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International prospective register of systematic reviews



UNIVERSITY *of* York
Centre for Reviews and Dissemination

Systematic review

1. * Review title.

Give the title of the review in English

Acupuncture related adverse events - a systematic review of prospective clinical trials

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

English

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

19/09/2019

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

31/12/2019

5. * Stage of review at time of this submission.

Tick the boxes to show which review tasks have been started and which have been completed. Update this field each time any amendments are made to a published record.

Reviews that have started data extraction (at the time of initial submission) are not eligible for inclusion in PROSPERO. If there is later evidence that incorrect status and/or completion date has been supplied, the published PROSPERO record will be marked as retracted.

This field uses answers to initial screening questions. It cannot be edited until after registration.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

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Provide any other relevant information about the stage of the review here.

Piloting of the study selection process

Piloting of the study selection process

6. * Named contact.

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

Dr. Petra Bäumlér

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Petra

7. * Named contact email.

Give the electronic email address of the named contact.

Petra.Baeumler@med.uni-muenchen.de

8. Named contact address

Give the full institutional/organisational postal address for the named contact.

Dr. Petra Bäumlér

Multidisciplinary Pain Center, Department of Anaesthesiology, University Hospital LMU Munich

Pettenkofenstr. 8a

80336 Munich, Germany

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

0049-89-4400-53625

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Multidisciplinary Pain Center, Department of Anaesthesiology, University Hospital LMU Munich

Organisation web address:

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country now MUST be entered for each person, unless you are amending a published record.**

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Dr Petra Baeumler. Multidisciplinary Pain Center, Department of Anaesthesiology, University Hospital LMU Munich

Professor Dominik Irnich. Multidisciplinary Pain Center, Department of Anaesthesiology, University Hospital LMU Munich

Mrs Theresa Stübinger. Multidisciplinary Pain Center, Department of Anaesthesiology, University Hospital LMU Munich

12. * Funding sources/sponsors.

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

No funding is received

State the funder(s) or award number and the date of award

13. * Conflicts of interest.

List actual or perceived conflicts of interest (financial or academic).

Yes

Petra Bäumler and Dominik Irnich receive honoraria and travel costs from non-profit academic organizations, physician chamber and universities for teaching and lecturing. Theresa Stübinger declares no conflict of interest

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country must be completed for each person, unless you are amending a published record.**

Dr Wenyue Zhang. School of Acupuncture, Moxibustion and Tuina, Beijing University of Chinese Medicine

15. * Review question.

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS or similar where relevant.

What is the risk for minor and serious adverse events caused by acupuncture?

What kind of adverse events can be caused by acupuncture?

What is the risk of the different types of acupuncture related adverse events?

16. * Searches.

State the sources that will be searched (e.g. Medline). Give the search dates, and any restrictions (e.g. language or publication date). Do NOT enter the full search strategy (it may be provided as a link or attachment below.)

Databases: PubMed, Scopus, EMBASE

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Publication period: inception to 15th September 2019

Search Terms: acupuncture, adverse event(s), adverse effect(s)

17. URL to search strategy.

Upload a file with your search strategy, or an example of a search strategy for a specific database, (including the keywords) in pdf or word format. In doing so you are consenting to the file being made publicly accessible. Or provide a URL or link to the strategy. Do NOT provide links to your search **results**.

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied in your systematic review.

Acupuncture is the insertion of fine needles at certain points, so called acupuncture points, on the patients body for therapeutic or preventive purposes. Acupuncture originates from ancient Chinese medicine, but is nowadays used worldwide in many different variations. There is level 1 for its effectiveness in acute and chronic pain. Needles are stimulated manually, electrically. Often moxibustion is used as an adjunct. The safety of acupuncture has been debated, and surely needle penetration can cause harms, such as tissue damage, peripheral nerve injury and bleeding. In comparison to analgesic drugs for example, risk and consequences of adverse events are deemed minor, but reviews on the safety of acupuncture are either outdated or lack an assessment of study quality.

19. * Participants/population.

Specify the participants or populations being studied in the review. The preferred format includes details of both inclusion and exclusion criteria.

Humans treated by needle acupuncture

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the interventions or the exposures to be reviewed. The preferred format includes details of both inclusion and exclusion criteria.

Acupuncture involving either manual or electrical needle stimulation with or without moxibustion

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the intervention/exposure will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

As the aim of this review is to estimate the crude risk of acupuncture related adverse events, comparator group data are not relevant.

22. * Types of study to be included.

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Give details of the study designs (e.g. RCT) that are eligible for inclusion in the review. The preferred format includes both inclusion and exclusion criteria. If there are no restrictions on the types of study, this should be stated.

Inclusion criteria:

Prospective study

Primary outcome is the risk of acupuncture related adverse events

Treatment involves acupuncture with needles that are stimulated manually or electrically either in combination with or without moxibustion

Articles published in English or German before 15th of September 2019

Exclusion criteria

Treatment involves injection

Treatment involves skin penetration with any other device than classical acupuncture needles such as press needles, cauterization devices etc.

Treatment is restricted to non-penetrating stimulation such as laser acupuncture, acupressure, transcutaneous electrical nerve stimulation or moxibustion

Treatment is restricted to particular body parts associated with low risk of adverse events such as auricular or one-point acupuncture

23. Context.

Give summary details of the setting or other relevant characteristics, which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

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Risk of serious and minor acupuncture related adverse events (AE) as number of AE per treatment and patients with AE per 100.000 patients treated

* Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.
adverse events occurring during or after acupuncture treatment

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

Type of adverse events caused by acupuncture

Risk of the different types of acupuncture related adverse-events

* Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.
adverse Events occurring during or after acupuncture treatment

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Incidence of acupuncture related adverse events will be extracted as the number of adverse events per treatment and as number of patients experiencing these adverse events per the total number of patients treated. Data extraction will be performed by two independent reviewers who will extract all available data on acupuncture related adverse events from identified studies. This includes extraction of the total number of and/or patients with minor and serious adverse events as well as extraction of the numbers of and/ or patients with all types of adverse events separately in relation to the number of treatments and/or total number of patients treated. The different types of adverse events will be categorized into supersets of adverse events whose risk is calculated separately.

27. * Risk of bias (quality) assessment.

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

Included studies will be assessed for risk of bias according to a checklist developed by Faillie and colleagues for systematic reviews focusing on adverse events.

28. * Strategy for data synthesis.

Describe the methods you plan to use to synthesise data. This **must not be generic text** but should be **specific to your review** and describe how the proposed approach will be applied to your data. If meta-analysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

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We will provide the reader with the range (min and max) and the median of the total risk to suffer from an minor and serious adverse event during or after acupuncture treatment that was identified by the studies. The same measures will be provided for the risks of the supersets of adverse events identified from the different studies.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

It is likely that certain subsets of patients are at a higher risk for acupuncture related adverse events.

According to the obtained results we will provide characteristics and separate summaries of studies including patients with a high and low risk profile.

30. * Type and method of review.

Select the type of review, review method and health area from the lists below.

Type of review

Cost effectiveness

No

Diagnostic

No

Epidemiologic

No

Individual patient data (IPD) meta-analysis

No

Intervention

No

Meta-analysis

No

Methodology

No

Narrative synthesis

No

Network meta-analysis

No

Pre-clinical

No

Prevention

No

Prognostic

No

Prospective meta-analysis (PMA)

No

Review of reviews

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No

Service delivery
No

Synthesis of qualitative studies
No

Systematic review
Yes

Other
No

Health area of the review

Alcohol/substance misuse/abuse
No

Blood and immune system
No

Cancer
No

Cardiovascular
No

Care of the elderly
No

Child health
No

Complementary therapies
Yes

COVID-19
No

Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders
No

Eye disorders
No

General interest
No

Genetics
No

Health inequalities/health equity
No

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Infections and infestations
No

International development
No

Mental health and behavioural conditions
No

Musculoskeletal
No

Neurological
No

Nursing
No

Obstetrics and gynaecology
No

Oral health
No

Palliative care
No

Perioperative care
No

Physiotherapy
No

Pregnancy and childbirth
No

Public health (including social determinants of health)
No

Rehabilitation
No

Respiratory disorders
No

Service delivery
No

Skin disorders
No

Social care
No

Surgery
No

Tropical Medicine
No

Urological
No

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

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English

There is an English language summary.

32. * Country.

Select the country in which the review is being carried out. For multi-national collaborations select all the countries involved.

Germany

33. Other registration details.

Name any other organisation where the systematic review title or protocol is registered (e.g. Campbell, or The Joanna Briggs Institute) together with any unique identification number assigned by them. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

The review has not been registered elsewhere.

34. Reference and/or URL for published protocol.

If the protocol for this review is published provide details (authors, title and journal details, preferably in Vancouver format)

Add web link to the published protocol.

Or, upload your published protocol here in pdf format. Note that the upload will be publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Do you intend to publish the review on completion?

Yes

Give brief details of plans for communicating review findings.?

A paper presenting the review results will be submitted to a journal listed in MEDLINE. Furthermore, results will be published at international congresses.

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords help PROSPERO users find your review (keywords do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

acupuncture, adverse-event, adverse-effect, safety, needling, moxibustion, traditional Chinese medicine

37. Details of any existing review of the same topic by the same authors.

If you are registering an update of an existing review give details of the earlier versions and include a full bibliographic reference, if available.

38. * Current review status.

Update review status when the review is completed and when it is published. New registrations must be ongoing.

Please provide anticipated publication date

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Review_Ongoing

39. Any additional information.

Provide any other information relevant to the registration of this review.

40. Details of final report/publication(s) or preprints if available.

Leave empty until publication details are available OR you have a link to a preprint. List authors, title and journal details preferably in Vancouver format.

Give the link to the published review or preprint.