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Title page

User involvement in adolescents' mental healthcare: Protocol for a systematic review

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User involvement in adolescents' mental healthcare: Protocol for a systematic review

ABSTRACT

Introduction: User involvement has become of growing importance in healthcare. The United Nations state that adolescents have a right to be heard and user involvement in healthcare is a legal right in some countries. Some research provides an insight into the field of user involvement in somatic and mental healthcare for adults, but little is known about user involvement in adolescents' mental healthcare and no overview of the existing research evidence exists.

Objective: To synthesize and assess the quality of the research literature reporting on experiences with, effectiveness of and safety issues associated with user involvement for adolescents' mental healthcare, for improvement of healthcare services and institutions, and for political decision-making processes.

Method: A systematic literature search and assessment of published research in the field of user involvement in adolescents' mental healthcare. Established guidelines are used for data extraction (Cochrane Collaboration guidelines, STROBE, CASP), critical appraisal (Cochrane Collaboration guidelines, PRECIS) and reporting of results (PRISMA, CONSORT, CASP). Confidence in the research evidence will be assessed using the GRADE approach. Adolescents are included as co-researchers for the planning and carrying out of this systematic review.

Discussion: This systematic review will provide an overview of the existing research literature and thereby fill a knowledge gap. It may provide various stakeholders, including decision makers, professionals, individuals and their families with an overview of existing knowledge in an underexplored field of research.

LAY ABSTRACT

Individuals have a right to be heard and involved in decisions that affect their current and future healthcare services. In several countries, this has become a legal right and it includes adolescents' right to be involved in decisions affecting their mental healthcare. This is referred to as user involvement. Some research has been carried out to assess user involvement in mental healthcare for adults, but little is known about user involvement for adolescents' mental healthcare. We are therefore planning to provide an overview of existing research reporting on adolescents and user involvement for mental healthcare services. This includes user involvement affecting adolescents'

own treatment for their mental health, and user involvement influencing existing healthcare services and political decisions. Adolescents are taking part in the planning, carrying out and publication of this research.

Keywords: User involvement; adolescents; mental health; systematic review; protocol

Strengths and limitations of this study

- This is the first systematic review assessing user involvement for adolescents' mental healthcare
- Established guidelines are used for data retrieval, data extraction, critical appraisal, data synthesis and reporting of results
- Adolescents are involved as co-researchers through all phases of the systematic review
- Wide inclusion criteria may represent challenges for synthesizing the research evidence, although it will also provide a more extensive overview of the research literature
- We expect to find limited research evidence in this field, which may also limit the extent to which we will be able to provide recommendations for clinical practice

INTRODUCTION

Mental health disorders affect a significant proportion of adolescents in countries all around the world. On average, 13.4 % (CI 95 % 11.3-15.9) in the age groups up to 18 years suffer from mental disorders, according to a meta-analysis of prevalence studies in 27 countries.[1] In many instances these complaints result in functional impairment. The age group from 10 to 24 years represents 16 % of all disability adjusted life years (DALYs) of all age groups and.[2]

According to the United Nations and the European Convention of Human Rights, children and adolescents have a right of access to high quality and safe healthcare services and their views must be heard and considered in any matters affecting them.[3,4] Although parents commonly have the authority to make decisions on behalf of their children, some national legislative frameworks (e.g. in Canada, Ireland and the United Kingdom) also emphasize children's right to be heard and actively involved in decision-making concerning their own health.[5] Adolescents at the age of 16 are in some countries considered to be competent and have the right to consent to or refuse treatment. This may in some instances extend down to the age of 12 (e.g. in Ireland, Netherlands, UK) or younger (e.g. in Canada, New Zealand, South Africa), provided they are able to fully understand what the interventions involve. Some of the basic principles underpinning national legislation and regulations include respect, taking the adolescent seriously, encouraging cooperation and encouraging adolescents to take responsibility for their own health.

Patient- and person-centered or person-directed care with patient or service user involvement has become increasingly common in various fields of healthcare and at various levels. The term patient-centered care was initially described as focusing on the patient as a whole, including both physical and psychological aspects.[6] It requires a more active and participating role on the part of the practitioner, compared to a more illness-oriented approach with uninvolved objective observation. In later years, the understanding of patient-centered care has taken into account service users' needs, priorities and expectations of healthcare services, and can lead to reorganization of services.[7] A person-centered approach moves one step further by taking the whole person into consideration, including mental, emotional, spiritual and social needs, and in a person-directed approach individuals take control of decisions affecting their own care.[8]

Person-centered or person-directed care provides a context for user involvement, which can be understood as engaging individual patients or users in processes of both planning and delivery of their own healthcare services (at the individual level), as well as their influence on provision of health services in general (at the organizational or institutional level), and for political decision-making processes.[9] Users may here be understood as any person who is currently using or who may in the future use care services. This does de facto include any person/citizen. User involvement is encouraged through processes of collaboration with two-way communication, where professionals provide individuals with sufficient and adequate information, by eliciting their views, opinions, perceptions and perspectives. Such a form of user involvement requires reduction of power differentials between service users and healthcare professionals, where professionals must be willing to take users' views and wishes into account.[10] When managed well, these processes may contribute to shared decision-making and self-determination for patients' healthcare services, provided within a context of person-centered or person-directed care.[9]

The active involvement of service users in healthcare decision-making has the potential to contribute to user empowerment and improvement of the quality and safety of healthcare systems.[11] National legislation and regulation in many countries requires healthcare services to involve users in their own treatment, as well as at an institutional/organizational and political level. This includes various areas associated with mental healthcare, for example in development of healthcare policies and strategies,[12] for implementation of clinical guidelines,[13] in education of health professionals,[14] and for employment of healthcare staff and user-to-user panels.[15] It has been suggested that users should be involved at every mental healthcare service level.[16]

Little is known about the existing research evidence reporting on user involvement for adolescents' mental healthcare. A literature search carried out in 2012 with an aim to assess the existing evidence of children's and adolescents' engagement in decision-making for their own healthcare, identified only a handful of studies, in asthma, HIV, cancer, learning and behavior problems, and sun protection behaviors.[17] No systematic review has focused specifically on user involvement in adolescents' mental healthcare.

A number of important research questions need clarification, such as: What efforts are commonly put into place to encourage user involvement in adolescents' mental healthcare and how do they perceive such efforts? User involvement is commonly perceived to contribute positively to clinical treatment outcomes and some research suggests shared decision-making for individuals' own healthcare may be associated with improved health outcomes.[18,19] But what are the results of the overall research evidence for the effect of service user involvement on adolescents' mental health outcomes? Furthermore, how does user involvement affect user safety? For example, adolescents who currently self-harm have by some been found to have reduced decision-making skills,[20] thereby suggesting particular measures are needed to ensure safety in attempts to increase user involvement in this group.

This systematic review therefore aims to provide an overview of existing research reporting on experiences with, and the effectiveness and safety issues associated with user involvement for adolescents' mental healthcare.

Objectives

The objectives of this review are, in the field of adolescents' mental healthcare, to synthesize and to assess the quality of the research literature reporting on experiences with, effectiveness of and safety issues associated with user involvement:

A. At an individual level for adolescents' own healthcare;
B. At an organizational and institutional level for improvement of healthcare services and institutions; and
C. At the political level for political decision-making processes.

METHODS

We will use pre-defined eligibility criteria and search strategies, and guidelines for data extraction, critical appraisal, data synthesis and reporting of results.

Eligibility criteria

The inclusion criteria for this systematic review are: Studies reporting on experiences with, effectiveness of and safety issues associated with user involvement (intervention) in the planning, delivery and development of adolescents' mental healthcare (participants). Users may be adolescents or their caretakers. Mental healthcare may include preventive or therapeutic interventions for diagnosed conditions or self-reported problems. User involvement may be aimed at the individual level (for adolescents' own healthcare), at the organizational or institutional level (to improve healthcare services/institutions), or at the political level (for making political decisions). It is unlikely that the effectiveness of user involvement has been tested in randomized controlled trials. We are therefore including non-randomized trials and studies (NRS). We are not limiting the literature search to any specific research methods, as this may lead to missing studies in systematic reviews including NRS.[21] Studies may include any research design (qualitative or quantitative) used to answer the research questions of this review, and may or may not include comparators/control groups (control). Outcomes will be reported according to the original trials and studies. User involvement may have been reported by adolescents, their caretakers, health professionals or other stakeholder groups. Adolescents will be defined as the age group from 10 to 19 years.[22] Exclusion criteria: Debate, commentaries, editorials, conference abstracts, non-peer reviewed studies, studies reporting on children (age below 10) or adults (age above 19). Conference abstracts will however be considered to determine the risk of publication bias. Languages will be limited to English, French, German, Danish, Norwegian and Swedish. No year limitation will be set.

Search strategy

A systematic search of the following databases will be carried out: Academic Search Premier, BNI, CINAHL, Cochrane Library, EMBASE, MEDLINE, Oria, PubMed, PsycINFO, Scopus, SocINDEX, SveMed+ and Web of Science (complete list in table 1). Reference lists of included studies will be hand searched for identification of additional titles. The grey literature will be searched using an advanced Google Scholar search limited to the first 50 results for each search string and through user/interest groups, experts and researchers in the field. An expert university librarian has been consulted as part of planning the literature search strategy. A draft search strategy for one electronic database (MEDLINE) is presented in Appendix A.

Table 1. Literature sources

Databases
Academic Search Premier
BNI: British Nursing Index
CINAHL: Cumulative Index to Nursing and Allied Health Literature
Cochrane Library
EMBASE: Exerpta Medica Database
MEDLINE: National Library of Medicine
Oria
PubMed*: National Library of Medicine
PsycINFO: American Psychological Association
Scopus
SocINDEX: Database for Sociological Research
SveMed+: Medical data by the Karolinska Institute Library
Web of Science

Other sources
Google Scholar
User groups
Experts and researchers

* PubMed search will be limited to the last 2 years, as older titles are likely to be covered by MEDLINE.

A wide range of search terms will be used in order to identify relevant literature, as user involvement may include a whole range of different activities. Search strategies aimed at maximising sensitivity and specificity will be customized to databases, where possible using MeSH/Subject terms, Explode function, wildcard symbols and Boolean operators. A combination of groups of search terms will be used, including the service user group (adolescents), the field of health (psychiatry/mental health) and the field of research (involvement), as presented in table 2. Additional search terms identified through initial literature searches will be used if considered relevant.

Table 2. Search terms

Area of health	**Field of research**			
Subject / MeSH Terms				
User group & field of health	Field of research			
Adolescent psychiatry	Clinical decision-making		Community participation	
Adolescent psychology	Consumer participation		Decision making	
	Cooperative behaviour		Decision making, organizational	
	Information sharing		Information dissemination	
	Patient participation		Personal autonomy	
	Public opinion		Self-determination	
Terms used in search of title or abstract				
User group	Field of health	Field of research		
Adolescents	Mental	Autonomy	Client-centred	Collaboration
Teenagers	Psychology	Consultation	Contribution	Decision-making
Youth	Psychiatry	Empowerment	Engagement	Governance
		Inclusion	Information sharing	Involvement
		Mutual agreement	Negotiation	Opinions
		Patient-centred	Participation	Partnership
		Perspectives	Peer support	Self-determination

A minimum of two reviewers will screen titles and abstracts to determine inclusion/exclusion of articles. All potentially relevant full text articles will be read and assessed according to the inclusion/exclusion criteria. In the event of continued doubt, a third reviewer will be included for consensus or majority vote decisions. Reasons for exclusion will be logged. Endnote (version X8) will be used to manage data records.

Data extraction

Data will be extracted and input by one reviewer into an Excel spreadsheet using the Cochrane Consumers and Communication Review Group's data extraction template for trials;[23] the STROBE statement checklist for cohort, case-control and cross-sectional studies;[24] and the Critical Appraisal Skills Programme (CASP) for qualitative studies.[25] A second reviewer will check the accuracy of input data. Cross-references to article publications may be used, but authors of original trials and studies will not be contacted for clarification as this may lead to too optimistic and biased responses.[26] For studies reporting on the effectiveness of interventions, a main outcome will be identified as defined by the authors of the original article. Reviewers will decide on which outcome measure to report in the event that no main outcome has been defined by study authors, as well as any additional outcomes of importance to users.

Critical appraisal

Including studies and trials using various research methods could potentially result in misleading effect estimates.[21] To avoid this, we will use the Cochrane Collaboration's guidelines to assess risk of bias at the outcome level.[26] We will assess the risk of selection bias, performance bias, detection bias, attrition bias and reporting bias. Particular attention will be paid to the potential influence of confounding factors for NRS, as suggested by the Cochrane Collaboration.[21] Moreover, we will assess the risk of meta-bias by searching for unpublished studies in the grey literature; by comparing protocols articles with results articles; and by assessing methods and results sections of individual study articles. If there is a sufficient number of studies (min. 10) with variation in trial sizes (at least one medium or large), funnel plot symmetry together with a regression analysis will be assessed to consider risk of publication bias, as suggested by Sterne et al.[27] However, whether a trial is free of bias does not address the question of its applicability and generalizability to end users, including patients, clinicians and policy makers.[28] We will therefore assess the external validity of trials using the PRECIS tool.[29] The Critical Appraisal Skills Programme (CASP) will be used for assessing qualitative studies.[25]

The confidence in the evidence resulting from the identified research literature will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.[30] This will include assessment of the risk of bias, inconsistency, indirectness, imprecision, publication bias and factors increasing the confidence in the effect of each outcome.

Data synthesis

The extent to which data will be synthesized, will depend on the degree of homogeneity of included studies. We will determine consistency of the evidence by assessing the variability of trials. Particular attention will be paid to clinical aspects (e.g. interventions, clinical conditions) and research methods. The effect of heterogeneity will be quantified using the I^2 statistic to calculate variability across trials.[31]

In the event of sufficient homogeneity, results of randomized trials will be presented collectively through a meta-analysis, presenting effect estimates with standard errors or confidence intervals. A summary statistic will be calculated for the main outcome in each trial, determining the risk ratio for dichotomous outcomes and standardized mean differences for continuous outcomes (both with 95 % confidence intervals). A weighted average will be calculated to determine the overall treatment effect in the included trials. We expect at least some heterogeneity between trials and will therefore apply a random effects model to estimate the mean of the distribution of effects. Analysis of sub-groups will be considered for specific clinical conditions (e.g. depression, anxiety or psychosis), for particular research methods (e.g. randomized controlled trials, cluster randomized trials or non-randomized studies and trials), and if the I^2 statistic supersedes 40 %. For groups of NRS applying similar study designs, summarized adjusted effect estimates will be presented (controlling for confounding factors) as suggested by Reeves et al.[21] Only a narrative summary will be developed in the event of considerable heterogeneity (I^2>75%). Dependent on a sufficient number of included studies, qualitative studies will be synthesized.[32] Some flexibility is needed with regards to choice of the most suitable approach for the qualitative synthesis as this will depend on the available research evidence, in particular with regards to the quality and heterogeneity of studies. We will therefore make a final decision to determine the synthesis approach after collection of data, but will aim at applying either a textual narrative synthesis or a thematic analytic synthesis approach.[33,34]

Reporting results

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement and flow diagram will be used to report the result of literature searches.[35] Results of randomized controlled trials will be reported according to the CONSORT statement,[36] for observational studies the STROBE statement,[24] and for qualitative studies the CASP checklist.[25] Results of all studies will be presented in tables, providing information on study design, results and quality of evidence. Separate tables will be provided in the event of different subgroups of patients. We will report results collectively for comparative (sufficiently homogenous) studies, grouped according to their associated risk of bias. Results will be presented separately for randomized controlled trials and NRS. Moreover, the nature of the data will also warrant presentation of results according to research methods (e.g. results of qualitative and quantitative studies will be reported separately). Information on methodological decisions made or modified after data collection will be reported. Moreover, we will report involvement of user/interest groups, experts and researchers.

Co-researchers and user involvement

Two adolescent co-researchers (NEC, JRG) have been involved in developing and writing the protocol for the systematic review and will be involved in the systematic review process. Mental health organizations have also been invited to the planning, carrying out and dissemination of the results of this systematic review.

DISCUSSION

User involvement has become a priority in healthcare systems in many countries, as it is considered a citizen right to be involved in decisions affecting one’s own healthcare. Although several systematic reviews have summarized existing evidence in user involvement in health research for adults in general or in areas such as safety and education of mental health professionals,[37-39] little is known about user involvement for adolescents’ mental healthcare. This systematic review therefore aims to fill an existing knowledge gap. It will provide an insight into users’ experiences, effectiveness of and safety issues associated with user involvement at an individual level for adolescents’ own healthcare, at an organizational or institutional level for improvement of healthcare services and institutions, and at the political level for political decision-making processes. It may thereby provide information that can be valuable for several stakeholder groups, such as patients and their families, healthcare providers, clinicians and decision makers, as well as for developing research strategies to further knowledge in an underexplored field of research. This may include knowledge about ways in which users are involved in decision-making affecting their own healthcare and the influence of such involvement on their health outcomes. It can also provide information on user involvement affecting delivery and healthcare service policy decisions.

There is considerable variation in the literature with regards to used terminology relating to user involvement. We have, in an attempt to capture the relevant research literature, included several search strategies using a variety of search terms. Moreover, we hope to capture most of the literature relevant to adolescents, although research carried out with varying age groups (single studies reporting on both children and adolescents, or adolescents and young people) may limit the breath of literature we will include in our review. The definition of “adolescents” varies within the context of different national legislations and individual researchers’ and clinicians’ understanding. We have chosen UNICEF’s definition of adolescents, thereby including any studies reporting on results in the age group ranging from 10 to 19 years. The results of this review will therefore not be applicable to children under the age of 10 or young persons above the age of 19 years.

A limitation of this systematic review is the restriction to only six languages. Although we expect to capture most of the published research literature through English language articles, and although some evidence suggests reduced importance of non-English language articles for assessing the effectiveness of interventions,[40] we cannot exclude the possibility that significant literature has been published in other languages. We have added five languages in an attempt to limit the gaps in the research evidence collected through our review. Our choice of languages is partly due to the strong tradition user involvement has in some of these countries, but is nevertheless limited by our available resources. The inclusion of a wide range of databases increases the likelihood of capturing most of the relevant literature in this field of research. Moreover, the inclusion of databases more specifically covering the Nordic literature will increase the chance of also capturing the evidence published in these countries.

AUTHOR CONTRIBUTIONS

PV is the guarantor. PV, SEB, SHB, NEC, JRG, KA and MS contributed to the development of the draft manuscript. PV, SEB, SHB, KA and MS contributed to development of the search and assessment strategies. PV, SEB, SHB, NEC, JRG, KA and MS read, provided feedback and approved the final manuscript.

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COMPETING INTERESTS

The authors have nothing to disclose.

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Search strategy example for: User involvement in adolescents' mental healthcare: Protocol for a systematic review

MEDLINE (1951 to Present)

Search date: 27.06.2017

1. MH "adolescent psychiatry" 2,572
2. MH "adolescent psychology" 12,640
3. 1 OR 2 15,024
4. MH "community participation" 35,999
5. MH "clinical decision-making" 1,553
6. MH "information dissemination" 13,253
7. MH "patient participation" 21,034
8. MH "personal autonomy" 14,930
9. 4 OR 5 OR 6 OR 7 OR 8 63,879

10 3 AND 9 209

Result: 209 titles for assessment

PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	3-4
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☐	☒	N/A
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-11
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	338-341
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	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☐	☒	N/A
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	N/A
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☐	☒	N/A
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	73-148
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to	☒	☐	150-158, 164-178

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		participants, interventions, comparators, and outcomes (PICO)			
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	164-184
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	186-195
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	☒	☐	Appendix A
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	207-219
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	207-211
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	215-224
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	166-179
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	178, 220-224
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	☒	☐	229-237
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☒	☐	250-254
	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 (e.g., I^2, Kendall's tau)	☒	☐	253-262
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-	☒	☐	262-268

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		regression)			
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	267-273
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	232-237
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	243-246

BMJ Open

User involvement in adolescents' mental healthcare: Protocol for a systematic review

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018800.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Sep-2017
Complete List of Authors:	Viksveen, Petter; University of Stavanger, SHARE - Centre for Resilience in Healthcare, Faculty of Health Sciences Bjønness, Stig; University of Stavanger, SHARE - Centre for Resilience in Healthcare, Faculty of Health Sciences Berg, Siv; Stavanger University Hospital, Department of psychiatry Cardenas, Nicole; St. Olav videregående skole, International Baccalaureate Game, Julia; St. Olav videregående skole, International Baccalaureate Aase, Karina; University of Stavanger, SHARE - Centre for Resilience in Healthcare, Faculty of Health Sciences; Stavanger University Hospital, Regional Centre for Age-related Medicine and Coordination Storm, Marianne; University of Stavanger, SHARE - Centre for Resilience in Healthcare, Faculty of Health Sciences
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Paediatrics, Patient-centred medicine
Keywords:	User involvement, Adolescents, MENTAL HEALTH, Systematic review, Protocol

Title page

User involvement in adolescents' mental healthcare: Protocol for a systematic review

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User involvement in adolescents' mental healthcare: Protocol for a systematic review

ABSTRACT

Introduction: User involvement has become of growing importance in healthcare. The United Nations state that adolescents have a right to be heard and user involvement in healthcare is a legal right in many countries. Some research provides an insight into the field of user involvement in somatic and mental healthcare for adults, but little is known about user involvement in adolescents' mental healthcare and no overview of the existing research evidence exists.

Methods and analysis: The aim of this systematic review is to provide an overview of existing research reporting on experiences with, and the effectiveness and safety issues associated with user involvement for adolescents' mental healthcare, at the individual and organizational level. A systematic literature search and assessment of published research in the field of user involvement in adolescents' mental healthcare. Established guidelines will be used for data extraction (Cochrane Collaboration guidelines, STROBE, CASP), critical appraisal (Cochrane Collaboration guidelines, PRECIS) and reporting of results (PRISMA, CONSORT, CASP). Confidence in the research evidence will be assessed using the GRADE approach. Adolescents are included as co-researchers for the planning and carrying out of this systematic review. This systematic review will provide an overview of the existing research literature and thereby fill a knowledge gap. It may provide various stakeholders, including decision makers, professionals, individuals and their families with an overview of existing knowledge in an underexplored field of research.

Ethics and dissemination: Ethics approval is not required for this systematic review as we are not collecting primary data. The results will be published in a peer-reviewed journal and at conference presentations, and will be shared with stakeholder groups.

Keywords: User involvement; adolescents; mental health; systematic review; protocol

Strengths and limitations of this study

- This is the first systematic review assessing user involvement for adolescents' mental healthcare
- Established guidelines are used for data retrieval, data extraction, critical appraisal, data synthesis and reporting of results
- Adolescents are involved as co-researchers through all phases of the systematic review

- Wide inclusion criteria may represent challenges for synthesizing the research evidence, although it will also provide a more extensive overview of the research literature
- We expect to find limited research evidence in this field, which may also limit the extent to which we will be able to provide recommendations for clinical practice

INTRODUCTION

Mental health disorders affect a significant proportion of adolescents in countries all around the world. A meta-analysis of prevalence studies in 27 countries indicated that on average 13.4 % (CI 95 % 11.3-15.9) in the age groups up to 18 years live with mental disorders.[1] In many instances these disorders result in functional impairment. The age group from 10 to 24 years represents 16 % of all disability adjusted life years (DALYs) of all age groups.[2]

According to the United Nations and the European Convention of Human Rights, children and adolescents have a right of access to high quality and safe healthcare services and their views must be heard and considered in any matters affecting them.[3,4] Although parents commonly have the authority to make decisions on behalf of their children, some national legislative frameworks (e.g. in Canada, Ireland and the United Kingdom) also emphasize children's right to be heard and actively involved in decision-making concerning their own health.[5] Adolescents at the age of 16 are in some countries considered to be competent and have the right to consent to or refuse treatment. This may in some instances extend down to the age of 12 (e.g. in Ireland, Netherlands, UK) or younger (e.g. in Canada, New Zealand, South Africa), provided they are able to fully understand what the interventions involve. Some of the basic principles underpinning national legislation and regulations include respect, taking the adolescent seriously, encouraging cooperation and encouraging adolescents to take responsibility for their own health.

Patient- and person-centered or person-directed care with patient or service user involvement has become increasingly common in various fields of healthcare and at various levels. The term patient-centered care was initially described as focusing on the patient as a whole, including both physical and psychological aspects.[6] It requires a more active and participating role on the part of the practitioner, compared to a more illness-oriented approach with uninvolved objective observation. In later years, the understanding of patient-centered care has taken into account service users' needs, priorities and expectations of healthcare services, and can lead to reorganization of services.[7] A person-centered approach moves one step further by taking the whole person into consideration, including mental, emotional, spiritual and social needs, and in a person-directed approach individuals take control of decisions affecting their own care.[8]

Person-centered or person-directed care provides a context for user involvement, which can be understood as engaging individual patients or users in processes of both planning and delivery of their own healthcare services (at the individual level), as well as their influence on provision of health services in general (at the organizational or institutional level), and for political decision-making processes.[9] Users may here be understood as any person who is currently using or who may in the future use care services. This does de facto include any person/citizen. User involvement is encouraged through processes of collaboration with two-way communication, where professionals provide individuals with sufficient and adequate information, by eliciting their views, opinions, perceptions and perspectives. Such a form of user involvement requires reduction of power differentials between service users and healthcare professionals, where professionals must be willing to take users' views and wishes into account.[10] When managed well, these processes may contribute to shared decision-making and self-determination for patients' healthcare services, provided within a context of person-centered or person-directed care.[9]

The active involvement of service users in healthcare decision-making has the potential to contribute to user empowerment and improvement of the quality and safety of healthcare systems.[11] National legislation and regulation in many countries requires healthcare services to involve users in their own treatment, as well as at an institutional/organizational and political level. This includes various areas associated with mental healthcare, for example in development of healthcare policies and strategies,[12] for implementation of clinical guidelines,[13] in education of health professionals,[14] and for employment of healthcare staff and user-to-user panels.[15] It has been suggested that users should be involved at every mental healthcare service level.[16]

Little is known about the existing research evidence reporting on user involvement for adolescents' mental healthcare. A literature search carried out in 2012 with an aim to assess the existing evidence of children's and adolescents' engagement in decision-making for their own healthcare, identified only a handful of studies, in asthma, HIV, cancer, learning and behavior problems, and sun protection behaviors.[17] No systematic review has focused specifically on user involvement in adolescents' mental healthcare.

Various definitions of adolescence exist.[18-20] The term "adolescence" comes from Latin and refers to "growing up". This phase of life involves the transition from childhood to adulthood. The time for the onset and conclusion of adolescence varies between individuals. In light of this, it may seem artificial to limit the age range when assessing mental healthcare services for adolescents. However, mental healthcare services for adolescents are commonly provided from the start of secondary school, typically around the age of 12 or 13 years. Moreover, in many countries the age of 18 is considered the legal transition into adulthood. The age range from 13 to 18 years corresponds to the MeSH definition of adolescence (Unique ID: D000293).

A number of important research questions need clarification, such as: What efforts are commonly put into place to encourage user involvement in adolescents' mental healthcare and how do they perceive such efforts? User involvement is commonly perceived to contribute positively to clinical treatment outcomes and some research suggests shared decision-making for individuals' own healthcare may be associated with improved health outcomes.[21,22] But what are the results of the overall research evidence for the effect of service user involvement on adolescents' mental health outcomes? Furthermore, how does user involvement affect patient safety? For example, some have found that adolescents who currently self-harm have reduced decision-making skills.[23] Are particular measures needed to ensure the safety of this group when increasing user involvement?

Objectives

This systematic review aims to provide an overview of existing research reporting on experiences with, and the effectiveness and safety issues associated with user involvement for adolescents' mental healthcare.

The objectives of this review are:

A. To assess the experiences with user involvement for adolescents' mental healthcare at the individual and organizational level.

B. To assess the effectiveness of user involvement for adolescents' mental healthcare at the individual and organizational level.

C. To assess safety issues associated with user involvement for adolescents' mental healthcare at the individual and organizational level.

METHODS

We will use pre-defined eligibility criteria and search strategies, and guidelines for data extraction, critical appraisal, data synthesis and reporting of results.

Eligibility criteria

The inclusion criteria for this systematic review are: Studies reporting on experiences with, effectiveness of and safety issues associated with user involvement (intervention) in the planning, delivery and development of mental healthcare for adolescents (participants). Mental healthcare may include preventive or therapeutic interventions for diagnosed conditions or self-reported problems. User involvement may be aimed at the individual level (for adolescents' own mental healthcare) or at the organizational or institutional level (to improve mental healthcare services/institutions). It is unlikely that the effectiveness of user involvement has been tested in randomized controlled trials. We will therefore include non-randomized trials and studies (NRS). Additionally, we will not limit the literature search to any specific research methods, as this may lead to missing studies in systematic reviews including NRS.[24] Studies may include any research design (qualitative or quantitative) used to answer the research questions of this review, and may or may not include comparators/control groups (control). Outcomes will be reported according to the original trials and studies. Adolescents' user involvement may have been reported by adolescents, their caretakers, health professionals or other stakeholder groups. Adolescents will be defined as the age group from 13 to 18 years (MeSH Unique ID: D000293). Studies reporting on adolescents and children or adults will be included if data for adolescents can be extracted and analysed separately. Results or the peer-reviewed and the grey literature will be reported separately. Exclusion criteria: Debate, commentaries, editorials, studies reporting on children (age below 13) or adults (age above 18). Languages will be limited to English, French, German, Danish, Norwegian and Swedish. The literature will be limited to the last 15 years (2002–2017).

Search strategy

A systematic search of the following databases will be carried out: Academic Search Premier, BNI, CINAHL, Cochrane Library, EMBASE, MEDLINE, PubMed, PsycINFO, Scopus, SocINDEX, SveMed+ and Web of Science (complete list in table 1). Reference lists of included studies will be hand searched for identification of additional titles. The grey literature will be searched using an advanced Google Scholar search limited to the first 50 results for each search string and through user/interest groups, experts and researchers in the field. An expert university librarian has been consulted as part of planning the literature search strategy. A draft search strategy for one electronic database (MEDLINE) is presented in Appendix A.

Table 1. Literature sources

Databases (with dates of coverage)
Academic Search Premier (2002–2017)
BNI: British Nursing Index (2002–2017)
CINAHL: Cumulative Index to Nursing and Allied Health Literature (2002–2017)
Cochrane Library (2002–2017)

EMBASE: Exerpta Medica Database (2002–2017)
MEDLINE: National Library of Medicine (2002–2017)
PubMed*: National Library of Medicine (2016–2017)
PsycINFO: American Psychological Association (2002–2017)
Scopus (2002–2017)
SocINDEX: Database for Sociological Research (2002–2017)
SveMed+: Medical data by the Karolinska Institute Library (2002–2017)
Web of Science (2002–2017)
Other sources
Google Scholar
User groups
Experts and researchers

* PubMed search will be limited to the last 2 years, as older titles are likely to be covered by MEDLINE.

A wide range of search terms will be used in order to identify relevant literature, as user involvement may include a whole range of different activities. Search strategies aimed at maximising sensitivity and specificity will be customized to databases, where possible using MeSH/Subject terms, Explode function, wildcard symbols and Boolean operators. A combination of groups of search terms will be used, including the service user group (adolescents), the field of health (psychiatry/mental health) and the field of research (involvement), as presented in table 2.

Table 2. Search terms

Area of health	**Field of research**			
Subject / MeSH Terms				
User group & field of health	Field of research			
Adolescent psychiatry	Clinical decision-making		Community participation	
Adolescent psychology	Consumer participation		Decision making	
	Cooperative behaviour		Decision making, organizational	
	Information sharing		Information dissemination	
	Patient participation		Personal autonomy	
	Public opinion		Self-determination	
Terms used in search of title				
User group	Field of health	Field of research		
Adolescents	Mental	Autonomy	Client-centred	Collaboration
Teenagers	Psychology	Consultation	Contribution	Decision-making
Youth	Psychiatry	Empowerment	Engagement	Governance
		Inclusion	Information sharing	Involvement
		Mutual agreement	Negotiation	Opinions
		Patient-centred	Participation	Partnership
		Perspectives	Peer support	Self-determination

A minimum of two reviewers will screen titles and abstracts to determine inclusion/exclusion of articles. All potentially relevant full text articles will be read and assessed by at least two reviewers according to the inclusion/exclusion criteria. In the event of continued doubt, a third reviewer will be included for consensus or majority vote decisions. Reasons for exclusion will be logged. Endnote (version X8) will be used to manage data records.

Data extraction

Data will be extracted and input by one reviewer into an Excel spreadsheet using the Cochrane Consumers and Communication Review Group's data extraction template for trials;[25] the STROBE statement checklist for cohort, case-control and cross-sectional studies;[26] and the Critical Appraisal Skills Programme (CASP) for qualitative studies.[27] A second reviewer will check the accuracy of input data. Cross-references to article publications may be used, but authors of original trials and studies will not be contacted for clarification as this may lead to too optimistic and biased responses.[28] For studies reporting on the effectiveness of interventions, a main outcome will be identified as defined by the authors of the original article. Reviewers will decide on which outcome measure to report in the event that no main outcome has been defined by study authors, as well as any additional outcomes of importance to users.

Critical appraisal

Including studies and trials using various research methods could potentially result in misleading effect estimates.[24] To avoid this, we will use the Cochrane Collaboration's guidelines to assess risk of bias at the outcome level.[28] We will assess the risk of selection bias, performance bias, detection bias, attrition bias and reporting bias. Particular attention will be paid to the potential influence of confounding factors for NRS, as suggested by the Cochrane Collaboration.[24] Moreover, we will assess the risk of meta-bias by searching for unpublished studies in the grey literature; by comparing protocols articles with results articles; and by assessing methods and results sections of individual study articles. If there is a sufficient number of studies (min. 10) with variation in trial sizes (at least one medium or large), funnel plot symmetry together with a regression analysis will be assessed to consider risk of publication bias, as suggested by Sterne et al.[29] However, whether a trial is free of bias does not address the question of its applicability and generalizability to end users, including patients, clinicians and policy makers.[30] We will therefore assess the external validity of trials using the PRECIS tool.[31] The Critical Appraisal Skills Programme (CASP) will be used for assessing qualitative studies.[27]

The confidence in the evidence resulting from the identified research literature will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.[32] This will include assessment of the risk of bias, inconsistency, indirectness, imprecision, publication bias and factors increasing the confidence in the effect of each outcome.

Data synthesis

The extent to which data will be synthesized, will depend on the degree of homogeneity of included studies. We will determine consistency of the evidence by assessing the variability of trials. Particular attention will be paid to clinical aspects (e.g. interventions, clinical conditions) and research methods. The effect of heterogeneity will be quantified using the I^2 statistic to calculate variability across trials.[33]

In the event of sufficient homogeneity, results of randomized trials will be presented collectively through a meta-analysis, presenting effect estimates with standard errors or confidence intervals. A summary statistic will be calculated for the main outcome in each trial, determining the risk ratio for dichotomous outcomes and standardized mean differences for continuous outcomes (both with 95 % confidence intervals). A weighted average will be calculated to determine the overall treatment effect in the included trials. We expect at least some heterogeneity between trials and will therefore apply a random effects model to estimate the mean of the distribution of effects. Analysis of sub-groups will be considered for specific clinical conditions (e.g. depression, anxiety or psychosis), for particular research methods (e.g. randomized controlled trials, cluster randomized trials or non-randomized studies and trials), and if the I^2 statistic supersedes 40 %. For groups of NRS applying similar study designs, summarized adjusted effect estimates will be presented (controlling for confounding factors) as suggested by Reeves et al.[24] Only a narrative summary will be developed in the event of considerable heterogeneity (I^2>75%). Dependent on a sufficient number of included studies, qualitative studies will be synthesized.[34] Some flexibility is needed with regards to choice of the most suitable approach for the qualitative synthesis as this will depend on the available research evidence, in particular with regards to the quality and heterogeneity of studies. We will therefore make a final decision to determine the synthesis approach after collection of data, but will aim at applying either a textual narrative synthesis or a thematic analytic synthesis approach.[35,36]

Reporting results

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement and flow diagram will be used to report the result of literature searches.[37] Results of randomized controlled trials will be reported according to the CONSORT statement,[38] for observational studies the STROBE statement,[26] and for qualitative studies the CASP checklist.[27] Results of all studies will be presented in tables, providing information on study design, results and quality of evidence. Separate tables will be provided in the event of different subgroups of patients. We will report results collectively for comparative (sufficiently homogenous) studies, grouped according to their associated risk of bias. Results will be presented separately for randomized controlled trials and NRS. Moreover, the nature of the data will also warrant presentation of results according to research methods (e.g. results of qualitative and quantitative studies will be reported separately). Information on methodological decisions made or modified after data collection will be reported. Moreover, we will report involvement of user/interest groups, experts and researchers.

Co-researchers and user involvement

Two adolescent co-researchers (NEC, JRG) have been involved in developing and writing the protocol for the systematic review and will be involved in the systematic review process. They were invited to participate in the systematic review as part of the InvolveMENT research project, which they are already involved in. The InvolveMENT project aims to assess factors affecting adolescents' mental health and to develop and assess the effectiveness of an e-interention. Mental health organizations have also been invited to the planning (but have not yet participated), carrying out and dissemination of the results of this systematic review.

The adolescent co-researchers' role and contribution:

We have participated in the process of developing the systematic review and we will contribute in the review process and for publishing the results. We have agreed to be asked for our opinion on articles the other researchers consider including, their evaluation of the content and quality of the articles, and how results will be reported. We will also publish a lay summary of the results on a Facebook site we are setting up for the research project.

We expressed our interest in being part of the InvolveMENT project team following a presentation that was given at our high school in January 2017 by a researcher (PV). Since then we have had monthly meetings and have been introduced to the field of adolescent mental health research, research terminology and methodology, and the systematic review process. We have also participated at a University workshop to learn the basics of systematic reviews and literature searches. We have asked not to be referred to as “user representatives”, as we are not participants in the research and the term can carry stigma. Instead we asked to be referred to as “adolescent representatives”. It was later decided we should be re-defined as “co-researchers” as we became more actively involved in the research. For examples, we have carried out a questionnaire survey in cooperation with one of the researchers (PV) to learn about the prevalence of mental disorders and stress in teenagers and their use of mental healthcare services. This research was started in June this year and is still ongoing. We plan to present the results to the students who took part in the survey, teachers and school nurses, and we hope it will help to reduce some of the stigma surrounding mental health and to improve mental health services.

DISCUSSION

User involvement has become a priority in healthcare systems in many countries, as it is considered a citizen right to be involved in decisions affecting one’s own healthcare. Although several systematic reviews have summarized existing evidence in user involvement in health research for adults in general or in areas such as safety and education of mental health professionals,[39-41] no review has been published assessing user involvement for adolescents’ mental healthcare. This systematic review therefore aims to fill an existing knowledge gap. It will provide an insight into users’ experiences, effectiveness of and safety issues associated with user involvement at an individual level for adolescents’ own mental healthcare, at an organizational or institutional level for improvement of mental healthcare services and institutions, and at the political level for political decision-making processes. It may thereby provide information that can be valuable for several stakeholder groups, such as patients and their families, healthcare providers, clinicians and decision makers, as well as for developing research strategies to further knowledge in an underexplored field of research. This may include knowledge about ways in which users are involved in decision-making affecting their own mental healthcare and the influence of such involvement on their mental health outcomes. It can also provide information on user involvement affecting delivery and mental healthcare service policy decisions.

There are some potential limitations to this systematic review. There is considerable variation in the literature with regards to used terminology relating to user involvement. This contributes to a risk of missing relevant studies. We have, in an attempt to capture the relevant research literature, included several search strategies using a variety of search terms. Moreover, not including search terms relating to specific mental diagnoses contributes to a risk of missing relevant studies. We are however interested in reviewing the mental health research literature overall, and not focus on a limited number of specific conditions. Inclusion of the breath of different diagnoses would also contribute to an unmanageable number of titles to screen. Moreover, we hope to capture most of the literature relevant to adolescents, although research carried out with varying age groups (single studies reporting on both children and adolescents, or adolescents and young people) may limit the breath of literature we will include in our review. The definition of “adolescents” varies within the context of different national legislations and individual researchers’ and clinicians’ understanding. . We have limited this literature review to adolescents in the age range from 13 to 18 years. It could be argued for a different age span for adolescents, e.g. using UNICEF’s definition and the results of this review will not be applicable to children under the age of 13 or young persons above the age of 18 years. We do however think that our search strategy will help us to capture most of the relevant literature that is of relevance to user involvement in adolescents’ mental healthcare.

Another limitation of this systematic review is the restriction to only six languages. Although we expect to capture most of the published research literature through English language articles, and although some evidence suggests reduced importance of non-English language articles for assessing the effectiveness of interventions,[42] we cannot exclude the possibility that significant literature has been published in other languages. We have selected six languages in an attempt to limit the gaps in the research evidence collected through our review. Our choice of languages is partly due to the strong tradition user involvement has in some of these countries, but is nevertheless limited by our available resources. The inclusion of a wide range of databases increases the likelihood of capturing most of the relevant literature in this field of research. Moreover, the inclusion a database more specifically covering the Nordic literature will increase the chance of also capturing the evidence published in these countries.

Our systematic review team includes adolescent co-researchers. Others have suggested public or user involvement may contribute significantly to various stages of the systematic review process.[43-47] It has however been pointed out that such involvement can in some cases be tokenistic,[47] and that power differentials may affect the usefulness of such involvement.[43] We argue that the involvement of adolescents as co-researchers may contribute by strengthening the usefulness of the review for different stakholder groups, in particular for adolescents themselves.

AUTHOR CONTRIBUTIONS

PV is the guarantor. PV, SEB, SHB, NEC, JRG, KA and MS contributed to the development of the draft manuscript. PV, SEB, SHB, KA and MS contributed to development of the search and assessment strategies. JRG and NEC developed the section reporting on Co-researchers and user involvement. PV, SEB, SHB, NEC, JRG, KA and MS read, provided feedback and approved the final manuscript.

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COMPETING INTERESTS

The authors have nothing to disclose.

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Search strategy example for: User involvement in adolescents' mental healthcare: Protocol for a systematic review

MEDLINE (2002 to 2017)

Search date: 04.08.2017. Limiters – Age Related: Adolescent: 13-18 years

1. (SU adolescent psychology) OR (SU adolescent psychiatry): 15,127
2. (SU clinical decision making) OR (SU community participation) OR (SU consumer participation) OR (SU information dissemination) OR (SU information sharing) OR (SU patient participation) OR (SU personal autonomy) OR (SU self-determination) OR (SU decision making) OR (SU cooperative behavior) OR (SU public opinion): 203,407
3. 1 AND 2: 545
4. (TI adolescen*) OR (TI teen*) OR (TI youth*): 163,384
5. (TI mental) OR (TI psycholog*) OR (TI psychiatr*): 232,363
6. (TI autonom*) OR (TI client-centred) OR (TI collaborat*) OR (TI consultat*) OR (TI contribut*) OR (TI decision making) OR (TI empower*) OR (TI engag*) OR (TI governance) OR (TI inclusi*) OR (TI information sharing) OR (TI involv*) OR (TI mutual agreement) OR (TI negotiat*) OR (TI opinion*) OR (TI patient-centred) OR (TI participat*) OR (TI partnership*) OR (TI perspective*) OR (TI peer support) OR (TI self-determination): 546,436
7. 9 AND 10 AND 11: 416
8. 3 OR 7: 952
9. 3 OR 7 Narrow by SubjectAge: - adolescent: 13-18 years: 817

<u>Result</u>: 817 titles for assessment

PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	3-4
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☐	☒	N/A
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-11
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	338-341
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	☐	☒	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	☐	☒	N/A
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	N/A
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☐	☒	N/A
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	73-148
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to	☒	☐	150-158, 164-178

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		participants, interventions, comparators, and outcomes (PICO)			
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	164-184
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	186-195
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	☒	☐	Appendix A
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	207-219
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	207-211
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	215-224
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	166-179
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	178, 220-224
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	☒	☐	229-237
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☒	☐	250-254
	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 (e.g., I^2, Kendall's tau)	☒	☐	253-262
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-	☒	☐	262-268

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		regression)			
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	267-273
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	232-237
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	243-246