Research types & methods-Part 2

Professor Dr Abubakir M. Saleh

Basic Research Methods NUR 308

5th week

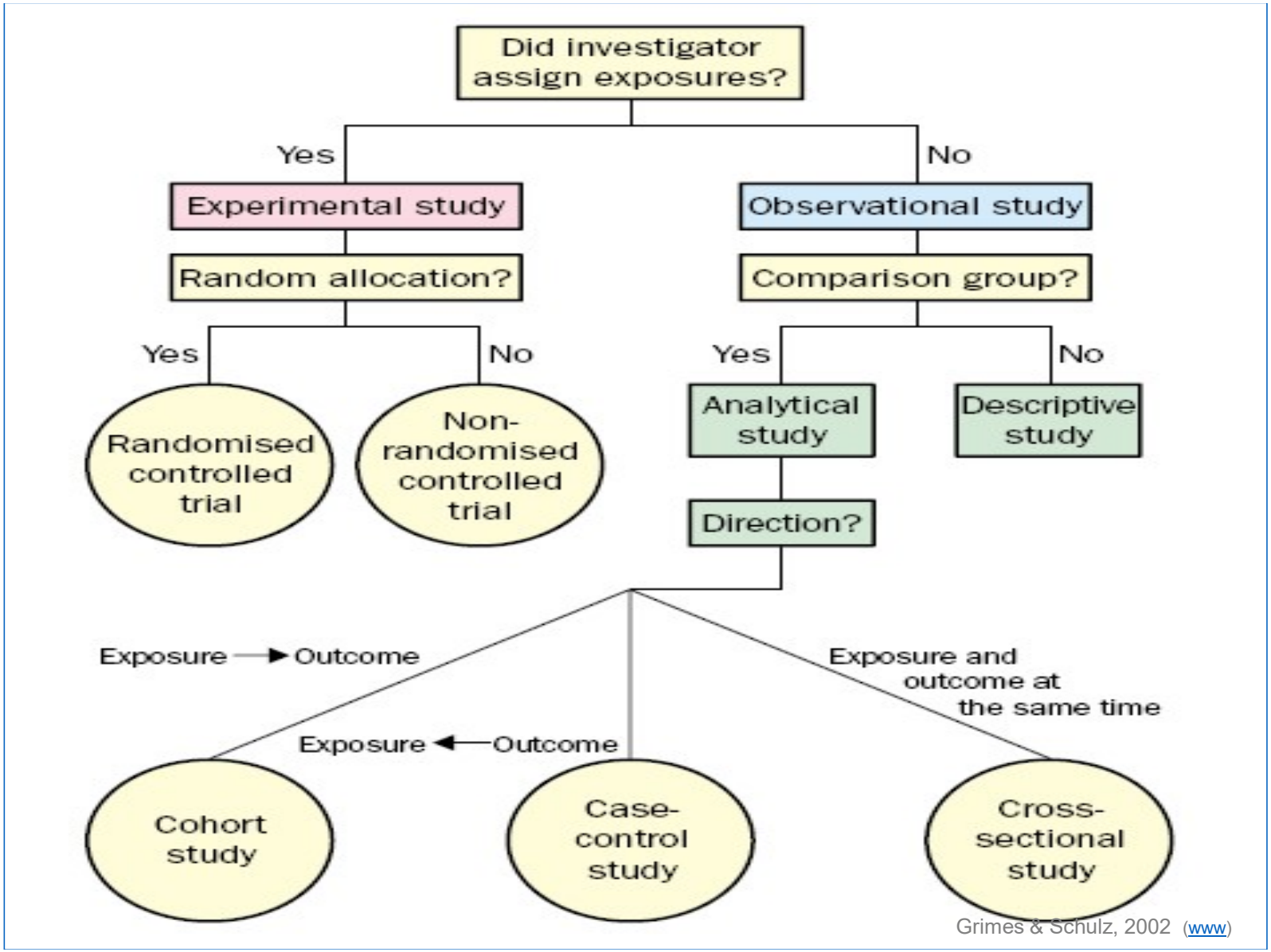
Outline

- Research types based on intervention:
  - Observational & Experimental research.
- Observational research:
  - Case-control research.
  - Cohort research.
  - Ecological research.

Research types: based on intervention

It divides the studies into two categories

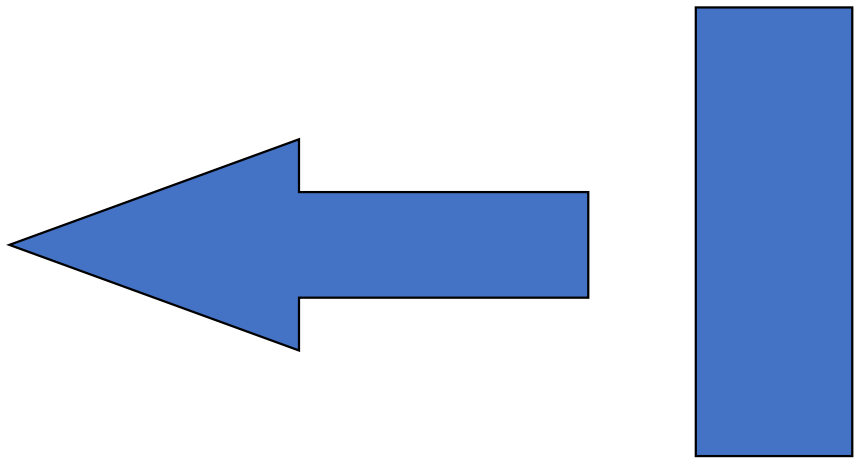
1. Observational researches (no intervention): the investigator measures but does not intervene.
2. Experimental researches / Interventional researches: involve an active attempt to change a disease determinant, such as an exposure or a behaviour, or the progress of a disease through treatment.



Grimes & Schulz, 2002 (www)

Case-Control research

Cases: Disease
Controls: No disease



Definition & selection of cases

- Case definition:

➢ Cases should be clearly defined .The eligibility criteria (inclusion and exclusion criteria) should be clear.

➢ Some cases need pathological examination for diagnosis.

Sources of cases

- Hospital and medical care facilities.
- Office records of physicians.
- Disease registries (e.g., cancer).
- Pathology department.

Definition & selection of control

- Controls: persons without the given disease.
- Controls must fulfill the same eligibility criteria defined for the cases, with the exception of the disease (outcome).
- Usually , they are assumed disease free if they have not been diagnosed.

Sources of control

Controls should be selected from the same population from which the cases are selected

Typical controls:

- Friend controls.
- Neighbourhood controls.
- Physician controls.
- Hospital controls.
- Population-based controls.

How many control per case:

- The optimal case-control ratio is 1:1.

- When the number of cases are small, the sample size of the study can be increased by increasing the number of control e.g., 1:2 , 1:3, 1:4.

Data collection

- Data must be collected in the same way from both groups: cases and controls.
- Investigators must be objective in the search for exposure, especially since the outcome is already known.
- Sometimes it is necessary to interview patients about potential factors, such

  as smoking history, use of medicine.

Biases in case-control research

- **Selection bias**

  Selection bias occurs when the subjects in one group are different, or the cases and

  controls are not comparable (other than disease).

  To prevent this bias, precise

  selection criteria should be defined for both cases and controls.

Biases in case-control research(Cont.)

- **Ascertainment bias**

It may happen because:

- Cases may recall exposure better than the controls.
- Investigators may search for exposure better in cases than in control.

Biases in case-control research(Cont.)

- **Limitations for recalling past events**

  In case-control studies much data is collected from interviews. Human beings differ in

  their capacity to recall information.

  Cases may have better recall than controls. It is also possible that the person may not have the information requested.

Biases in case-control research(Cont.)

- **Confounding**

It occurs when the observed result between exposure and disease is distorted because

of the influence of the third variable.

Strengths of case-control research:

- Case-control studies cost less than other studies, e.g., cohort studies.
- Case-control studies are more appropriate for rare diseases.
- The association between diseases and multiple exposures can be studied at the same time.

Weaknesses of case-control research:

- Case-controls are subject to multiple biases (especially selection and recall biases).
- Case-control studies are difficult for determining the period between
  the exposure and disease.
- Identifying control may be difficult.

Case-control research: measure of association

- Compare the proportion of exposure by means of a ratio : Odds ratio (OR)

OR=odds for exposure among cases/ odds for exposure among control

D+ D- OR=(a/c)/(b/d)

Exposure +

-

a	b
c	d

Example: in a case-control study to investigate association between smoking and infarction, 100 cases and controls were studies. 60 0f the cases and 40 of the controls were smokers. Calculate odds ratio for the effect of smoking on MI

First we tabulate the data as below and then do the calculations

Smoking	Myocardial infarction	No Myocardial infarction
Yes	**60**	**40**
No	**40**	**60**

Odds of exposure among cases= a/c= 60/40=1.5

Odds of exposure among controls= b/d= 40/60= 0.66

Odds ratio= 1.5/0.66= 2.25

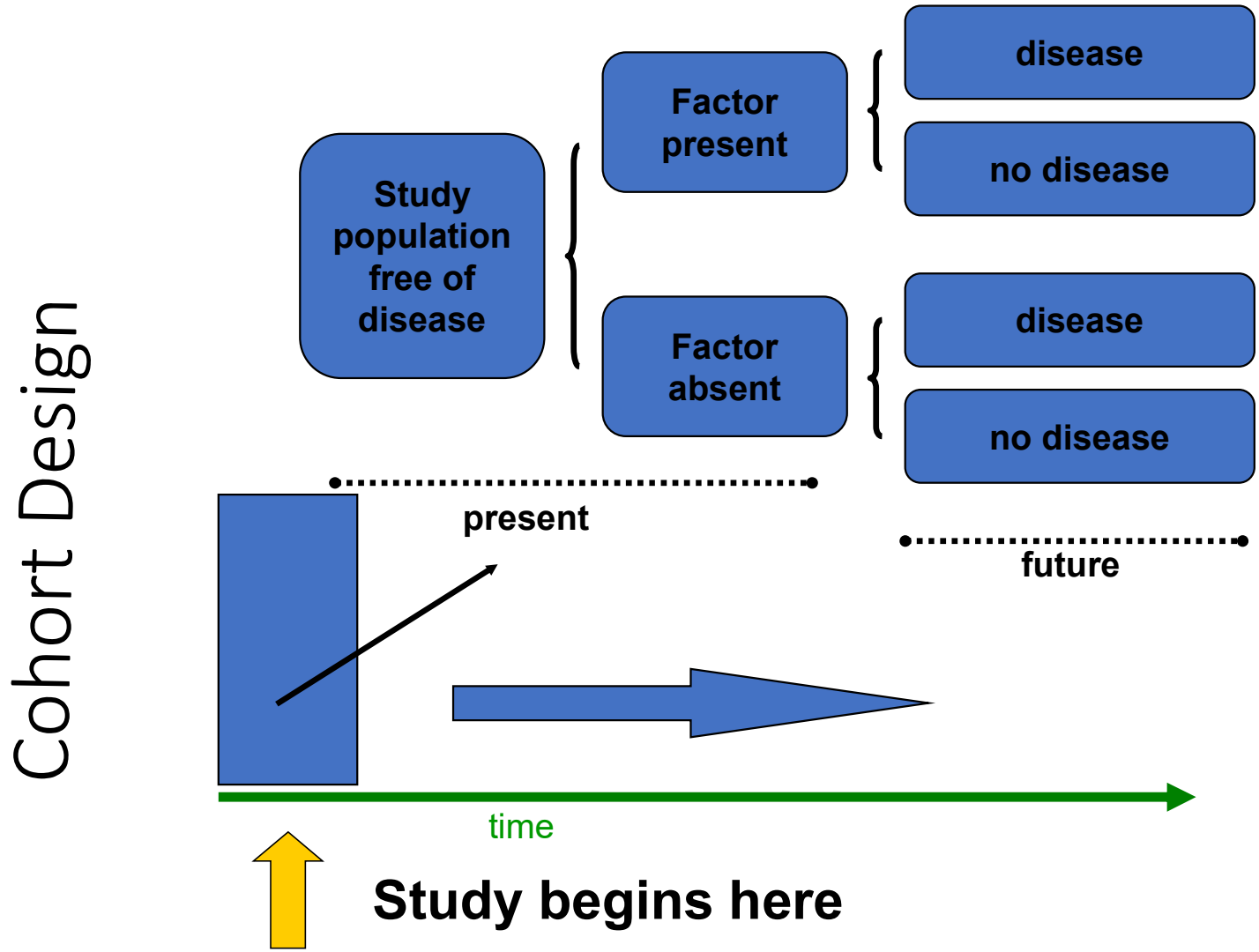
Odds ratio= ad/bc= 60x60/40x40= 360/160 = 2.25

This means that people with MI in our study were 2.25 times more likely to be smokers than were controls.

Cohort-research

- "A study in which two or more groups of individuals those are free of disease and those differ according to the extent of exposure to a factor of interest, are followed over a period of time to see how their exposures affect"

Cohort Design



Basic measures

- **Measures of disease occurrence:**

— Incidence Rate (IR).

- **Measures of association between a factor and a disease:**

– Relative Risk (RR).
– Attributable Risk (AR).

Basic measures(Cont.):

- **Incidence:**

Risk of developing disease

Number of new cases of disease/ persons at risk (during the same time period)

Basic measures(Cont.):

- **Relative Risk (RR):**

Determine the strength of the association between exposure and disease

➢RR=1 (no association)

➢RR>1 (exposure increases risk for disease, e.g. RR=2.0 can be interpreted as two fold increase in risk)

➢RR<1 (exposure decreases risk for disease).

Basic measures(Cont.):

- ***Attributable Risk (AR):***

The excess risk of disease observed among exposed subjects.

AR= IR (exposed) – IR(non-exposed).

Cohort-research: example:

- Two hundred alcoholic persons were compared with 200 non-alcoholic individuals. After 5 years, 40 of the alcoholics developed Tuberculosis (TB), while only 5 of the non-alcoholics developed TB.

First we tabulate the data as below and then do the calculations

	TB	No TB
Alcoholic	**40**	**160**
Non-alcoholic	**5**	**195**

Incidence rate among exposed (Alcoholic)= 40/200x100= 20 per 100 per 5 years.

Incidence rate among non-exposed (Non-alcoholic)= 5/200x100= 2.5 per 100 per 5 years.

Relative risk =incidence among exposed/incidence among non-exposed 20/2.5=8.

Incidence rate of TB is 8 times higher in alcoholic than non-alcoholics.

Strengths of cohort-research

- Ideal for studying the association between risk factor and outcome.
- Can evaluate multiple outcomes/diseases.
- Clear time sequence.

Strengths of cohort-research(Cont.)

- Less bias due to prospective evaluation of exposures.

- Efficient for rare exposures.

- The best or only ethical way, sometimes, to do the study (situations where randomization is not possible).

Weaknesses of cohort research

- Time consuming.
- loss of participants.
- Unexpected changes over time:

– Changes to the environment can influence the association of disease and possible cause.

Weaknesses of cohort research (Cont.)

Changes in diagnostic criteria and methods.

– Changes of staff.

• Financial problems: lack of funding and the high costs of record keeping.

References

1. Bob Mathews & Liz Ross. *Research Methods*, a practical guide for the social sciences. Pearson Education limited 2010. England.

1. Jonathan Grix. *The Foundation of Research*. Palgrave Macmillan 2004. London.

2. Geoffrey Marczy k, David DeMatteo& David Festinger. *Essentials of Research Design & Methodology*. John Wiley & Sons, Inc 2005. New Jersey.

3. SK Gupta. *Basic principles of clinical research & methodology*. Jaypee brothers medical publishers (P) limited 2007. New Delhi.

4. RL Bijlani. *Medical Research*. Jaypee brothers medical publishers (P) limited 2008. New Delhi.

5. Catherin Dawson. *Practical Research Methods, A user-friendly guide to mastering research*. British Library Cataloguing in Publication Data 2002. UK.

•