**STUDY QUESTION & DESIGN:**
describe with PECOT

**STUDY NUMBERS:**
hang on GATE frame

**STUDY ERROR:**
assess using RAMBOMAN

---

**STUDY QUESTION & DESIGN:**

**STUDY NUMBERS:**

**STUDY ERROR:**

---

**Participants:**

P = Participants:

- Setting
- Eligibility criteria
- Recruitment process
- % of eligibles who participated

**Eligibles:**

n = ___________

**Setting:**

- Setting appropriate to study goals?
- Setting/eligible population appropriate, given study goals?

**Eligibles:**

n = ___________

**Participants:**

EG = Exposed Group [Intervention/Risk factor]

Method of allocation

Describe E (how measured if not RCT)

CG = Comparison Group [Control/comparison]

Describe C (how measured if not RCT)

**Outcomes & Time:**

O = Outcomes: Primary (& 2' include adverse)

T = Time when outcomes counted (at what point in time or over what time period)

Describe O & T: how / when measured

---

**ANALYSES**

Outcome & Time| EGO = a/EG| CGO = b/CG| RR = EGO/CGO ± 95% CI| RD = EGO-CGO ± 95% CI| NNT = 1/RD ± 95% CI
---|---|---|---|---|---

ANalyses: Intention to treat (if RCT)?_______Adjusted if EG & CG different?_______95% CI or p-values given?_______

**Summary:**

Non-random error: amount & direction of bias (RAMBOM)?

ANalyses done well?

Random error: sufficiently low

Power/sample size sufficiently high (if no statistically significant effects demonstrated)?

Applicability of findings? Any important adverse effects?

Size of effects sufficient to be meaningful (RR &/or RD)?

Can findings be applied in practice?
Evidence
REFERENCE:
Applicability:
Effect sizes:
Power:
Random error
Non-STUDY
NNT(H) often called NNH.
one (in a specified time).
Relative Risk. Odds Ratios & Hazards ratios are similar to RR.
measured
document over what time period (cumulative incidence) or at what point in time (prevalence) EGO & CGO are
(EER)
for any differences, e
Adjusted
to EG & CG, including anyone who dropp
Intention to treat (or expose)
were participants / received unequally by EG&CG during
allocated to CG who crossover to EG (& visa versa if CG an exposure)?
Maintenance
differences b
randomisation
from staff
Blind
were investigators blind to whether participants were exposed to E or CG?
Blind Measurement
of outcomes: were outcome assessors unaware if participants in EG or CG?
or
Objective Measurement
of outcomes. eg. based on biopsies; automated tests, x-rays, validated questionnaires?

STUDY VALIDITY (non random error or bias): use RAMBOM to identify possible non random errors
Recruitment (mainly about external validity): were setting/Eligibles appropriate given the study goals &/or the
reviewer’s interests? If relevant, were participants representative of Eligibles? Could the results be generalised to
relevant populations? This should be able to be determined from risk factor/prognostic profile of participants. In
prognostic studies – were participants at similar stage in progression of their disease or condition?
Allocation: how well were participants allocated to E&C? If a trial were they randomised to E&C?
• If randomised, was allocation concealed (i.e. knowledge of group [EG or CG] participants allocated to concealed
from staff & participants until after allocation documented)? Was randomization successful (i.e. EG & CG similar after
randomisation – were baseline characteristics similar in each group)?
• If not randomised (observational study) were measurements of E&C accurate & done similarly for EG & CG? Were
differences between EG & CG documented.
Maintenance: did participants remain in the groups [EG or CG] they were initially allocated to?
Compliance: % participants allocated to EG (or CG) who remained exposed to E (or C) during study?
Contamination: % participants allocated to CG who crossover to EG (& visa versa if CG an exposure)?
Co-intervention: other significant interventions received unequally by EG&CG during follow-up?
Completeness of follow-up: was it high & similar in EG & CG?
Blinding: were participants / investigators blind to whether participants were exposed to E or C?
Blind Measurement of outcomes: were outcome assessors unaware if participants in EG or CG?
or
Objective Measurement of outcomes. eg. based on biopsies; automated tests, x-rays, validated questionnaires?

STUDY ANALYSES (estimates of occurrence [EGO & CGO], effect sizes [RR & RD]) and random error [95% CI]
Intention to treat (or expose) analyses: did analyses (i.e. calculation of EGO & CGO) include all participants allocated
to EG & CG, including anyone who dropped out during study or did not complete follow-up)?
Adjusted analyses (for confounders): Were EG & CG similar at baseline? If not, were analytical methods used to adjust
for any differences, e.g. stratified analyses, multiple regression?
EGO: Exposure Group Occurrence (either incidence or prevalence measures; also known as Experimental Event Rate
[EER] in RCTs). CGO: Comparison Group Occurrence (or Control Event Rate [CER] in RCTs). Most studies report
cumulative incidence or prevalence measures of occurrence and EGO = a/EG & CGO = b/CG, and you should
document over what time period (cumulative incidence) or at what point in time (prevalence) EGO & CGO are
measured. However if EGO & CGO are calculated as incidence rates per unit time (T) (e.g. per year), then EGO =
a/[EG x T] & CGO = b/[CG x T]. EG x T and CG x T describe ‘person-time.’
Effect estimates (measures for comparing EGO & CGO): Risk Ratio (RR) = EGO/CGO: more commonly known as
Relative Risk. Odds Ratios & Hazards ratios are similar to RR. Risk Difference (RD) = EGO-CGO: also known as absolute
risk difference. NNT (or NNE) = 1/RD: the number Needed to Treat (or expose) to change the number of outcomes by
one [in a specified time]. NNT[B]: if exposure/intervention BENEFICIAL. NNT[H]: if exposure/intervention HARMFUL. Note:
NNT[H] often called NNH.
Random error in estimates of EGO, CGO, RR, RD & NNT/E is assessed by width of confidence interval (CI). A wide CI (i.e.
big gap between upper & lower confidence limits [CL] = more random error = less precision.

STUDY SUMMARY
Non-random error (bias): what was the likely amount & direction of bias: is bias likely to substantially increase or
decrease the observed difference between EGO & CGO (and therefore the effect sizes)?
Random error: would you make a different decision if the real effect was closer to upper CL than lower CL?
Power: if the effect sizes were not statistically significant, was study just too small to show meaningful effects?
Effect sizes: was the magnitude of the RR or RD (or NNT) sufficient to be meaningful/useful in practice?
Applicability: if effect sizes meaningful & errors small, are the findings likely to be applicable in practice?

REFERENCE: Jackson et al. The GATE frame: critical appraisal with pictures. In: Evidence-Based Medicine. 2006;11:35-38. Also in: