|  |  |
| --- | --- |
| cid:98ba00bc-09fe-4cce-a74d-5fb2725fb519 | **Title Registration Form: interventions** Version 4, July 2020 |

Please complete this form to outline your proposal for a Cochrane Review. Complete all sections in full. Email the completed form to Ms. Gudrun Paletta, Assistant Managing Editor, Cochrane Metabolic and Endocrine Disorders Group: paletta@med.uni-duesseldorf.de.

|  |
| --- |
| **Data Protection**The personal data included in this form will be used to complete your Cochrane author profiles if the title is accepted. Both successful and unsuccessful submissions may be archived for the Review Group’s records. Please see the [Cochrane Privacy Policy](https://community.cochrane.org/organizational-info/resources/policies/policies-all-members-and-supporters/cochrane-privacy-policy) for further information. 🞏By submitting this form, we give Cochrane permission to process the data included here. |

|  |
| --- |
| **IMPORTANT: Disclosure of Conflicts of interest**Please read Cochrane’s policy on [Conflicts of interest and Cochrane Reviews (2) Authors of Cochrane Reviews](https://community.cochrane.org/editorial-and-publishing-policy-resource/ethical-considerations/conflicts-interest-and-cochrane-reviews). Confirm below whether any member of the author team has a potential conflict of interest. If your title is accepted, the Review Group will request a full Declaration of Interest from each member of the author team. The title will not be registered until the Review Group has assessed any relevant Conflict of Interest. |
| **Declarations of interest** |
| All authors must read [Cochrane's Conflict of Interest Policy](https://community.cochrane.org/editorial-and-publishing-policy-resource/ethical-considerations/conflicts-interest-and-cochrane-reviews). Before the title can be registered, each author must declare any relevant financial interest from the three years prior to the date of this submission. **Important information**• Individuals who are employed (or were employed in the previous 3 years) by a company that has a real or potential financial interest in the outcome of the Cochrane Review (including but not limited to drug companies or medical device manufacturers), or who hold or have applied for a patent related to the Cochrane Review are prohibited from being Cochrane Review authors.• Commercial interests that should be declared include, but are not limited to: income from private clinical practice (if relevant to the topic); ownership of stocks related to industry; legal advice related to the topic; consultancies; honoraria; fellowships; speaker’s fees; involvement in primary research in the subject area of their review; funding for primary research in the subject area of the review; and any other interests that others may judge relevant. (Also: such financial support may include remuneration from a consultancy, grants, fees, fellowships, support for sabbaticals, royalties, stocks from pharmaceutical companies, advisory board membership or otherwise.)• A commercial sponsor or source is defined as any for-profit manufacturer or any other for-profit source with a real or potential vested interest in the findings of a specific Cochrane Review. • There must be a majority of non-conflicted authors for any particular review and the lead (first) author must have no conflicts. For example, if two authors in a review team have received travel grants from a commercial interest, there must be at least three other non-conflicted authors and the lead (first) author must have no conflicts. |
| **Have all members of the author team read** [Cochrane's Conflict of Interest Policy](https://community.cochrane.org/editorial-and-publishing-policy-resource/ethical-considerations/conflicts-interest-and-cochrane-reviews)**?** Yes 🞏 No 🞏**Do any members of the author team authors have a potential conflict of interest?** Yes 🞏 No 🞏 |
| If yes, you should discuss these potential conflicts with the Review Group’s Managing Editor before submitting this form. Failure to disclose potential conflicts at this stage, or at any point during the writing of the review, may lead to it being rejected for publication or being removed from the Cochrane Library at a later date. |

|  |
| --- |
| Essential checks before title submission:* We have searched the [*Cochrane Database of Systematic Reviews*](https://www.cochranelibrary.com/advanced-search) in the Cochrane Library for published reviews and protocols and can confirm that this proposal has not been covered by another Cochrane Review.
* We have checked that this proposal falls within the scope of Cochrane Metabolic and Endocrine Disorders Group and that it has not already been covered in another Cochrane review (check our existing registered titles at <https://endoc.cochrane.org/our-reviews> ).
* We understand that all authors must follow the [*Cochrane Handbook for Systematic Reviews of Interventions*](http://handbook.cochrane.org/).
* We have read Cochrane’s policy on [Conflicts of interest and Cochrane Reviews (2) Authors of Cochrane Reviews](https://community.cochrane.org/editorial-and-publishing-policy-resource/ethical-considerations/conflicts-interest-and-cochrane-reviews) and have informed the Cochrane Metabolic and Endocrine Disorders Group Managing Editor of any potential conflict of interest.
* We have read [Managing expectations: what does Cochrane expect of authors, and what can authors expect of Cochrane?](https://community.cochrane.org/editorial-and-publishing-policy-resource/cochrane-review-development/managing-expectations) andare aware that preparing a Cochrane Review requires a significant commitment from all authors.
* At least one author must have published a Cochrane Review before.
 |

|  |
| --- |
| **1. Proposed title** *(*see [Cochrane Handbook/section-ii-1-3](https://training.cochrane.org/handbook/current/chapter-ii)) **Your proposal should not overlap with an existing Cochrane Review.** You must use one of the standard formats for Cochrane Review titles:* You must use one of the standard formats for Cochrane Review titles: *intervention]* FOR *[health problem / issue]* e.g. dipeptidyl peptidase-4 (DPP-4) inhibitors for type 2 diabetes mellitus
* *[intervention A]* VERSUS *[intervention B]* FOR *[health problem/ issue]*e.g. extended-release metformin versus immediate-release metformin for type 2 diabetes mellitus *[intervention*] *FOR [health problem/issue]* IN *[participant group]*e.g. interventions for the prevention of nutritional rickets in term born children
 |
| **Title:**  |  |

|  |
| --- |
| **2. Contact person** (this is the person to whom correspondence about the review should be addressed, and who has agreed to take responsibility for maintaining and developing the review. Most usually, this person would (i) be responsible for developing and organizing the review team; (ii) communicate with the editorial base; (iii) ensure that the review is prepared within agreed timescales; (iv) submit the review to the editorial base; (v) communicate feedback to co-authors; and (vi) ensure that the updates are prepared. The contact person need not be the first listed author, and the choice of contact person will not affect the citation for the review) |
| Name: |  |  |
| Email: |  |  |

|  |
| --- |
| **3. Consumer/Patient involvement**  |
| Enlisting a consumer author may not be possible or practical but we now require you to consider how you could involve consumers in the production and/or dissemination of your review. Consumers could, for example, help frame the research question, identify important outcomes and/or give feedback of their understanding of the background section of your protocol. |
| Please state if there has been any consumer involvement in identifying the topic of your review |  |
| Please state your plans for consumer involvement in your review |  |

|  |
| --- |
| 4. Review proposal and inclusion criteria (see [Cochrane Handbook/current/chapter-01-03](https://training.cochrane.org/handbook/current/chapter-01)) |
| What is the **focussed clinical question** your review will address?  |
| Why is it important to do this review? | Why are you proposing to undertake this review? For example, is it particularly topical at the present time?Please use the ‘Review context’ section below to state if this review would form part of a Masters or Doctorate, or of a larger research project. |
| Description of the condition: |  |
| Description of the intervention: |  |
| How the intervention might work: |  |
| Review objectives: | Give a short statement of the primary aim of the review, e.g. to assess the effects of your intervention. |
| Types of study: ([section 3.3](https://training.cochrane.org/handbook/current/chapter-03#a-33-determining-which-study-designs-to-include))  | Outline the types of study that will be included in the review. Most Cochrane Reviews of interventions focus on randomised controlled trials (RCTs). If your review will include non-randomised studies, please provide specific reasons for this. |
| **P**articipants / population: ([section 3.2.1](https://training.cochrane.org/handbook/current/chapter-03#section-3-2-1)) | Outline the types of populations to be included and excluded. Consider demographic factors, the type/stage of disease/condition, and care setting. |
| **I**ntervention: ([section 3.2.2](https://training.cochrane.org/handbook/current/chapter-03#section-3-2-2))*(Outline the details of the intervention you wish to investigate. Consider the dose, intensity, mode of delivery, and combinations of interventions. Are there variations you wish to exclude?)* | Precise definition of intervention(s): |
| **C**omparison: ([section 3.2.3](https://training.cochrane.org/handbook/current/chapter-03#section-3-2-3)) *(What will the intervention be compared to, e.g. placebo, no intervention, standard care?)* | Precise definition of comparator(s): |
| Minimum duration of intervention: |
| Minimum duration of follow-up: |
| **O**utcomes and adverse effects: ([section 3.2.4](https://training.cochrane.org/handbook/current/chapter-03#section-3-2-4)) | List the primary and secondary outcomes you will measure. Please note that all-cause mortality, morbidity/complications, adverse events, health-related quality of life and socioeconomic effects have to be investigated and reported in every CMED review. Adverse events should be a primary outcome parameter. Evaluation of surrogate outcomes only will not be possible. |
| Primary outcome measures (a maximum of three): 1.2.3. Adverse events |
| Secondaryoutcome measures: * …
* …
* …
* …
 |
| **E**xclusion criteria: |  |
| Planned subgroup analyses: ([section 10.11](https://training.cochrane.org/handbook/current/chapter-10#section-10-11)) | Outline any subgroups you plan to investigate for their influence on the size of the treatment effect, e.g. subgroups of the population, variations of the intervention |
| What is the present state of your knowledge? | Please provide references for at least two RCTs relevant to this topic in order to proceed with your review (exceptions have to be negotiated with the CMED:1.2. |
| Did a database search (at least PubMed) for systematic reviews / meta-analyses identify a publication relevant for your question? |
| No | Yes (cite) |
| Other information: | Outline any other factors you plan to consider in your review, or other information you would like to provide, e.g. relevance to consumers, how this review complements other published Cochrane Reviews.(If there are no RCTs or ongoing studies, please explain why it is important to do this review.) |
| Related Cochrane Reviews or protocols: |  |

|  |
| --- |
| **5. Review context** |
| Is the review subject to any specific funding? |  |
| Would the review form part of your postgraduate study, or of a larger research project? |  |
| Has the review already been submitted for publication or published elsewhere? |  |

|  |
| --- |
| **6. Author’s responsibilities** |
| By completing this form, you accept responsibility for preparing, maintaining and updating the review in accordance with Cochrane policy. Cochrane Metabolic and Endocrine Disorders Group will provide support to assist with the preparation of the review.If drafts are not submitted by the agreed deadlines, or if the Review Group is unable to contact you for an extended period, Cochrane has the right to de‑register the title or transfer the title to alternative authors. Cochrane has the right to reject a Cochrane Review at any stage before publication (including unpublished protocols, unpublished Cochrane Reviews, and Cochrane Reviews that are being updated). Please see Cochrane’s [Rejection Policy](https://documentation.cochrane.org/display/EPPR/Rejection%2Bof%2BCochrane%2BReviews)You accept responsibility for maintaining the review in light of new evidence, comments and criticisms, and other developments, and updating the review based on need, or, if requested, transferring responsibility for maintaining the review to others. |
| Publication in the Cochrane Database of Systematic Reviews (CDSR) |
| Cochrane’s support in preparing your review is conditional upon your agreement to publish the protocol, finished review and subsequent updates in the *CDSR*. By completing this form you undertake to publish this review in the *CDSR* before publishing elsewhere (concurrent publication in other journals may be allowed in certain circumstances with prior permission from the CRG).  |
| I understand the commitment required to undertake a Cochrane Review, and agree to publish first in the *CDSR*.**Signed on behalf of the authors:** |
| **Form completed by: …**  |
| **Date:** |  |

|  |
| --- |
| **7. Proposed deadlinesPlease be aware that in case you did not check a protocol draft into Archie (the Cochrane Collaboration’s information and management system) three months after the protocol template was sent to you, your title may be de-registered!** |
| Date you plan to submit a draft protocol (within three months after the protocol template was sent to you): |  |
| Date you plan to submit a draft review (within 12 months after publication of protocol): |  |

|  |
| --- |
| **8. Proposed referees for your review**Please suggest up to three referees for your review question and specify contact details: |
| *Referee 1* | Name:Institution: Email: |
| *Referee 2* | Name:Institution: Email: |

|  |
| --- |
| **9. Review author team** *(*see [Cochrane Handbook/current/chapter-ii#section-ii-2](https://training.cochrane.org/handbook/current/chapter-ii#section-ii-2)*)* In accordance with Cochrane’s [Publication Policy](https://community.cochrane.org/editorial-and-publishing-policy-resource/ethical-considerations/authorship-and-contributorship), each person named as an author must: * Make a substantial contribution to the conception and design, or analysis and interpretation of the data in the review
* Be involved in drafting the review
* Approve the final version of the review before publication
* Agree to be accountable for the accuracy and integrity of the review
 |
| **Contact person / Author 1** *You must have at least two authors to register a title.* |
| Is the contact person an author of the review? | Yes 🞏 No 🞏 |
| Full name and qualifications: *e.g.* *Dr Xia Li, PhD* |  |
| Email addresses: | 1)2) |
| Job title: *e.g. Registrar* |  |
| Department: |  |
| Organisation: e.g. West China Hospital, Sichuan University |  |
| Street: |  |
| City: |  |
| Zip/Postal code: |  |
| State/Province: |  |
| Country: |  |
| What expertise do you bring to the review (e.g. clinical, review methods, statistics)? |  |
| Have you prepared a systematic review before? | Yes 🞏 No 🞏 |
| If yes, have you prepared a Cochrane Review? | Yes 🞏 No 🞏 |
| If yes, please state most recent title: |  |
| Do you already have a role in another Cochrane Review Group? | Yes 🞏 No 🞏 |
| If yes, which one(s)? |  |
| How many titles, protocols, unfinished reviews do you currently have registered with Cochrane Review Groups? |  |
| Level of spoken and written English:*First language / Basic / Average / Fluent* |  |
| Translating clinical trials published in languages other than English is a vital role in Cochrane. I would be willing to assist with translation of clinical trials published in these language(s): | Yes 🞏 No 🞏 |

|  |
| --- |
| **Author 2** *(copy this table for additional authors)* |
| Full name and qualifications: *e.g.* *Dr Xia Li, PhD* |  |
| Email addresses: | 1)2) |
| Job title: e.g. Registrar |  |
| Department: |  |
| Organisation: e.g. West China Hospital, Sichuan University |  |
| Street: |  |
| City: |  |
| Zip/Postal code: |  |
| State/Province |  |
| Country |  |
| What expertise do you bring to the review (e.g. clinical, review methods, statistics)? |  |
| Have you prepared a systematic review before? | Yes 🞏 No 🞏 |
| If yes, have you prepared a Cochrane Review? | Yes 🞏 No 🞏 |
| If yes, please state most recent title: |  |
| Do you already have a role in another Cochrane Review Group? | Yes 🞏 No 🞏 |
| If yes, which one(s)? |  |
| How many titles, protocols, unfinished reviews do you currently have registered with Cochrane Review Groups? |  |
| Level of spoken and written English:*First language / Basic / Average / Fluent* |  |
| Translating clinical trials published in languages other than English is a vital role in Cochrane. I would be willing to assist with translation of clinical trials published in these language(s): | Yes 🞏 No 🞏 |

|  |
| --- |
| **10. Roles and responsibilities**Please advise who has agreed to undertake each of the following tasks: |
| Authors | **Initials** | **Initials** | **Initials** | **Initials** | **Initials** | **Initials** | **Initials** | **Initials** |
|  |  |  |  |  |  |  |
| **PROTOCOL** |
| Draft the protocol |  |  |  |  |  |  |  |  |
| **REVIEW** |
| Develop and run the search strategy: |  |  |  |  |  |  |  |  |
| Obtain copies of studies |  |  |  |  |  |  |  |  |
| Select which studies to include (min. 2 people) |  |  |  |  |  |  |  |  |
| Extract data from studies (min. 2 people) |  |  |  |  |  |  |  |  |
| Enter data into RevMan (checked by 2nd person) |  |  |  |  |  |  |  |  |
| Carry out the analysis |  |  |  |  |  |  |  |  |
| Interpret the analysis |  |  |  |  |  |  |  |  |
| Draft the final review |  |  |  |  |  |  |  |  |
| Update the review |  |  |  |  |  |  |  |  |
| Preliminary order of review authors for citation (initials):  |

|  |
| --- |
| **11. Team resources**  |
| Have you read the *Cochrane Handbook for Systematic Reviews of Interventions*?(see [Cochrane Handbook](https://training.cochrane.org/handbook)) | Yes 🞏  | No 🞏 |
| Do you require training?  | Yes 🞏  | No 🞏 |
| If yes, on which topics?  |  |
| Have you attended a Cochrane Review training workshop? (see <http://www.cochrane.org/tags/events/workshops>) | Yes 🞏  | No 🞏 |
| If yes, on which topics?  |  |
| If no, do you plan to register for a [future Cochrane training event](https://training.cochrane.org/search/site?f%5B0%5D=bundle%3Aworkshop&f%5B1%5D=bm_field_archived%3Afalse)? | Yes 🞏  | No 🞏 |
| Which workshop did you/will you attend?  |
| Have you downloaded and installed the newest version of RevMan, the Cochrane review software? (see [*http://ims.cochrane.org/revman*](http://ims.cochrane.org/revman)) | Yes 🞏  | No 🞏 |
| Have you read the information for review authors on the Cochrane Metabolic and Endocrine Disorders Review Group website? (see [*http://www.endoc.cochrane.org*](http://www.endoc.cochrane.org/)) | Yes 🞏  | No 🞏 |
| Do you have access to these electronic databases:  |
|  *The Cochrane Library* | Yes 🞏  | No 🞏 |
|  MEDLINE *(which interface?, e.g. PubMed):*  | Yes 🞏  | No 🞏 |
|  EMBASE:  | Yes 🞏  | No 🞏 |
|  Other databases (please specify):  | Yes 🞏  | No 🞏 |
| Do you have access to a medical library? | Yes 🞏  | No 🞏 |
|  If yes, can you order journal articles not held in the library? | Yes 🞏  | No 🞏 |
| Do you have access to advice from a medical librarian or information specialist?If yes, please provide information specialist name:  | Yes 🞏  | No 🞏 |
| Do you have access to reference management software (e.g. Endnote)?If yes, which software, and what version?  | Yes 🞏  | No 🞏 |
| Do you have access to a statistician (strongly recommended)?If yes, please provide statistician’s name:  | Yes 🞏  | No 🞏 |
| Have you identified appropriate time and resources to complete the review? | Yes 🞏  | No 🞏 |