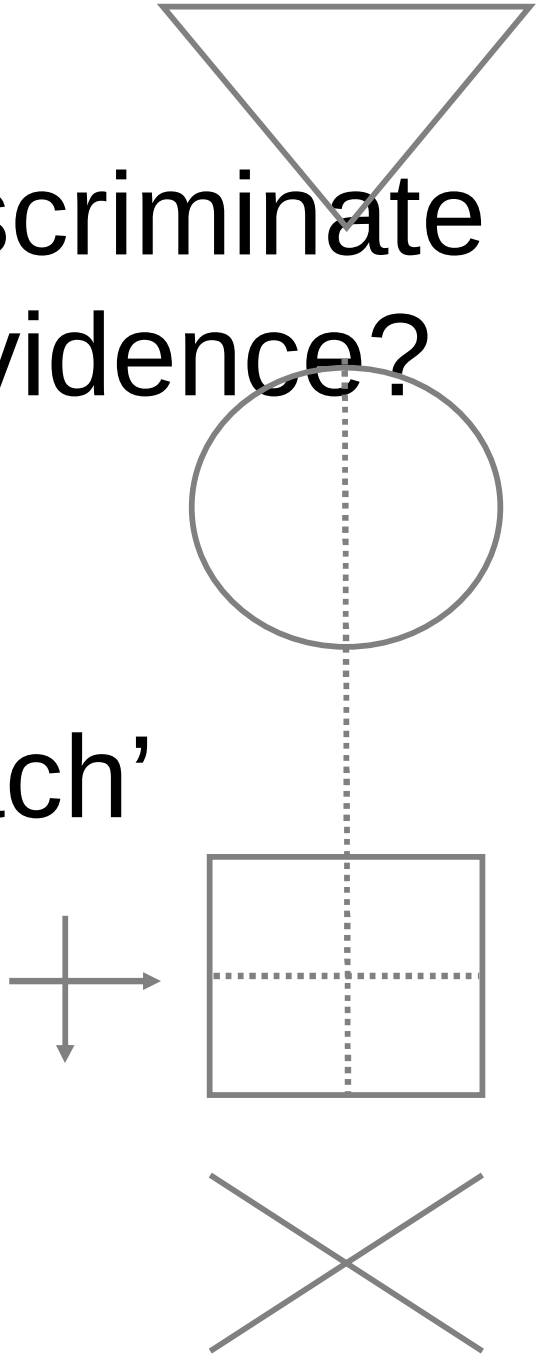
Can we teach how to discriminate between good & bad evidence?

in 20 minutes!

‘the GATE approach’

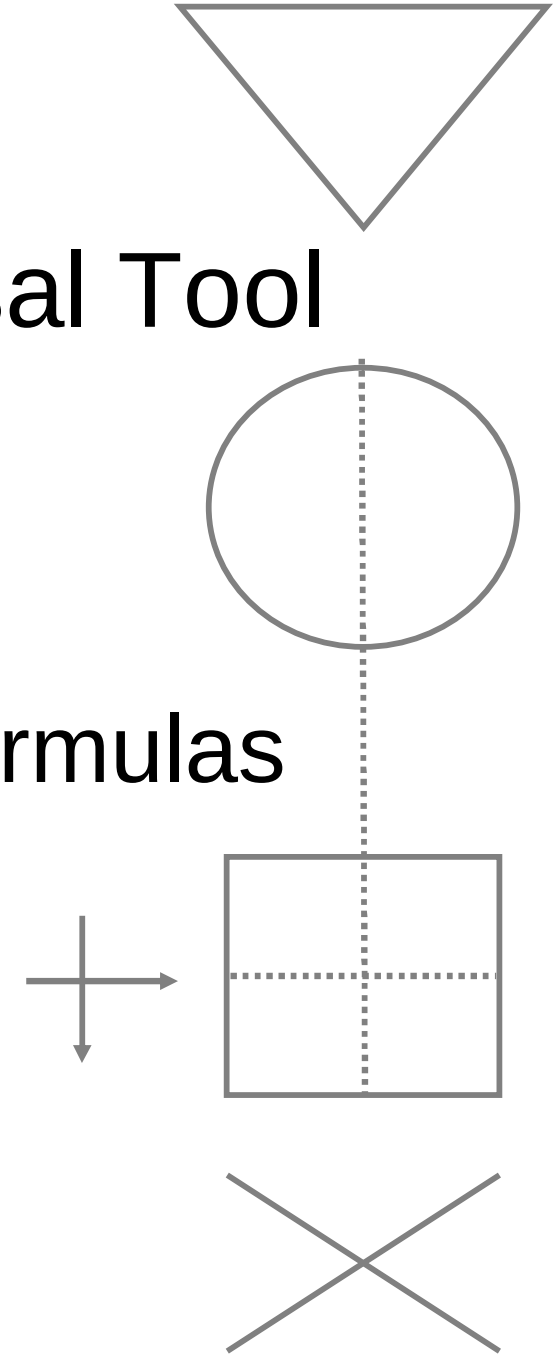
Rod Jackson

June 2010

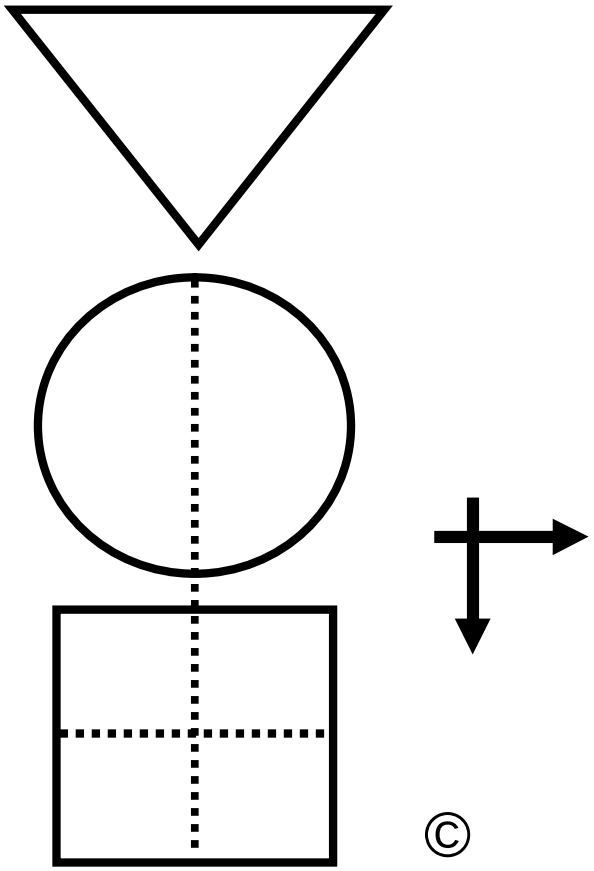


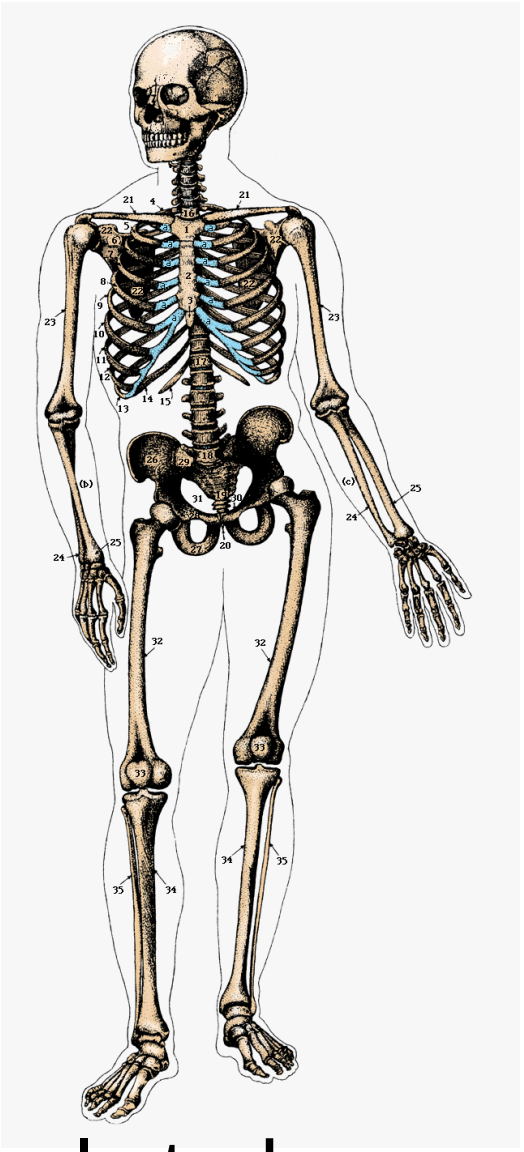
GATE: a Graphic Appraisal Tool for Epidemiology

A picture, 2 acronyms & 2 formulas



A picture: the GATE frame

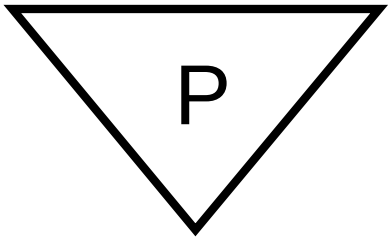




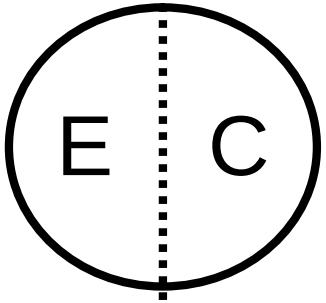
the shape of every epidemiological study

The PECOT acronym: the 5 parts of every epidemiological study

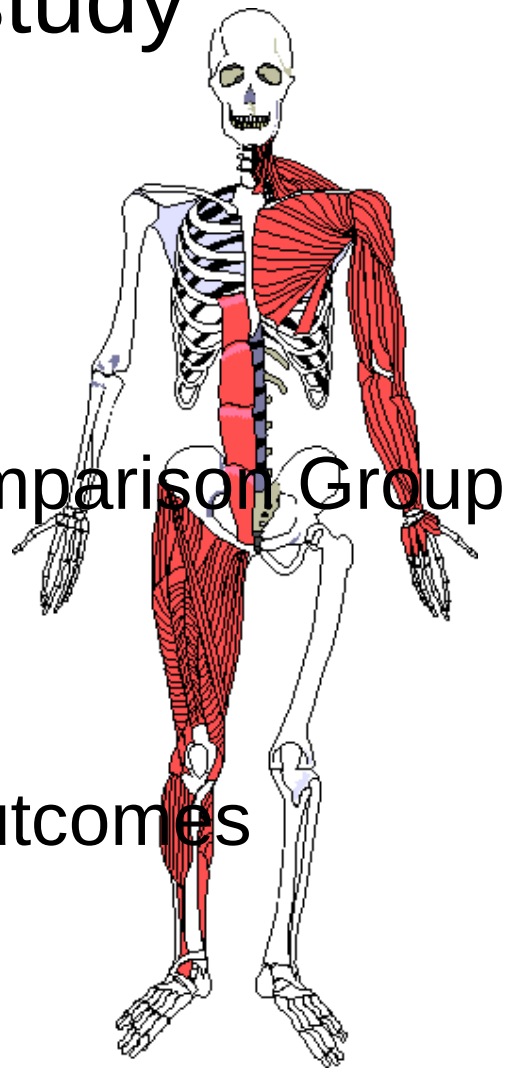
Participants



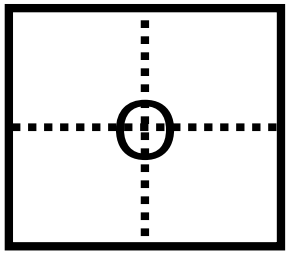
Exposure Group



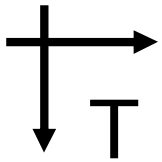
Comparison Group



Outcomes

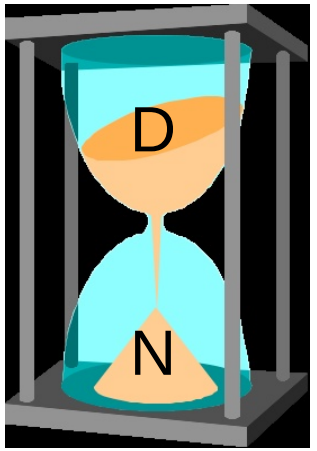


Time



All epidemiological studies can be hung on the GATE frame

2 formulas: study analyses



1. Occurrence of disease

= Numerator ÷ Denominator ÷ Time

2. Random error (95% Confidence Interval)

= 1.96 x Standard Error

The RAMMbo* acronym: assessing study bias

P

E

C

O

T

Recruitment

Allocation

Maintenance

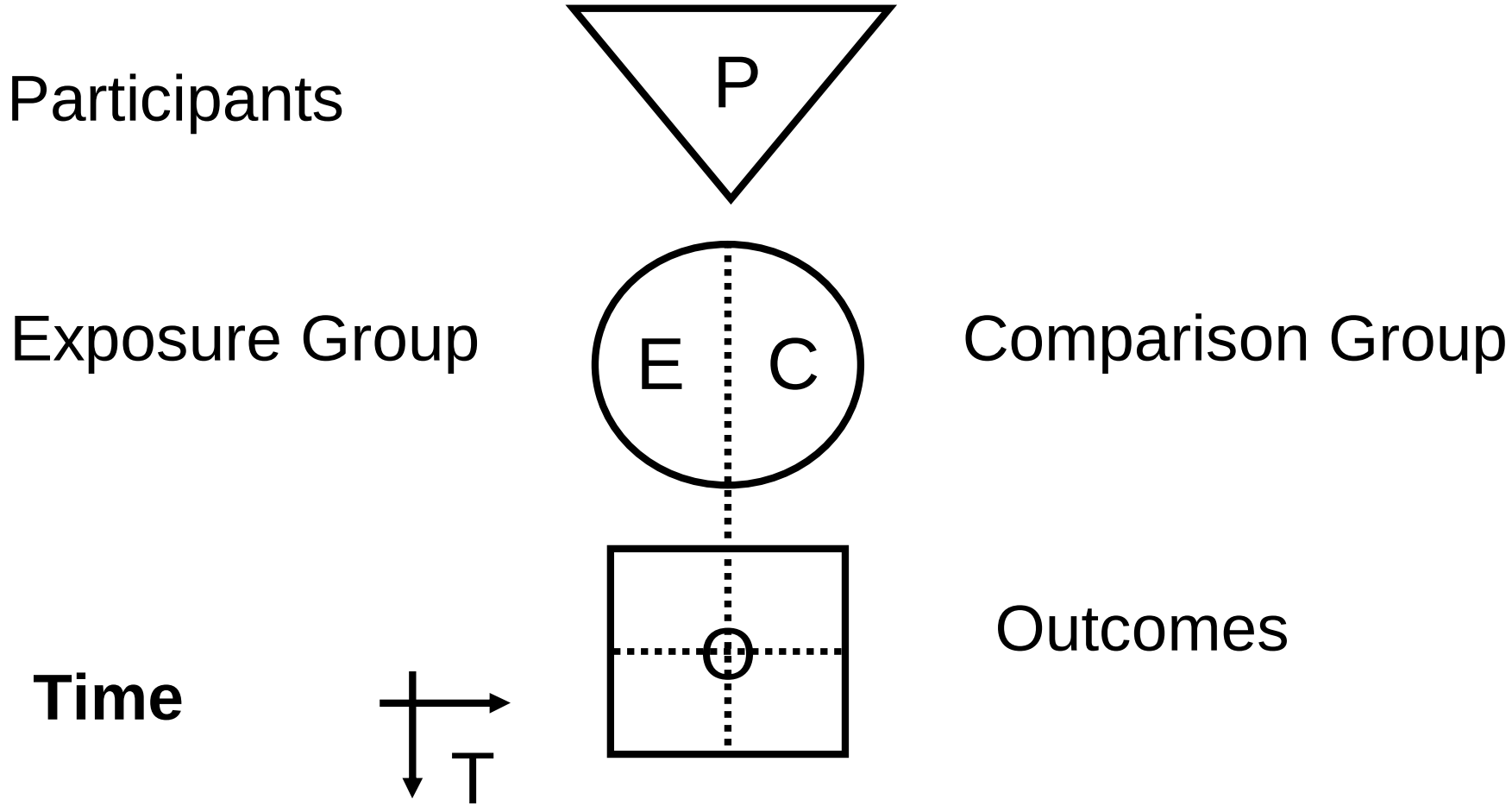
Measurement of outcomes

blind or

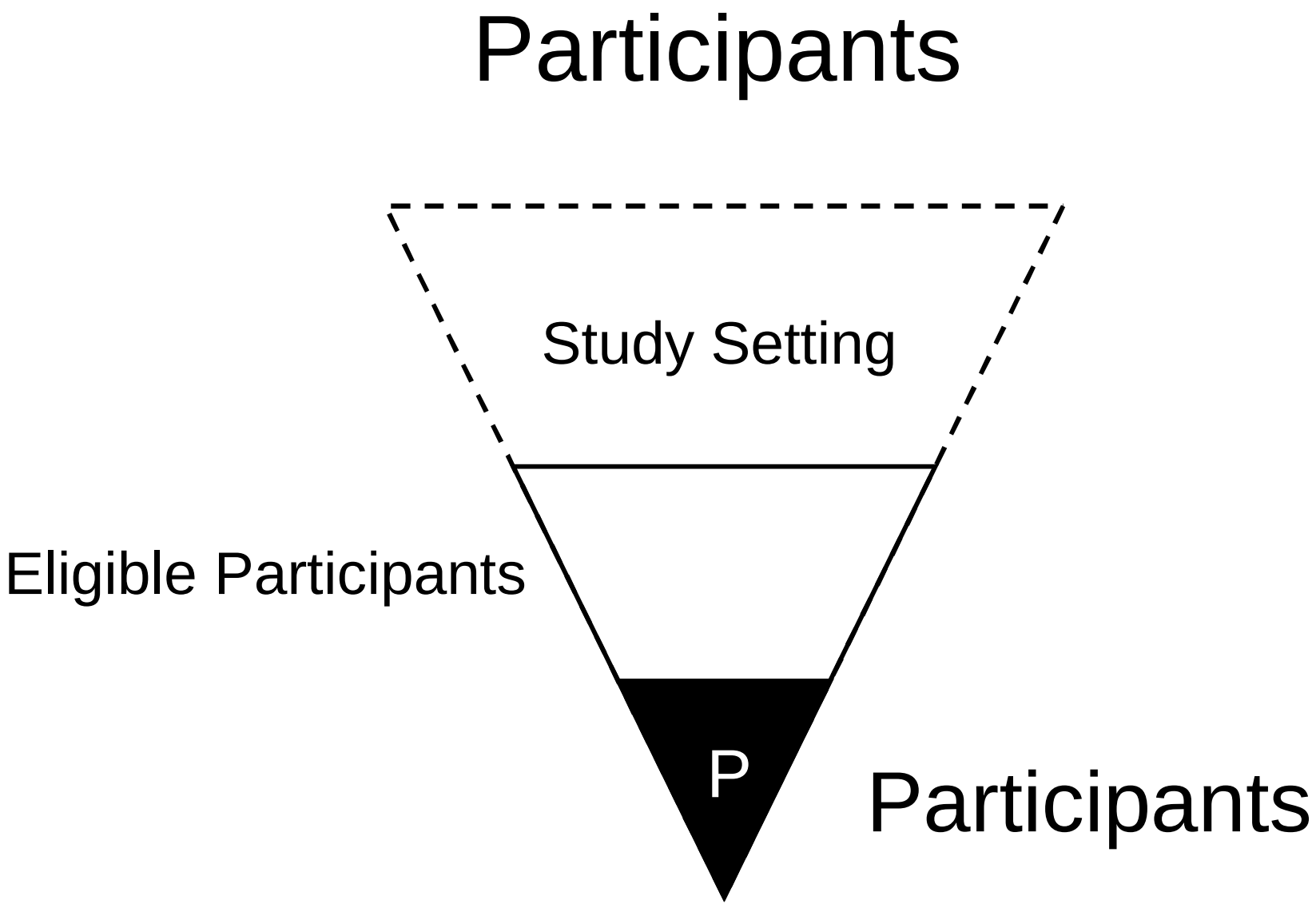
objective

* Paul Glasziou

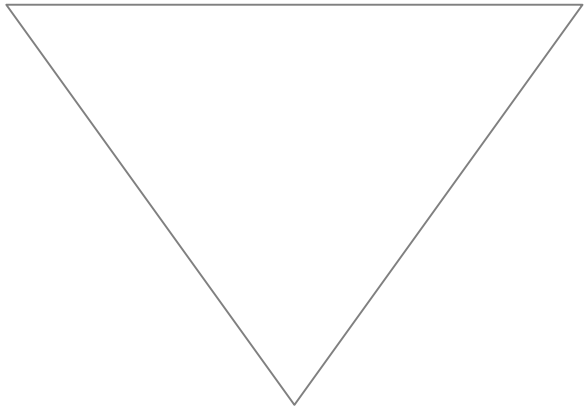
GATE frame picture & PECO**T** acronym



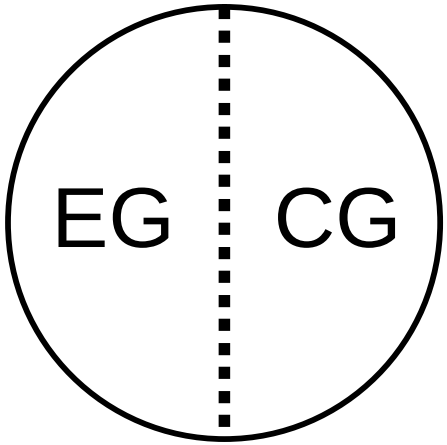
Describe a study's design by hanging PECOT on the frame


Participants
Study Setting
Eligible Participants
P
Participants

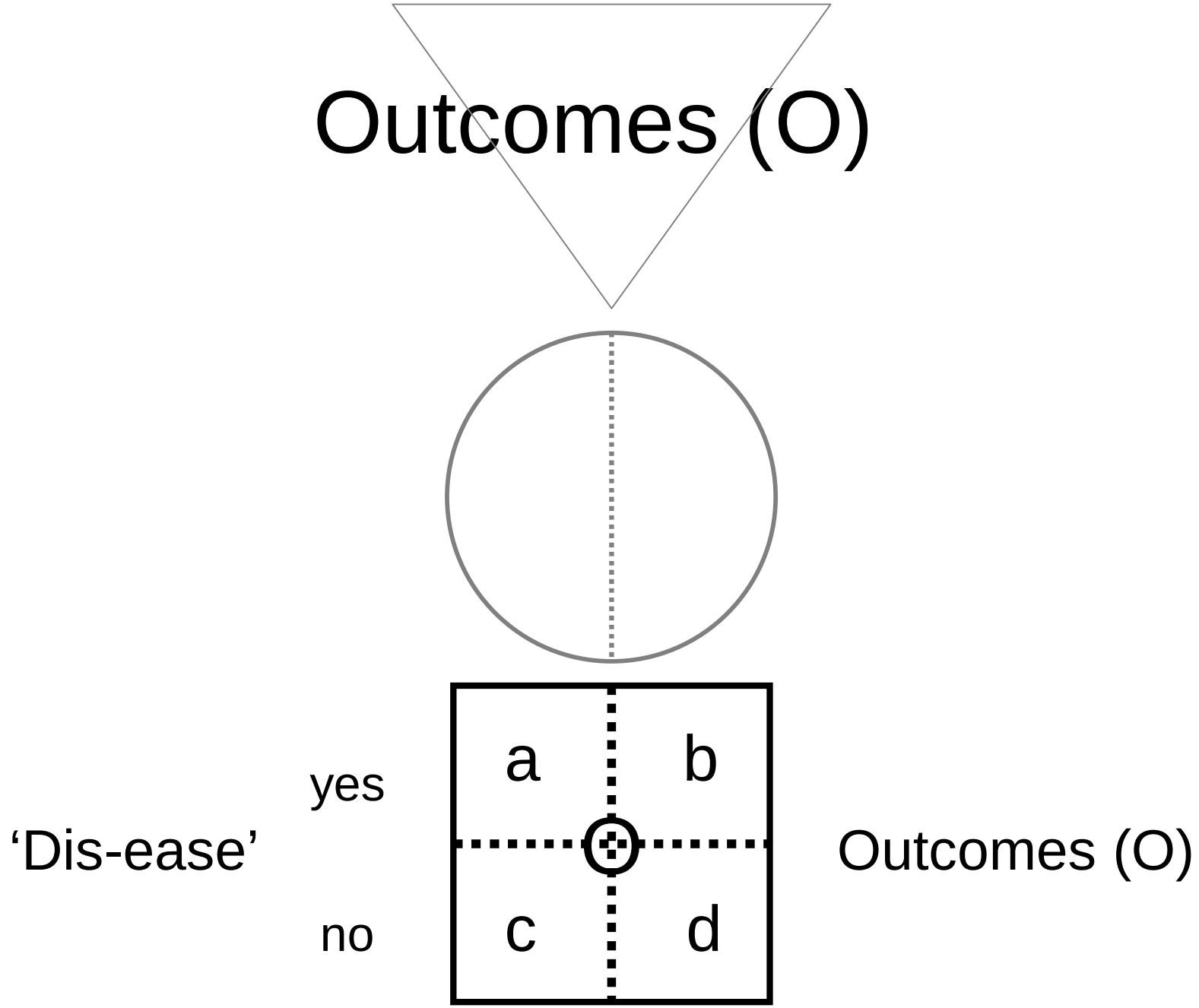
Exposure & Comparison Groups

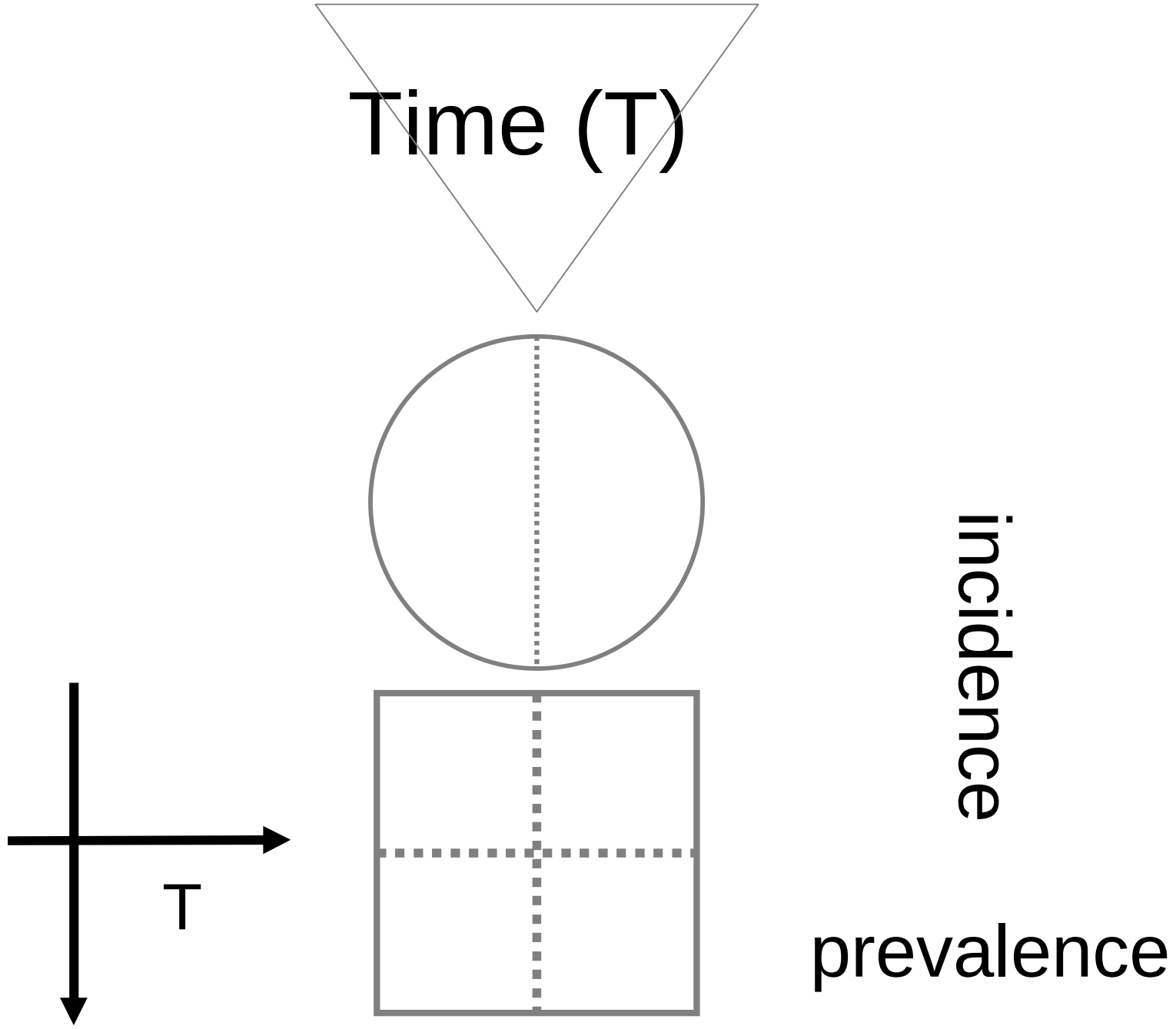


Exposure or Intervention Group (EG)

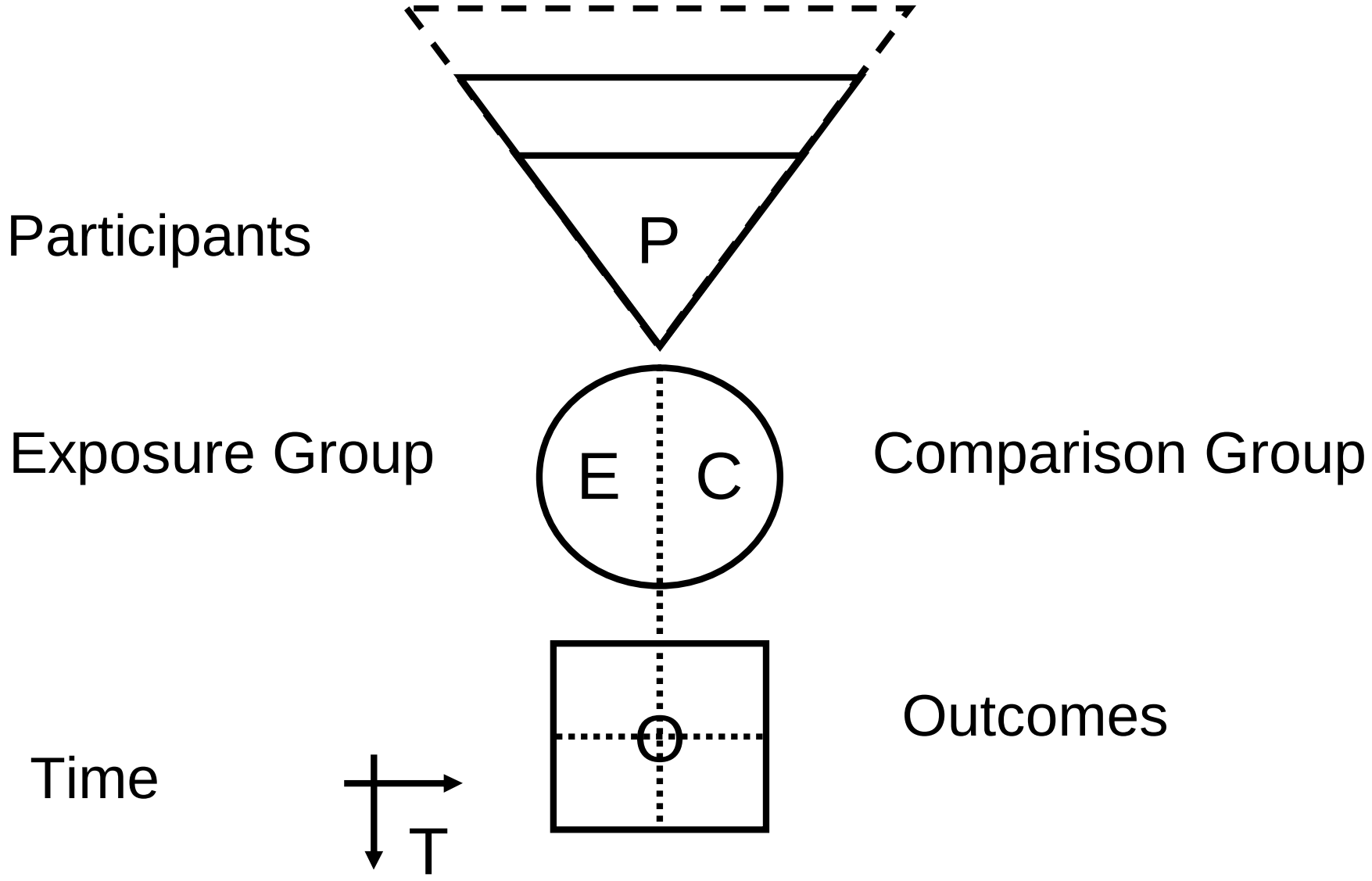


Comparison or Control Group (CG)


Outcomes (O)
a
b
yes
‘Dis-ease’
Outcomes (O)
no
c
d


Time (T)
T
incidence
prevalence

Study design: GATE frame & PECOT

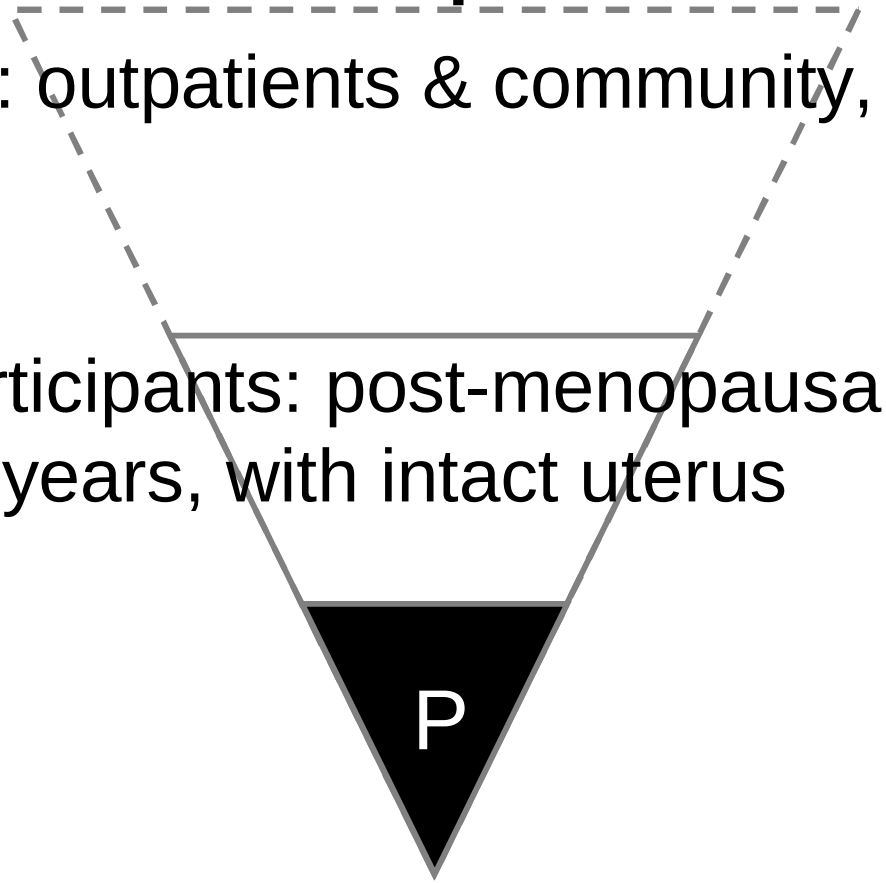


Every epidemiological study hangs on the GATE frame

HERS example JAMA 1998;280:605-613

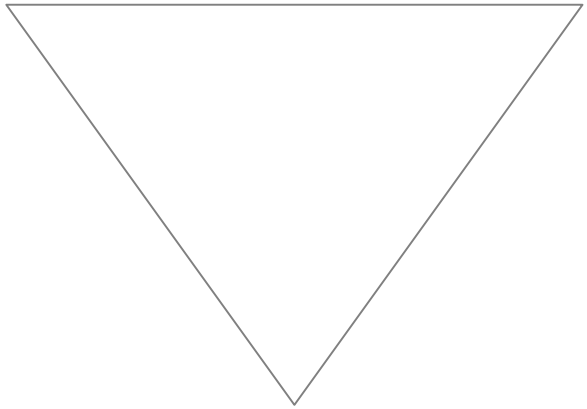
Participants

Study Setting: outpatients & community, 20 US centres



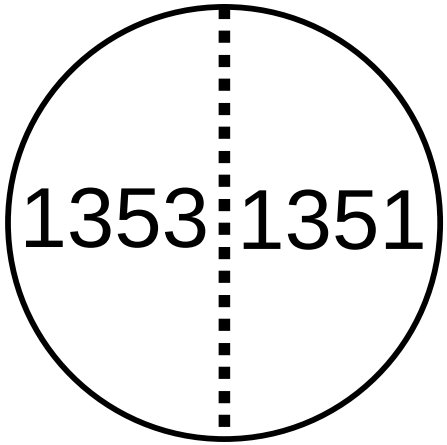
Participants: 2763, mean age 66.7 years

Exposure & Comparison Groups



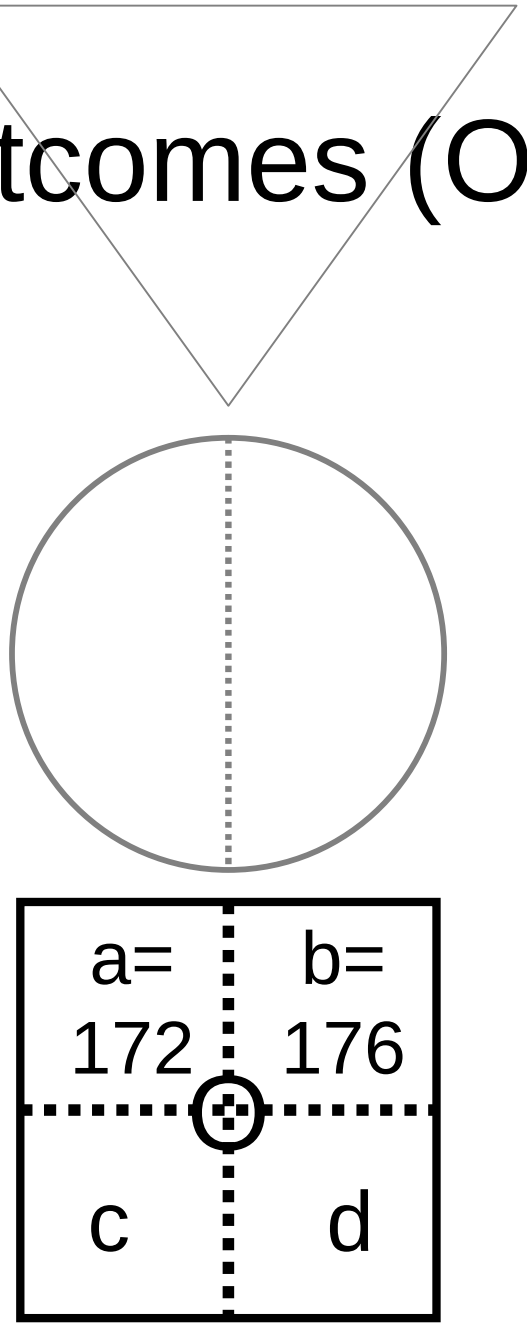
1380 1383

Exposure or Intervention Group (EG): 0.625mg conj equine estrogen& 2.5mg progesterone in 1 tablet



Comparison or Control Group (CG): placebo tablet of identical appearance

Outcomes (O)

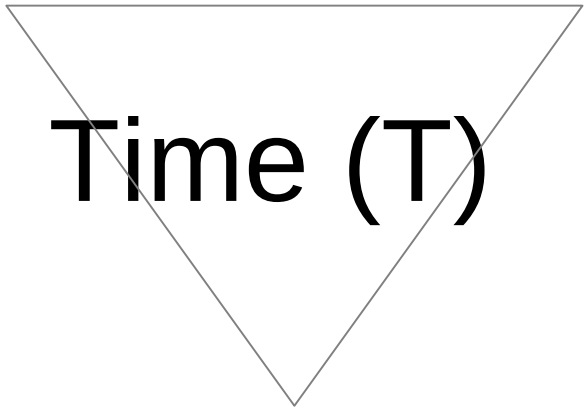


‘Dis-ease’: non-fatal MI or CHD death

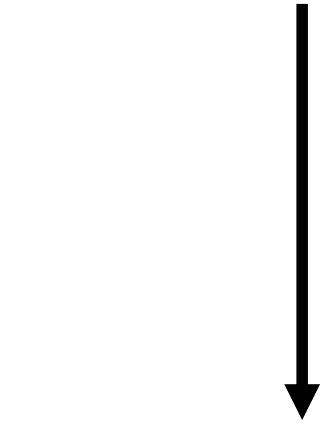
yes

no

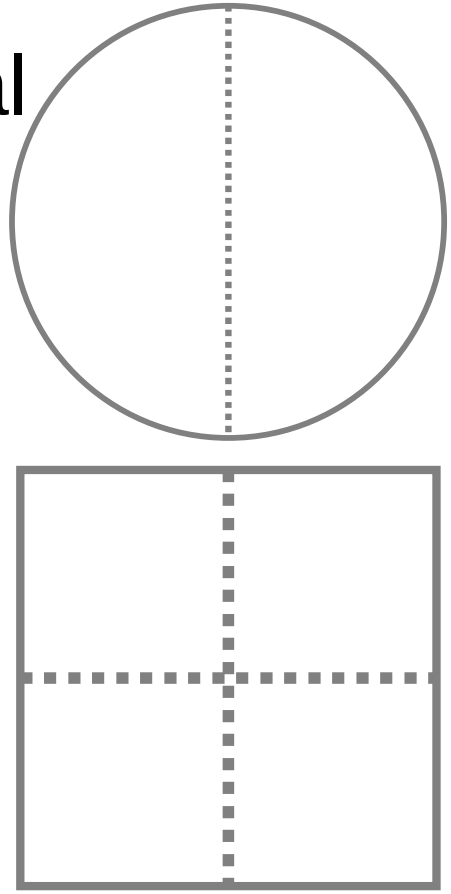
Outcomes (O)



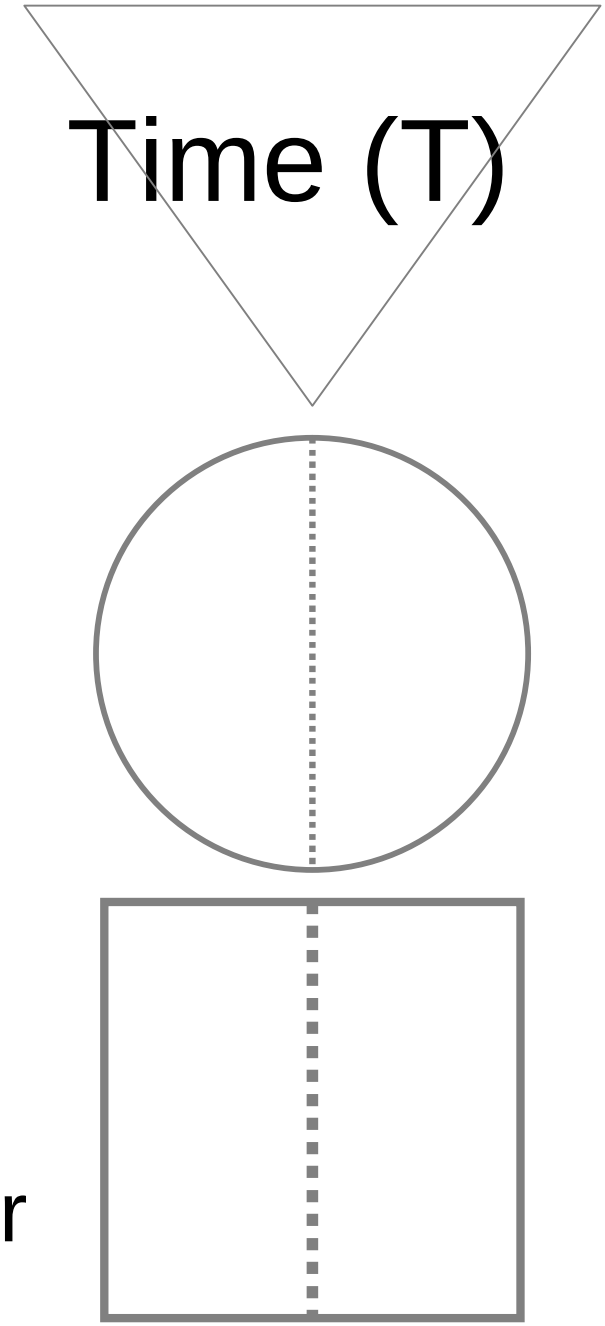
Outcome: non-fatal
MI & CHD death



T= 4.1 years
(av. follow-up)



incidence

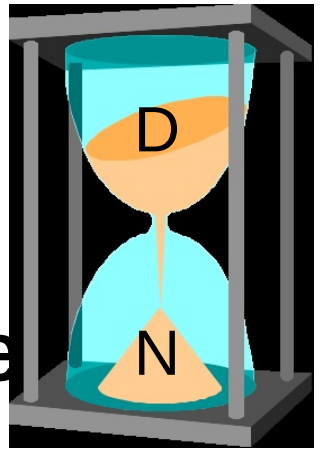


Outcome:
lipid levels

T = at 1 year

prevalence

2 formulas: study analyses



1. **Occurrence of disease**

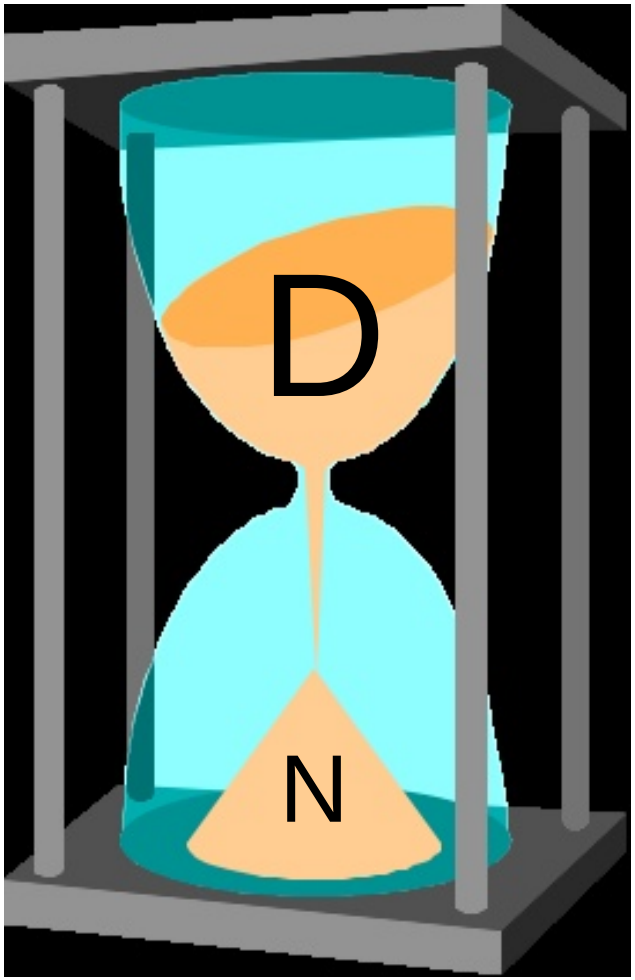
= Numerator ÷ Denominator ÷ Time

2. Random error (95% Confidence Interval)

= 1.96 x Standard Error

All epidemiological studies involve measuring the OCCURRENCE of disease

Occurrence = Numerator ÷ Denominator

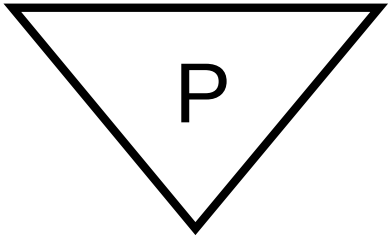


Denominator (Participants)

$$O = N \div D$$

Numerator (Outcomes)

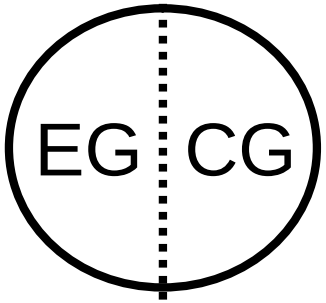
GATE study analyses



Overall Denominator

Denominator 1:

Exposure Group (EG)

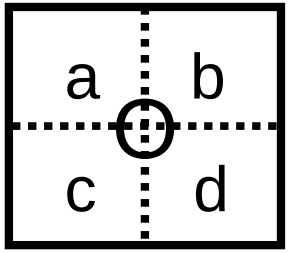


Denominator 2:

Comparison Group (CG)

Numerator 1:

a

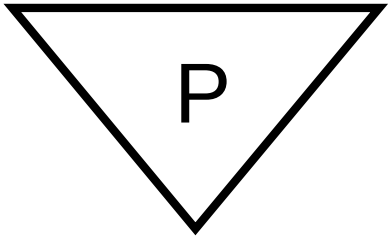


Numerator 2:

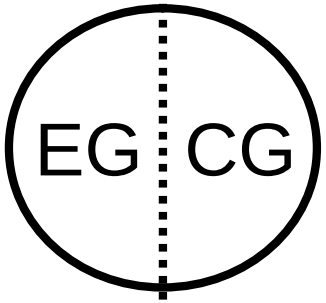
b

Describe a study's analyses by hanging the numbers on the frame

Occurrence = N ÷ D

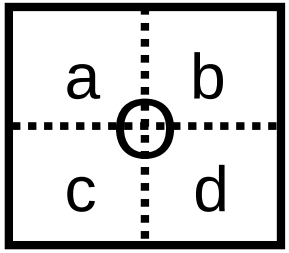


Denominator 1:
Exposure Group
EG



Denominator 2:
Comparison Group
CG

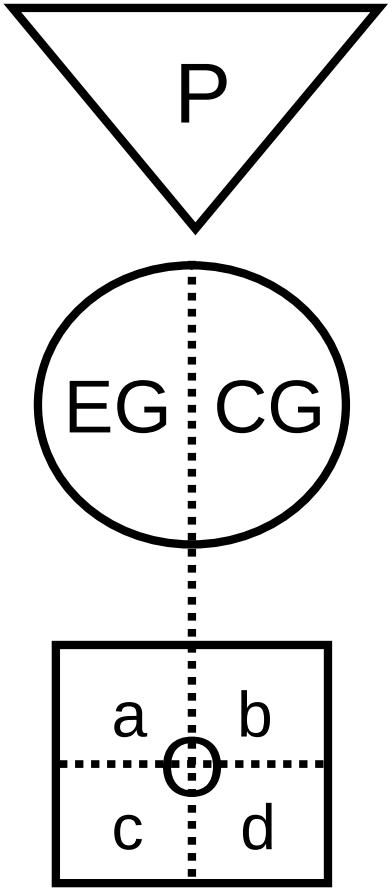
Numerator 1:
a



Numerator 2:
b

Exposure Group Occurrence:	Comparison Group Occurrence:
EGO = a ÷ EG	CGO = b ÷ CG

Calculate EGO & CGO for the outcome ‘MI & CHD death’ in HERS



Denominator 1:
Exposure Group
EG = 1380

Denominator 2:
Comparison Group
CG = 1383

Numerator 1:
a = 172

Numerator 2:
b = 176

EGO = 172/1380 =
12.46/100 people **in 5yrs**

CGO = 176/1383 =
12.73/100 people **in 5 yrs**

Describing differences between occurrences

Relative difference or Relative Risk = EGO ÷ CGO

Absolute Difference or Risk Difference = EGO - CGO

Number Needed To Treat (NNT) = 1 ÷ RD

Analyses

it’s all about EGO & CGO

The RAMMbo acronym: assessing study bias

P

E

C

O

T

Recruitment

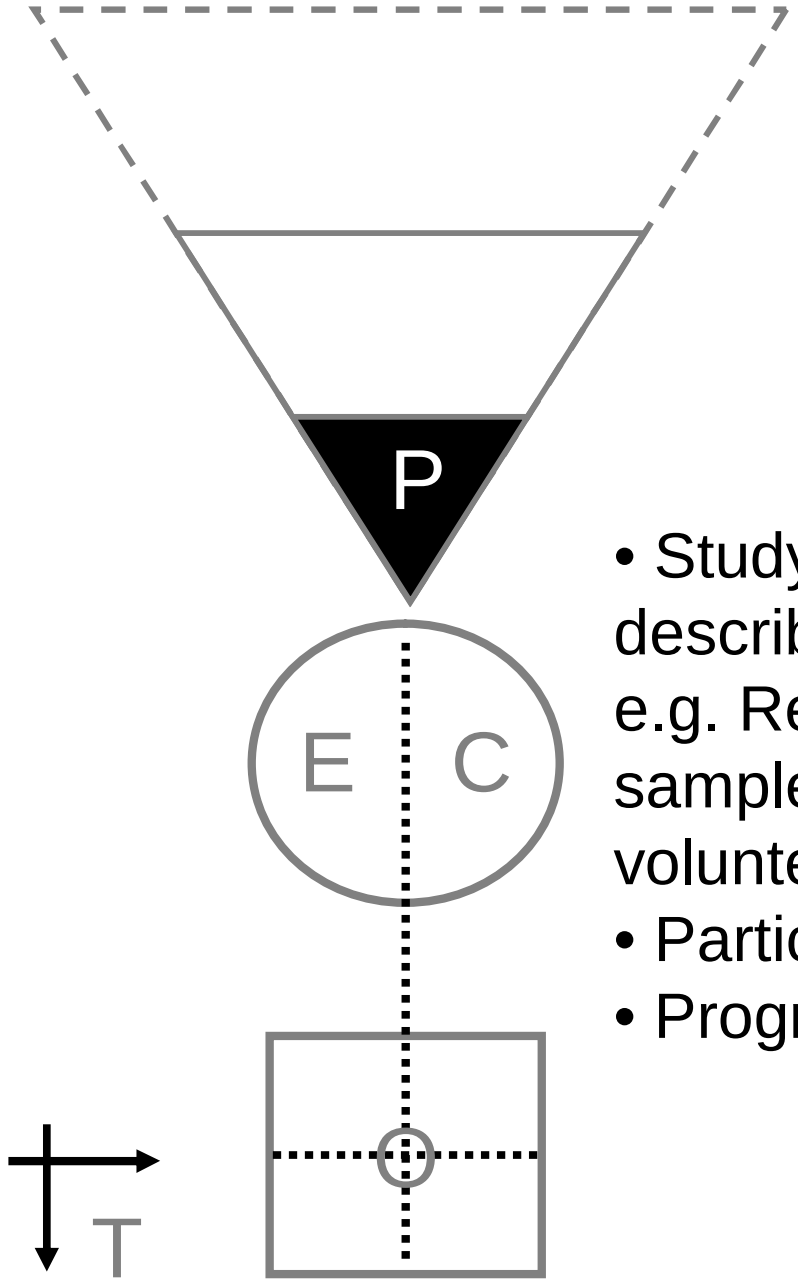
Allocation

Maintenance

Measurement of outcomes

blind or

objective



RAMMbo

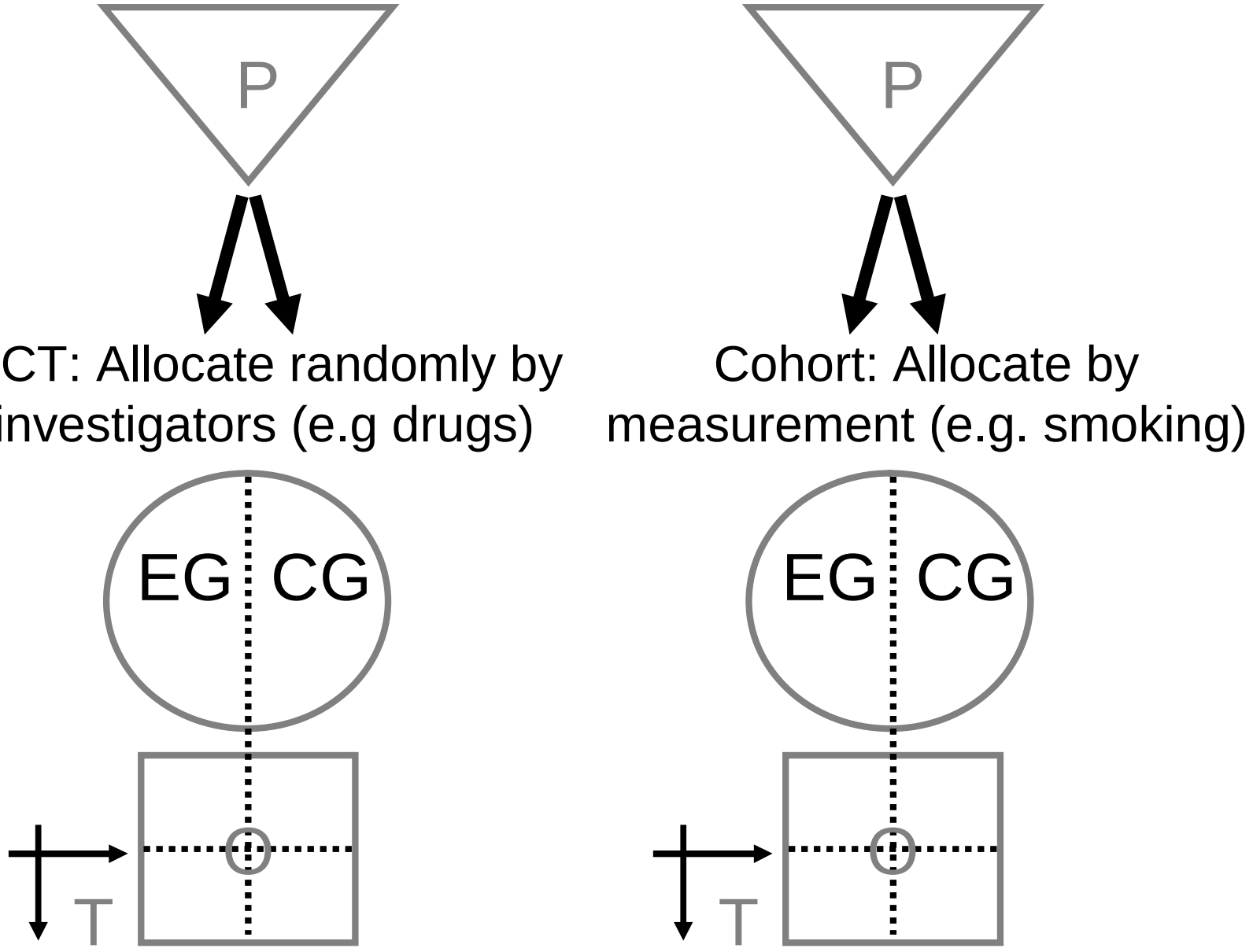
appropriate **Recruitment** processes?

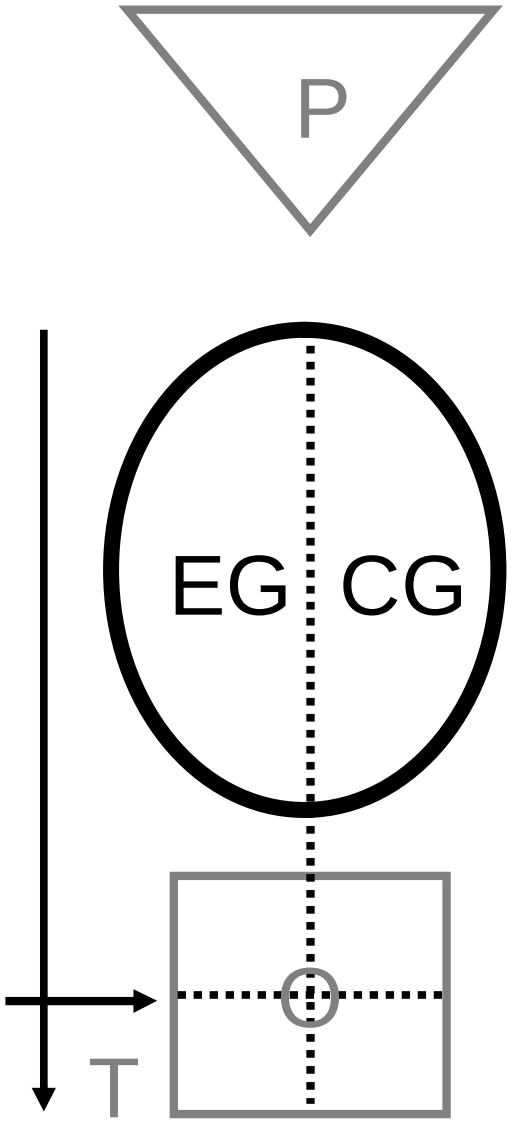
- Study setting & eligibility criteria well described?

e.g. Recruit random/representative sample OR consecutive eligiblesOR volunteers from advertisements

- Participants representative of eligibles?
- Prognostic/risk profile appropriate?

RAMBbo: A is for Allocation





RAMMbo

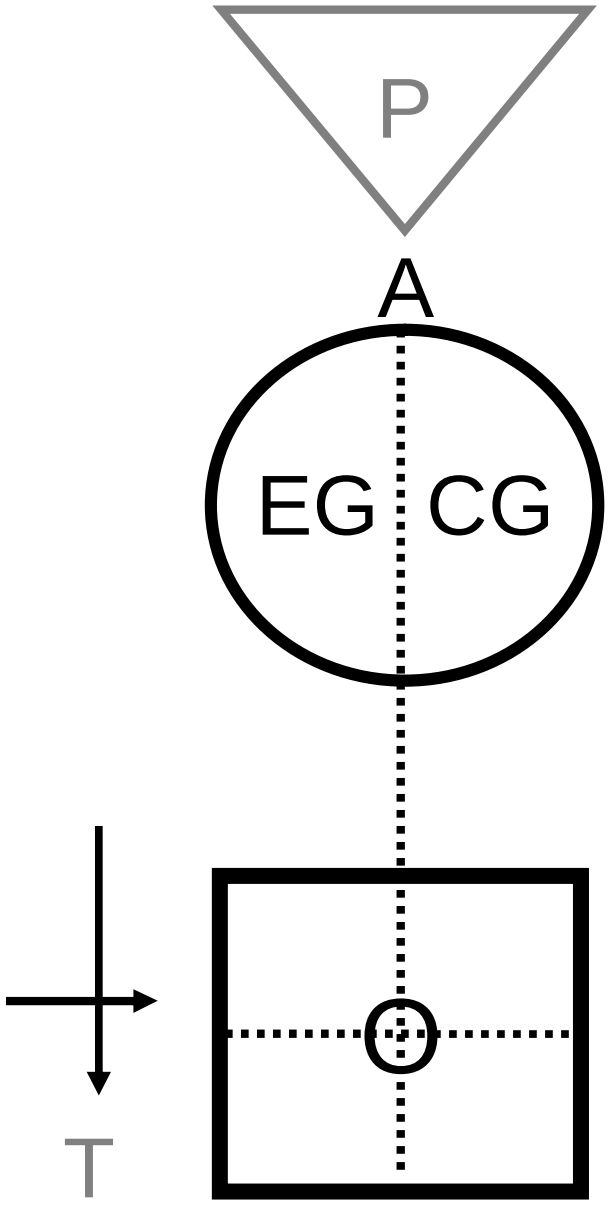
good **Maintenance**?

did most participants remain in allocated groups (EG & CG)

Participants &/or investigators blind to exposure (and comparison exposure)?

Compliance high & similar in EG &CG?
Contamination low & similar in EG &CG?
Co-interventions low & similar in EG &CG?

Completeness of follow-up high & similar in EG &CG?

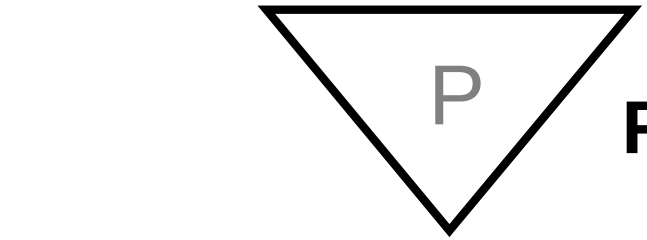


RAMMbo

Measurement of outcomes
blind or**objective**?

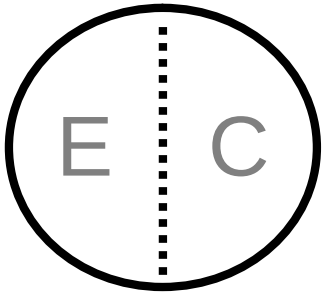
If outcome measurements not Objective (eg. automated or definitive) were investigators blind to exposure (and comparison exposure)

The 4 (GATE) study biases

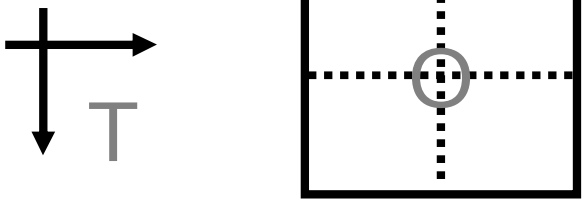


Recruitment bias

Allocation bias

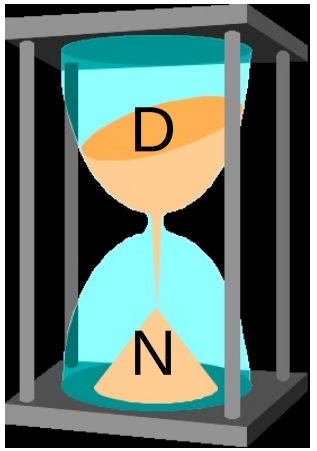


Maintenance bias



Measurement (of outcomes) bias

2 formulas: study analyses



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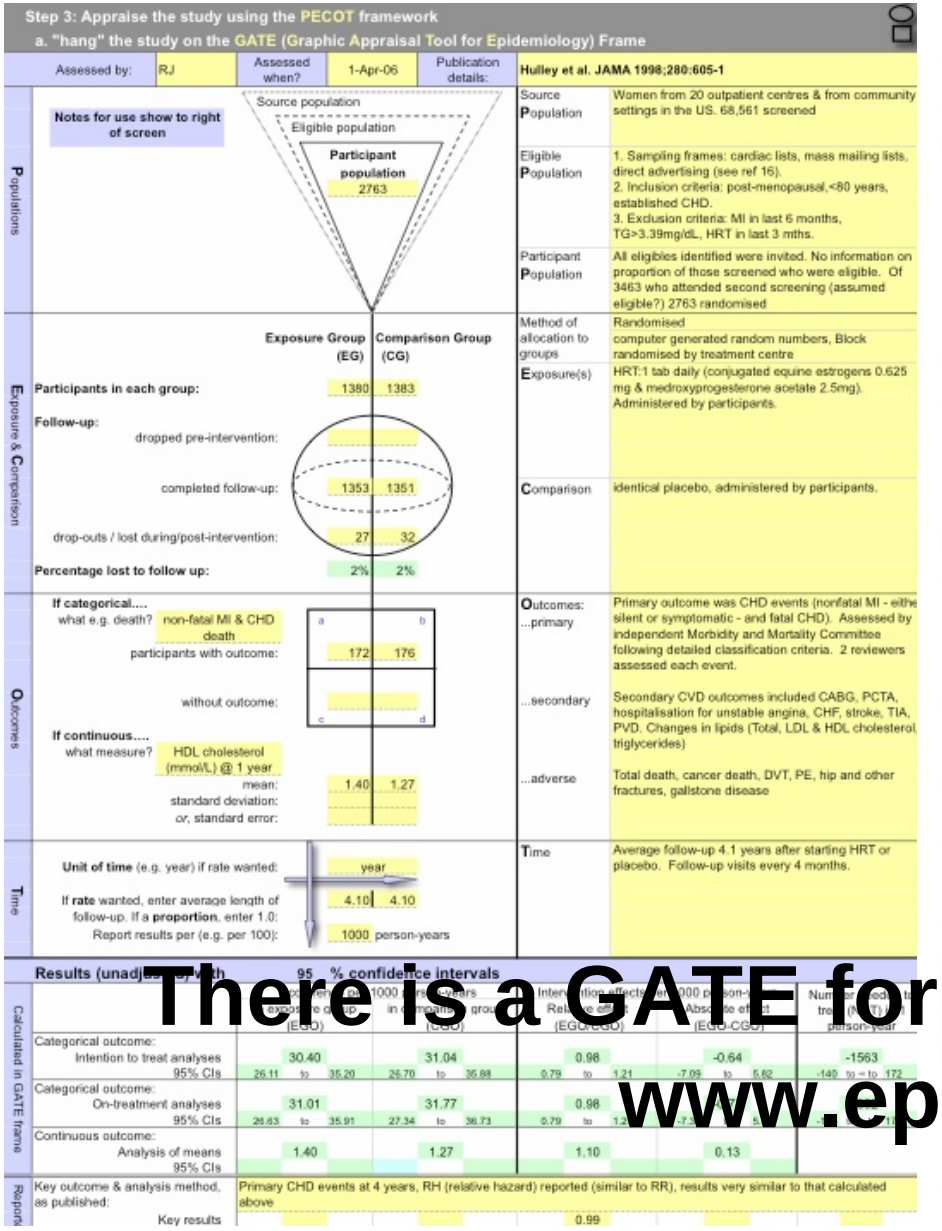
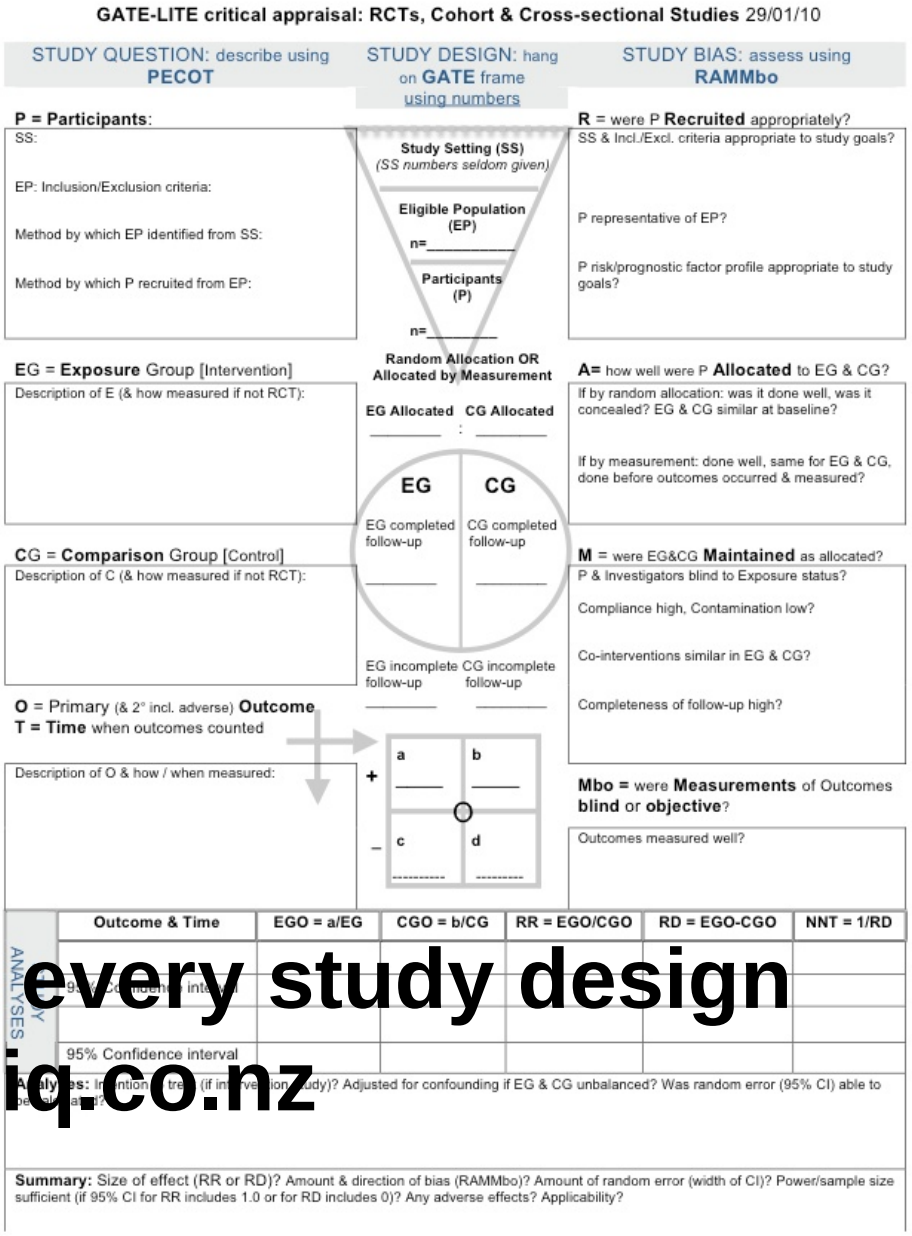
= Numerator ÷ Denominator ÷ Time

2. **Random error (95% Confidence Interval)**

= 1.96 x Standard Error

Excel CATs& paper Gate-lites





There is a GATE for every study design

www.epiq.co.nz

Including SRs & meta-analyses (the 3rd acronym!)

- **F**ind *appropriate studies?*
- **A**ppraise *selected studies?*
- **I**nclude *only valid studies?*
- **T**otal-up *(synthesise) appropriately?*
- **H**eterogeneity *adequated addressed?*