The Effective Public Health Practice Project Tool

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Potential bias in an epidemiological study

- Recruit participants
  - Allocate to group
    - Intervention group
      - Implement intervention
      - Follow-up participants
      - Measure outcomes
      - Analyse data
    - Control group
      - Implement intervention
      - Follow-up participants
      - Measure outcomes
      - Analyse data
  - Selection bias
  - Allocation bias
  - Confounding
  - Integrity of intervention
  - Intention-to-treat
  - Attrition bias
  - Detection bias/recall bias
  - Reliability/validity of data collection methods
  - Statistical analysis
Components of the EPHPP tool

A. Selection bias
B. Study design
C. Confounders
D. Blinding
E. Data collection methods
F. Withdrawals and drop-outs
G. Intervention integrity
H. Analyses

Assessment and component rating as strong, moderate or weak

Assessment but no component rating

Overall study rating as strong, moderate or weak based on component ratings

A. Selection bias

... systematic differences in characteristics between those who are selected for study and those who are not

Example:

Medical students without any prior skin disease are asked to volunteer for a randomised controlled trial on the effectiveness of an information package about UV radiation and sun protection.

EPHPP Tool: Selection bias

Are the individuals selected to participate in the study likely to be representative of the target population?

What percentage of selected individuals agreed to participate?
B. Allocation bias

... systematic differences in the characteristics of those assigned to intervention versus control groups

Methods of allocation:
• Randomisation (e.g. coin toss, computer-generated random number tables)
• Quasi-randomised (e.g. alternation, allocation by date of birth)
• Selection by researcher, self-identification, etc.

EPHPP Tool: Study design
Indicate the study design ...
Was the study described as randomised?
  If Yes, was the method of randomisation described?
  If Yes, was the method appropriate?

C. Confounding

... factors that are associated with the intervention and causally related to the outcome of interest (known and unknown confounders)

Example:
Fair skin is associated with the likelihood of using sunscreen (intervention) and the likelihood to develop skin cancer (outcome).

EPHPP Tool: Confounders
Were there important differences between groups prior to the intervention?
  If Yes, indicate the percentage of relevant confounders that were controlled (either in the design or analysis).
D. Blinding

Detection bias
… systematic differences between groups in how outcomes are determined
-> blinding of outcome assessors to the intervention/control status of participants

Recall (reporting outcome) bias:
… systematic differences in the way groups answer questions
-> blinding of participants to research question

EPHPP Tool: Blinding
Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?
Were the study participants aware of the research question?

E. Data collection methods

Validity
… the degree to which a measurement accurately reflects or assesses the specific phenomenon that the researcher is attempting to measure

Reliability
… repeatability of measurement, or the degree to which an instrument measures the same way each time it is used under the same condition with the same subject

Example:
Testing of questionnaire components on behaviour change against observed behaviour change (validity); repeated pre-testing of questionnaire with the same group of individuals (repeatability).

EPHPP Tool: Data collection methods
Were data collection tools shown to be valid?
Were data collection tools shown to be reliable?
F. Attrition bias

… systematic differences between groups in withdrawals from a study

Example:
Completed follow-up responses were obtained from 87% of those in the intervention group and 69% of those in the control group. There were no significant differences between respondents and non-respondents in age, sex, skin type and socio-economic status.

EPHPP Tool: Withdrawals and drop-outs
Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?
Indicate the percentage of participants completing the study.

Applying the EPHPP tool

Process:
• Independent rating of study quality by two persons
• Comparison of individual ratings to reach consensus on each component
• Involvement of a third person in case of lack of consensus
• Overall study quality is rated based on combination of component ratings
  • STRONG: 4 strong ratings with no weak ratings
  • MODERATE: less than four strong ratings and one weak rating
  • WEAK: two or more weak ratings

Components of EPHPP tool:
• Form
• Accompanying dictionary http://www.ephpp.ca/tools.html