STUDY DESIGNS II

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OTHER OBSERVATIONAL DESCRIPTIVE STUDIES

- ▣ Biometric study

- ▣ Registry based Study

- ▣ Systematic review

- ▣ Meta-analysis

Can descriptive studies test hypothesis??

ANALYTIC STUDIES
all types:

Purposes:

- Are studies used to test hypotheses (Hypothesis testing studies).

- And to measure the magnitude of the association

OBSERVATIONAL ANALYTIC STUDIES

- **Case control study:** **disease** ⟶ **exposure**

- **Cohort study:** **exposure** ⟶ **disease**

- *Exposure & disease* can be the InDependent or Dependent variable according to the study used.
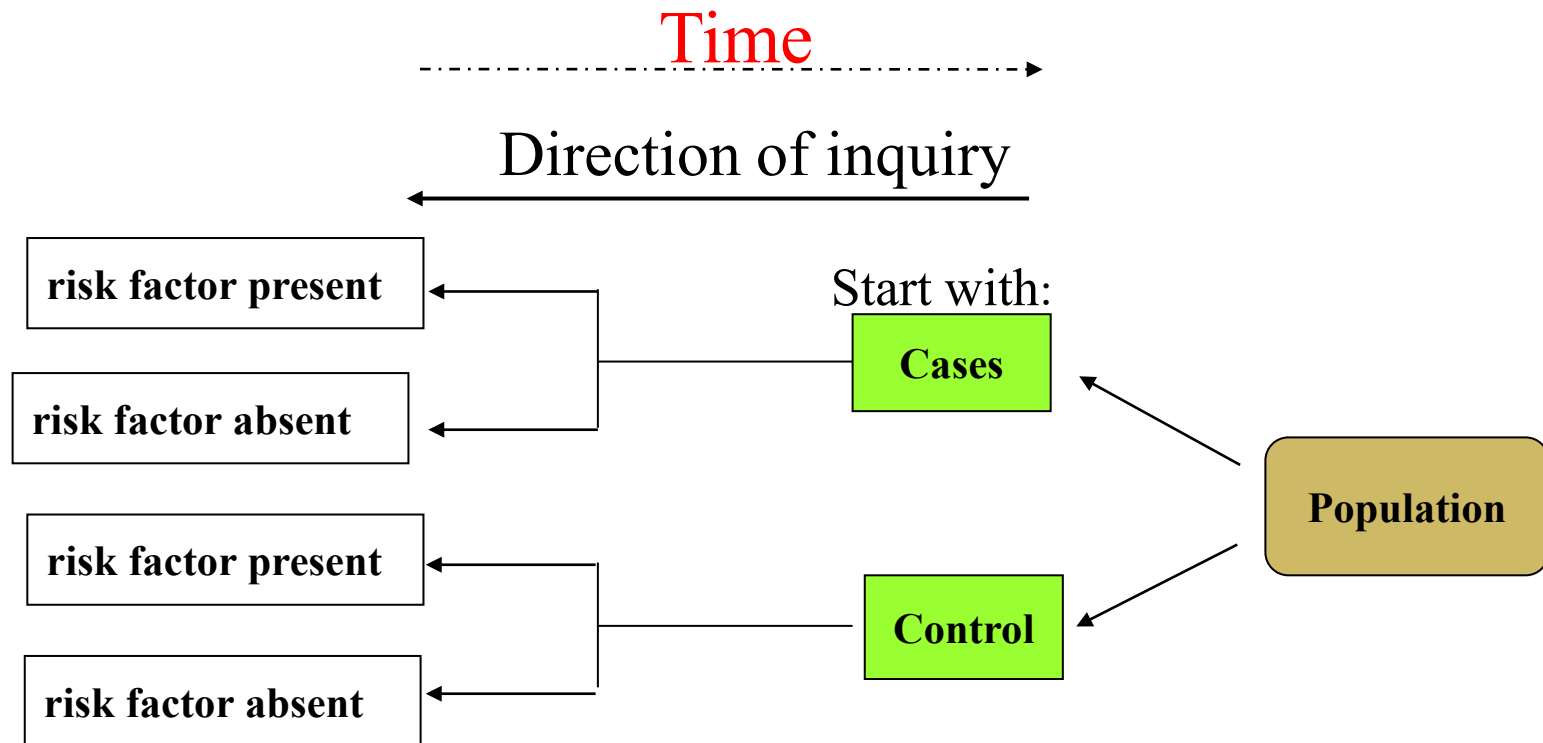
CASE-CONTROL STUDY

A type of observational analytic studies, where the subjects are selected on basis of "whether they do have the disease (*cases*) or they do not have the disease (*control*) under study".

▣ The 2 groups then compared for the proportion of having a previous exposure (s) or characteristic of interest.

Incident cases (newly diagnosed cases) are preferred .. Why?

Design of a Case - Control

CASE-CONTROL STUDIES

Advantages:

- Is relatively quick and inexpensive

- Is optimal for the evaluation of rare diseases, long latency?.

- Can examine multiple etiologic factors for a single disease.

- "Odds ratio" can be estimated

Disadvantages:

- Is inefficient for the evaluation of rare exposures

- Cannot compute incidence rates. *Why??*

- Is particularly prone to bias, selection and recall bias.

CASE-CONTROL STUDY

Selection of control group:

- **is a major determinant validity!**

- **Similarity .. Matching ..** as similar as the cases except the disease status (**account for confounding**).

- **from the same source pop.**

- **The number of control should be (up to 1:4)**

COHORT STUDY

- A study in which two or more groups of people that are free of disease and that differ according to the extent of exposure (exposed and unexposed) are compared with respect to disease development(incidence).

- Synonyms : incidence study, longitudinal study,
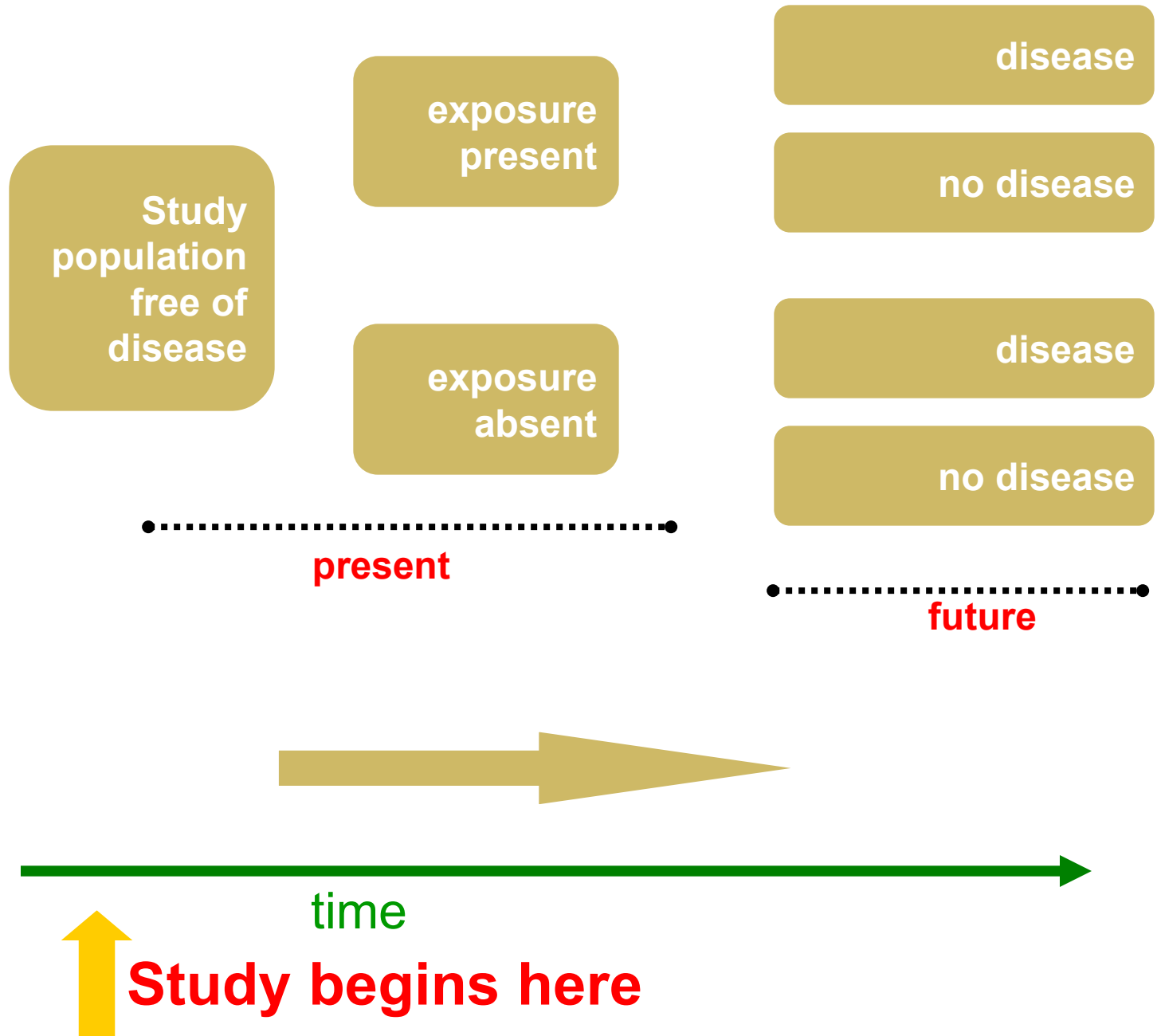
Purpose Of A Cohort Study

- To identify risk, protective factors.
- When exposure is rare.
- assessing effectiveness of preventive measures.

COHORT STUDY

Strengths:

- of particular value when the exposure is rare

- Can examine multiple effects of a single exposure

- Allows direct measurement of incidence of disease.

- Estimate the strength of association by RR.

- Temporal sequence between exposure & disease can be more clearly established

COHORT STUDY

Limitations:

- Is inefficient for the evaluation of rare diseases

- Expensive and time consuming

- Validity seriously affected by losses to follow-up (attrition).

Type Of Cohort Study

Prospective Cohort Study

▫ the exposure at the start, follow-up, to determine the incidence.

Historical Cohort Study

▫ the exposure in the past (before onset of the study) and are followed through existing records in to the future.

Exposure   * Start of the study   outcome

Retrospective cohort

▫ the exposure and disease before the time of the study, (cannot know which precedes which).

▫ It is especially important in diseases with long latency period.

Exposure

out come   * start of the study

A well designed cohort study is a reliable means of showing an association between risk factors and disease .

Why ?

Experimental or Interventional study

Is a planned trial, in which individuals are randomly allocated to two groups. **experimental group** is subject to an intervention, while the other group is control. Effects are measured by comparing the outcomes in both.

What differs it from cohort?

❑ **manipulation of the study exposures under control of investigator …**

Experimental or Interventional study

- Intervention in the form of a new drug, surgical procedure, vaccine, test, or new method of diagnosis.

It can give a degree of assurance about the validity, not provided with any observational design option.

- Is a study design that gives the most reliable proof for causation.

Experimental or Interventional study

. **Randomized Clinical Trial (RCT)**

. **Community trials**

. **Field trial.**

• **Quasi experimental studies.**

Types Of Interventional Studies

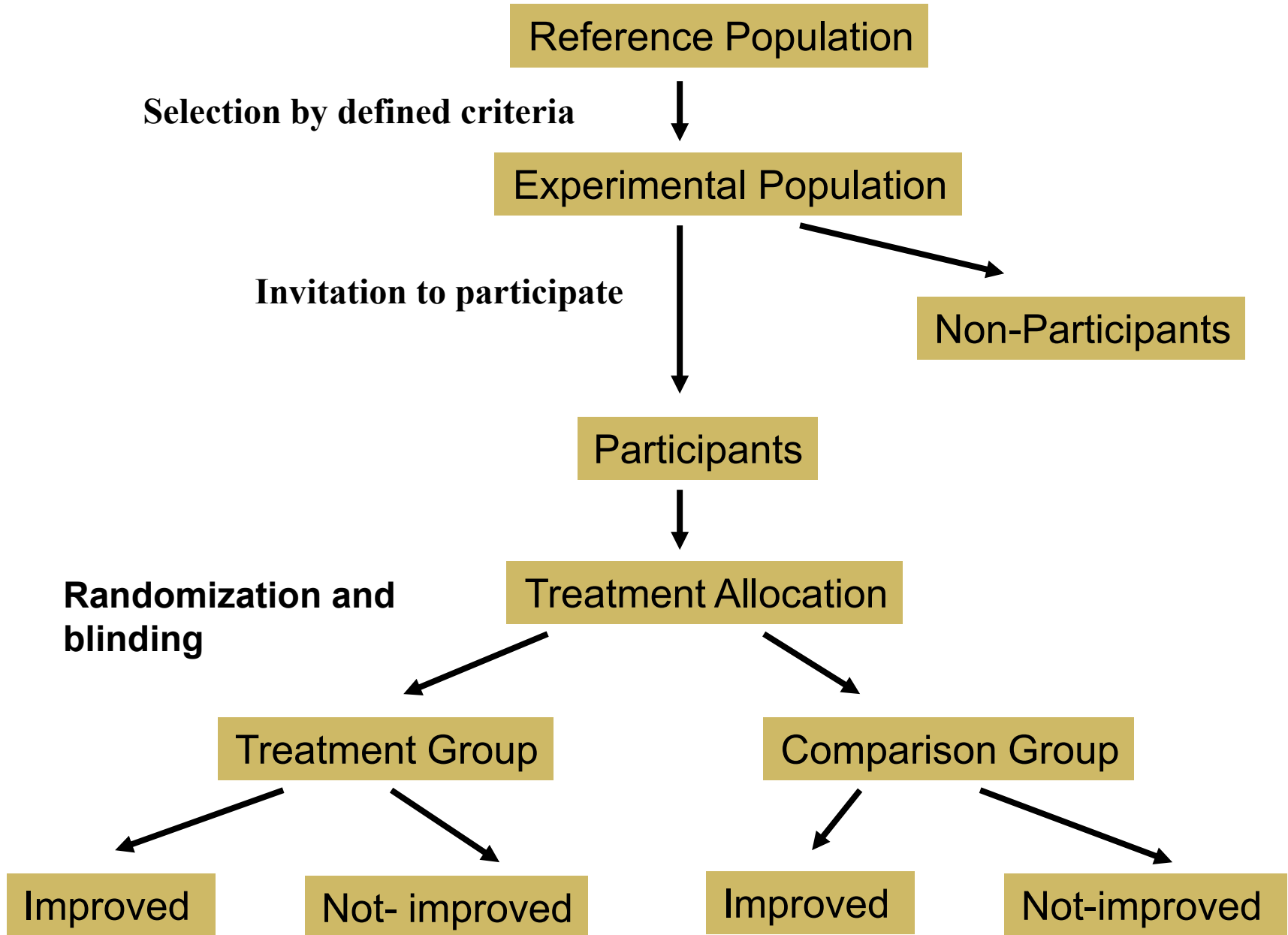- **Randomized Controlled Trail (Therapeutic trial) RCT:**
  - Two different drugs or procedures.
  - Drug & placebo
  - Single drug (before & after Rx).

- Therapeutic trials are conducted among patients with a particular disease to determine the ability of an agent or procedure to diminish symptoms, prevent recurrence, or decrease risk of death from that disease.

Steps in conduct of RCT

1. The protocol
2. Selecting reference and experimental populations.
3. Measure baseline variables.
4. Randomization
5. Blinding the Intervention
6. Follow up
7. Assessment the outcomes.

Detailed design of a RCT

Reference Population

Selection by defined criteria

Experimental Population

Invitation to participate

Non-Participants

Participants

Randomization and blinding

Treatment Allocation

Treatment Group

Comparison Group

Improved

Not- improved

Improved

Not-improved

Types Of Interventional Studies

- **Field Trail; (Preventive trial)**
  - Conducted on *healthy people* at risk of developing a disease

  - Data collection takes place "in the field" from the general population.

  - Example: salk vaccine to prevent poliomyelitis on > 1 million child were divided randomly into 2 groups, salk vaccine group & placebo group

Types Of Interventional Studies

- **Community Trail (Preventive trial)**
  - the treatment groups are communities rather than individuals.

  - Entire pop. (community trial) on fluoride fortification of water.

- **Quasi experimental studies.**

- (study and control groups) have not been randomly assigned.)

EXPERIMENTAL STUDIES

- ☐ **Advantages:**

- High validity of results..

- Can prove causality with minimal bias and confounding factors ...

- ☐ **Unique problems:**
  Ethical
  - Feasibility
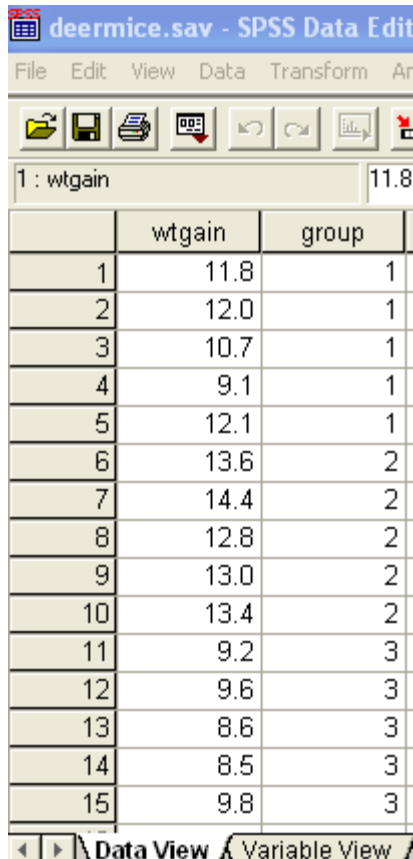
  - Cost

Weight Gain on Different Diets

deermice.sav (Labs 2 & 3)
Explanatory variable = diet group (1=standard, 2=junk, 3=health) **Response variable** = weight gain (grams)

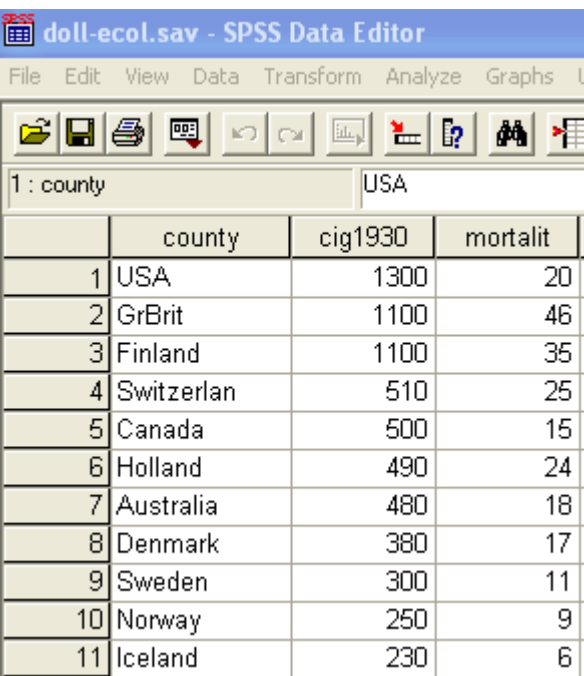|	wtgain	group
1	11.8	1
2	12.0	1
3	10.7	1
4	9.1	1
5	12.1	1
6	13.6	2
7	14.4	2
8	12.8	2
9	13.0	2
10	13.4	2
11	9.2	3
12	9.6	3
13	8.6	3
14	8.5	3
15	9.8	3

*Data are **experimental** because the investigator assigned the explanatory variable*

Cigarettes and Lung Cancer Mortality

doll-ecol.sav (Chap 12 and 13 labs)
Explanatory var = per capita cigarette consumption (cig1930)
Response var = lung cancer mortality per 100,000 (mortalit)

Data are observational with data on aggregate-level. This is an
ecological study

	county	cig1930	mortalit
1	USA	1300	20
2	GrBrit	1100	46
3	Finland	1100	35
4	Switzerlan	510	25
5	Canada	500	15
6	Holland	490	24
7	Australia	480	18
8	Denmark	380	17
9	Sweden	300	11
10	Norway	250	9
11	Iceland	230	6

How to select study design?

Questions that need to be answered

- ?distribution of blindness – **descriptive**
- ?correlation between import of fruits and visual acuity among the population – **ecological correlation**
- ?prevalence of blindness, cataract or poor vision – **cross-sectional/survey**
- ?association between vit A def. and blindness – **case-control**

Questions that need to be answered

☐ ?incidence and relative risk of radiation cataract among radiographers- cohort

☐ ?therapy/preventive methods useful or effective , daily vit A supplementation to prevent xeropthalmia - intervention