Data Collection Form Template

Developed for the Risk of Bias 2.0 Pilot 2019

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# Notes on Using this Form

This form updates the Cochrane Editorial Resources Committee’s ‘[Data collection form for RCTs’](https://community.cochrane.org/organizational-info/resources/resources-groups/managing-editors-portal/editorialpolicy/editorial-resources-committee) as part of the pilot of Risk of Bias 2.0 in Cochrane Reviews. The previous version of this form included a separate table to record risk of bias assessments. Information is included throughout this form that will help to provide answers to the signalling questions for Risk of Bias 2.0 (see [Handbook Chapters 7 and 8](https://training.cochrane.org/handbook/version-6), and <https://www.riskofbias.info>).

The form can be used to help you to develop your own data collection form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and to design your form accordingly. Information included in the form should be comprehensive and will form the basis of information used in preparing the review, such as summarising the characteristics of included studies, answering signalling questions for assessing the risk of bias, and the synthesis of study results.

Using this form, or an adaptation of it, will help you to meet [MECIR standards](http://www.editorial-unit.cochrane.org/mecir) for collecting and reporting information about studies in your review, and the analysis of their results (see MECIR standards C43 to C73; R39 to R55).

## Notes on developing and using a data collection form for a Cochrane Review:

* Be consistent in the order and style you use to describe the information for each study (using all documents available).
* Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
* Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

# General Information

|  |  |
| --- | --- |
| Review title or ID |  |
| Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)* |  |
| Report ID |  |
| Report ID of other reports of this study including errata or retractions |  |
| Date form completed *(dd/mm/yyyy)* |  |
| Name/ID of person extracting data |  |
| Reference citation |  |
| Trial registration details |  |
| Study author contact details |  |
| Study funding sources *(including role of funders)* |  |
| Possible conflicts of interest *(for study authors)* |  |
| Which of the following sources were obtained? (tick as many as apply) | □ Journal article(s) with results of the trial  □ Trial protocol  □ Statistical analysis plan (SAP)  □ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)  □ Company-owned trial registry record (e.g. GSK Clinical Study Register record)  □ “Grey literature” (e.g. unpublished thesis)  □ Conference abstract(s) about the trial  □ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)  □ Research ethics application  □ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)  □ Personal communication with trialist  □ Personal communication with the sponsor |

# Study eligibility

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study Characteristics | Eligibility criteria  *(Insert inclusion criteria for each characteristic as defined in the Protocol)* | | Eligibility criteria met? | | | Location in text or source *(pg & ¶/fig/table/other)* |
|  |  | | Yes | No | Unclear |  |
| Type of study | Randomised controlled trial | |  |  |  |  |
|  | Quasi-randomised controlled trial | |  |  |  |  |
| Participants |  | |  |  |  |  |
| Types of intervention |  | |  |  |  |  |
| Types of comparison |  | |  |  |  |  |
| INCLUDE | | EXCLUDE | | | | |
| Reason for exclusion |  | | | | | |

**DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW**

# Characteristics of included studies

## Methods

|  |  |  |
| --- | --- | --- |
|  | **Descriptions as stated in report/paper** | **Location in text or source** *(pg & ¶/fig/table/other)* |
| Aim of study*(e.g. efficacy, equivalence, pragmatic)* |  |  |
| Design*(e.g. parallel, crossover, non-RCT. If crossover, details on washout period)* |  |  |
| Unit of allocation*(by individuals, cluster/ groups or body parts)* |  |  |
| Start date |  |  |
| End date |  |  |
| Duration of individual participation *(from recruitment to last follow-up)* |  |  |

## Participants

|  |  |  |
| --- | --- | --- |
|  | Description  *Include comparative information for each intervention or comparison group if available* | Location in text or source *(pg & ¶/fig/table/other)* |
| Population description *(from which study participants are drawn)* |  |  |
| Setting *(including location and social context)* |  |  |
| Inclusion criteria |  |  |
| Exclusion criteria |  |  |
| Method of recruitment of participants *(e.g. phone, mail, clinic patients). If Cluster trials are included, information on when participants were identified.* |  |  |
| Sequence generation |  |  |
| Allocation concealment |  |  |
| Informed consent obtained | Yes No Unclear |  |
| Clusters *(if applicable, no., type, no. people per cluster, intra cluster correlation coefficient and outcome it was calculated for)* |  |  |
| Baseline imbalances *(note particularly if they might raise concerns about the randomisation process)* |  |  |
| Age |  |  |
| Sex |  |  |
| Race/ethnicity |  |  |
| Severity of illness |  |  |
| Co-morbidities |  |  |
| Other relevant sociodemographics |  |  |
| Subgroups planned/measured |  |  |
| Subgroups reported |  |  |

## Participant flow

|  |  |  |
| --- | --- | --- |
| Assessed for eligibility (number) |  | |
| Excluded (number with reasons) |  | |
| Randomised (number) |  | |
| Allocated to intervention (number) *(specify whether no. people or clusters. Add more columns if there are more than two arms)* | Intervention A | Control |
| Received allocated intervention (number) |  |  |
| Did not receive allocated intervention (number) *(give reasons)* |  |  |
| Lost to follow-up (n= ) *(give reasons)* |  |  |
| Discontinued intervention (n= ) *(give reasons)* |  |  |
| Analysed (n= ) *(note that this may differ by outcome and timepoint so add rows as necessary)* |  |  |
| Excluded from analysis (n= ) *(give reasons. Note that this may differ by outcome and timepoint so add rows as necessary)* |  |  |

## Intervention groups

*Copy and paste table for each intervention and comparison group*

**Intervention Group 1: {NAME}**

|  |  |  |
| --- | --- | --- |
|  | Description as stated in report/paper | Location in text or source *(pg & ¶/fig/table/other)* |
| Theoretical basis *(include key references)* |  |  |
| Description *(include sufficient detail for replication, e.g. content, dose, components, details if an adverse event occurs)* |  |  |
| Duration of treatment period |  |  |
| Timing *(e.g. frequency, duration of each episode)* |  |  |
| Delivery *(e.g. mechanism, medium, intensity, fidelity)* |  |  |
| Providers *(e.g. no., profession, training, ethnicity etc. if relevant)* |  |  |
| Blinding of participants, carers and personnel *(in the case of cluster trials, note whether participants or outcome assessors were aware of the trial)* |  |  |
| Co-interventions *(including number of participants for each cointervention)* |  |  |
| Resource requirements *(e.g. staff numbers, cold chain, equipment)* |  |  |
| Integrity of delivery |  |  |
| Compliance |  |  |

# Data and analysis

*Copy and paste the appropriate table for each outcome.*

***Outcome {NAME}***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Description as stated in report/paper | | | | | | Location in text or source *(pg & ¶/fig/table/other)* |
| Comparison |  | | | | | |  |
| Outcome *(Include definition of outcome as provided in report)* |  | | | | | |  |
| Outcome measurement *(Provide information about instruments and scales used to measure the outcome and who measured the outcome and if they were blinded to intervention)* |  | | | | | |  |
| Time points *measured and reported* |  | | | | | |  |
| Person measuring/ reporting |  | | | | | |  |
| Unit of analysis *(by individuals, cluster/ groups or body parts). For cluster trials, were any clusters or participants analysed in a different group to which they were assigned?* |  | | | | | |  |
| Statistical methods used and appropriateness of these *(e.g. I.T.T., adjustment for correlation, imputation, sensitivity analyses, test for carryover in crossover trials)* |  | | | | | |  |
| DICHOTOMOUS (Delete as appropriate) | | | | | | | |
| Results  *(Add rows and cells in accordance with the results reported, e.g. for each time point or subgroup)* | Intervention | | | Comparison | | |  |
| No. with event | Total in group | | No. with event | Total in group | |
|  |  | |  |  | |
| CONTINUOUS/ OTHER (Delete as appropriate) | | | | | | | |
| Scales: upper and lower limits *(indicate whether high or low score is good)* |  | | | | | |  | |
| Is outcome/tool validated? *(include reference for validation if provided)* | Yes No Unclear | | | | | |  | |
| Post-intervention, change from baseline or both? |  | | | | | |  | |
| Results *(Add rows and cells in accordance with the results reported by the trial, e.g. for each timepoint or subgroup, or change and endpoint values)* | Intervention | | | Comparison | | |  |
| Mean (or other result, specify) | SE (or other variance, specify) | No. participants | Mean (or other result, specify) | SE (or other variance, specify) | No. participants |  |
|  |  |  |  |  |  |
| Other outcome information | | | | | | | |
| Any other results reported *(e.g. mean difference, odds ratio, risk difference, CI or P value)* |  | | | | | |  |
| Reanalysis required? *(specify, e.g. correlation adjustment)* | Yes No Unclear | | |  | | |  |
| Reanalysis possible? | Yes No Unclear | | | | | |  |
| Reanalysed results |  | | | | | |  |

Other information

|  |  |  |
| --- | --- | --- |
|  | **Description as stated in report/paper** | **Location in text or source** *(pg & ¶/fig/table/other)* |
| Other outcomes included in the trial but not relevant for the review1 |  |  |
| Economic information *(i.e. intervention cost, changes in other costs as result of intervention)* |  |  |
| Key conclusions of study authors |  |  |
| References to other relevant studies |  |  |
| Correspondence required for further study information *(from whom, what and when)* |  | |

1. This information is useful as it can help determine if other outcomes have been measured but not reported for outcomes that are related, for example progression free survival/ overall survival, hospital admission/length of stay, subdomains of QoL instruments etc.

**Sources:**

Cochrane Glossary. Available from <https://community.cochrane.org/glossary>.

Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.0 (updated July 2019). Cochrane, 2019. Available from [www.training.cochrane.org/handbook](http://www.training.cochrane.org/handbook).