

Review proposal form: prognosis reviews

Version 2.1.1, June 2020

Please complete this form to outline your proposal for a Cochrane Review. Complete all sections in full.

Email the completed form to Melina Willson, Managing Editor, Cochrane Breast Cancer Group: cochrane@ctc.usyd.edu.au.

**Please note:** Cochrane Reviews of prognosis studies differ from reviews of interventions and diagnostic test accuracy in many important areas; including searching, data extraction, critical appraisal and meta-analysis. Use the papers in the [Reference list](#_Reference_list) for guidance on prognosis studies and the process of conducting a prognosis review.

**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 note that your names and academic/professional affiliations will be circulated to editors considering this title proposal / this form will be anonymised before circulation to editors considering this title proposal, for reasons of equity and confidentiality.

Please see the [Cochrane Privacy Policy](https://community.cochrane.org/organizational-info/resources/policies/cochrane-privacy-policy) for further information. Please direct any queries about data protection to support@cochrane.org.

🞏 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 in Section 6 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.**

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| Essential checks before title submission:* We are aware that preparing a Cochrane Review requires a significant commitment. At least two authors are required before a title can be registered. The author team should involve someone with statistical and methodological expertise, someone with clinical experience in the topic area, as well as someone who has a high standard of written English.
* We have checked that this proposal falls within the scope of the Cochrane Breast Cancer Group. We have checked the list of [existing registered titles](https://www.cochrane.org/search/site/?adv=1&f%255b0%255d=im_field_stage%253A1&f%255b1%255d=im_field_stage%253A2&f%255b2%255d=im_field_stage%253A3&f%255b3%255d=im_field_terms_archie_topics%253A572&f%5B0%5D=im_field_stage%3A1&f%5B1%5D=im_field_stage%3A2&f%5B2%5D=im_field_stage%3A3&f%5B3%5D=im_field_terms_archie_topics%3A572) and 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 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) and are aware that preparing a Cochrane Review requires a significant commitment from all authors.
* We have created a [Cochrane account](https://account.cochrane.org) for each potential contributor.
* We understand that if the standard of work delivered at protocol or review stage does not meet the standards of the Cochrane Breast Cancer Group and Cochrane within agreed upon timeframes, we reserve the right to withdraw the topic at any stage during the editorial process.
* 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 Managing Editor of any potential conflict of interest.
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| Author registrationNOTE TO REVIEW GROUPS: PLEASE DELETE THIS SECTION BEFORE CIRCULATING THIS FORM. |
| All authors should create [Cochrane Accounts](https://account.cochrane.org/) before submitting this form.To enable editorial staff to identify you in our contributor management system, please list the email addresses used at account registration.  |
| Author 1 | Email used to register for Cochrane Account |
| Author 2 | Email used to register for Cochrane Account |
| Author 3 | Email used to register for Cochrane Account |
| Add other rows as required for other author team members.  |

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| Proposed titleYour proposal should not overlap with an existing Cochrane Review. Choose from the suggested formats below. Use the [CHARMS checklist](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001744) for additional guidance on defining a review question for prognosis studies.* Incidence of [outcome] within [time] in [population]
* [Prognostic factors] for predicting incidence of [outcome] in [population]
* Prediction of [outcome] in [population] using [prognostic factors]
* Prognostic models for predicting [outcome] in [population]
* Performance of [prognostic model] for predicting [outcome] in [population]
* Added/Incremental value of [prognostic factor] on top of [existing prognostic factors/prognostic model] for predicting [outcome] in [population]
* [Predictive factors] predicting the [outcome of treatment] in [population]
* [Factors / Models] predicting differential treatment response in [population]
* [Factors / Models] for predicting treatment response in [population]
 |
| Title: |  |

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| Contact person and review author team(see [Handbook sections II.2.1](https://training.cochrane.org/handbook/current/chapter-ii#section-ii-2-1) and [II.2.2](https://training.cochrane.org/handbook/current/chapter-ii#section-ii-2-2)).Please confirm if the review author team contains at least one person with each of the below areas of expertise. You can provide further author details in Section 8. If additional expertise is required, please [contact the Cochrane Prognosis Methods Group](https://methods.cochrane.org/prognosis/contact-us) before submitting this form.  |
| Yes 🞏 No 🞏 | Clinical content expert: expertise in clinical management of target condition and population under review |
| Yes 🞏 No 🞏 | Systematic reviewer: expertise in preparing systematic reviews of prognosis studies. Please list relevant publications |
| Yes 🞏 No 🞏 | Methodologist: expertise in primary prognostic research methods |
| Yes 🞏 No 🞏 | Statistician: statistical expertise and specific knowledge or training in the meta-analysis of prognostic studies |
| Contact person: | Author who will take responsibility for the review and communicate with the editorial base throughout review development; does not need to be the first listed author. |

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| Review proposal and inclusion criteria(see [Handbook chapter 2](https://training.cochrane.org/handbook/current/chapter-02))Refer to the papers in the [Reference list](#_Reference_list) for guidance when answering the questions below.Ensure your answers can be understood by non-content experts.  |
| Type of prognosis review: | See [Types of primary prognosis studies](#_Types_of_primary).🞏 Overall prognosis🞏 Prognostic factors🞏 Prognostic models🞏 Predictive / treatment selection factors |
| Background:  | Please outline the clinical problem.You may wish to include the following information: * short description of the existing clinical pathway of targeted individuals or patients
* how patients might present with this clinical problem or how targeted healthy individuals might be identified
* the time point of the moment of prognosis in the existing clinical pathway
* relevant outcomes to be predicted

For predictive factor reviews, please refer to the role of treatment.  |
| 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 refer to existing non-Cochrane systematic reviews on this topic to establish relevancy.How will the prognostic or predictive factor(s) or model(s) under review be used, e.g. to determine treatment allocation or abstention, to decide on closer follow-up or monitoring?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. |
| Review objectives: | Outline the review question using the PICOTS format (see [Box 1: PICOTS system](https://www.bmj.com/content/356/bmj.i6460)). |
| Participants / population and setting: ([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. |
| Prognostic model / factor:  | This section is not applicable for overall prognosis reviews.Give a short description of the prognostic / predictive factor(s) or model(s) of interest. Are you proposing to conduct a review of* a specific prognostic factor or model?
* a certain factor-treatment interaction?
* all predictive or prognostic factors / models for a certain outcome in certain patients?
 |
| Outcomes of interest:  | Give a short description of the prognostic outcomes of interest, including the timing of the prediction horizon (days, months, years). |
| Potential included studies: | (Please supply references for at least 3 studies that you would consider for inclusion.) |
| 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 relevant studies, please explain why it is important to do this review.) |
| Related Cochrane Reviews or protocols: |  |

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| 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? |  |

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| 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.*** |

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| Authors' responsibilities |
| By completing this form, you accept responsibility for preparing, maintaining and updating the review in accordance with Cochrane policy. Cochrane [CRG name] 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://community.cochrane.org/editorial-and-publishing-policy-resource/cochrane-review-management/rejection-cochrane-reviews).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).  |
| **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:** |

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| Review authors(see [Handbook sections II.2.1](https://training.cochrane.org/handbook/current/chapter-ii#section-ii-2-1) and [II.2.2](https://training.cochrane.org/handbook/current/chapter-ii#section-ii-2-2))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 Author who will take responsibility for the review, and communicate with the editorial base throughout review development; does not need to be the first listed author – please adjust numbering above. |
| Full name and qualifications: *e.g.* *Dr Xia Li, PhD* |  |
| Job title: *e.g. Registrar* |  |
| Organisation: *e.g. West China Hospital, Sichuan University* |  |
| Data protection and privacy If your title is accepted,as the review contact person, your affiliation and email address will be published with the completed protocol or review in the *Cochrane Database of Systematic Reviews*.Personal data collected and used for publication in the Cochrane Library are covered by the [Wiley Privacy policy](https://www.wiley.com/en-gb/privacy).Your Cochrane Account details will be visible to other groups and contributors in our contact database. If you are allocated a role as a Cochrane author, you will be able to update your profile and can choose to hide your email address and affiliation from contributors not in your primary group. |
| 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)? |  |
| Level of spoken and written English: |  |
| 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): |  |

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| Author 2 You must have at least two authors to register a title. Copy this table for additional authors. |
| Full name and qualifications: *e.g.* *Dr Xia Li, PhD* |  |
| Job title: *e.g. Registrar* |  |
| Organisation: *e.g. West China Hospital, Sichuan University* |  |
| Data protection and privacy If your title is accepted,your affiliation will be published with the completed protocol or review in the *Cochrane Database of Systematic Reviews*.Personal data collected and used for publication in the Cochrane Library are covered by the [Wiley Privacy policy](https://www.wiley.com/en-gb/privacy).Your Cochrane Account details will be visible to other groups and contributors in our contact database. If you are allocated a role as a Cochrane author, you will be able to update your profile and can choose to hide your email address and affiliation from contributors not in your primary group. |
| 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)? |  |
| Level of spoken and written English: |  |
| 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): |  |

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| Roles and responsibilitiesPlease advise who has agreed to undertake each of the following tasks: |
| Draft the protocol: |  |
| Develop and run the search strategy: |  |
| Obtain copies of studies: |  |
| Select which studies to include (2 people): |  |
| Extract data from studies (2 people): |  |
| Enter data into RevMan Web: |  |
| Carry out the analysis: |  |
| Interpret the analysis: |  |
| Draft the final review: |  |

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| Team resources |
| Have you read the two papers listed under [Introduction to systematic reviews of prognosis studies](#_Introduction_to_systematic)? |  |
| Have you attended a Cochrane Prognosis Review training workshop? | Yes 🞏 No 🞏 |
| 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?  |  |
| Which computer operating system do you use? |  |
| Are you familiar with Cochrane’s Review Manager (RevMan) review production tool?  | Yes 🞏 No 🞏 |
| Have you read the information for review authors on the [Cochrane Breast Cancer Group](https://breastcancer.cochrane.org/) website? | Yes 🞏 No 🞏 |
| Do you have access to the [*Cochrane Database of Systematic Reviews*](https://www.cochranelibrary.com/advanced-search)? | Yes 🞏 No 🞏 |
| Do you have access to MEDLINE and Embase? | 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? | Yes 🞏 No 🞏 |
| Do you have access to reference management software (e.g. Endnote)? | Yes 🞏 No 🞏 |
| If yes, which software, and what version? |  |
| Do you have access to a statistician (required)? | Yes 🞏 No 🞏 |
| If yes, please provide statistician’s name: |  |
| Does your statistician have access to advanced statistical software such as STATA, SAS or WinBugs? | Yes 🞏 No 🞏 |
| Do you have contact with consumer groups relevant to this review? | Yes 🞏 No 🞏 |
| If yes, please list relevant consumer groups: |  |
| Have you identified appropriate time and resources to complete the review? | Yes 🞏 No 🞏 |
| Would you like to be assigned a mentor (an experienced author who has volunteered to help new authors)? | Yes 🞏 No 🞏 |

# Reference list

**Essential guidance on conducting systematic reviews of prognosis studies**

Use the papers listed below for guidance when completing this review proposal form and conducting your review, if your title is accepted.

Topics covered:

* framing the review question
* developing the search strategy
* inclusion and exclusion criteria
* critical appraisal
* risk of bias assessment
* meta-analysis
* reporting

## Introduction to systematic reviews of prognosis studies

* Prognosis research: toward evidence-based results and a Cochrane methods group (Riley et al, [J Clin Epidemiol 2007](https://www.jclinepi.com/article/S0895-4356%2807%2900063-7/fulltext)).
* Implementing systematic reviews of prognosis studies in Cochrane (Moons et al, [Cochrane Database Syst Rev 2018](https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.ED000129/full?highlightAbstract=)).

## Full description of the review process (including meta-analysis), from A to Z

* A guide to systematic review and meta-analysis of prediction model performance (Debray et al, [BMJ 2017](https://www.bmj.com/content/356/bmj.i6460)).
* A guide to systematic review and meta-analysis of prognostic factor studies (Riley et al, [BMJ 2019](https://www.bmj.com/content/364/bmj.k4597)).

## Searching for studies

* Search filters for finding prognostic and diagnostic prediction studies in Medline to enhance systematic reviews (Geersing et al, [PLOS One 2012](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0032844)).
* Optimal search strategies for retrieving scientifically strong studies of treatment from Medline: analytical survey (Haynes et al, [BMJ 2005](https://www.bmj.com/content/330/7501/1179)).
* Searching for clinical prediction rules in MEDLINE (Ingui et al, [J Am Med Inform Assoc 2001](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC130084/)).

## Formulating the review question, data extraction and critical appraisal

* Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies: The CHARMS Checklist (Moons et al, [PLOS Med 2014](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001744)).

## Risk of bias assessment

* Assessing bias in studies of prognostic factors (Hayden et al, [Ann Intern Med 2013](https://annals.org/aim/article-abstract/1650776/assessing-bias-studies-prognostic-factors?doi=10.7326%2f0003-4819-158-4-201302190-00009)).
* Evaluation of the quality of prognosis studies in systematic reviews (Hayden et al, [Ann Intern Med 2006](https://annals.org/aim/article-abstract/721332/evaluation-quality-prognosis-studies-systematic-reviews?volume=144&issue=6&page=427))
* PROBAST: A Tool to Assess the Risk of Bias and Applicability of Prediction Model Studies (Wolff et al, [Ann Intern Med 2019](https://annals.org/aim/fullarticle/2719961/probast-tool-assess-risk-bias-applicability-prediction-model-studies)).
* PROBAST: A Tool to Assess Risk of Bias and Applicability of Prediction Model Studies: Explanation and Elaboration (Moons et al, [Ann Intern Med 2019](https://www.ncbi.nlm.nih.gov/pubmed/30596876)).
* See [www.probast.org](http://www.probast.org) for the latest version of the PROBAST tool and examples

## Meta-analysis

* Meta-analysis and aggregation of multiple published prediction models (Debray et al, [Stat Med 2014](https://onlinelibrary.wiley.com/doi/abs/10.1002/sim.6080)).
* External validation of clinical prediction models using big datasets from e-health records or IPD meta-analysis: opportunities and challenges (Riley et al, [BMJ 2016](https://www.bmj.com/content/353/bmj.i3140)).
* Meta-analysis of prediction model performance across multiple studies: Which scale helps ensure between-study normality for the C-statistic and calibration measures? (Snell et al, [Stat Methods Med Res 2017](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6193210/)).
* Meta-analysis of a binary outcome using individual participant data and aggregate data (Riley et al, [Res Synth Methods 2010](https://onlinelibrary.wiley.com/doi/abs/10.1002/jrsm.4))

## GRADE

* Judging the quality of evidence in reviews of prognostic factor research: adapting the GRADE framework (Huguet et al, [Syst Rev 2013](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3930077/))
* Use of GRADE for assessment of evidence about prognosis: rating confidence in estimates of event rates in broad categories of patients (Iorio et al, [BMJ 2015](https://www.bmj.com/content/350/bmj.h870))

## Reporting of systematic reviews

* Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement (Moher et al, [PLOS Med 2009](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000097))
* Meta-analysis of observational studies in epidemiology: a proposal for reporting (Stroup et al, [JAMA 2000](https://jamanetwork.com/journals/jama/article-abstract/192614))

## Types of primary prognosis studies

* Prognosis Research Strategy (PROGRESS) 1: A framework for researching clinical outcomes (Hemingway et al, [BMJ 2013](https://www.bmj.com/content/346/bmj.e5595.long)).
* Prognosis Research Strategy (PROGRESS) 2: Prognostic Factor Research (Riley et al, [PLOS Med 2013](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001380)).
* Prognosis Research Strategy (PROGRESS) 3: Prognostic Model Research (Steyerberg et al, [PLOS Med 2013](https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001381)).
* Prognosis Research Strategy (PROGRESS) 4: Stratified medicine research (Hingorani et al, [BMJ 2013](https://www.bmj.com/content/346/bmj.e5793.long)).