Study selection
for
systematic review & meta-analysis

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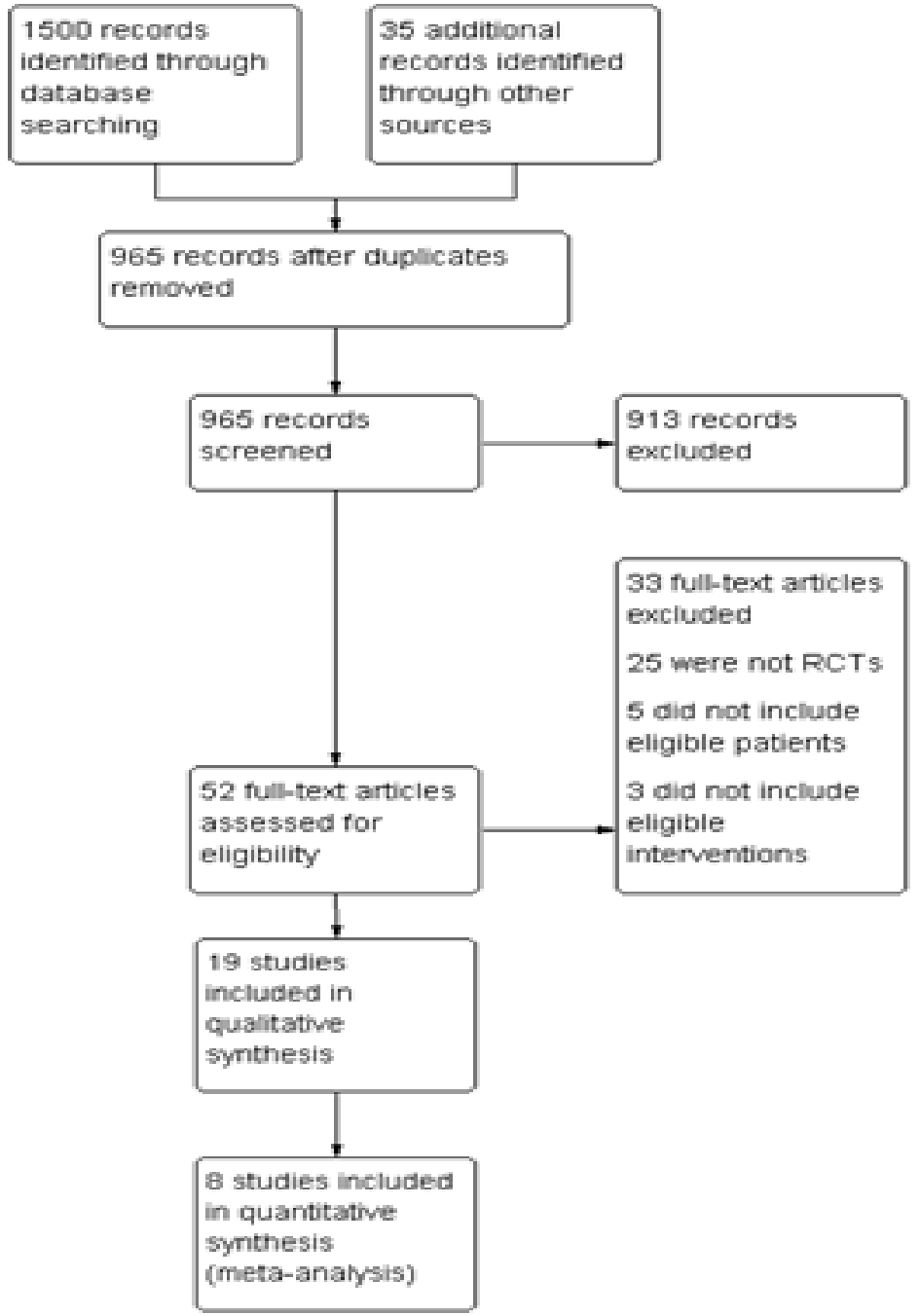
Steps of a Cochrane Review

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



Study selection

- Selecting studies involves judgement, and is highly influential on the outcomes of the review
- compare each record with pre-specified eligibility criteria
  - written summary or checklist may be helpful
- Two authors should independently select studies
  - discussion may identify issues for clarification or gaps in your eligibility criteria
  - pilot selection on a few papers first
  - how will disagreements be resolved? e.g. discussion or referral to a third author

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Practically……

- 1. examine titles and abstracts
  - could the record meet all eligibility criteria?
  - remove obviously irrelevant studies, but be inclusive
- 2. retrieve and examine full text reports
  - does the record meet all eligibility criteria?
  - link together multiple reports of the same study
    - may need all records to make a final decision
    - look for authors, study name, location, intervention, participants, baseline data, dates, registration no.
    - look for errata, comments and retractions
  - correspond with authors if further information is needed

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What about studies with no usable data?

- studies must be included in the review if they meet your criteria
  - results reported in non-standard ways should still be reported in the review
  - studies that do not report outcomes of interest may have measured them – beware of selective reporting
  - studies that did not measure outcomes of interest may only be excluded if outcomes were pre-specified as part of your eligibility criteria

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How to select eligibility criteria

- The choice of inclusion and exclusion criteria should logically follow from the review question (PICO) and should be straightforward.
- Each systematic review has its own purpose and questions, so its inclusion and exclusion criteria are unique.
- Inclusion and exclusion criteria typically belong to one or more of the following categories:
  - (a) study population,
  - (b) nature of the intervention,
  - (c) outcome variables,
  - (d) time period,
  - (e) cultural and linguistic range,
  - (f) methodological quality

Timothy Meline (2006): Selecting Studies for Systematic Review: Inclusion and Exclusion Criteria

study population

- Pertinent characteristics of the study population may include features such as
  - age,
  - gender
  - Disease severity,
  - clinical diagnosis,
  - Population language,
  - Geographic region
  - … .

Timothy Meline (2006): Selecting Studies for Systematic Review: Inclusion and Exclusion Criteria

nature of the intervention

- Nature of the intervention is particularly important if the reviewer addresses the question of treatment efficacy
  - (a) operational definitions for interventions;
  - (b) length, timing, and intensity (dosage) of interventions
  - Defining the dealing with cointervention

Timothy Meline (2006): Selecting Studies for Systematic Review: Inclusion and Exclusion Criteria

outcome variables

- When doing systematic review, you may find a variety of outcome measures represented in the study population—both quantitative and qualitative ones.

- Identifying whether a study can contribute usable data is not always straightforward.
  - Sometimes studies report data, but in a format that does not appear useful or familiar. These studies and their results must be included to give a complete picture of the evidence

- If the study doesn't **report** your outcomes of interest, that doesn't necessarily mean that the study didn't **measure** these outcomes.

- Even if you're really sure that the study did not measure your outcomes of interest at all, you'll need to refer back to your pre-specified eligibility criteria before excluding a study.

Timothy Meline (2006): Selecting Studies for Systematic Review: Inclusion and Exclusion Criteria
Cochrane Handbook section 7.2

Time period

- Systematic reviewers ask what the **relevant time period** within which studies will be selected is.

Timothy Meline (2006): Selecting Studies for Systematic Review: Inclusion and Exclusion Criteria

Cultural and linguistic range

- This item usually reflect in the
  - language
  - place of publication

- Excluding non-English studies limits the scope and validity of results and may introduce publication bias

- In any case, if reviewers choose to restrict the cultural and linguistic range of a review, they should justify the decision in relation to the purpose of the systematic review

(Khan & Kleijnen, n.d.).

Timothy Meline (2006): Selecting Studies for Systematic Review: Inclusion and Exclusion Criteria

Other possible inclusion/exclusion criteria

(a) peer review

(b) study design

(c) sample size

(d) availability of a relevant comparison group in the study

...

Timothy Meline (2006): Selecting Studies for Systematic Review: Inclusion and Exclusion Criteria

Cochrane Training

Caffeine for daytime drowsiness

Eligibility checklist

Study ID: _____

Screened by: _____

1. Study design

Is the study a randomised controlled trial?

❑ Yes ❑ No **(exclude)** ❑ Can't tell

2. Participants

Did the study include adults undergoing normal daily activities?

❑ Yes ❑ No **(exclude)** ❑ Can't tell

Did the study include adults reporting symptoms of daytime drowsiness (e.g. reduced alertness, fatigue or lowered mood)?

❑ Yes ❑ No **(exclude)** ❑ Can't tell

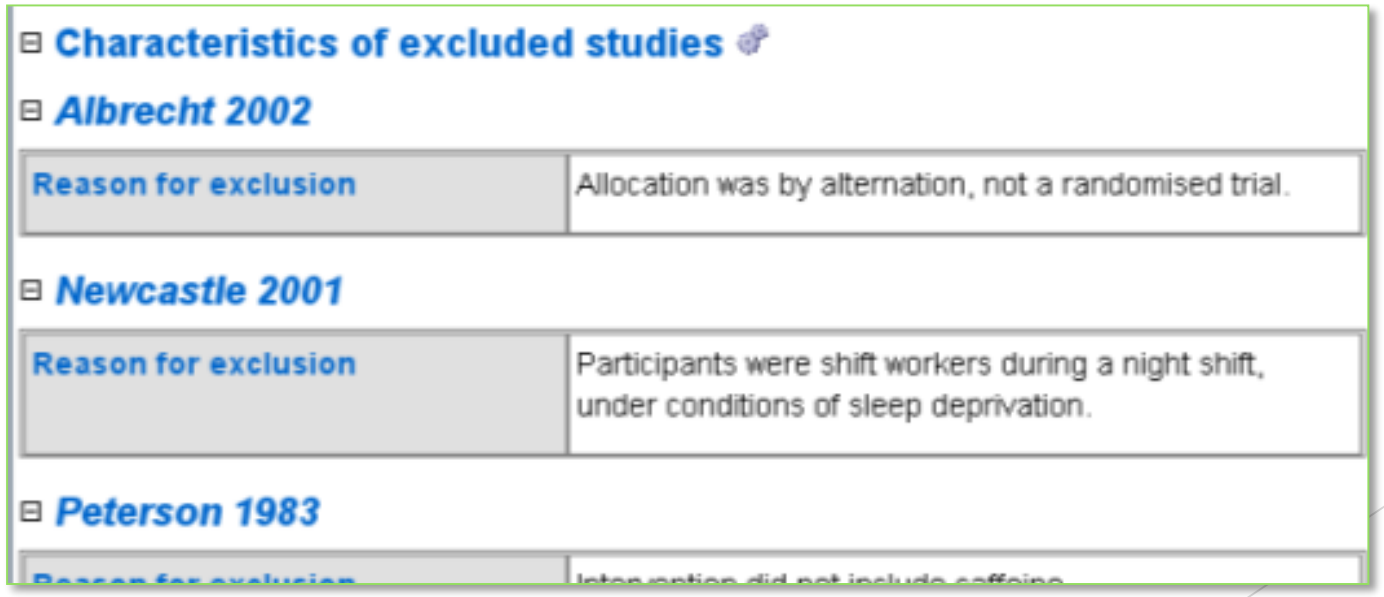
Did the study include participants under conditions of sleep deprivation?

❑ Yes **(exclude)** ❑ No ❑ Can't tell

	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, Th	(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 2007l The efficacy c	y	y	?	y	n							
16	Proper KI, Koning M, Van c	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													

Reporting excluded studies

- ‘Results’ section
  - Search results, including no. identified and excluded at each stage
- ‘Characteristics of excluded studies’ table
  - list of key excluded studies, with primary reason for exclusion
    - list studies that may appear to readers to meet the eligibility criteria, but on closer inspection do not
    - no need to list studies that obviously do not meet criteria



Characteristics of excluded studies

Albrecht 2002

Reason for exclusion	Allocation was by alternation, not a randomised trial.

Newcastle 2001

Reason for exclusion	Participants were shift workers during a night shift, under conditions of sleep deprivation.

Peterson 1983

Reason for exclusion	Intervention did not include caffeine

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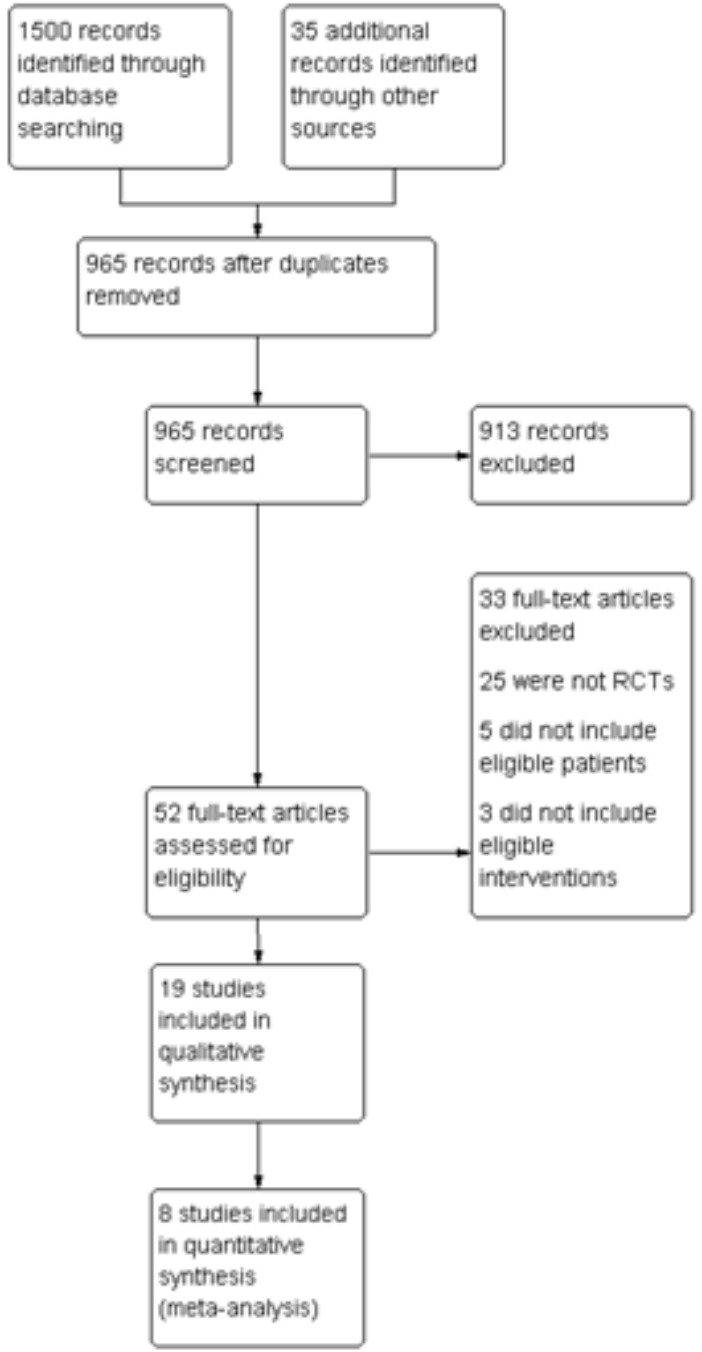
PRISMA flow chart



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See www.prisma-statement.org

What to include in your protocol

1. whether two authors will independently assess studies
2. process of assessment (e.g. abstracts, full text)
3. how disagreements will be managed
4. any other methods used

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A practical example

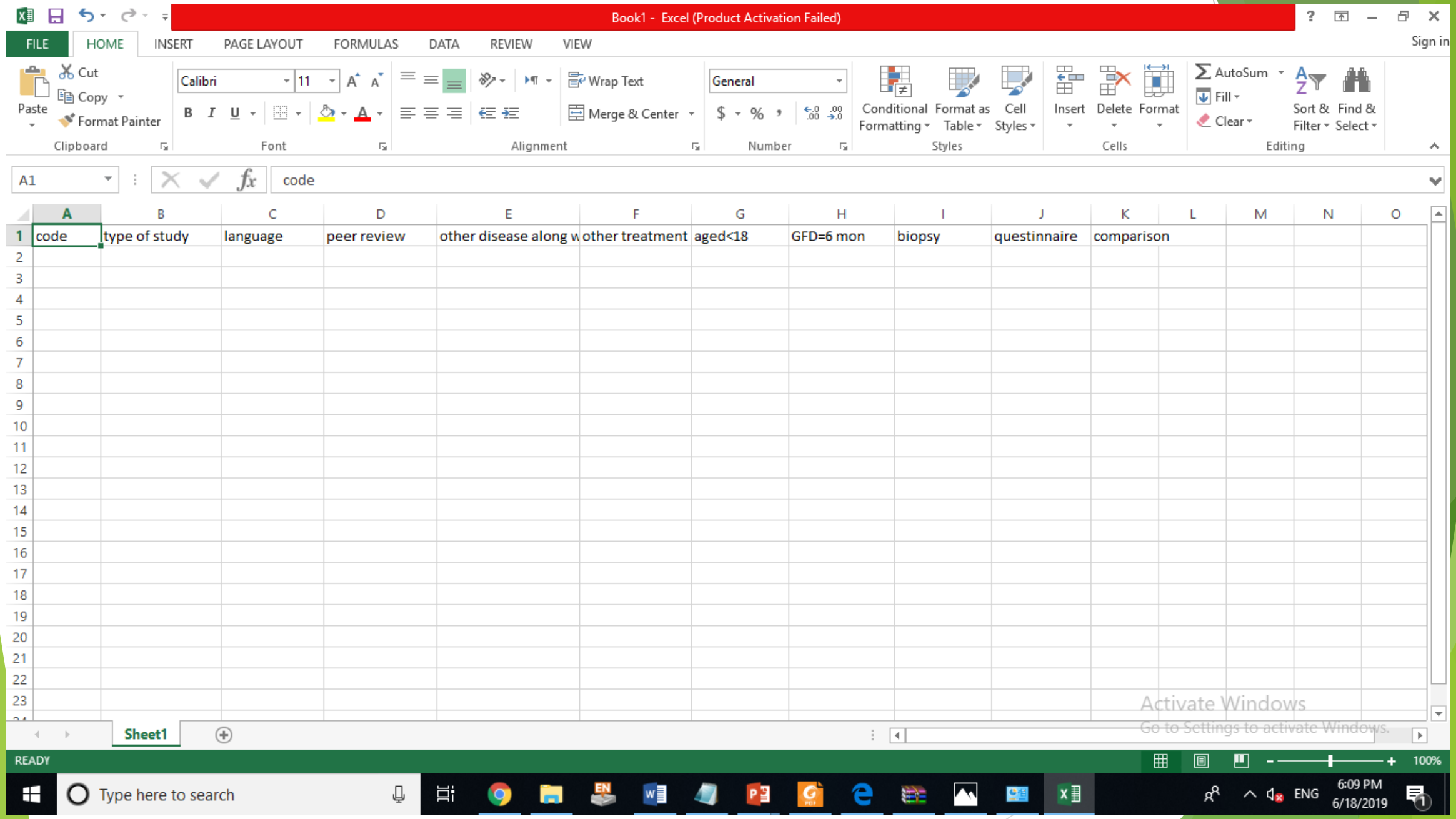
I want to assess the “effect of gluten free diet on quality of life in children with celiac diseases”

- Inclusion criteria:
  - Population:
    - Children (aged <=18 y) with celiac disease
    - Celiac proven by biopsy
  - Intervention:
    - “gluten free diet”
    - At least 6 month on gluten free diet

  Outcome:
    - assessing QOL by valid questionnaire
    - Compare the results with pre diet values

- Exclusion criteria:
  - Population:
    - Children with celiac along with other autoimmune diseases
  - Intervention:
    - Other treatment along with GFD
  - Conference papers
  - Letters
  - Book chapters
  - Other languages except English

Databases	Terms	Results	Notes
Pubmed	((("quality of life"[Title/Abstract]) OR "life quality"[Title/Abstract])) AND ((((celiac[Other Term]) OR coeliac[Title/Abstract]) OR anthropathy[Title/Abstract]) OR celiac[Title/Abstract])	524	
Embase	'celiac disease':ti,ab AND 'quality of life':ab,ti	407	
Total		931	
duplicate		766	
Not English		48	
reviews		x	
Not RCT		X	
Not children		x	
With diabetes		X	
Not biopsy proven		x	
Using invalided questionnaire		X	
xxx		x	
xxx		x	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Different software can be used for article selecting

- **Endnote:** A gold standard reference management system for systematic reviews
- **Rayyan:** Screening software for managing the citation selection process
  - https://rayyan.qcri.org/welcome
- Abstrackr: Screening software for managing the citation selection process
  - http://abstrackr.cebm.brown.edu/account/login

Thanks for your attention

Data Collection

Data collection

- Data: Any information about (or deriving from) a study, including details of
  - Methods: study type/ blinding/ randomized.....
  - Participants: age sex, SES.....
  - Setting/context,
  - interventions, indicators with method of measurement
  - Outcomes with method of measurement
  - Results: Dichotomous, Continuous, Ordinal, Counts and rates, Time-to-event
  - publications
  - Investigators: not blind

Methods	Single centre, two arm, blinded (investigators and outcome assessors), parallel group RCT; allocation by "chit method". Allocation concealment: sequentially numbered sealed envelopes.
Participants	50 participants with mixed depth (partial and full thickness) burns recruited between January 1996 and December 1997. Setting: hospital. Country: India. Inclusion criteria: Aged 10-40 years, haemodynamically stable, no systemic illness or smoke inhalation injury, total body surface area burnt <30%. Exclusion criteria: Not reported
Methods	RCT Number Analyzed/ Randomized: 169/282 (from table III N = 155 with neck disorders) Intention-to-treat Analysis: NR Power Analysis: NR
Participants	Mechanical neck disorder, duration disorder NR
Interventions	Group 1 (n=25): Unprocessed honey every second day, with autologous skin grafting as required. Group 2 (n=25): Tangential excision and skin grafting between days 3 and 6 after admission Treatment duration: Until healed
Outcomes	Mean time to healing Group 1: 32.0 days (SD 8.1) Group 2: 18.4 days (SD 4.2)

Data collection

- Review authors should plan in advance what data will be required for their systematic review, and develop a strategy for obtaining them

- Develop outlines of tables and figures expected to appear in the systematic review
  - This step will help review authors decide the right amount of data to collect (not too much or too little)

- Order: reference information, followed by eligibility criteria, intervention description, statistical methods, baseline characteristics and results).

Source of data collection:

- Reports
- Correspondence with investigators

Who should extract data?

- It is strongly recommended that more than one person extract data from every report

  - minimize errors and reduce potential biases being introduced by review authors

Examples of what data should be collected

	Descriptions as stated in report/paper		Location in text or source
Aim of study (e.g. efficacy, equivalence, pragmatic)			
Design(e.g. parallel, crossover, non-RCT)			
Unit of allocation **(by individuals, cluster/ groups or body parts)**			
Start date			
End date			
Duration of participation **(from recruitment to last follow-up)**			
Ethical approval needed/ obtained for study	Yes No Unclear		
Notes:			

	Description Include comparative information for each intervention or comparison group e	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)		
Informed consent obtained	Yes No Unclear	
Total no. randomised (or total pop. at start of study for NRCTs)		
Clusters (if applicable, no., type, no. people per cluster)		

Baseline imbalances	Include comparative information for each intervention or comparison group	Location in text or sourc
Withdrawals and exclusions (if not provided below by outcome)		
Age		
Sex		
Race/Ethnicity		
Severity of illness		
Co-morbidities		
Other relevant sociodemographics		
Subgroups measure		
Subgroups reported		

	Description as stated in report/paper	Location in text or source
Group name		
No. randomised to group (specify whether no. people or clusters)		
Theoretical basis (include key references)		
Description (include sufficient detail for replication, e.g. content, dose, components)		
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)		
Co-interventions		
Economic information (i.e. intervention cost, changes in other costs as result of intervention)		
Compliance		

outcomes	Description as stated in report/paper	Location in text or source
Outcome name		
Time points measured (specify whether from start or end of intervention)		
Time points reported		
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?	Yes No Unclear	

Imputation of missing data (e.g. assumptions made for ITT analysis)		
Assumed risk estimate (e.g. baseline or population risk noted in Background)		
Power (e.g. power & sample size calculation, level of power achieved)		
Notes:		

Study funding sources (including role of funders)		
Possible conflicts of interest (for study authors)		
Notes:		


Thank
you!