belief or personal confidence in one's ability to perform a specific action for one's own benefit. Thus, self-efficacy is a mental process that guides behavior and exerts an influence on the establishment of goals, one's motivation level, perseverance in the presence of setbacks and resilience in the face of adversity.[8-11]

Different subtypes of self-efficacy are described in the literature[12] and several assessment tools have been developed to measure this construct among individuals who are dependent on alcohol[13-16] and/or other drugs.[17-25] Self-efficacy with regard to resisting the urge to take drugs in high-risk situations is considered a strong predictor of abstinence or a reduction in drug use and is related to the results of treatment.[26-28] Considering the importance of this subtype, the number of assessment tools developed to measure this phenomenon and the lack of recommendations regarding the most robust assessment tools, there is a need to evaluate the psychometric properties of available measures and recommend an assessment tool that can serve as the gold standard.

The proposed systematic review will be able to assist healthcare professionals in the choice of the most adequate assessment tools for their clinical practice with the aim of monitoring levels of self-efficacy to resist the urge to take drugs in high-risk situations.[29,30] The guiding question of the study will be "Do assessment tools designed to measure self-efficacy with regard to resisting the urge to take drugs in high-risk situations have adequate psychometric properties?"

Thus, the aim of this protocol is to propose a systematic review to analyze the psychometric properties of assessment tools developed to measure the self-efficacy of drug users to resist the urge to consume these substances in high-risk situations.

Method/Design

Design and registration of the study

The systematic review is registered with the International Prospective Registry of Systematic Reviews (PROSPERO) in CRD 42017068555 (https://www.crd.york.ac.uk/PROSPERO/register_new_review.asp). The protocol was written in accordance with the PRISMA-P declaration.[31]

Inclusion of articles

All methodological articles developed for the validation of assessment tools with a quantitative approach for adult drug users (≥ 18 years of age) based on self-reported data and that describe psychometric properties, the clinical usefulness of which consists of the measurement of self-efficacy in users of alcohol and/or other drugs with regard to resisting the urge to use such substances in high-risk situations will be included. No restrictions will be imposed with regard to language or publication date. Review studies will be excluded.

Search strategy

The search strategy will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA statement) and the PICOS (Population - Intervention - Comparator - Outcome - Setting) framework. Electronic searches will be conducted in the Pubmed, PsycINFO, SCOPUS and CINAHL databases. The following MeSH terms will be employed in the searches: "self-efficacy", "coping", "validation studies", "drug users", "scale", "instrument", "questionnaire" and "outcome assessment". Adjustments to the keywords may be made during the execution of the systematic review. After the retrieval of articles from the databases, the snowball strategy will be employed.[32] Grey literature will not be considered.

To reduce the risk of bias in this step, two independent reviewers will perform the searches and preselect articles based on an analysis of the titles and abstracts for potentially eligible articles and assessment tools. Preselected articles will be submitted to full-text analysis for the determination of the studies that will make up the final sample. The level of agreement between the two reviewers will be calculated. In cases of divergences of opinion, the reviewers will discuss the article in question until reaching a consensus. A third reviewer will be consulted, if necessary.

The entire process will be stored in a databank to ensure access to the records of the initial search strategy, the snowball strategy as well as the excluded articles and the reasons for exclusion. Duplicate articles will only be counted once.

Tracking, data extraction, and content comparison analysis

The data extracted from the articles selected will be organized on a chart specifically designed for the systematic review, which will contain the following:

- General characteristics of the study: Authors, date of publication, country of origin, objective, sample size and main outcomes.
- Description of assessment tools: Name and acronym; objective; domains, dimensions or subscales; description of high-risk situations; number of items; method of collecting self-reported data; description of scoring and classification of levels of self-efficacy; administration method; cutoff points; and psychometric properties validated by the authors.

When necessary, the author of the articles and assessment tools will be contacted to obtain further information.

Following the guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P),[31] a flowchart will be created illustrating the selection and analysis methods. Relevant data from all articles will be summarized in tables and/or charts. Thus, the systematic review will offer a general overview of all available instruments for measuring the self-efficacy of drug users for resisting the urge to take these substances in high-risk situations.

Appraisal of methodological quality of selected articles and measures

To evaluate the risk of bias, the articles included in the final sample will be analyzed with regard to methodological quality and the strength or certainty of the evidence offered using the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation).[33]

The appraisal of the methodological quality of the assessment tools will follow the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) criteria, using only the A-H boxes on the checklist to rate the quality of each property.[34] The checklists for interpretability and generalization will not be used because these lists are only related to data extraction.

The four-point COSMIN scoring system will be used to classify the assessment tools as excellent (adequate methodological quality), good (missing information, but quality could be considered fair) or poor (inadequate quality). Assessment tools with varied results (some points considered excellent and others considered poor) will be classified based on the lower scores.[35] Two reviewers will analyze the risk of bias and classify the assessment tools in an independent manner.[33-37]

Evaluation of clinical usefulness of assessment tools

The analysis of clinical usefulness will follow the criteria proposed by Tyson and Brown (2014)[38] related to interpretability and viability, with the aim of quantifying the practical aspects of the measures based on factors that can influence the decision-making process of health professionals in clinical practice.[39] These criteria are listed below:

- Total time required for the administration, analysis and interpretation of the data obtained using the measure: < 10 min (3 points); 10-30 min (2 points); 30-60 min (1 point) and > 1 h (0 points).
- Cost of assessment tool: < £ 100 (3 points); £ 100-500 (2 points); £ 500-1000 (1 point); £ 1000 (zero).
- Need for specialized equipment and training for use: none (2 points); yes, but simple and clinically viable (1 point); yes and not clinically viable/unknown (zero).
- Portability of assessment 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 data will be synthesized in accordance with the PRISMA recommendations.[40] The assessment tools will be described in tables and/or charts highlighting the general

characteristics, application contexts, applicability and information on the evaluation methods of the measures. At the end of the analyses, assessment tools with the following qualities will be considered adequate for measuring self-efficacy with regard to resisting the urge to consume drugs in high-risk situations:

- Those with a methodology considered "good" or "excellent" based on the COSMIN checklist;[33-37]
- Those with a score of 10 or more points on the clinical usefulness evaluation scale proposed by Tyson and Brown (2014).[38]

Discussion

The proposed review will investigate the psychometric properties and clinical usefulness of assessment tools developed to measure the self-efficacy of drug users with regard to resisting the urge to take drugs in high-risk situations. The aim is to recommend a gold standard among the different assessment tools used to measure self-efficacy in this context and offer a discussion on the strong points and limitations of the measures through an analysis of the general characteristics, psychometric properties and clinical usefulness of the measures as well as the methodological quality of the studies.

The review intends to be clear and specific with regard to methodological rigor, employing a replicable systematic approach for the search strategy, screening, evaluation and data extraction of the studies retrieved from the available databases. Validated instruments for measuring given phenomena, such as self-efficacy, offer valid, reliable results that can guide health professionals with regard to interventions for drug users and assist in the adoption of adequate strategies for the promotion of self-efficacy and the minimization of the harm caused by substance abuse.

Competing Interests

The authors declare that they have no conflicts of interest.

Authors' Contributions

All authors made substantial contributions to the concept and study design and participated in the drafting of the submission request. Authors SCV[1] and TPSS[5] conceived the study, developed the inclusion criteria, performed the search and selection of the studies and wrote the present systematic review protocol article. ISF[2], EBS[3], SLS[4] and MDCL[5] guided all phases of this systematic review protocol article and

performed a critical review of the manuscript. All authors read and approved the final version.

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

Section and topic	Item No	Checklist item
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 CRD42017068555
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

Assessment tools for the measurement of the self-efficacy of drug users: Protocol for a systematic review

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Manuscripts

Assessment tools for the measurement of the self-efficacy of drug users: Protocol for a systematic review

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- The article will recommend a gold standard among existing assessment tools for the measurement of self-efficacy related to resisting the urge to take drugs in high-risk situations.
- The study will involve the use of quantitative methods for appraising the strength of the evidence encountered.
- This will be the first review on assessment tools for measuring self-efficacy related to resisting the urge to take drugs in high-risk situations.
- The study will be developed at a single research center.
- Grey literature will not be included.

ABSTRACT

Introduction: The abuse of alcohol and other drugs is a worldwide problem, the treatment of which poses a challenge to healthcare workers. **Objective**: Present a proposal for a systematic review to analyze the psychometric properties of assessment tools developed to measure the self-efficacy of drug users with regard to resisting the urge to take drugs in high-risk situations. **Methods and Analysis:** The guiding question was based on PICOS (Population Intervention Comparator Outcome Setting) and the protocol of this review is in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols. Searches will be performed in the PsycINFO, Cochrane, Pubmed, Web of Science, SCOPUS and CINAHL databases, followed by the use of the "snowball" strategy. The inclusion criteria for the articles will be 1) assessment tool validation studies; 2) assessment tools developed to measure self-efficacy; 3) quantitative measures; 4) measures designed for use on adults; 5) data from self-reports of the participants; 6) studies involving a description of psychometric properties of the measures; and 7) studies that explain how the level of self-efficacy is scored. The search, selection and analysis will be performed by two independent reviewers. In cases of a divergence of opinion, a third reviewer will be consulted. The COSMIN checklist will be used for the appraisal of the methodological quality of the assessment tools and the certainty of the evidence in the articles (risk of bias) will be analyzed using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. **Discussion:** This protocol will offer a clear explanation of the method to be employed in the systematic review, which will give an overview of the available assessment tools and will recommend a gold standard for measuring the phenomenon in question.

Registration number at PROSPERO: CRD42017068555

Keywords: Nursing; Self-efficacy; Drug users; Systematic review; Validation studies; Mental health.

Background

Dependence on alcohol and other drugs is characterized by behavior aimed at maintaining use as well as the loss of pleasure in habitual activities. It is a maladaptive way to cope with stressful situations and is considered a serious public health problem throughout the world.[1-3] Cognitive and behavioral alterations are among the harmful effects of substance abuse,[4-6] affecting personal, familial and social relations as well as compromising an individual's self-efficacy with regard to resisting the urge to take drugs in high-risk situations.[7]

Bandura (1977)[8] conceives self-efficacy as a belief or personal confidence in one's ability to perform a specific action for one's own benefit. Thus, self-efficacy is a mental process that guides behavior and exerts an influence on the establishment of goals, one's motivation level, perseverance in the presence of setbacks and resilience in the face of adversity.[8-11]

Different subtypes of self-efficacy are described in the literature[12] and several assessment tools have been developed to measure this construct among individuals who are dependent on alcohol[13-16] and/or other drugs,[17-21] and in situations of combined use[22-25].

Self-efficacy with regard to resisting the urge to take drugs in high-risk situations is considered a strong predictor of abstinence or a reduction in drug use and is related to the results of treatment.[26-28] Considering the importance of this subtype, the number of assessment tools developed to measure this phenomenon and the lack of recommendations regarding the most robust assessment tools, there is a need to evaluate the psychometric properties of available measures and recommend an assessment tool that can serve as the gold standard.

The proposed systematic review will be able to assist healthcare professionals in the choice of the most adequate assessment tools for their clinical practice with the aim of monitoring levels of self-efficacy to resist the urge to take drugs in high-risk situations.[29] The guiding question of the study will be "Do assessment tools designed to measure self-efficacy with regard to resisting the urge to take drugs in high-risk situations have adequate psychometric properties?"

Thus, the aim of this protocol is to propose a systematic review to analyze the psychometric properties of assessment tools developed to measure the self-efficacy of drug users to resist the urge to consume these substances in high-risk situations.

Method/Design

Design and registration of the study

This proposal for a systematic review is registered with the International Prospective Registry of Systematic Reviews (PROSPERO) in CRD 42017068555 (https://www.crd.york.ac.uk/PROSPERO/register_new_review.asp). The review protocol was written in accordance with the PRISMA-P declaration.[30]

Inclusion of articles

All methodological articles developed for the validation of assessment tools with a quantitative approach for adult drug users (≥ 18 years of age) based on self-reported data and that describe psychometric properties, the clinical usefulness of which consists of the measurement of self-efficacy in users of alcohol and/or other drugs with regard to resisting the urge to use such substances in high-risk situations will be included. No restrictions will be imposed with regard to language or publication date. Review studies will be excluded.

Search strategy

The guiding question was based on the PICOS strategy[31] (Population Intervention Comparator Outcome Setting). Electronic searches will be conducted in the Pubmed, PsycINFO, SCOPUS and CINAHL databases. After the retrieval of articles from the databases, the snowball strategy will be employed.[32] Grey literature will not be considered.

To reduce the risk of bias in this step, two independent reviewers will perform the searches and preselect articles based on an analysis of the titles and abstracts for potentially eligible articles and assessment tools. Preselected articles will be submitted to full-text analysis for the determination of the studies that will make up the final sample. The level of agreement between the two reviewers will be calculated. In cases of divergences of opinion, the reviewers will discuss the article in question until reaching a consensus. A third reviewer will be consulted, if necessary.

The entire process will be stored in a databank to ensure access to the records of the initial search strategy, the snowball strategy as well as the excluded articles and the

reasons for exclusion. Duplicate articles will only be counted once. The following MeSH terms and combinations will be employed in the searches: "self-efficacy", "coping", "validation studies", "drug users", "scale", "instrument", "questionnaire" and "outcome assessment". Adjustments to the keywords may be made during the execution of the systematic review.

Tracking, data extraction, and content comparison analysis

The data extracted from the articles selected will be organized on a chart specifically designed for the systematic review, which will contain the following:

- General characteristics of the study: Authors, date of publication, country of origin, objective, sample size and main outcomes.
- Description of assessment tools: Name and acronym; objective; domains, dimensions or subscales; description of high-risk situations; number of items; method of collecting self-reported data; description of scoring and classification of levels of self-efficacy; administration method; cutoff points; and psychometric properties validated by the authors.

When necessary, the author of the articles and assessment tools will be contacted to obtain further information.

Following the guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA),[33] a flowchart will be created illustrating the selection and analysis methods. Relevant data from all articles will be summarized in tables and/or charts. Thus, the systematic review will offer a general overview of all available instruments for measuring the self-efficacy of drug users for resisting the urge to take these substances in high-risk situations.

Appraisal of methodological quality of selected articles and measures

To evaluate the risk of bias, the articles included in the final sample will be analyzed with regard to methodological quality and the strength or certainty of the evidence offered using the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation).[34]

The appraisal of the methodological quality of the assessment tools will follow the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) criteria, using only the A-H boxes on the checklist to rate the quality of

each property.[35] The checklists for interpretability and generalization will not be used because these lists are only related to data extraction.

The four-point COSMIN scoring system will be used to classify the assessment tools as excellent (adequate methodological quality), good (missing information, but quality could be considered fair) or poor (inadequate quality). Assessment tools with varied results (some points considered excellent and others considered poor) will be classified based on the lower scores.[35-39] Two reviewers will analyze the risk of bias and classify the assessment tools in an independent manner.

Evaluation of clinical usefulness of assessment tools

The analysis of clinical usefulness will follow the criteria proposed by Tyson and Brown (2014)[40] related to interpretability and viability, with the aim of quantifying the practical aspects of the measures based on factors that can influence the decision-making process of health professionals in clinical practice.[41] These criteria are listed below:

- Total time required for the administration, analysis and interpretation of the data obtained using the measure: < 10 min (3 points); 10-30 min (2 points); 30-60 min (1 point) and > 1 h (0 points).
- Cost of assessment tool: < £ 100 (3 points); £ 100-500 (2 points); £ 500-1000 (1 point); £ 1000 (zero).
- Need for specialized equipment and training for use: none (2 points); yes, but simple and clinically viable (1 point); yes and not clinically viable/unknown (zero).
- Portability of assessment 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 data will be synthesized in accordance with the PRISMA recommendations.[33] The assessment tools will be described in tables and/or charts highlighting the general characteristics, application contexts, applicability and information on the evaluation methods of the measures. At the end of the analyses, assessment tools with the following qualities will be considered adequate for measuring self-efficacy with regard to resisting the urge to consume drugs in high-risk situations:

- Those with a methodology considered "good" or "excellent" based on the COSMIN checklist;[35-39]
- Those with a score of 10 or more points on the clinical usefulness evaluation scale proposed by Tyson and Brown (2014).[40]

Discussion

The proposed review will investigate the psychometric properties and clinical usefulness of assessment tools developed to measure the self-efficacy of drug users with regard to resisting the urge to take drugs in high-risk situations. The aim is to recommend a gold standard among the different assessment tools used to measure self-efficacy in this context and offer a discussion on the strong points and limitations of the measures through an analysis of the general characteristics, psychometric properties and clinical usefulness of the measures as well as the methodological quality of the studies.

The review intends to be clear and specific with regard to methodological rigor, employing a replicable systematic approach for the search strategy, screening, evaluation and data extraction of the studies retrieved from the available databases. Validated instruments for measuring given phenomena, such as self-efficacy, offer valid, reliable results that can guide health professionals with regard to interventions for drug users and assist in the adoption of adequate strategies for the promotion of self-efficacy and the minimization of the harm caused by substance abuse.

Ethics and Dissemination

This study received approval from the Human Research Ethics Committee of the Federal University of Pernambuco (reference number: 1.179.162) for being part of the thesis entitled Drug-Taking Confidence Questionnaire for use in Brazil, presented for obtaining a doctorate in neuropsychiatry and behavioral sciences from the Federal University of Pernambuco.

Special care will be taken regarding the storage and adequate use of the data produced in this study.

Dissemination

Self-efficacy is considered an important component of the treatment process for drug users and many assessment tools have been developed to measure this phenomenon, which justifies the need to identify which of these assessment tools could be considered the gold standard for this purpose.

The proposed study will present the psychometric data of assessment tools developed to measure self-efficacy with regard to resisting the urge to take drugs in high-risk situations in order to identify a gold standard for the analysis of this construct.

The results will be disseminated to clinicians and researchers through peer-reviewed publications and conferences.

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Authors' Contributions

All authors made substantial contributions to the concept and study design and participated in the drafting of the submission request. Authors:

Selene Cordeiro Vasconcelos/SCV[1] conceived the study, developed the inclusion criteria, performed the search and selection of the studies and wrote the present systematic review protocol article

Tatiana de Paula Santana da Silva/TPSS[5] conceived the study, developed the inclusion criteria, performed the search and selection of the studies and wrote the present systematic review protocol article.

Iracema da Silva Frazão/ISF[2] guided all phases of this systematic review protocol article and performed a critical review of the manuscript. All authors read and approved the final version.

Everton Botelho Sougey/EBS[3] guided all phases of this systematic review protocol article and performed a critical review of the manuscript. All authors read and approved the final version.

Sandra Lopes Sousa/SLS[4] guided all phases of this systematic review protocol article and performed a critical review of the manuscript. All authors read and approved the final version.

Murilo Duarte da Costa Lima/MDCL[5] guided all phases of this systematic review protocol article and performed a critical review of the manuscript. All authors read and approved the final version.

Competing Interests

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

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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 CRD42017068555
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

Assessment tools for the measurement of the self-efficacy of drug users: Protocol for a systematic review

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-019019.R4
Article Type:	Protocol
Date Submitted by the Author:	04-Jan-2018
Complete List of Authors:	Vasconcelos, Selene; Federal University of Pernambuco, Neuropsychiatry and behavior sciences Frazão, Iracema; Federal University of Pernambuco, Nursing Sougey, Everton; Federal University of Pernambuco, Neuropsychiatry Souza, Sandra; Universidade Federal de Pernambuco, Anatomy Silva, Tatiana ; Universidade Federal de Pernambuco, neuropsiquiatria Lima, Murilo; Universidade Federal de Pernambuco
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Mental health, Addiction, Nursing
Keywords:	Nursing, Self-efficacy, Drug users, Systematic review., Validation studies, MENTAL HEALTH

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Assessment tools for the measurement of the self-efficacy of drug users: Protocol for a systematic review

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ABSTRACT

Introduction: The abuse of alcohol and other drugs is a worldwide problem, the treatment of which poses a challenge to healthcare workers. **Objective**: Present a proposal for a systematic review to analyze the psychometric properties of assessment tools developed to measure the self-efficacy of drug users with regard to resisting the urge to take drugs in high-risk situations. **Methods and Analysis:** The guiding question was based on PICOS (Population Intervention Comparator Outcome Setting), and the report of the methods of review protocol was written in accordance with the PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols). Searches will be performed in the PsycINFO, Cochrane, Pubmed, Web of Science, SCOPUS and CINAHL databases, followed by the use of the "snowball" strategy. The inclusion criteria for the articles will be 1) assessment tool validation studies; 2) assessment tools developed to measure self-efficacy; 3) quantitative measures; 4) measures designed for use on adults; 5) data from self-reports of the participants; 6) studies involving a description of psychometric properties of the measures; and 7) studies that explain how the level of self-efficacy is scored. The search, selection and analysis will be performed by two independent reviewers. In cases of a divergence of opinion, a third reviewer will be consulted. The COSMIN checklist will be used for the appraisal of the methodological quality of the assessment tools and the certainty of the evidence in the articles (risk of bias) will be analyzed using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. **Ethics and dissemination:** This protocol does not require ethical approval. It will offer a clear explanation of the method to be employed in the systematic review, which will give an overview of the available assessment tools and will recommend a gold standard for measuring the phenomenon in question.

Registration number at PROSPERO: CRD42017068555

Strengths and Limitations

- The article will recommend a gold standard among existing assessment tools for the measurement of self-efficacy related to resisting the urge to take drugs in high-risk situations.

- The study will involve the use of quantitative methods for appraising the strength of the evidence encountered.

- This will be the first review on assessment tools for measuring self-efficacy related to resisting the urge to take drugs in high-risk situations.

- The study will be developed at a single research center.

- Grey literature will not be included.

Background

Dependence on alcohol and other drugs is characterized by behavior aimed at maintaining use as well as the loss of pleasure in habitual activities. It is a maladaptive way to cope with stressful situations and is considered a serious public health problem throughout the world.[1-3] Cognitive and behavioral alterations are among the harmful effects of substance abuse,[4-6] affecting personal, familial and social relations as well as compromising an individual's self-efficacy with regard to resisting the urge to take drugs in high-risk situations.[7]

Bandura (1977)[8] conceives self-efficacy as a belief or personal confidence in one's ability to perform a specific action for one's own benefit. Thus, self-efficacy is a mental process that guides behavior and exerts an influence on the establishment of goals, one's motivation level, perseverance in the presence of setbacks and resilience in the face of adversity.[8-11]

Different subtypes of self-efficacy are described in the literature[12] and several assessment tools have been developed to measure this construct among individuals who are dependent on alcohol[13-16] and/or other drugs,[17-21] and in situations of combined use[22-25].

Self-efficacy with regard to resisting the urge to take drugs in high-risk situations is considered a strong predictor of abstinence or a reduction in drug use and is related to the results of treatment.[26-28] Considering the importance of this subtype, the number of assessment tools developed to measure this phenomenon and the lack of recommendations regarding the most robust assessment tools, there is a need to evaluate the psychometric properties of available measures and recommend an assessment tool that can serve as the gold standard.

The proposed systematic review will be able to assist healthcare professionals in the choice of the most adequate assessment tools for their clinical practice with the aim of monitoring levels of self-efficacy to resist the urge to take drugs in high-risk situations.[29] The guiding question of the study will be "Do assessment tools designed to measure self-efficacy with regard to resisting the urge to take drugs in high-risk situations have adequate psychometric properties?"

Thus, the aim of this protocol is to propose a systematic review to analyze the psychometric properties of assessment tools developed to measure the self-efficacy of drug users to resist the urge to consume these substances in high-risk situations.

Method/Design

Design and registration of the study

This proposal for a systematic review is registered with the International Prospective Registry of Systematic Reviews (PROSPERO) in CRD 42017068555 (https://www.crd.york.ac.uk/PROSPERO/register_new_review.asp). The report of the methods of review protocol was written in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P).[30] The report of the methods of systematic review article will follow the guidelines of the Preferred Reporting Items for report to Systematic Review and Meta-Analysis Protocols (PRISMA).[31]

Inclusion of articles

All methodological articles developed for the validation of assessment tools with a quantitative approach for adult drug users (≥ 18 years of age) based on self-reported data and that describe psychometric properties, the clinical usefulness of which consists of the measurement of self-efficacy in users of alcohol and/or other drugs with regard to resisting the urge to use such substances in high-risk situations will be included. No restrictions will be imposed with regard to language or publication date. Review studies will be excluded.

Search strategy

The guiding question was based on the PICOS strategy[32] (Population Intervention Comparator Outcome Setting). Electronic searches will be conducted in the Pubmed, PsycINFO, SCOPUS and CINAHL databases. After the retrieval of articles from the databases, the snowball strategy will be employed.[33] Grey literature will not be considered.

To reduce the risk of bias in this step, two independent reviewers will perform the searches and preselect articles based on an analysis of the titles and abstracts for potentially eligible articles and assessment tools. Preselected articles will be submitted to full-text analysis for the determination of the studies that will make up the final

sample. The level of agreement between the two reviewers will be calculated. In cases of divergences of opinion, the reviewers will discuss the article in question until reaching a consensus. A third reviewer will be consulted, if necessary.

The entire process will be stored in a databank to ensure access to the records of the initial search strategy, the snowball strategy as well as the excluded articles and the reasons for exclusion. Duplicate articles will only be counted once. The following MeSH terms and combinations will be employed in the searches: "self-efficacy", "coping", "validation studies", "drug users", "scale", "instrument", "questionnaire" and "outcome assessment". Adjustments to the keywords may be made during the execution of the systematic review.

Tracking, data extraction, and content comparison analysis

The data extracted from the articles selected will be organized on a chart specifically designed for the systematic review, which will contain the following:

- General characteristics of the study: Authors, date of publication, country of origin, objective, sample size and main outcomes.

- Description of assessment tools: Name and acronym; objective; domains, dimensions or subscales; description of high-risk situations; number of items; method of collecting self-reported data; description of scoring and classification of levels of self-efficacy; administration method; cutoff points; and psychometric properties validated by the authors.

When necessary, the author of the articles and assessment tools will be contacted to obtain further information.

A flowchart will be created illustrating the selection and analysis methods. Relevant data from all articles will be summarized in tables and/or charts. Thus, the systematic review will offer a general overview of all available instruments for measuring the self-efficacy of drug users for resisting the urge to take these substances in high-risk situations.

Appraisal of methodological quality of selected articles and measures

To evaluate the risk of bias, the articles included in the final sample will be analyzed with regard to methodological quality and the strength or certainty of the evidence offered using the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation).[34]

The appraisal of the methodological quality of the assessment tools will follow the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) criteria, using only the A-H boxes on the checklist to rate the quality of each property.[35] The checklists for interpretability and generalization will not be used because these lists are only related to data extraction.

The four-point COSMIN scoring system will be used to classify the assessment tools as excellent (adequate methodological quality), good (missing information, but quality could be considered fair) or poor (inadequate quality). Assessment tools with varied results (some points considered excellent and others considered poor) will be classified based on the lower scores.[35-39] Two reviewers will analyze the risk of bias and classify the assessment tools in an independent manner.

Evaluation of clinical usefulness of assessment tools

The analysis of clinical usefulness will follow the criteria proposed by Tyson and Brown (2014)[40] related to interpretability and viability, with the aim of quantifying the practical aspects of the measures based on factors that can influence the decision-making process of health professionals in clinical practice.[41] These criteria are listed below:

- Total time required for the administration, analysis and interpretation of the data obtained using the measure: < 10 min (3 points); 10-30 min (2 points); 30-60 min (1 point) and > 1 h (0 points).
- Cost of assessment tool: < £ 100 (3 points); £ 100-500 (2 points); £ 500-1000 (1 point); £ 1000 (zero).
- Need for specialized equipment and training for use: none (2 points); yes, but simple and clinically viable (1 point); yes and not clinically viable/unknown (zero).
- Portability of assessment 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 assessment tools will be described in tables and/or charts highlighting the general characteristics, application contexts, applicability and information on the evaluation methods of the measures. At the end of the analyses, assessment tools with the following qualities will be considered adequate for measuring self-efficacy with regard to resisting the urge to consume drugs in high-risk situations:

- Those with a methodology considered "good" or "excellent" based on the COSMIN checklist;[35-39]
- Those with a score of 10 or more points on the clinical usefulness evaluation scale proposed by Tyson and Brown (2014).[40]

Ethics and Dissemination

This protocol does not require ethical approval. However, this protocol is part of the thesis entitled Drug-Taking Confidence Questionnaire for use in Brazil, presented for obtaining a doctorate in neuropsychiatry and behavioral sciences from the Federal University of Pernambuco, and has received approval from the Human Research Ethics Committee of the Federal University of Pernambuco (reference number: 1.179.162). Special care will be taken regarding the storage and adequate use of the data produced in this study.

Self-efficacy is considered an important component of the treatment process for drug users and many assessment tools have been developed to measure this phenomenon, which justifies the need to identify which of these assessment tools could be considered the gold standard for this purpose.

The proposed study will present the psychometric data of assessment tools developed to measure self-efficacy with regard to resisting the urge to take drugs in high-risk situations in order to identify a gold standard for the analysis of this construct.

The results will be disseminated to clinicians and researchers through peer-reviewed publications and conferences.

Therefore, the proposed review will investigate the psychometric properties and clinical usefulness of assessment tools developed to measure the self-efficacy of drug users with

regard to resisting the urge to take drugs in high-risk situations. The aim is to recommend a gold standard among the different assessment tools used to measure self-efficacy in this context and offer a discussion on the strong points and limitations of the measures through an analysis of the general characteristics, psychometric properties and clinical usefulness of the measures as well as the methodological quality of the studies. The review intends to be clear and specific with regard to methodological rigor, employing a replicable systematic approach for the search strategy, screening, evaluation and data extraction of the studies retrieved from the available databases. Validated instruments for measuring given phenomena, such as self-efficacy, offer valid, reliable results that can guide health professionals with regard to interventions for drug users and assist in the adoption of adequate strategies for the promotion of self-efficacy and the minimization of the harm caused by substance abuse.

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Authors' Contributions

All authors made substantial contributions to the concept and study design and participated in the drafting of the submission request. Authors:

Selene Cordeiro Vasconcelos[1], and Tatiana de Paula Santana da Silva[5] conceived the study, developed the inclusion criteria, performed the search and selection of the studies and wrote the present systematic review protocol article.

Iracema da Silva Frazão[2], Everton Botelho Sougey[3], Sandra Lopes Sousa[4], and Murilo Duarte da Costa Lima[5] guided all phases of this systematic review protocol article and

performed a critical review of the manuscript. All authors read and approved the final version.

Competing interests statement.

The authors declare that they have no conflicts of interest.