UE : ANGLAIS

ENSEIGNANT : Mme. York

DATE : 03/10/24

GROUPE : Prono Eve, Ruan Oriane

REMARQUES : **RCTs important, présentation par groupe à faire en novembre (dates en fonction des stages de sémio). Allez voir le vocab sur moodle.**

CLINICAL TRIAL AND RTC'S

Table des matières

I) Different phase of a clinical trial

Video : The clinical trial journey from "mayo clinic"

Quizz Socrative :

1) Phases are designed to help decide whether a drug or device moves from an idea to patient care.

A- True
B-False

Réponse : TRUE

2) lab experimentations

A- Can be referred to as discovery science
B- Are performed using computers
C- Always require cell studies
D- Can use animal models
E- Are carried out before clinical research starts
F- All of the above

Réponse : A, B, D, E

3) Phase one clinical trials

A- Enrol volunteers with or without the condition under study
B- Require high number of participants
C- Focus on the safety of the medical intervention
D- Study drugs but also devices or procedures
E- Focus on tolerance or participants to intervention
F- Usually take years to complete

Réponse : C, D, E

ps : low number of healthy volunteers, over a short period of time, to study safety and tolerance of participants to an intervention

4) Phase two clinical trials

a- Enrols participants with or without the health condition under study
B- Need medium sized participant samples
C- Compare the drug to a placebo
D- Focus on side effect/adverse events
E- Take years to complete

Réponse : B, C, D

5) If phase 2 trials have been successfully completed, phase 3 trials always follow

A- True
B- False

Réponse : FALSE

Ps : many phase 1 and 2 trials meet a dead end : funding disappears, result are inconclusive, intervention fails

6) Phase three trials are conducted

a- with a larger group of volunteers with a certain condition
b- over several years
c- to confirm previous results
d- to compare the intervention with another
e-after FDA approval
f-none of the above

Réponse : A, B, C, D

PS : to see if efficacy on a lot more people, in comparison to other treatment, over a long period, to confirm previous results

7) FDA approval

a-occurs before phase 3 trials
b-requires reviews all trial data, intervention and intended use
c-requires assessment of benefits over risks
d-all the above

Réponse : B, C

FDA : food and drug administration (à connaître +++)

8) Intervention becomes treatment for patients after FDA approvial

A- True
B- False

Réponse : TRUE

9) Once treatment has been approved, monotoring still continues to ensure treatment is still safe and effective

A- True
B- False

Réponse : TRUE

II) Study analysis

A) Discuss study about vaping

Article : Vaping damages young people's lungs as much as smoking, study suggests | Vaping | The Guardian

From the information in the article, what do you think of the study that was conducted ? Discuss this in groups.

Write a list of the **strengths** and **weaknesses** about the study that was conduct **:**

Strengths

- it is great to start talking about vaping because there are a lot of health issues that can be conduct by vaping
- it is a relevant study in our days, it show the increase of the vaping habits and the impact it may have
- it is a recent study
- they compare blood vessels diameter and blood oxygen levels : so we can talk about objective criteria

Weaknesses

- What is the age of the people included in the study ? Does it represent the population
- They don't describe the characteristics volunteers in the study
- Only 60 participants (small sample of the population)
- There are only young people
- Lack of information/data
- No info on the vaping product

If you wanted to assess the dangers of vaping how would you design a study ?

Discuss in groups and then write down the key details of your study sush as :

- **who** you would include and why
- what **data** you would collect and why
- **what** you would do with the data
- how **long** the study would run
- **where** you would conduct the trial

Who : we include more people with different generation, the two gender in the same proportion
- 10000 person : 2 000 North America, 2 000 South America, 2 000 …
- students and non-students : age groups (tranche d'âge), under 18, …

Data : lung capacity, cardiovascular function, quality of life, frequent

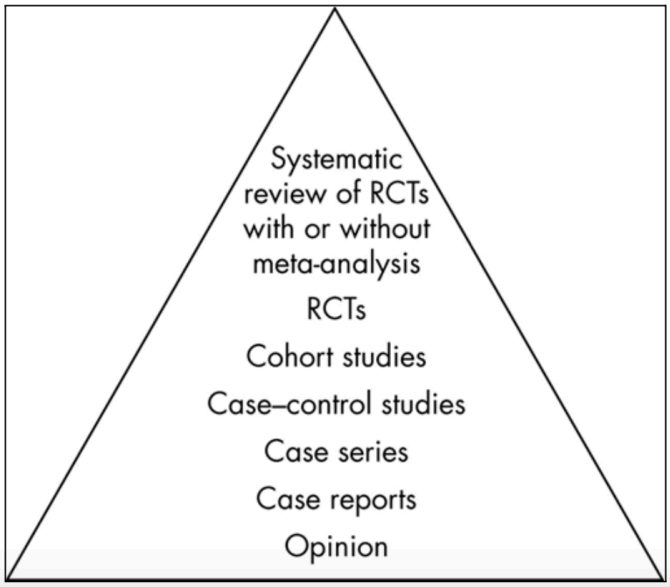
What : compare data with previous study (**meta-analysis**), over time

How long : 1 year, 2 years …

Where : in the hospital, a university, a city, a country

III- What is an RCT?

A) Hierarchy of evidence for questions of efficiency of intervention and treatment



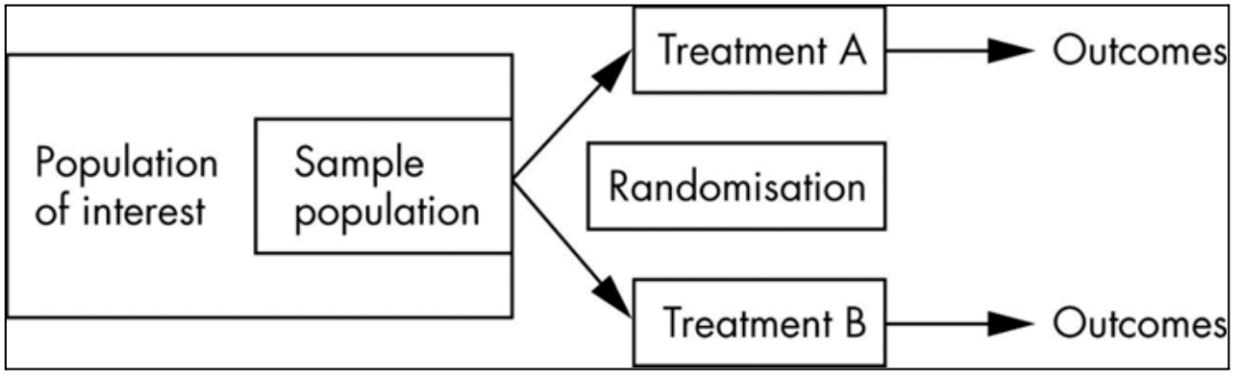
RCT : randomized controlled trial (+++)

Explication du schéma :

- Opinion is the lowest level of evidence, when we start a study we start with an opinion
- Case reports don't have control, they are based on just one person.
- Case series : a group of a case report
- Case-control studies : when we have people who are sick and a groupe who are in good health and we compare (with a groupe control)
- Cohort studies with a lot of people (observational study)
- The higher up the pyramid the less chance for bias (systematic review = re analyzing RCT results).

In conclusion : Randomized controlled trial (RCT) is the most scientifically rigorous method to test hypotheses. It is the "**Gold standard**" for evaluating effectiveness of interventions.

B) Basic structure of RCT



In the population, we take a sample which is going to receive the treatment A or B.

population of interest = target
RCTs :
meta-analysis
with or without review of RCTs systematic

C) IMRAD = Structure of the abstract

1) Methods

Introduction :

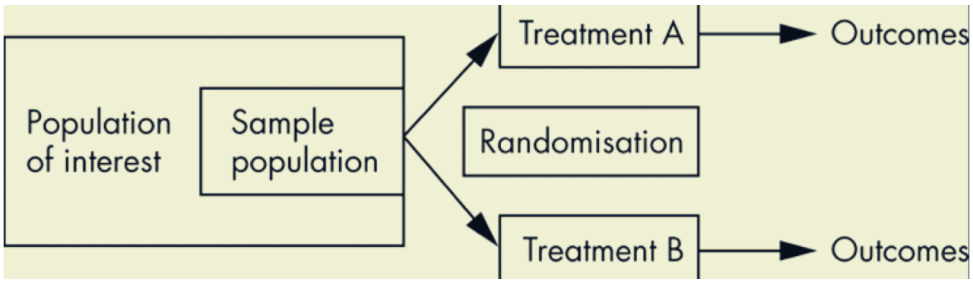
- problem addressed/context
- reasons for (lack of consistent data)
- research questions

Methods :

- detailed study design/protocol (accord avec comité d'éthique)
- follow up period and frequency
- parallel vs crossover vs factorial
- randomisation and blinding (double, single and open label)
- primary/secondary endpoint

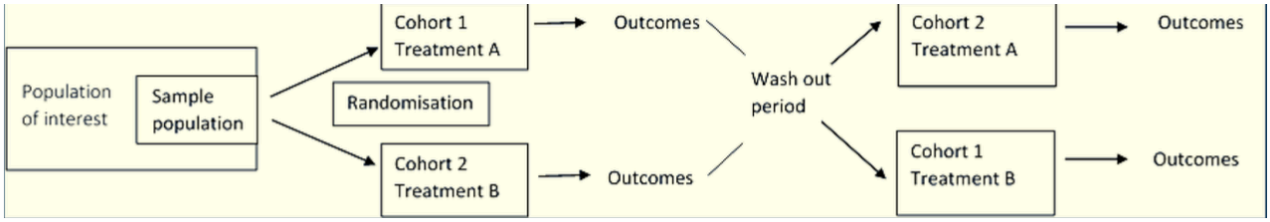
Parallel, **cross over** and **factorial** group design relate to the course a study group takes through the study.

A parallel design specifies that the groups will receive a single intervention and thus be compared.

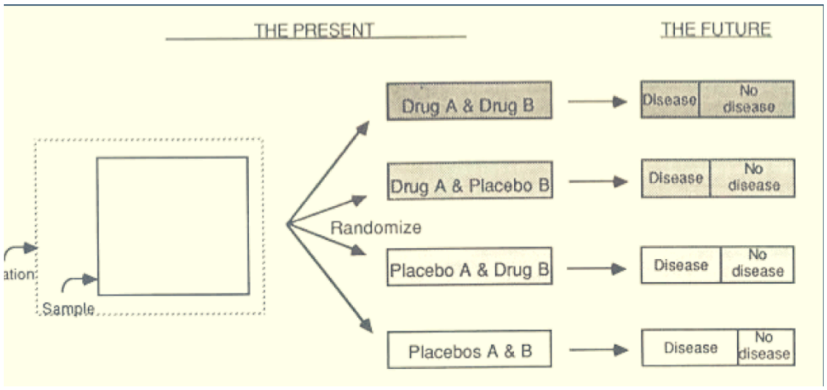


A cross over design (seen in oncology ++) is where the patients will follow each treatment but not in the same order (thus the order of treatment is randomized), rather than allocation of intervention. Crossover trials mean that fewer participants are needed and there is no need for a control group

we test both treatment on both group (+++)



A factorial group design is where two independent interventions are assessed at the same time. This saves time by essentially combining two studies into one. (juste savoir que ça existe)



- Randomized and blinding (double, single (only the doctor knows the treatment) and open label (everyone knows, in case of ethical problems/ recognizable taste or side effects of the drug).

- Primary/secondary endpoints/ outcome

Participants :

- Inclusion and exclusion criteria (eligibility) => bias (health of the participants at the time of the study, question this)
- Required an sample size

Settings/Location :

- single vs multiple site
- national/international

Statistical tools :

- Types of analysis

2) Results/findings (we will learn more about it next time)

They should be detailed and clearly explained
Adverse events/side effects : if you have found an effective treatment but has very severe side effects... Is it safe, is it going to include quality of life for the patient ?
Graphs, flow charts (dit combien de personnes ont quitté l'étude et à quel moment), figures, tables clearly present data : forest plot / Kaplan Meier curves *(savoir ce que c'est, les comprendre/les expliquer selon la prof mais elle n'a pas développé plus que ça dessus*).

forest plot (terme important +++)

3) Discussion

In the discussion you :

- reformulates results
- discusses the context of findings
- compares results with literature
- lists strengths and limitations of the study
- do a short conclusion
- but it's not systematic (if the conclusion is already sufficiently clear)

IV- RCT presentations : introduction guide

Questions to consider when assessing an RCT

- Did the study ask a clearly focused question?
- Was the study actually an RCT?
- Were participants appropriately allocated to intervention and control groups?
- Were participants, staff, and study personnel blinded to participants' study groups?
- Were all the participants who entered the trial accounted for at its conclusion?
- Were participants in all groups followed up and data collected in the same way?
- Did the study have enough participants to minimise the play of chance?
- How are the results presented and what are the main results?
- How precise are the results?
- Were all important outcomes considered and can the results be applied to your local population ?

RCT Presentations :

You will work in 7 groups to read and analyse an RCT concerning a novel treatment for cancer. Your presentation will be in 2 parts

PART 1 :

- 5 minutes max
- The background/context of the research
- The methodology (how, when, where , who, etc...)
- The main results making use of the most relevant graphs and tables from the article
- The conclusions reached by the authors of the article

PART 2 : should ...

- Critically appraise the article
- Give your (reasoned) opinion about the study
- Refer to ideas seen in class (e.g. bias and other key concepts seen over the coming weeks)
- This part should also last around **5 minutes**

Presentations : 7th Nov Please take the time to read AT LEAST the abstract of the other articles and think about some questions that you could ask.
Practice your presentation as a group to ensure that it lasts no longer than 10 minutes.
Upload your slides in the dropbox on moodle before coming to the class.