Data collection form

Intervention review – RCTs only

No single form will be appropriate for all reviews. This form should be used as a starting point for to consider the information you need to collect for your review, and design your own form accordingly. Sections can be expanded and added, and irrelevant sections should be removed. Information included should be comprehensive, for use in the text of your review, ‘Characteristics of included studies’ table and statistical analysis.

For extracting data needed for assessing risk of bias in included studies, you are advised to use the Excel tool or Word template available at <https://www.riskofbias.info/welcome/rob-2-0-tool/current-version-of-rob-2>

Notes on using a data collection form:

* 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.
* The form fields in the document allow the form to be completed while locked for editing, or can be deleted.

|  |
| --- |
| **Notes:**       |

General Information

|  |  |
| --- | --- |
| **Study ID***(e.g. author name, year)* |       |
| **Form completed by** |       |
| **Study author contact details** |       |
| **Publication type***(e.g. full report, abstract, letter)* |       |
| **List of included publications** |       |
| **Notes:**       |

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, cluster)* |       |       |
| **Unit of allocation***(by individuals, cluster/ groups or body parts)* |       |       |
| **Start & end dates** |       |       |
| **Total study duration** |       |       |
| **Study funding sources***(including role of funders)* |       |       |
| **Possible conflicts of interest***(for study authors)* |       |       |
| **Notes:**       |

## Participants

|  |  |  |
| --- | --- | --- |
|  | **Description***Include comparative information for each intervention or comparison group if available* | **Location in text or source** *(pg & ¶/fig/table/other)* |
| **Population description***(Company/companies; occupation)* |       |       |
| **Setting***(including location (city, state, country) and social context)* |       |       |
| **Inclusion criteria**  |       |       |
| **Exclusion criteria**  |       |       |
| **Method of recruitment of participants** *(e.g. phone, mail, clinic patients, voluntary)* |       |       |
| **Total no. randomised** |       |       |
| **Clusters***(if applicable, no., type, no. people per cluster)* |       |       |
| **No. randomised per group***(specify whether no. people or clusters)* | *Group 1 name*      | *Group 2 name*      |       |
| **No. missing***(if overall, e.g. exclusions & withdrawals, whether or not missing from analysis)* |       |       |
| **Reasons missing** |       |       |
| **No. missing***(if by group, e.g. exclusions & withdrawals, whether or not missing from analysis)* |       |       |       |
| **Reasons missing** |       |       |       |
| **No. participants moved from one group to another** |       |       |       |
| **Reasons moved** |       |       |       |
| **Baseline imbalances** |       |       |
| **Age** |       |       |
| **Sex (proportion male)** |       |       |
| **Race/Ethnicity** |       |       |
| **Other relevant sociodemographics** |       |       |
| **Subgroups measured** *(eg split by age or sex)* |       |       |
| **Subgroups reported** |       |       |
| **Notes:**       |

Intervention groups

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

## Intervention Group 1

|  |  |  |
| --- | --- | --- |
|  | **Description as stated in report/paper** | **Location in text or source** *(pg & ¶/fig/table/other)* |
| **Group name***(from paper or abbreviation)* |  |  |
| **Theoretical basis** *(include key references)* |       |       |
| **Description** *(include sufficient detail for replication, e.g. components)* |       |       |
| **Duration of treatment period** |       |       |
| **Timing** *(e.g. frequency, duration of each episode)* |       |       |
| **Delivery** *(e.g. type of pedometer, medium, intensity, fidelity)* |       |       |
| **Providers***(e.g. no., profession, training, ethnicity etc. if relevant)* |       |       |
| **Economic information***(e.g. pedometer cost, changes in other costs as result of intervention)* |       |       |
| **Resource requirements***(e.g. staff numbers, equipment)* |       |       |
| **Integrity of delivery** |       |       |
| **Compliance** |       |       |
| **Notes:**       |

Data and analysis

*Copy and paste the appropriate table for each outcome, as required.*

Dichotomous outcome

|  |  |  |
| --- | --- | --- |
|  | **Description as stated in report/paper** | **Location in text or source** *(pg & ¶/fig/table/other)* |
| **Outcome definition** *(with diagnostic criteria if relevant)* |       |       |
| **Person measuring/reporting** |       |       |
| **Unit of measurement** *(if relevant)* |       |       |
| **Scales: upper and lower limits** *(indicate whether high or low score is good)* |       |       |
| **Is outcome/tool validated?** | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Imputation of missing data***(e.g. assumptions made for ITT analysis)* |       |       |
| **Power** *(e.g. power & sample size calculation, level of power achieved)* |       |       |
| **Results** | **Intervention** | **Comparison** |       |
| No. with event | No. measured | No. with event | No. measured |
| *(time point or subgroup, copy rows as needed)*      |       |       |       |       |       |
| **Time points measured but not reported** |       |       |
| **Any other results reported** *(e.g. odds ratio, risk difference, CI or P value)* |       |       |
| **Unit of analysis** *(by individuals, cluster/groups or body parts)* |       |       |
| **Statistical methods used and appropriateness of these** *(e.g. adjustment for correlation)* |       |       |
| **Reanalysis required?** *(specify)* | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Reanalysis possible?** | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Reanalysed results** |       |       |
| **Notes:**       |

Continuous outcome

|  |  |  |
| --- | --- | --- |
|  | **Description as stated in report/paper** | **Location in text or source** *(pg & ¶/fig/table/other)* |
| **Outcome definition** *(with diagnostic criteria if relevant)* |       |       |
| **Person measuring/reporting** |       |       |
| **Unit of measurement** *(if relevant)* |       |       |
| **Scales: upper and lower limits** *(indicate whether high or low score is good)* |       |       |
| **Is outcome/tool validated?** | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Minimally important difference** |       |       |
| **Imputation of missing data***(e.g. assumptions made for ITT analysis)* |       |       |
| **Power** *(e.g. power & sample size calculation, level of power achieved)* |       |       |
| **Post-intervention or change from baseline?** |       |       |
| **Results** | **Intervention** | **Comparison** |  |
| Mean | SD *(or other variance, specify)*  | No. participants | Mean | SD *(or other variance, specify)* | No. participants |       |
| *(time point or subgroup, copy rows as needed)*      |       |       |       |       |       |       |
| **Time points measured but not reported** |       |       |
| **Any other results reported** *(e.g. mean difference, CI, P value)* |       |       |
| **Unit of analysis** *(by individuals, cluster/groups or body parts)* |       |       |
| **Statistical methods used and appropriateness of these** *(e.g. adjustment for correlation)* |       |       |
| **Reanalysis required?** *(specify)* | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Reanalysis possible?** | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Reanalysed results** |       |       |
| **Notes:**       |

Other outcome type

|  |  |  |
| --- | --- | --- |
|  | **Description as stated in report/paper** | **Location in text or source** *(pg & ¶/fig/table/other)* |
| **Outcome definition** *(with diagnostic criteria if relevant)* |       |       |
| **Person measuring/reporting** |       |       |
| **Unit of measurement** *(if relevant)* |       |       |
| **Scales: upper and lower limits** *(indicate whether high or low score is good)* |       |       |
| **Is outcome/tool validated?** | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Imputation of missing data***(e.g. assumptions made for ITT analysis)* |       |       |
| **Power** *(e.g. power & sample size calculation, level of power achieved)* |       |       |
| **Results** | Intervention result | SE (or other variance) | Control result | SE (or other variance) |       |
| *(time point or subgroup, copy rows as needed)*      |       |       |       |       |
|  | Overall results | SE (or other variance) |
| *(time point or subgroup, copy rows as needed)*      |       |       |
| **Time points measured but not reported** |       |       |
| **Any other results reported** *(e.g. mean difference, CI, P value)* |       |       |
| **Unit of analysis** *(by individuals, cluster/groups or body parts)* |       |       |
| **Statistical methods used and appropriateness of these** *(e.g. adjustment for correlation)* |       |       |
| **Reanalysis required?** *(specify)* | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Reanalysis possible?** | [ ] [ ] [ ] YesNoUnclear |       |       |
| **Reanalysed results** |       |       |

Other information

|  |  |  |
| --- | --- | --- |
|  | **Description as stated in report/paper** | **Location in text or source** *(pg & ¶/fig/table/other)* |
| **Key conclusions of study authors** |       |       |
| **References to other relevant studies** |       |       |
| **Correspondence required for further study information** *(from whom, what and when)* |       |
| **Notes:**       |

Definitions

|  |  |
| --- | --- |
| Change from baseline | A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.  |
| Clusters | A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms. |
| Co-morbidities | The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes. |
| Compliance | Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance). |
| Exclusions | Participants who were excluded from the study or the analysis by the investigators. |
| Imputation | Assuming a value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants). |
| Integrity of delivery | The degree to which the specified procedures or components of an intervention are delivered as originally planned. |
| Post-intervention | The value of an outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period). |
| Power | In clinical trials, power is the probability that a trial will obtain a statistically significant result when the true intervention effect is a specified size. For a given size of effect, studies with more participants have greater power. Note that power should not be considered in the risk of bias assessment. |
| Providers | The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training. |
| Reanalysis | Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors). |
| Sociodemographics | Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc. |
| Theoretical basis | The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention |
| Unit of allocation | The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people. |
| Unit of analysis | The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study. |
| Unit of measurement  | The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale. |
| Validation | A process to test and establish that a particular measurement tool or scale is a good measure of that outcome. |

**Sources:**

Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.1 (updated September 2020). Cochrane, 2020. Available from [www.training.cochrane.org/handbook](http://www.training.cochrane.org/handbook).

Last JM (editor), A Dictionary of Epidemiology, 4th Ed. New York: Oxford University Press, 2001.