STRATEGIES FOR DATA ANALYSIS: RCT AND COMMUNITY INTERVENTIONS

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STRATEGIES FOR DATA ANALYSIS: RCT AND COMMUNITY INTERVENTIONS (1)

Introduction and definitions.

RCT is a control experiment in which the investigator assigns treatment (T3) at random.

Used to assess safety and efficacy of T3 for human diseases / health problems.

From scientific perspective, the RCT with adequate sample size and blinding is the preferred study design.

RCT INVOLVES 2 STAGES (2)

1) Laboratory expts — using animals
   — in vitro procedures

2) Human subjects *

Stage 2 categorised into four phases

Phase I: Initial evaluation using 20-100 subjects to assess safety and tolerance

Phase II: 100-200 subjects to evaluate effectiveness

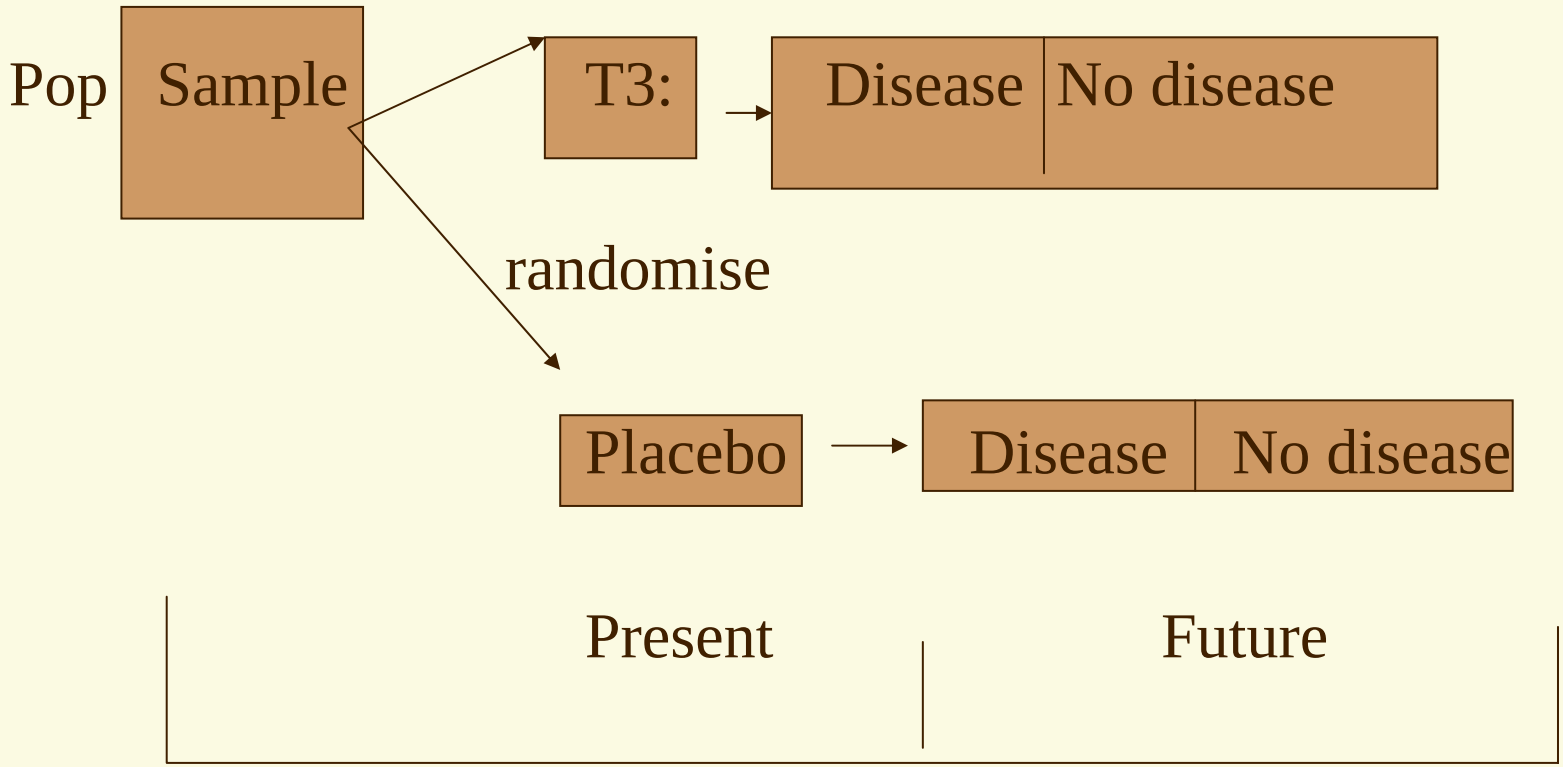
Phase III: 500-1500 subjects to assess further effectiveness and safety information

Phase IV: Post marketing – long term effects

PROCEDURE (3)

- Assembling the study cohort
- Measuring base line information
- Randomising the study subjects
- Applying the intervention
- Measuring the outcome
- Analysing the results

FIGURE 1 (4)


Pop
Sample
T3:
Disease
No disease
randomise
Placebo
Disease
No disease
Present
Future

ASSEMBLING THE STUDY COHORT (5)

- Kind of subject e.g. malaria + pregnancy
- Inclusion and exclusion - primiparae / multiparae
- Adequate sample size - Large size preferred but finances and time?
- Measuring baseline information
- Characterise the study cohort e.g. preeclampsia
- Identification - name, hospital
- Demographic factors - age, sex,

- Clinical factors (diagnosis) e.g. pre-eclampsia
- Measuring outcome variables:
  - At the beginning – e.g. BP
  - At the end
- Continuous outcome variable

MEASURING PREDICTORS OF OUTCOME (7)

- Baseline variables that can predict outcome e.g. is preeclampsia more serious in primiparae ?

Randomising the subjects

- Eliminates baseline information influence
- Main predictor variable of the study
- Different procedures of randomisation

Applying the intervention

Experimental group that receives the T3

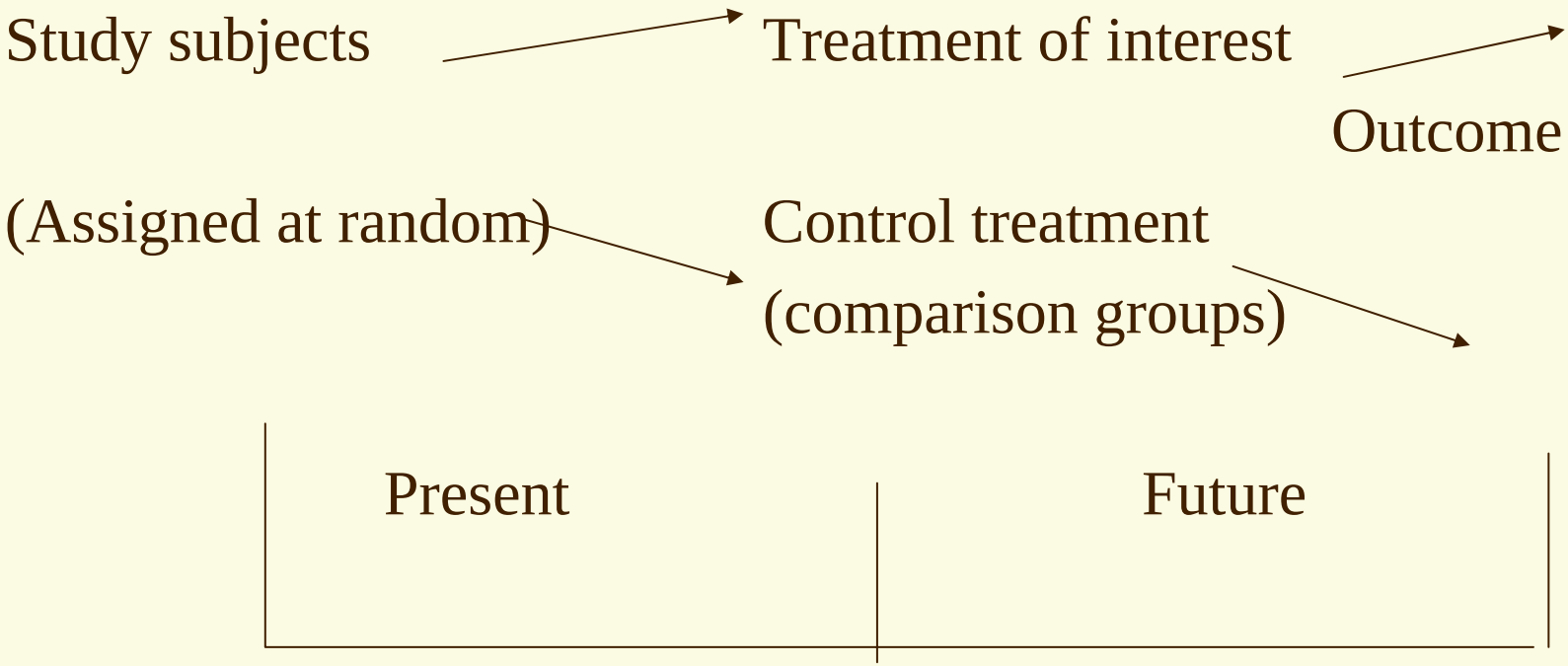
Control group that receives no T3 or a standard comparison T3

BLINDING:
T3 CONCEALED FROM PARTICIPANTS (8)

- Type:
  - Single: T3 concealed from subjects
  - Double: T3 concealed from subjects and investigator
  - Triple: T3 concealed from subjects, investigator and evaluator
- Importance: eliminates unintended interventions ex:
- Choice of a comparison group
- Assuring compliance by attending clinic visits
- Adhering to the intervention protocol

USUALLY INVOLVES COMPARISON GROUPS DEFINED AS FOLLOWS (9)

Fig 2:



DESIGN AND DATA COLLECTION METHODS (10)

RCT designs have two basic forms: Parallel design and successive treatment design. Parallel design: see figure I

Successive treatment design has two variations:

replacement treatment design and crossover design

SUCCESSIVE REPLACEMENT TREATMENT DESIGN (11)

Figure 3 (comparison groups)

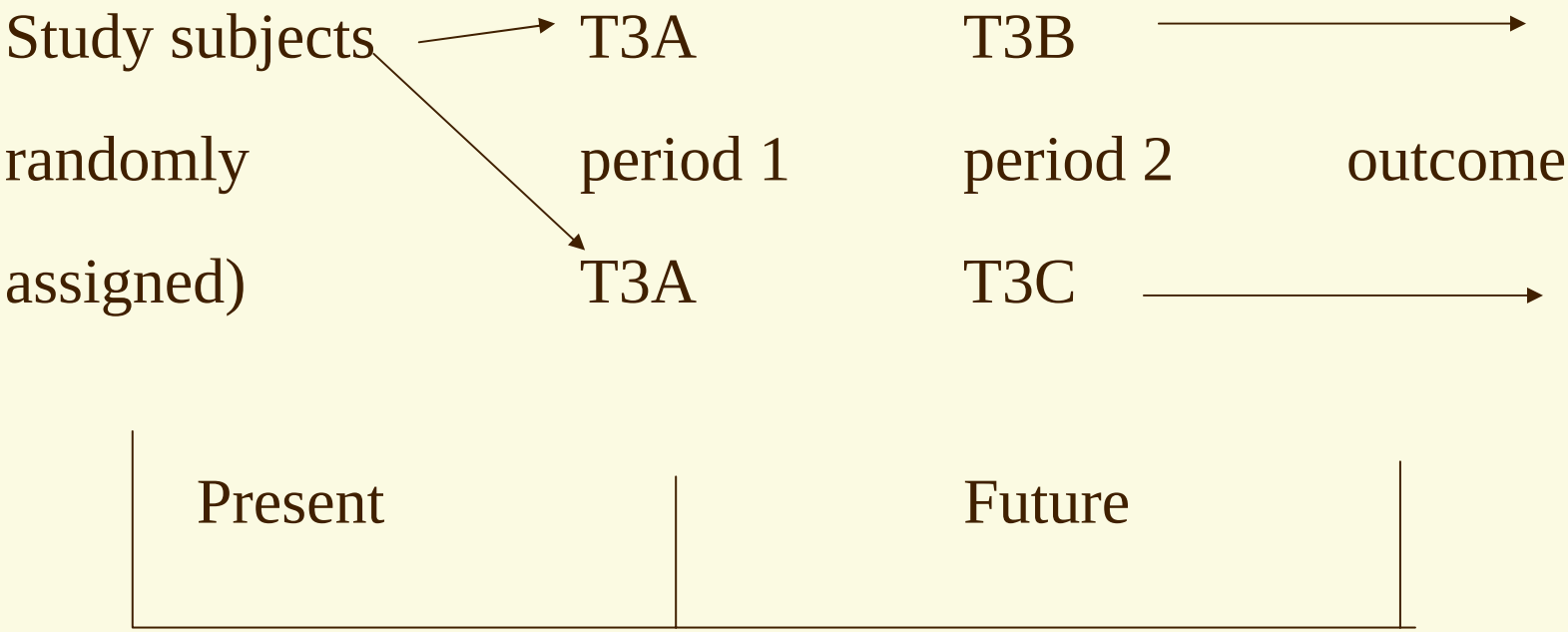
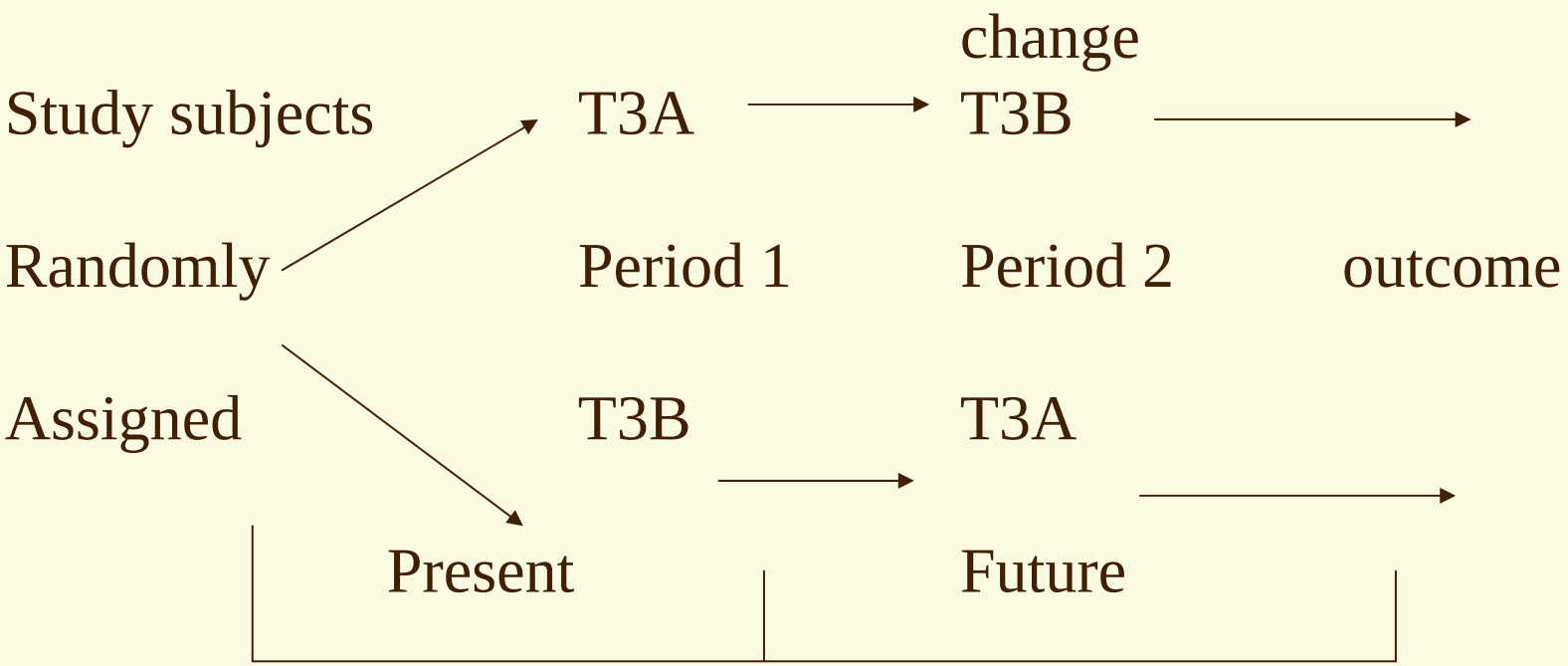


Figure 4:

Comparison groups



- Measuring Outcome
- Research question
- Statistical characteristics
- Assessed accurately and precisely
- Continuous e.g. age in years, parity, birth weight
- Dichotomous e.g. exposed or unexposed never or ever etc.
- Polychotomous – measure on more than two levels – never, occasional, frequent e.g. condom use alcohol consumption
- Number of outcome variables
- Death as an outcome measure
- Morbidity as an outcome measure

ANALYSIS (14)

Planned concurrently with designing the study protocol and data collection.

Why?

Ensure that information is collected for all variables for analysis

Organise data into tables to compare cases and controls e.g. demographic xtics, risk factors etc.

Careful examination of differences of various characteristics:

- Comparability between cases and controls
- Comparability with studies published
- Comparability with known risk factors
- Comparability with other studies
- Identify factors that will potentially confound an association between the health problem and the exposure under study ex
- Evaluate similarities or dissimilarities between cases and controls

- internal control - to see whether the subjects were selected or interviewed in a comparable manner ex multicentre studies
- Estimate of Relative Risk (RR)
- Odds Ratio (OR) : when health problem is rare among the subject; OR = RR

DEFINTIIONS:

RR: Measures of the magnitude of the association between the T3 and outcome under study (incidence of outcome among case / incidence of outcome among controls).

Odds of disease = proportion of persons with the health problem / proportion of persons without the health problem.

Ex	D+	D-	
Factor f+	a	b	a+b
Factor F-	c	d	c+d
	a+c	b+d	a+b+c+d

RR = a/a+b / c/c+d

CONCLUSION (19)

Statistics = roles in epidemiology.

Data description is one role statistical influence is another role. Also viewed as a collection of methods for making decision such as whether an association is present or not.