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Primary Subject Heading:	Surgery
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Keywords:	pain, hardware removal, ankle fracture

The benefits of hardware removal in patients with pain after fracture healing of the ankle: a systematic review protocol

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ABSTRACT

Introduction

Residual pain is common in patients after surgical treatment of fractures of the ankle. Sometimes it is hard to determine whether the pain is due to the implants left in situ or the primary injury itself. In many cases decision is made to remove the implants. Extraction of internal fixation material from the ankle is a common procedure in many orthopedic clinics. There is no evidence based guidelines or consensus regarding the effect of hardware removal from the ankle. The aim of this protocol is to describe the method that will be used to collect, describe and analyse the current evidence regarding hardware removal after fracture healing of the ankle.

Methods and analysis

We will conduct a systematic review on studies regarding the benefits of hardware removal in patients with pain after fracture healing of the ankle that were published after 1960. Study selection will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. We will make a predefined search strategy and use it in several databases. We will include both randomised and non-randomised studies. We will use descriptive statistics to summarize the studies collected. If more than one RCT is collected a meta-analysis will be conducted. The quality of evidence will be assessed using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) guidelines.

Ethics and dissemination

No ethics approval is required as no primary data will be collected. Once complete, the results will be made available by peer-reviewed publication.

Trial registration number

PROSPERO registration number CRD42016039186

STRENGTHS AND LIMITATIONS

- Hardware removal of the ankle after fracture healing is a very common procedure and this study will be relevant to many orthopaedic clinics and patients.
- It will provide current evidence on hardware removal from the ankle after fracture healing in adults.
- Exclusion of studies published in other languages than English may lead to language bias.
- Controlled randomised studies with comparable outcomes may not be available for meta-analysis.

BACKGROUND

Rationale

Ankle fractures are among the most common fractures and are often treated with surgery using metal implants [1]. The incidence of ankle fracture peaks in elderly women due to osteoporosis and in younger men related to high-energy trauma [2] and accounts for 9% of all adult fractures [3]. The majority of patients surgically treated for ankle fractures report high rates of functional outcomes [4 5] and in long-term follow-up this seems to improve even further [6]. Although persistent pain is common among patients surgically treated for ankle fractures [7]. After healing of the fracture the implant has no further function. There are different opinions among surgeons whether the metal implants should be routinely removed after fracture healing or not. The aim of the procedure is often pain relieve and improved function of the ankle but can also be associated with complications such as infection, neurovascular damage or even refractures. In a survey from 2008, surgeons from 65 countries took part. 58% of the participants did not agree that routine implant removal (overall, not only regarding the ankle) is necessary and 85% of all participants agreed that implant removal poses a burden to hospital resources [8]. In 1996 a study from Finland showed that of all orthopedic operations in Finland 6,3% was removal of implants where implants of the ankle was the most common [9].

Objectives

There are as of yet no evidence-based guidelines on removal of implants after healing of ankle fractures. In the light of the above there is need of a systematic review to determine the evidence available today and if there is none suggest studies for the future.

METHOD AND ANALYSIS

The objective of this study is to systematically review the literature for qualitative evidence that explores patient outcomes regarding pain and patient satisfaction in adults after implant removal following fracture healing of the ankle. This protocol will conform to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol guidelines (PRISMA-P) [10].

Eligibility criteria

This protocol is developed on the basis of population, intervention, comparators and outcomes (PICO) questions.

Population
We will include studies examining all human adults (18 years or older) surgically treated for any type of traumatic fracture of the ankle.

Intervention
Intervention of interest is hardware removal from the ankle after fracture healing. Removal of syndesmotic screw is not included because this is a common routine treatment in many orthopedic institutions that aims to increase joint movement rather than pain relief [11]. Type of hardware (plates, screws, material, model or manufacturer) will not be differentiated.

Comparison
For the intervention all comparators will be of interest. All studies except systematic reports and case studies will be included in this systematic review.

Outcome
Reduced pain and patient satisfaction are of primary interest. If reported on, this will be analysed and graded. Pain will be assessed using the visual analogue scale (VAS) (0–100) or any other analogue pain scale. Patient satisfaction will be assessed using any self-reporting form. Self-reporting forms anticipated to be used by included studies are Short Form-36 Health Survey (SF-36) [12], The Short-Form McGill Pain Questionnaire [13] and Short Form Musculoskeletal Functional Assessment (SMFA) [14]. The scores will be modified to make comparison possible. A standardized mean difference will be calculated for each study and all scales will be modified so that lower score is worse outcome.
Secondary outcomes will be complication rate of wound infection following intervention or re-fracture within the time of follow-up. The complication rate will be measured as percentage of included patients in the studies.

Search strategy

The search strategy will be constructed by the first author. A librarian with expertise in healthcare databases and systematic reviews will be consulted. Literature search will be conducted using medical subject headings (MeSH) and text words related to hardware removal after fracture healing in the ankle. Searches will be done in PubMed/MEDLINE, Cochraine Collaboration and EMBASE. Only studies written in English will be included and studies published before 1960 will be excluded. The reference list of eligible studies will be scanned. Should the time consumption of the review process be more than 12 months an update search will be made to include all the latest articles that might be of interest. The initial search strategy in PubMed will be as follows:

(ankle[MeSH Terms] OR ankle injuries[MeSH Terms] OR ankle fractures[MeSH Terms] OR ((fracture OR fractures) AND (ankle OR malleolus OR malleolar OR bimalleolar OR trimalleolar))) AND (("device removal"[MeSH Terms] OR removal OR extraction) AND (hardware OR implant OR implants OR "internal fixation" OR metal OR device OR devices OR "Internal Fixators"[Mesh]))

Study records

Search results from Pubmed/MEDLINE, Cochraine Collabortation and Embase will be downloaded and managed in Endnote X7 (Thomson Reuters, Philadelphia, PA, USA). Two members of the review team (A.T and M.H) will independently screen the titles and abstracts yielded by the search against the inclusion criteria. The selected studies will then be studied in full text by A.T and M.H whom will decide if they meet the inclusion criteria. If different opinions weather a study meets the inclusion criteria or not a third party (O.S) will make the final decision. Rejected articles in the search will be commented on and filed for record. Neither of the review authors will be blind to the journal titles or to the study authors or institutions. A standardized data collection form, REDCap (Research Electronic Data Capture) [15], will be used to extract data that includes all patient related outcomes. Data extraction will be carried out by A.T and then verified by M.H to reduce bias. If disagreement or discussion occurs, a senior member of the review team (O.S) will act as arbitrator. Data to be extracted is publication year, author, study design, size of population, time to follow-up, drop-out-rate, patient reported outcome score(s), complication rate, mean age and female percentage. All authors will read an have input on the final report.

Risk of bias assessment

For randomized controlled studies, the Cochraine Collaboration tool for assessing the risk of bias will be used[16]. The methodological quality of included non-randomised studies will be evaluated using the validated Newcastle–Ottawa scale (NOS)[17] as recommended by the Cochrane Non-Randomized Studies Methods Working Group. Using NOS the quality of a study will be judged on the selection of the study groups, the comparability of the groups and the ascertainment of outcome of interest. Each study included will be investigated and judged by A.T and M.H independently. In case of discrepancy or disagreement O.S will act as an arbitrator. Studies with high risk of bias will be omitted.

Data synthesis and analysis

I case of two or more comparable randomised studies a meta-analysis will be conducted.

For non-RCT studies we will use descriptive statistics to summarise characteristics and findings of the included studies.

The quality of evidence for all outcomes in the included studies will be graded using the Grading of Recommendation Assesment, Development and Evalutation working group methology (GRADE) [18]. The GRADE score is based on study quality, inconsistency of result, indirectness of evidence, imprecision, publication bias, large magnitude of effect, effect of plausible residual confounding. The final GRADE score is devided into 4 categories (high, moderate, low or very low) reflecting the quality of the evidence.

If important data is missing attempt will be made to contact the corresponding author.

If we need to amend this protocol, we will give the date of each amendment, describe the change and give the rational. Changes will not be incorporated into the protocol.

DISCUSSION

Today, removal of metal implants after ankle surgery is a common surgical procedure in many orthopedic clinics. Whether this procedure is beneficial to the patient is not clear and therefor a systematic review is needed.

A quick scan of the literature prior to this review did not come across any randomised studies regarding this subject and it is possible that this systematic review will not offer evidence-based recommendations on weather or not metal implants should be removed after ankle surgery. However, since this procedure is very common this systematic review may contribute to state what is known today and inspire to further studies in the future.

ETHICS AND DISSEMINATION

No ethics approval is required as no primary data will be collected. Once complete, the results will be made available by peer-reviewed publication.

FUNDING STATEMENT

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

COMPETING INTERESTS

None

DATA SHARING STATEMENT

No additional data are avalible.

AUTHORS CONTRIBUTIONS

A.T is the main author of the protocol and will also write the final report. Selection of studies and data extraction will be conducted by A.T and M.H. O.S will act as arbitrator in case of disagreement and supervise A.T and M.H. H.N will act as an advisor for A.T throughout the process. All authors will read and provide input for improvements of the final report.

ACKNOWLEDGMENTS

Many thanks to librarian Alena Haarmaan for help in constructing the database search strategy.

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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	Page number in main document
ADMINISTRATIVE INFORMATION			
Title:			1
Identification	1a	Identify the report as a protocol of a systematic review	
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	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	6
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	5
Support:			6
Sources	5a	Indicate sources of financial or other support for the review	
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
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	4
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	4,5
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	5

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	5
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)	5
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	5
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	4
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	4
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	5
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	5
	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 I^2, Kendall's τ)	5
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	-
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	5
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	5
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	5

*** 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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The benefits of hardware removal in patients with pain or discomfort after fracture healing of the ankle: a systematic review protocol

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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Emergency medicine
Keywords:	pain, hardware removal, ankle fracture

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Word count: 1486

Key words: ankle fracture, hardware removal, pain

ABSTRACT

Introduction

For any orthopaedic surgeon working with trauma, ankle fractures is one of the most common injuries treated. The treatment of ankle fractures can be conservative, using external fixation but more commonly the fractures are treated with open reduction and internal fixation. Residual pain and discomfort is common in patients after surgical treatment of fractures of the ankle. Sometimes it is difficult to determine whether the pain or discomfort is due to the implants left in situ or the primary injury itself. In many cases decision is made to remove the implants. Extraction of internal fixation material from the ankle is a common procedure in many orthopaedic clinics. There is no evidence based guidelines or consensus regarding the effect of hardware removal from the ankle. The aim of this protocol is to describe the method that will be used to collect, describe and analyse the current evidence regarding hardware removal after fracture healing of the ankle.

Methods and analysis

We will conduct a systematic review on studies regarding the benefits of hardware removal in patients with pain or discomfort after fracture healing of the ankle that were published after 1967. Study selection will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. We will make a predefined search strategy and use it in several databases. We will include both randomized (RCT) and non-randomized studies. We will use descriptive statistics to summarize the studies collected. If more than one RCT is collected a meta-analysis will be conducted. The quality of evidence will be assessed using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) guidelines.

Ethics and dissemination

No ethics approval is required as no primary data will be collected. Once complete, the results will be made available by peer-reviewed publication.

Trial registration number

PROSPERO registration number CRD42016039186

STRENGTHS AND LIMITATIONS

- Hardware removal of the ankle after fracture healing is a very common procedure and this study will be relevant to many orthopaedic clinics and patients.
- We hope to provide evidence based data on outcome following hardware removal from the ankle after fracture healing in adults.
- Studies published in other languages than English may lead to language bias and are therefore excluded. However, this may also lead to exclusion bias as relevant studies may be published in other languages.
- Randomized control trials with comparable outcomes may not be available for meta-analysis.

BACKGROUND

Rationale

Ankle fractures are among the most common fractures and are often treated with surgery using metal implants [1]. The internal fixation often consist of some kind of metallic implant such as screws, plates and cerclage. The implants are then either removed or left in situ after fracture healing. The incidence of ankle fracture peaks in elderly women due to osteoporosis and in younger men related to high-energy trauma [2]. Ankle fractures account for 9% of all adult fractures [3]. The majority of patients surgically treated for ankle fractures report high rates of functional outcomes [4 5] and in long-term follow-up this seems to improve even further [6]. However, persistent pain is common among patients surgically treated for ankle fractures [7]. Once the fracture has healed the implant has no further function. There are different opinions among surgeons as to whether the metal implants should be routinely removed after fracture healing or not. The indication to remove the hardware is often pain relief and improved function of the ankle but the procedure can also be associated with complications such as infection, neurovascular damage or even refractures. In a survey from 2008, surgeons from 65 countries took part. The survey showed that 58% of the participants did not agree that routine implant removal was necessary in general (not limited to ankle fractures) and 85% of all participants concurred that implant removal poses a burden to hospital resources [8]. In 1996 a study from Finland showed that of all orthopaedic operations in Finland 6,3% was removal of implants whereas implants of the ankle was the most common [9]. There are currently no evidence-based guidelines on removal of implants after healing of ankle fractures. A systematic review is needed to assess the evidence available and to determine if further studies are required.

Objectives

The objective of this study is to systematically review the literature for qualitative evidence that explores patient outcomes regarding pain and patient satisfaction in adults after implant removal following fracture healing of the ankle.

METHOD AND ANALYSIS

This protocol will conform to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol guidelines (PRISMA-P) [10].

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This protocol is developed on the basis of population, intervention, comparators and outcomes (PICO) questions.

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We will include studies examining all human adults (18 years or older) surgically treated for any type of traumatic fracture of the ankle.

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Intervention of interest is hardware removal from the ankle after fracture healing. Removal of syndesmotic screws are not included since this is a common routine treatment in many orthopaedic institutions that aims to increase joint movement rather than pain relief [11]. Type of hardware (plates, screws, material, model or manufacturer) will not be differentiated.

Comparison
For the intervention all comparators will be of interest. All studies except systematic reviews and case studies will be included in the systematic review.

Outcome
Reduced pain and patient satisfaction are of primary interest. If reported on, this will be analysed and graded. Pain will be assessed using the visual analogue scale (VAS) (0–100) or any other analogue pain scale. Patient satisfaction will be assessed using any self-reporting form. Self-reporting forms anticipated to be used include Short Form-36 Health Survey (SF-36) [12], The Short-Form McGill Pain Questionnaire [13] and Short Form Musculoskeletal Functional Assessment (SMFA) [14]. The scores will be modified to make comparison possible. A standardized mean difference will be calculated for each study and all scales will be modified so that lower score is worse outcome.
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Study records

Search results from Pubmed/MEDLINE, Cochraine Collabortation and Embase will be downloaded and managed in Endnote X7 (Thomson Reuters, Philadelphia, PA, USA). Two members of the review team (A.T and M.H) will independently screen the titles and abstracts yielded by the search against the inclusion criteria. The selected studies will then be studied in full text by A.T and M.H who will assess if they meet the inclusion criteria. If there is disagreement whether a study meets the inclusion criteria or not a third party (O.S) will make the final decision. Rejected articles in the search will be commented on and filed for record. Neither of the review authors will be blind to the journal titles or to the study authors or institutions. A standardized data collection form, REDCap (Research Electronic Data Capture) [15], will be used to extract data that includes all patient related outcomes. Data extraction will be carried out by A.T and then verified by M.H to reduce bias. If disagreement or discussion occurs, a senior member of the review team (O.S) will act as arbitrator. Data to be extracted is publication year, author, study design, size of population, time to follow-up, drop-out-rate, patient reported outcome score(s), complication rate, mean age and gender. All authors will read and have the chance to contribute to the final report.

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In the event of the search strategy yielding two or more comparable randomised studies, a meta-analysis will be conducted.

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If important data is missing attempt will be made to contact the corresponding author.

If we need to amend this protocol, we will give the date of each amendment, describe the change and give the rational. Changes will not be incorporated into the protocol.

DISCUSSION

Today, removal of metal implants after ankle surgery is a common surgical procedure in many orthopaedic clinics. Whether this procedure is beneficial to the patient or not is unclear and a systematic review is needed.

A brief scan of the literature prior to this review did not reveal any relevant RCTs and it is possible that this systematic review will therefore not be sufficient to offer evidence-based recommendations on whether or not metal implants should be removed after ankle surgery. In that case the systematic review may reveal that further studies are needed.

ETHICS AND DISSEMINATION

No ethics approval is required as no primary data will be collected. Once complete, the results will be made available by peer-reviewed publication.

FUNDING STATEMENT

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

COMPETING INTERESTS

None

DATA SHARING STATEMENT

No additional data are available.

AUTHORS CONTRIBUTIONS

A.T is the main author of the protocol and will also write the final report. Selection of studies and data extraction will be conducted by A.T and M.H. O.S will act as arbitrator in case of disagreement and supervise A.T and M.H. H.N will act as an advisor for A.T throughout the process. All authors will read and provide input for improvements of the final report.

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Supplementary file

Initial search strategy in PubMed

(ankle[MeSH Terms] OR ankle injuries[MeSH Terms] OR ankle fractures[MeSH Terms] OR ((fracture OR fractures) AND (ankle OR malleolus OR malleolar OR bimalleolar OR trimalleolar))) AND (("device removal"[MeSH Terms] OR removal OR extraction) AND (hardware OR implant OR implants OR "internal fixation" OR metal OR device OR devices OR "Internal Fixators"[Mesh]))

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	Page number in main document
ADMINISTRATIVE INFORMATION			
Title:			1
Identification	1a	Identify the report as a protocol of a systematic review	
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	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	6
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	5
Support:			6
Sources	5a	Indicate sources of financial or other support for the review	
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
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	4
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	4,5
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	4

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	5
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)	5
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	5
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	4
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	3, 4
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	5
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	5
	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 I^2, Kendall's τ)	5
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	-
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	5
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	5
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	5

*** 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.**

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