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Collecting data

Trusted evidence.
Informed decisions.
Better health.

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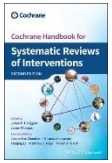
Steps of a Cochrane Review

1. define the question
2. plan eligibility criteria
3. plan methods
4. search for studies
5. apply eligibility criteria
6. **collect data**
7. assess studies for risk of bias
8. analyse and present results
9. interpret results and draw conclusions
10. improve and update review

Session outline

- **data to be collected**
- putting it into practice



See Chapter 5 of the Handbook

What data should you collect?

- comprehensive information about each study
  - population and setting (e.g. age, race, sex, socioeconomic details, disease status, duration, severity, comorbidities)
  - interventions and integrity of delivery
  - methods and potential sources of bias
  - outcomes, authors' conclusions
  - citation, author contact details
  - sources of funding, etc.
- information required for:
  - references
  - description of included studies
  - risk of bias assessment
  - analyses

Characteristics of included studies

Add Note

Amore-Coffea 2000

Add Note

Methods	Randomised parallel group trial.	Add Note
Participants	65 regular coffee drinkers (> 2 cups per day), aged between 20 and 55 years, complaining of regular day time drowsiness. Exclusion criteria: fatigue score < 50 on VAS scale. Setting: Melbourne, Australia.	Add Note
Interventions	Intervention group (n = 31) received one cup of café latte with 100 mg of caffeine. Control group (n = 34) received one cup of decaffeinated café latte, identical in taste.	Add Note
Outcomes	Fatigue (visual analogue scale (VAS)) and irritability (Irritability Negative Affectivity Subscale (INAS)) were measured at 30 minutes and reported as change from baseline. Headache and time to headache were measured at 24 hours.	Add Note
Notes	Published as abstract only.	Add Note
Footnotes (shared)		

Risk of bias

Random sequence generation (selection bias)

Collecting outcome data

- focus on those outcomes specified in your protocol
  - be open to unexpected findings, e.g. adverse effects
- measures used
  - definition (e.g. diagnostic criteria, threshold)
  - timing
  - unit of measurement
  - for scales – upper and lower limits, direction of benefit, modifications, validation, minimally important difference
- numerical results
  - may be in many formats - conversion may be required
  - collect whatever is available
  - no. participants for each outcome & time point

Data types

Data can be presented in various types and formats:

- **Dichotomous data:** Only two categories (binary data)
  - e.g. pregnant or not pregnant
- **Continuous data:** Data measured on a scale
  - e.g. weight
- **Ordinal data:** Categories with a meaningful order (e.g. mild, moderate, severe)
  - e.g. degree of burns (I-IV)
- **Counts and rates:** Number of times an event happens to an individual (counts) over a certain period of time (rates)
  - e.g. number of falls per person in a year
- **Time to event:** time taken before each participant experiences the event
  - e.g. time to discharge from hospital

Data to collect for different types

- **Dichotomous data**
  - Number of participants with events in the experimental group
  - Number of participants with events in the control group
  - Total number of participants in the experimental group
  - Total number of participants in the control group
- **Continuous data**
  - Mean value of the outcome measurements in each group
  - Standard deviation of the outcome measurements in each group
  - Number of participants on whom the outcome was measured in each group

Data to collect for different types

- **Ordinal data**
  - Data in any form they are given in the study report
- **Counts and rates**
  - Data in any form they are given in the study report
- **Time to event**
  - Data in any form they are given in the study report

Data in many formats

Outcome	Reported as	Trials
Volume transfused (ml)	Mean and Standard Error of the Mean (SEM)	4
	Mean and Standard Deviation (SD)	2
	Mean and something in brackets	1
	Median and something in brackets	1
	Two unlabelled numbers e.g. x(y)	1
	Bar chart showing mean per person per day	1
Units transfused	Mean and SEM	1
	Mean only	1
	Total in each group	1
Volume adjusted for patient mass (ml/kg)	Mean and SD	1
Patients who had a transfusion	Number of patients	3
Not reported	Not reported	1

Source: Phil Wiffen

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Session outline

- data to be collected
- **putting it into practice**

Data collection forms

- organise all the information you need
  - reminds you what to collect
  - records what was not reported in the study
  - records the decisions you make about each study
  - source document for data entry into your review
- must be tailored to your review
  - adapt from a good example
- electronic or paper – your choice

Hints and tips

- plan what you need to collect – not too much or too little
- consider including:
  - review title
  - name of author completing the form
  - Study ID (and Record ID if multiple reports of a study)
  - plenty of space for notes (at beginning and throughout)
  - eligibility criteria at the beginning
  - source of each piece of information (e.g. page no.)
  - tick boxes or coded options to save time
  - ‘not reported’ and ‘unclear’ options
  - format to match RevMan data entry
- provide instructions for all authors

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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, risk of bias assessment, and statistical analysis.

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			

Source: Miranda Cumpston

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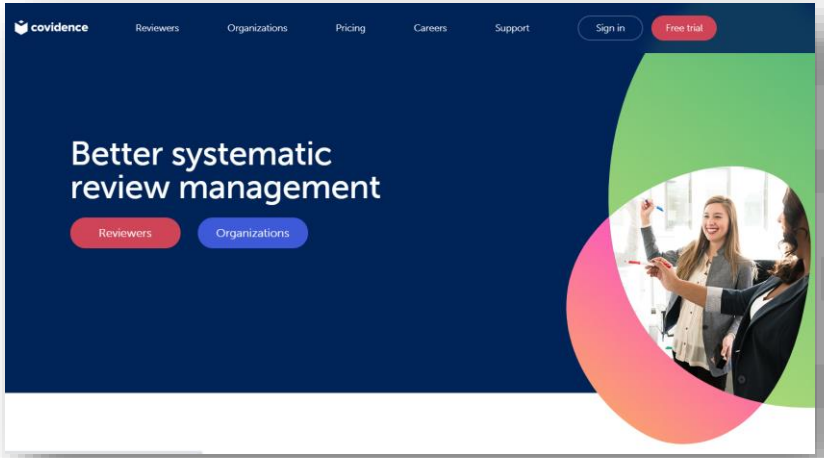
	B	C	D	E	F	G	H	I	J	K	L	M	N
1		**Study**	**Participants**			**Intervention**						**Outcomes**	
2		RCT	16+	employed	not athletes	workplace setting	pedometers	used for entire length	not just accelerometer	controls did not get pedometer	participants could view step count	measured physical activity	
9	Goetzel RZ, Baker KM, Sho	quasi	(y)	y	y	y	This is an environmental intervention, not individual. Individually-focused interventions, ap						
10	Goetzel RZ, Roemer EC, P	quasi	(y)	y	y	y	This is an environmental intervention, not individual. Individually-focused interventions, ap						
11	Hultquist CN, Albright C, The	(y)	y	?Volunteer:	y	?Volunteer	y	y	y	n	n		
12	Lauzon N, Chan CB. Myer	n -Participant Experiences											
13	McAuley, E. (1992). "The rc	n											
14	Morgan, P.J., et al., Efficac	y	y	y	y	y - Tomago	y - YamaxSW:	(y)	y	y	y	y - Leisure-time phys	
15	Polzien 2007I The efficacy (	y	y	?	y	n							
16	Proper KI, Koning M, Van d	systematic review - no new refs											
17	Slootmaker, S. M., M. J. Ch	y	y	y	y	y			n - PAM accelerometer				
18	Touger-Decker R, Denmark	y	y	y	y	y	y	y	y	n - delivery method tested			
19	Tudor-LockeTudor-Locke C	y	(y)	?		n - diabetes education centre							
20													
21	Croteau KA. A preliminary	n		y			y						
22	Wyatt HR, Peters JC, Reed	n											
23	Thomas L, Williams M. Pro												
24	Butler, L and Dwyer, D. Pe	y	y	unclear	y	unclear	y	y	y	unclear - but	y	only Step co	unclear
25	MOREAU, K. L., R. DEGAR	y	y	unclear	y	unclear	y	y	y	not mention	y	only step da	unclear
26													
27													
28													

Author support tools

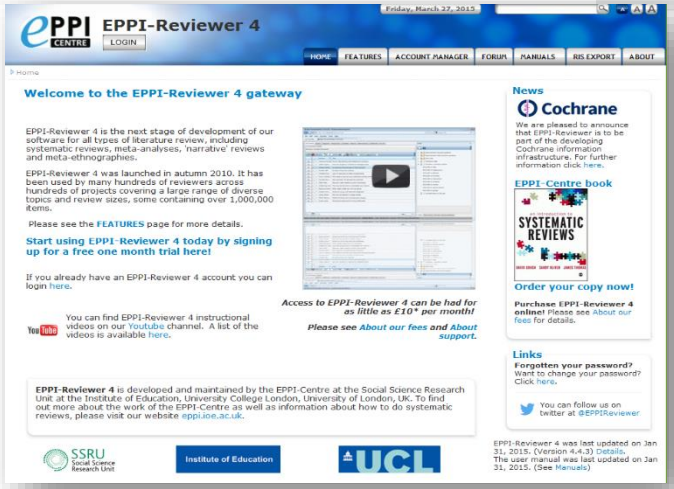
Covidence

- Intervention reviews
- www.covidence.org



EPPI Reviewer

- for complex reviews (non randomised, qualitative studies)
- eppi.ioe.ac.uk/cms/er4



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Minimising bias in data collection

- two authors should independently collect study characteristics and outcome data
  - reduces error
  - checks agreement on subjective judgments and interpretations
- resolving disagreements
  - can usually be resolved by discussion
  - if not, refer to a third author
- pilot data collection process
  - include each person assisting
  - check criteria are consistently applied
  - may need to revise form or instructions

Contacting study authors

- to obtain unreported data or confirm unclear data
  - e.g. unclear risk of bias, missing outcomes, missing SDs
- finding contact details
  - check the study reports
  - check PubMed for recent publications
  - check Google for current staff profiles
- save all your queries for one request
- be clear about what you need
  - avoid sounding critical
  - ask for descriptions rather than yes/no answers
  - providing a table to complete may be helpful

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Managing data

- can enter data directly from form to RevMan
- may need to consider intermediate steps
  - e.g. Excel spreadsheet
  - group studies by comparison & outcomes measured
  - calculations to convert into required statistics
- don’t forget to check your final results against those reported in the study

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What to include in your protocol

- data categories to be collected
- whether two authors will independently extract data
- piloting and use of instructions for data collection form
- how disagreements will be managed
- processes for managing missing data

Take home message

- think carefully about the data you wish to collect
- design and pilot a data collection form
- should be done independently by two authors to minimise error and bias

References

- Li T, Higgins JPT, Deeks JJ (editors). Chapter 5: Collecting data. In: 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.

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