

# Homework 2

- Optional Homework 2 file with the exercises was uploaded on Teams
- **Deadline 2<sup>nd</sup> December 2025**
- Complete the **Quiz** after you resolve the exercises from the file
- The link for the quiz is on chat of the channel Biostatistics and Medical Informatics in Teams

# The precision of the estimation of a population parameter

depend on

- the estimator
  - ex. mean is more precise than median
- the sample size
  - law of big numbers – bigger sample size – bigger precision
- variation of the data
  - less variation – bigger precision
- needed precision
  - bigger precision – wider interval

# Example

- We want to estimate the frequency of parodontosis in population with age higher than 60 years old.
- In a study with 1000 participants, 300 had parodontosis

$$f = \frac{300}{1000} = 0.30 = 30\%$$

95% confidence intervals for the frequency of mouth cancer

$$\left[ f - 1.96 \sqrt{\frac{f(1-f)}{n}}; f + 1.96 \sqrt{\frac{f(1-f)}{n}} \right]$$
$$\left[ 0.3 - 1.96 \sqrt{\frac{0.3(1-0.3)}{1000}}; 0.3 + 1.96 \sqrt{\frac{0.3(1-0.3)}{1000}} \right]$$

$$[0.3 - 0.028; 0.3 + 0.028]$$

$$[0.27; 0.33] = [27%; 33%]$$

Interpretation: with a 5% error we estimate that the population frequency of parodontosis in the population over 60 years is between 27% and 33%

# If we select a small sample size?

- We want to estimate the frequency of parodontosis in population with age higher than 60 years old.
- In a study with 100 participants, 30 had parodontosis

$$f = \frac{30}{100} = 0.30 = 30\%$$

$$f = \frac{30}{100} = 0.3$$

$$\left[0.3 - 1.96 \sqrt{\frac{0.3(1-0.3)}{100}}; 0.3 + 1.96 \sqrt{\frac{0.3(1-0.3)}{100}}\right]$$
$$[0.3 - 0.09; 0.3 + 0.09]$$

[0.21; 0.39] – interval for n=100

frequency of parodontosis between 21% și 39% with a 95% probability

[0.27; 0.33] – interval for n=10.000

frequency of parodontosis between 27% și 33% with a 95% probability

Answer: **smaller the sample → wider the interval**  
an increasing n at the denominator, an opposite effect

If the sample increase → it increases the measurement precision by decreasing the interval required for estimation

# If the probability decrease 95% → 80%

- We want to estimate the frequency of parodontosis in population with age higher than 60 years old.
- In a study with 100 participants, 30 had parodontosis

For 80% confidence, Z critic = 1.29

$$f = \frac{30}{100} = 0.3$$

$$\left[ 0.3 - 1.29 \sqrt{\frac{0.3(1-0.3)}{100}}; 0.3 + 1.29 \sqrt{\frac{0.3(1-0.3)}{100}} \right]$$

$$[0.3 - 0.059; 0.3 + 0.059]$$

[0.24; 0.36] – interval for 80%

frequency of parodontosis between 24% și 36% with a 95% probability

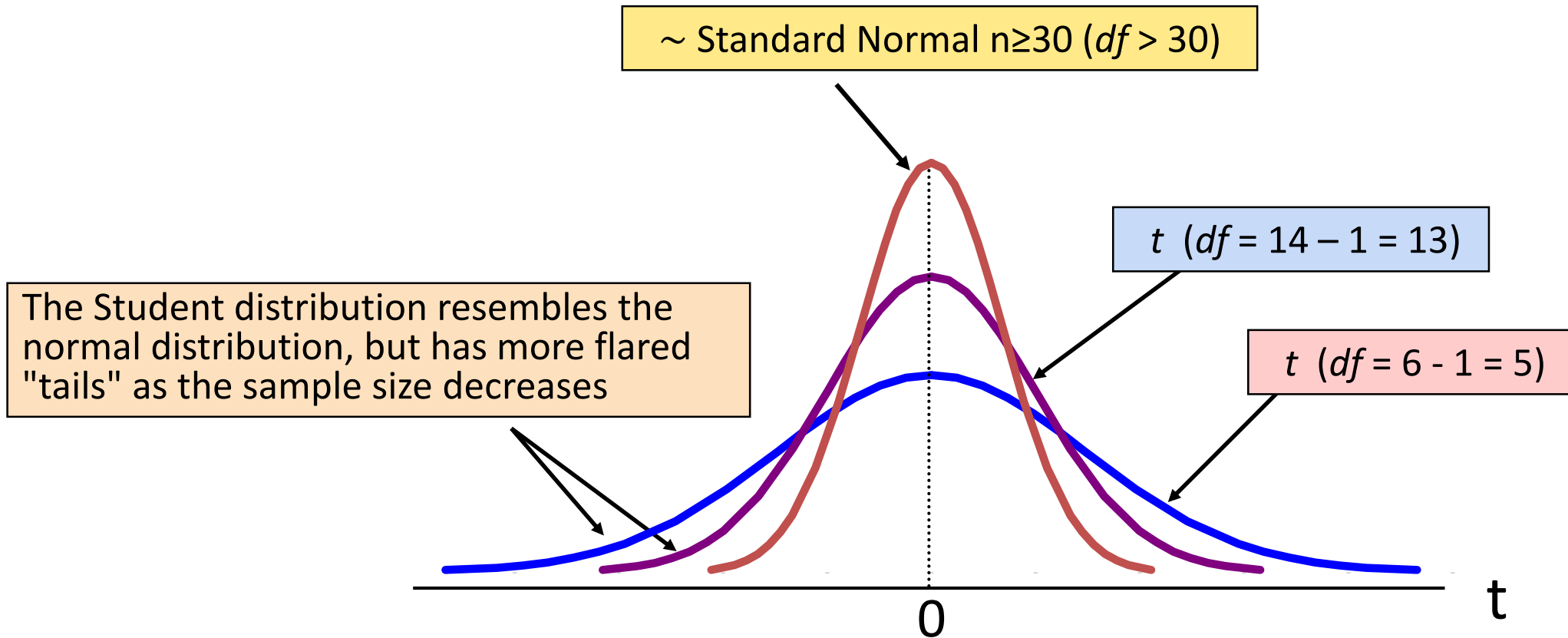
[0.21; 0.39] – interval for 95%

frequency of parodontosis between 21% și 39% with a 95% probability

Answer: the smaller the probability – the narrower the interval  
Z at numerator

Increasing precision → interval increase

# If $n < 30$ : we estimate with Student distribution



Student's law varies with sample size  
depends on the degrees of freedom

# 1- $\alpha$ % confidence interval for the average $\mu$ in the case of small samples $n < 30$ with $\sigma$ unknown

- using Student t distribution

$$\left[ \bar{X} - t_{n-1, 1-\frac{\alpha}{2}} \frac{s}{\sqrt{n-1}}, \bar{X} + t_{n-1, 1-\frac{\alpha}{2}} \frac{s}{\sqrt{n-1}} \right]$$

where

$\bar{X}$  - sample arithmetic mean,

$s$  - sample standard deviation,

$n$  - sample size,

$t_{n-1, 1-\frac{\alpha}{2}}$  critical t for  $n-1$  degree of freedom

$1 - \alpha$  level of confidence

# Example

Study of mobility by extension of the lumbar spine in individuals aged between 30 and 39 years

$n=17$ , mean= $40^\circ$   $\text{şi}$   $t_\alpha=2.11$ ,  
 $s=2.36^\circ$

$$\left[ 40 - 2.11 * \sqrt{\frac{2.36}{17 - 1}}; 40 - 2.11 * \sqrt{\frac{2.36}{17 - 1}} \right]$$

$$[40 - 1.24; 40 + 1.24]$$

$$[38.76^\circ; 41.24^\circ]$$

Answer: mobility of the lumbar spine in young people is between  $38.76^\circ$  and  $41.24^\circ$  with a 5% error



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# Hypothesis Testing I



ALWAYS



SEEK



KNOWLEDGE

# Aim

Compare two groups

Compare one group with the population

Compare multiple groups

} two approaches:  
with confidence intervals  
with statistical tests

Objective: to find difference  $\delta$  (delta)

# Examples of medical questions

- Treatments
  - Is Losartan more efficient than Furosemide in reducing systolic blood pressure?
- Risk factors
  - Is Borrelia burgdorferi virus a risk factor for neuropathy?
  - Is the weight related to oxidative stress ?

- Medical question
  - if the premature-born boy's **weight** during childhood is influenced by the condition of their birth
- we cannot respond exactly to the question
  - but we can compare **the average** weight of **2 years boys** who were born prematurely with the 2 years boys who were not
    - we will compare something with something to see a difference  $\delta$
    - what to compare
    - condition of what we compare should be similar except the feature of interest

Objective:  
 $\delta$

## Step 1: establishing the objective

Transform the medical question into statistical hypotheses

ex. Is the infection with Covid-19 virus the cause of depression? → Is the **frequency** of depression higher in people **who tested positive** for Covid-19 in **the last year** compared to those **who did not**?

**Objective of the research:** demonstrate that **there is a difference  $\delta$**  between two groups **which will maintain in majority** of the studies if we repeat the study on all possible samples

Observation: there are design of the studies where we compare one group with a value (ex. the known mean of the population), or with a historical group or compare multiple groups

Objective:  $\delta$  –  
clinically  
important

## Step 1: establishing the difference $\delta$

- the difference  $\delta$  should be **clinically important**
- What difference  $\delta$  should be between two drugs to declare one is more efficient than the other for the treatment of the targeted disease?
- In how many people (frequency  $\delta$ ) the treatment with the drug should be successful compare with the placebo that one can say that the drug is more efficient than the placebo?

## Step 2: establish the design of the study based on:

Objective:  $\delta$  – clinically important

Study design

- what you want to compare:
  - 2 frequencies
  - 2 means
  - 2 medians
  - 3 frequencies
  - 3 means
  - etc...
- the groups
  - dependent
  - independent

meaning: finding the right statistical test

# Independent or dependent samples

- **Independent samples**

- there is no connection between subjects in the two samples

- **Dependent samples**

- subjects are related somehow

- subjects are paired,

- subjects are matched

- age,

- gender

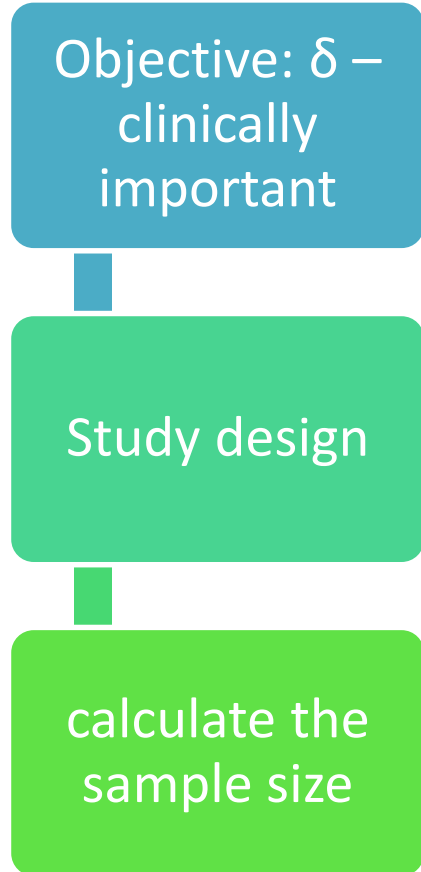
- etc.,

- the same subjects tested two/multiple times

- after the treatment

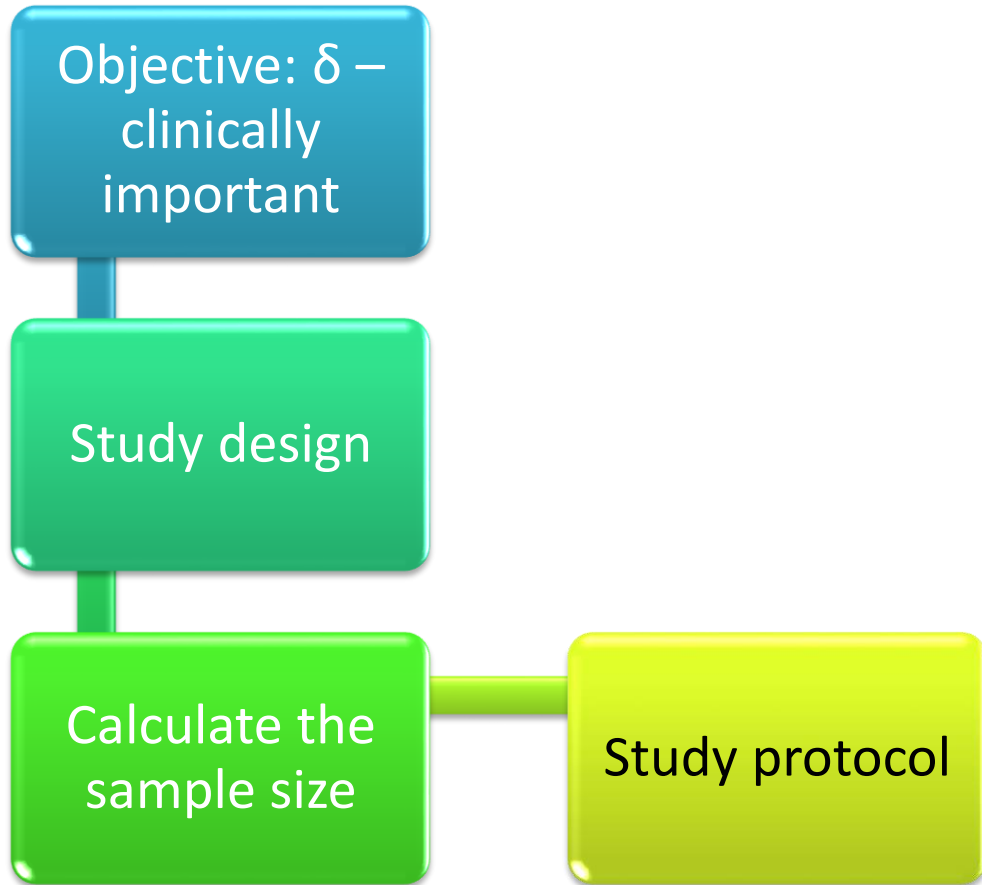
- before the treatment

# Step 3: compute the needed **samples size**



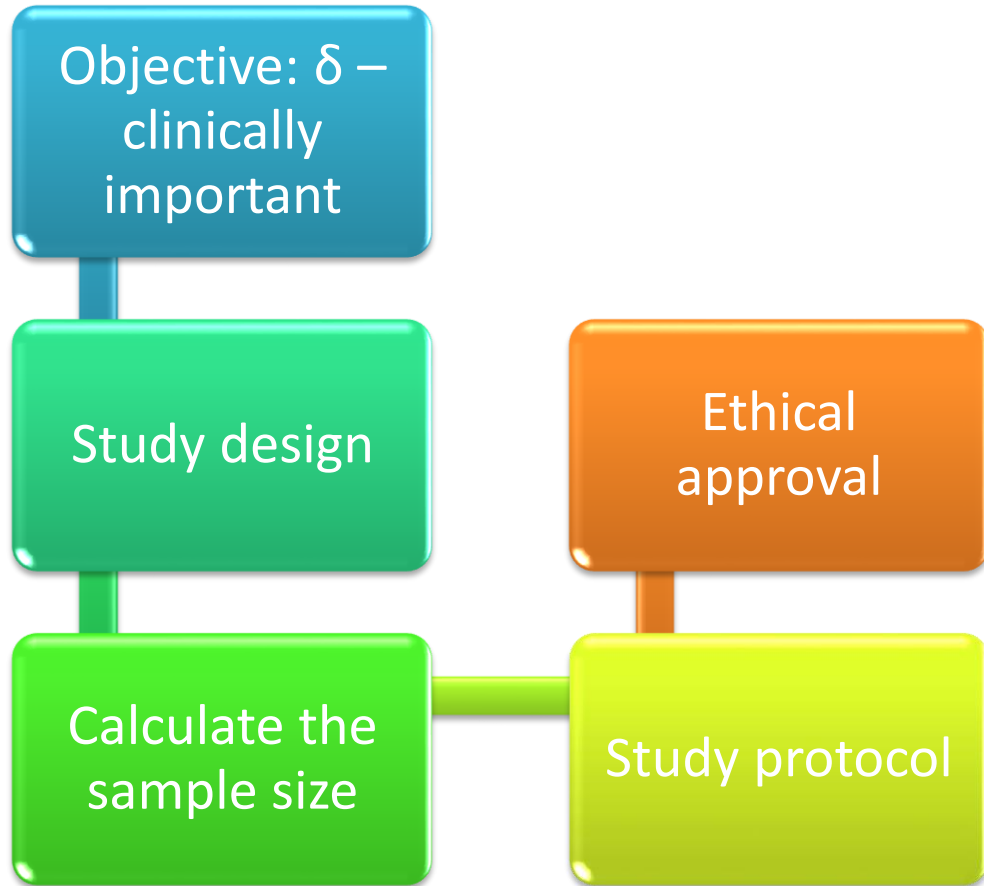
- different formulas for different designs
- a lot of possible design: you will need a statistician
- there are online calculators
- example for two proportion:
- <https://statpages.info/proppowr.html>

# Step 4: making the **protocol** of the study



- there are templates for each kind of study,
- a protocol of the study have to answer to the questions:
  - where?
  - when?
  - how?
  - who?
  - etc.

# Step 5: apply for ethical approval

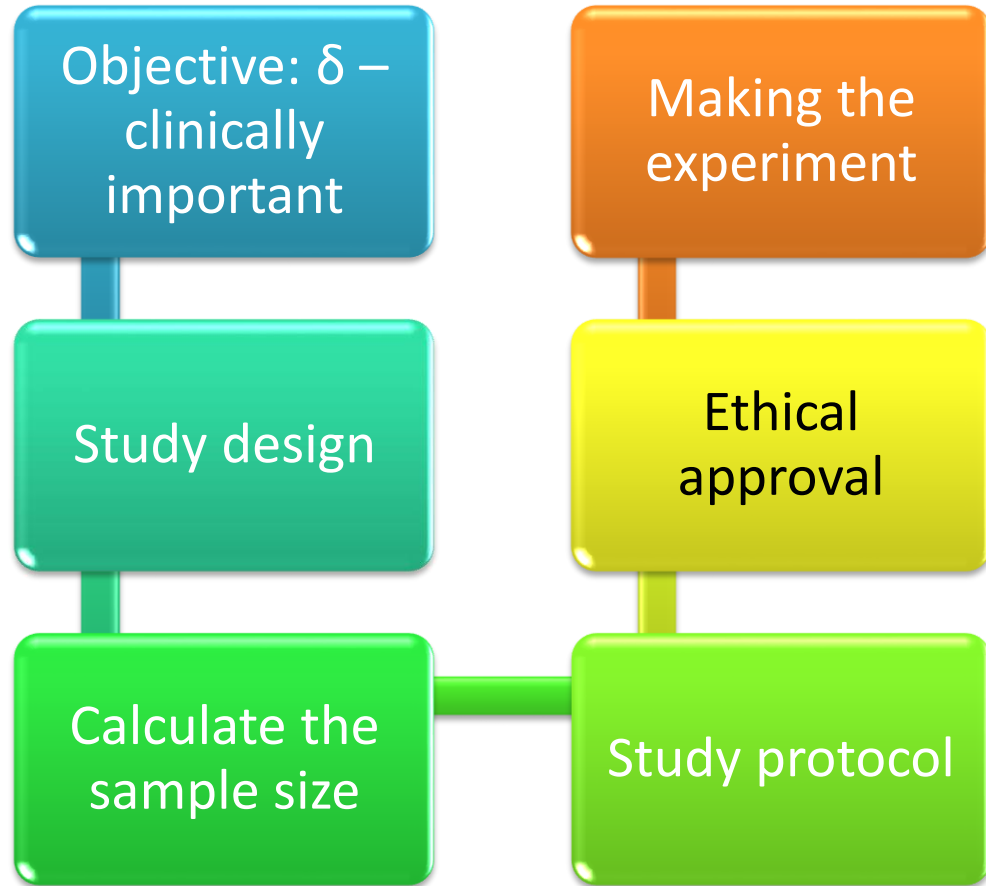


- each health institution should have a research ethics committees
- submit the protocol to the **ethic committee**
- wait for approval

## Step 5: only for clinical trial

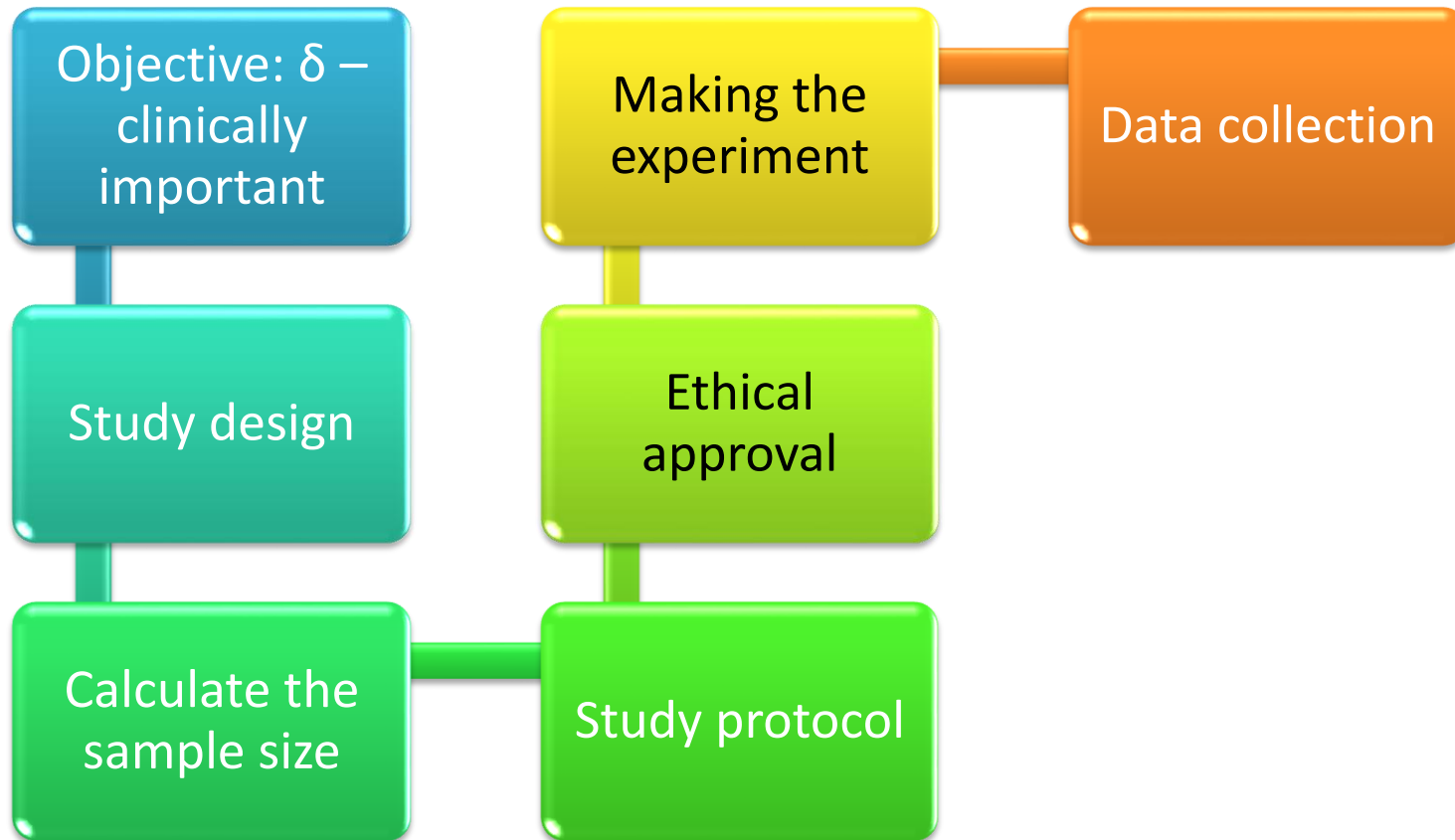
- registration of the trial at the WHO International Clinical Trials Registry Platform (ICTRP) before starting the trial

# Step 6: carrying out **the study**



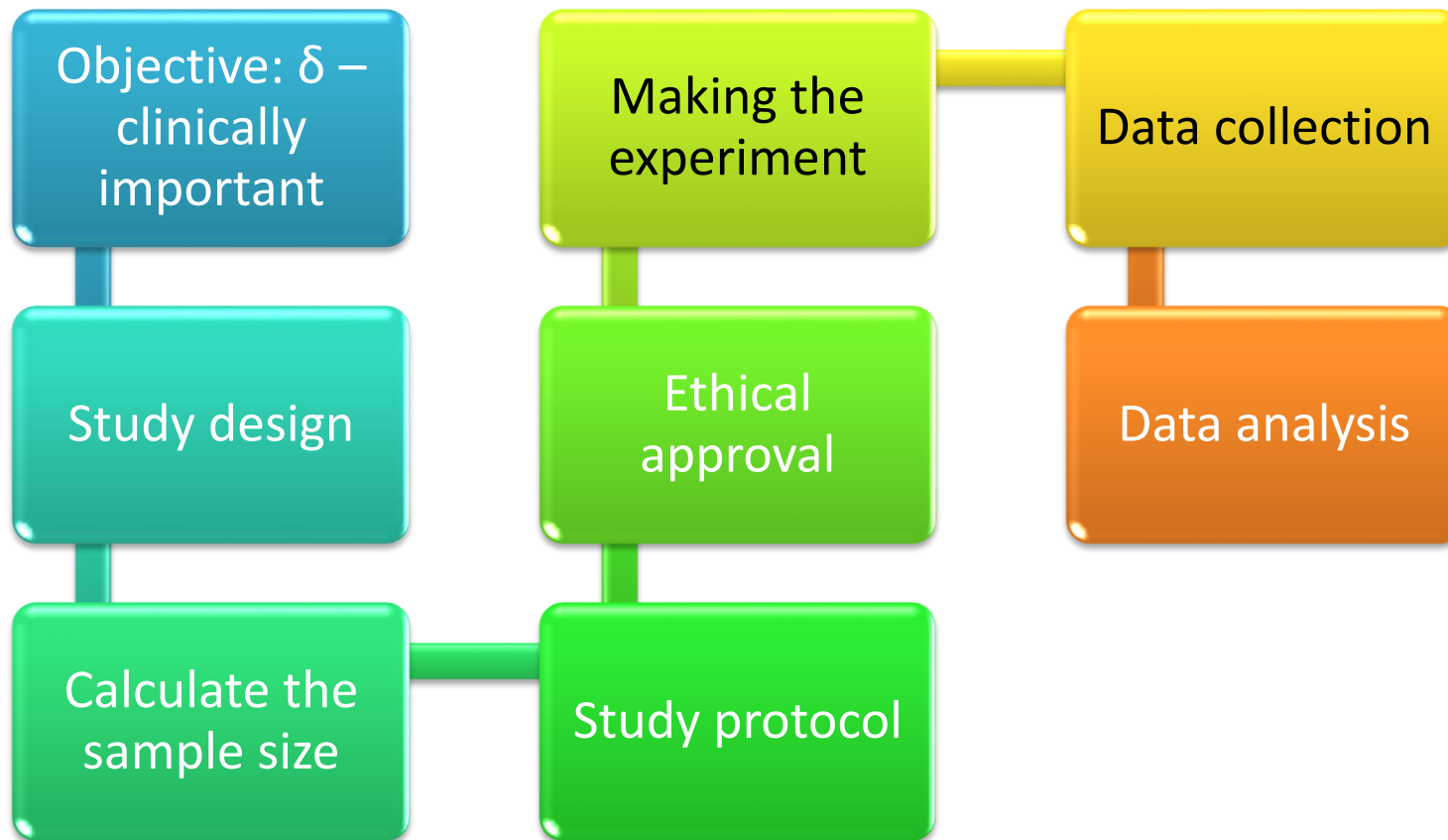
- after you establish the protocol of the study in all details you can start the experiment

# Step 7: collect the data



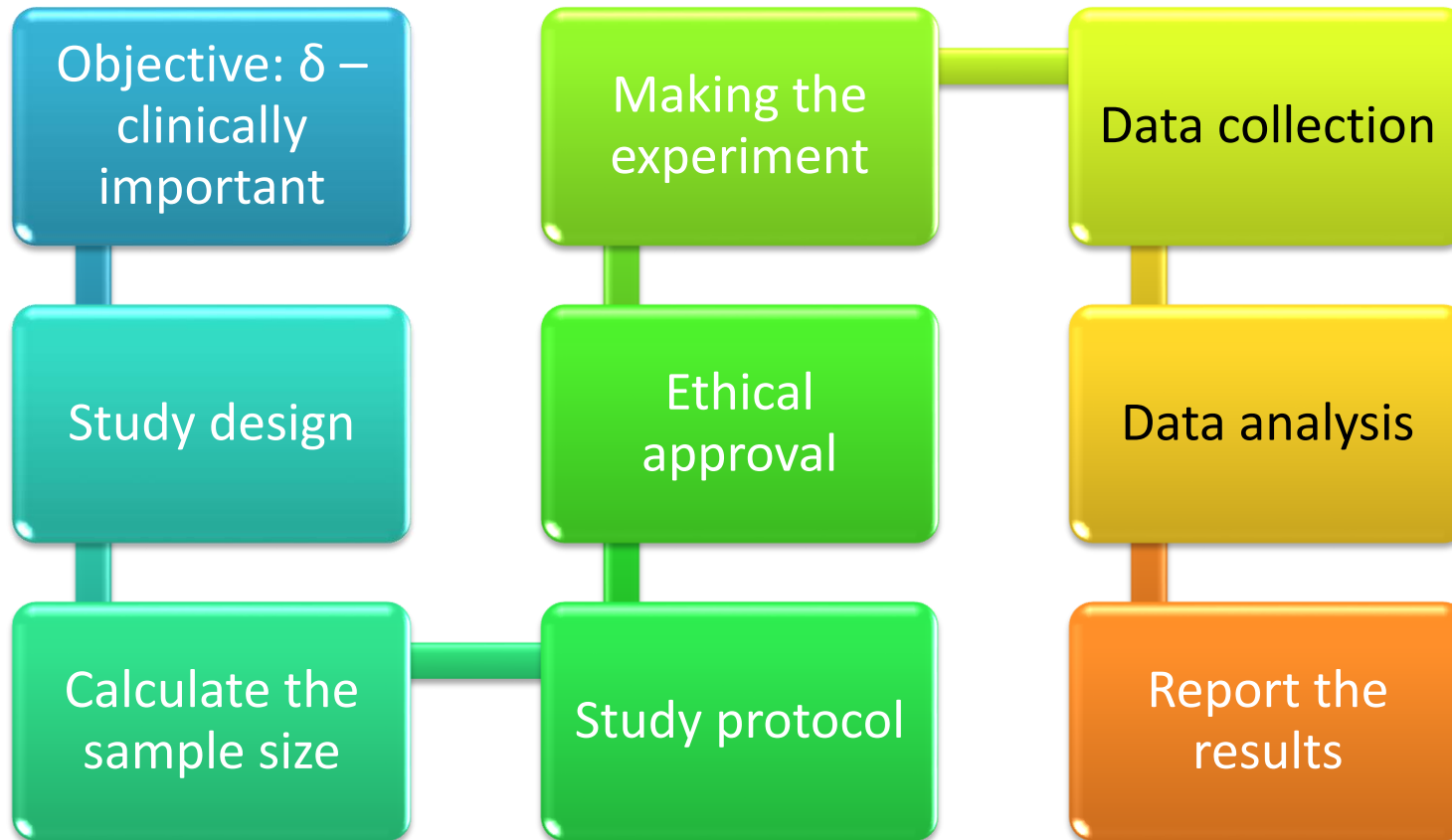
- collect the data about the variables of interest in Excel table or other applications
- data should be deidentified (no personal data should be collected)

# Step 8: analyze the data



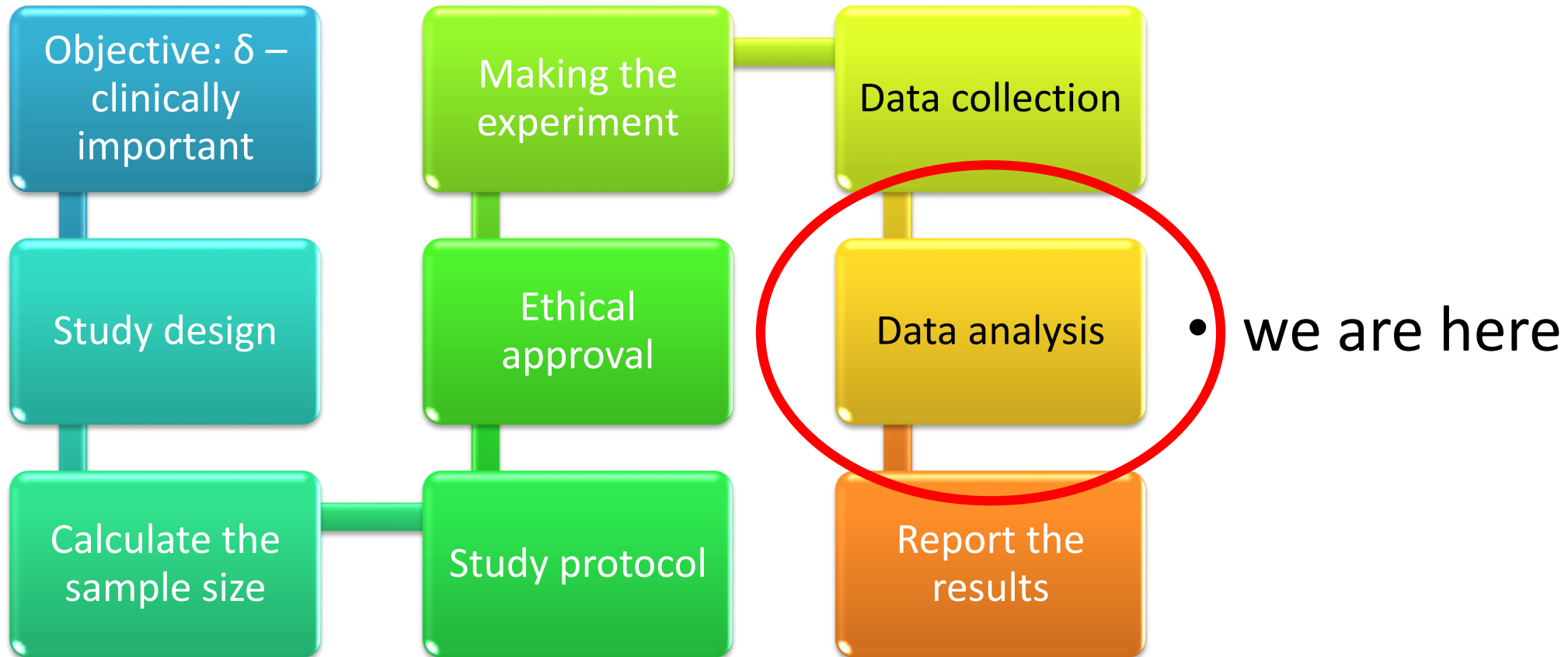
- use an application to analyze the data **with statistical tests**
  - SPSS
  - SAS
  - STATA
  - STATISTICA
  - R language (Jamovi)
  - etc.
- **choose the conclusion for the medical question**

# Step 9: report the results

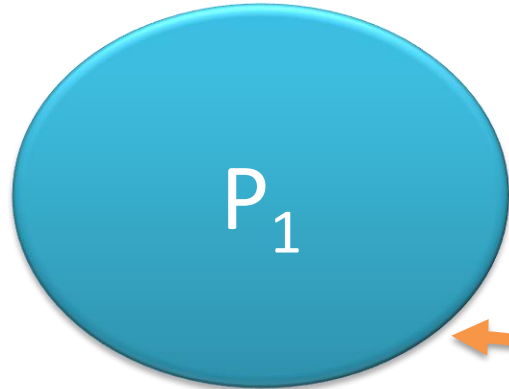


- **report the results** of the study in:
  - medical conferences
  - mass media
  - journals as original articles
  - for clinical trial in WHO International Clinical Trials Registry Platform

# Compare samples

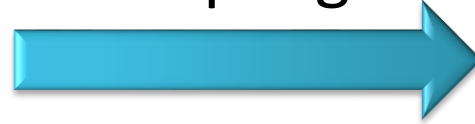


Population 1



the observed samples serve to appreciate what is happening in the populations from which they were extracted

sampling



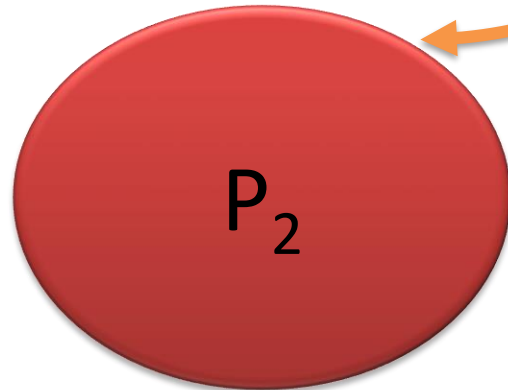
Sample 1  
 $n_1$  subjects



inference

Result

compare



Population 2



sampling

Sample 2  
 $n_2$  subjects



we do not compare 2 samples  
inference = compare all possible samples of  $n_1$  respectively  $n_2$   
subjects that can be taken from the populations

Compare two groups with confidence intervals method

# Research question example

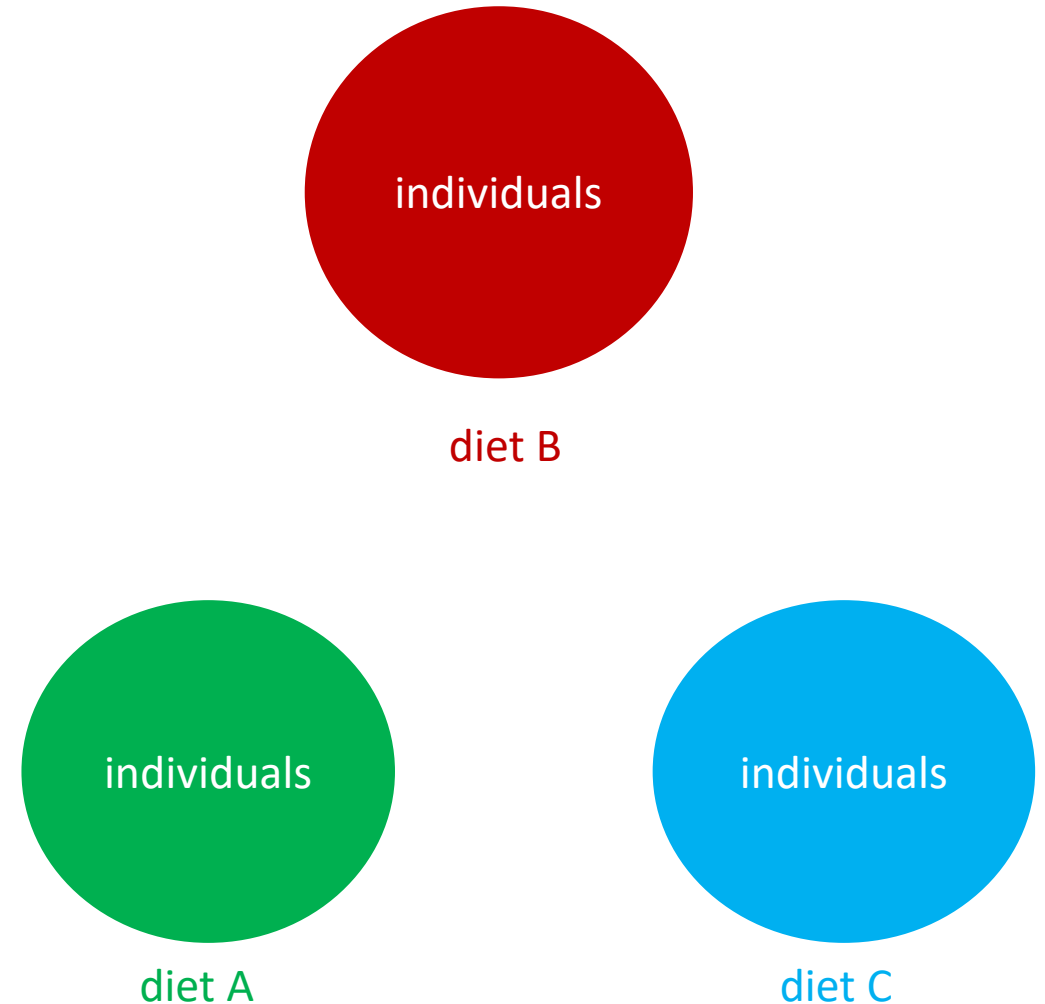
- Which diet is the best diet in lowering the cholesterol in people with hipercholesterolemia?
  - mediteranean diet
  - paleo diet
  - high-protein diet

# Compare two groups with confidence intervals method

- subjects with hipercholesterolemia

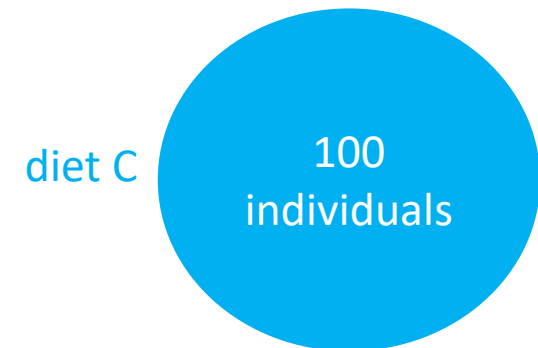
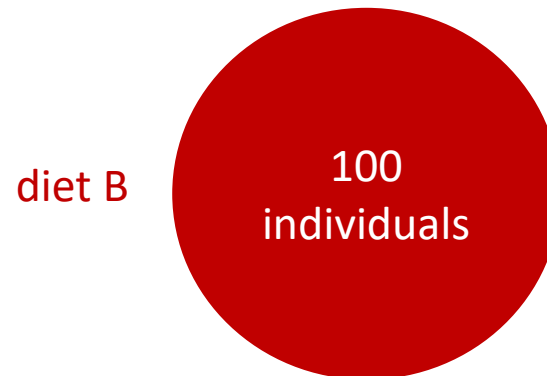
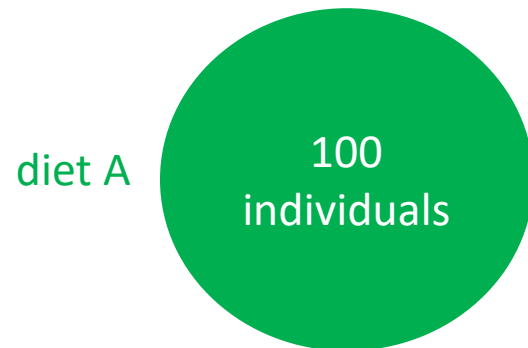
Objectiv: To compare cholesterol

- diet A (mediteranean diet)
- diet B (paleo diet)
- diet C (high-protein diet).

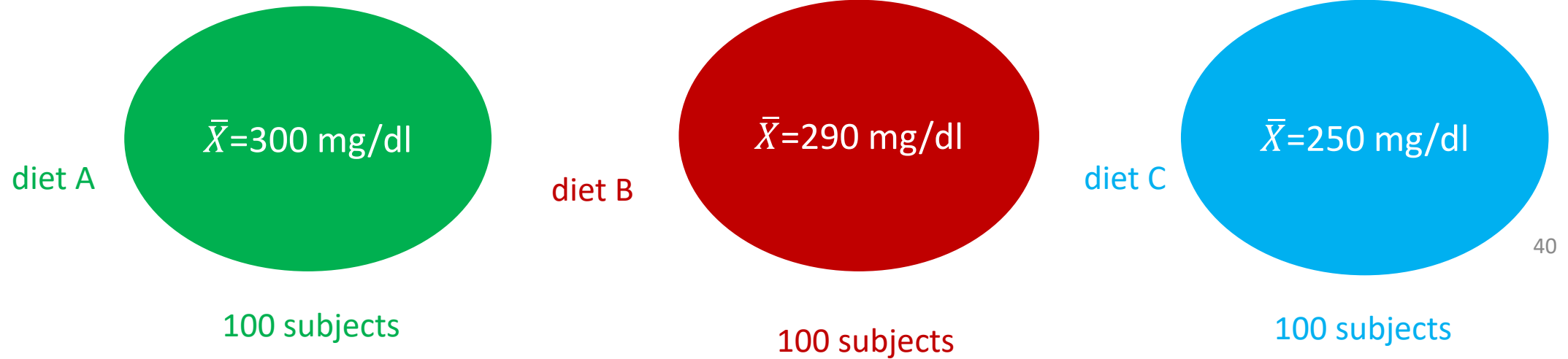


# Compare two groups with confidence intervals method

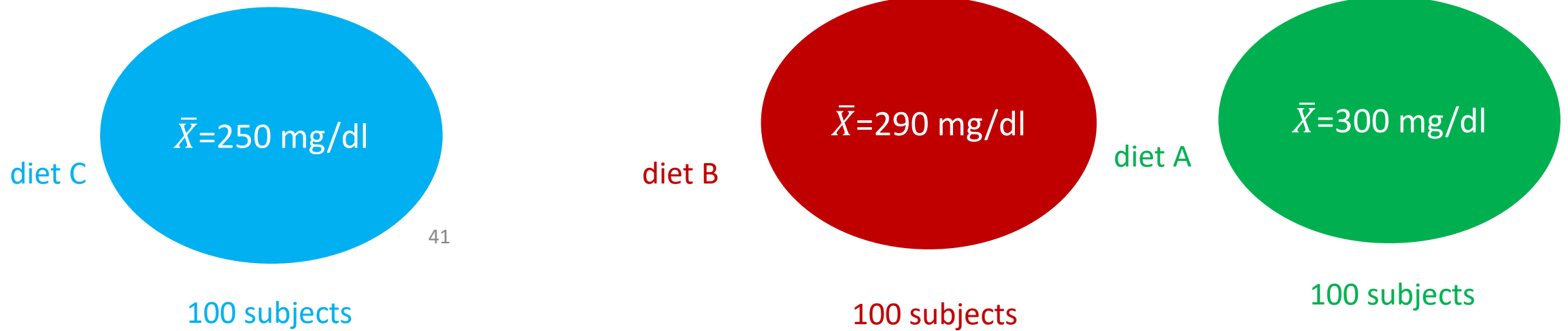
- Objective: To compare **cholesterol** in subjects with hypercholesterolemia who followed **diet A** (Mediterranean diet) versus **diet B** (Paleo diet) versus **diet C** (High-protein diet).
- Method:
- a **difference** by 10mg/dl we consider it **clinically important**.
- We design the study to detect a difference of the cholesterol by 10mg/dl or more between the diets in the population with a 95% probability
  - we calculate the needed sample size take into the study **300 subjects** randomly selected

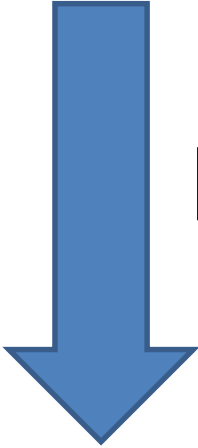
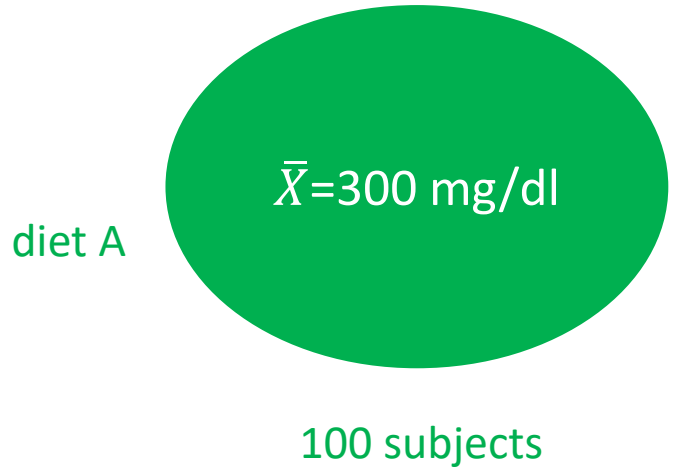
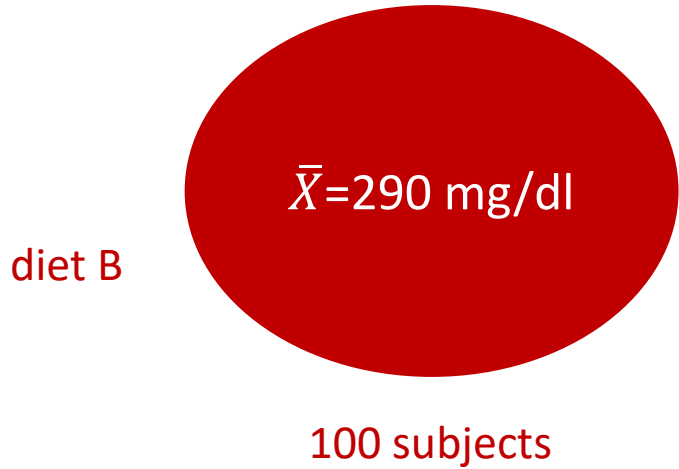
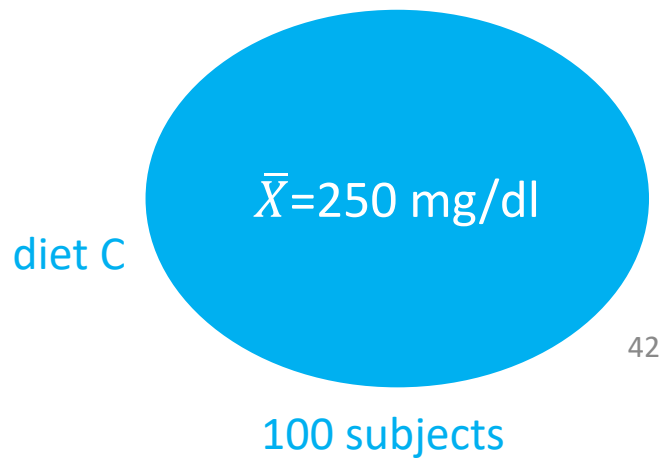


# Findings on the samples



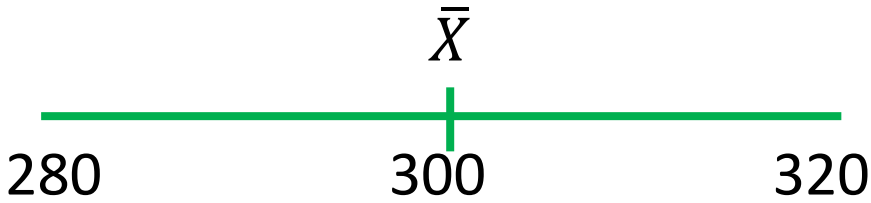
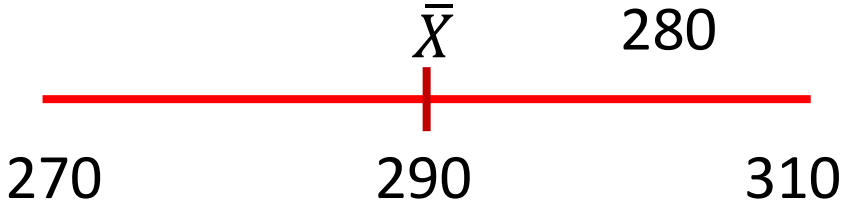
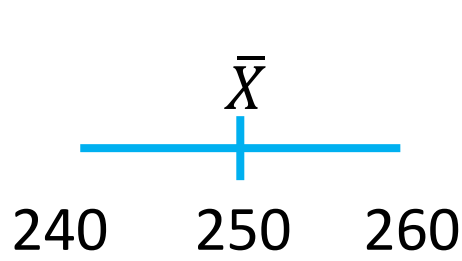
# Findings on the samples





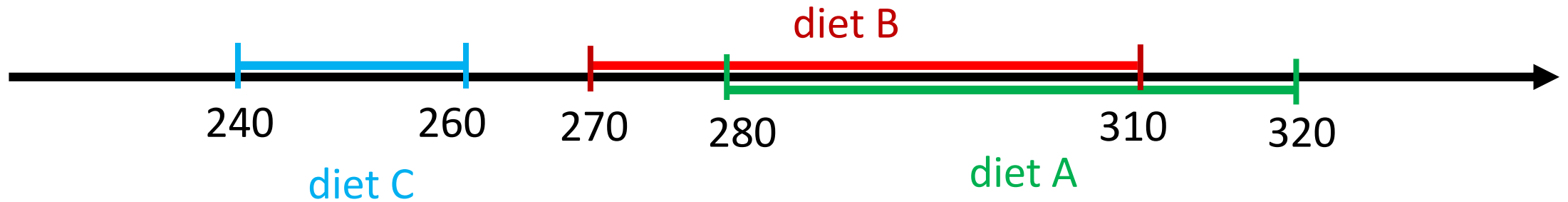
**Inference to the population**  
we estimate 95% confidence intervals

diet A:  $\bar{X}=300$ mg/dl, 95%CI 280-320  
diet B:  $\bar{X}=290$ mg/dl, 95%CI 270-310  
diet C:  $\bar{X}=250$ mg/dl, 95%CI 240-260



# Inference to the population

we estimate 95% confidence intervals



diet A:  $\bar{X} = 300$ mg/dl, 95%CI 280-320

diet B:  $\bar{X} = 290$ mg/dl, 95%CI 270-310

diet C:  $\bar{X} = 250$ mg/dl, 95%CI 240-260

## diet C



- 95% CI 240-260

Interpretation: if we measure the whole population of subjects following diet C (high protein diet) than average cholesterol of whole population will be somewhere between 240mg/dl and 260mg/dl with 5% error,

(we do not know where exactly in this interval will be, only that it is in this interval with 95% probability.

Observation: if we want more precise results we should take more subjects into the study).

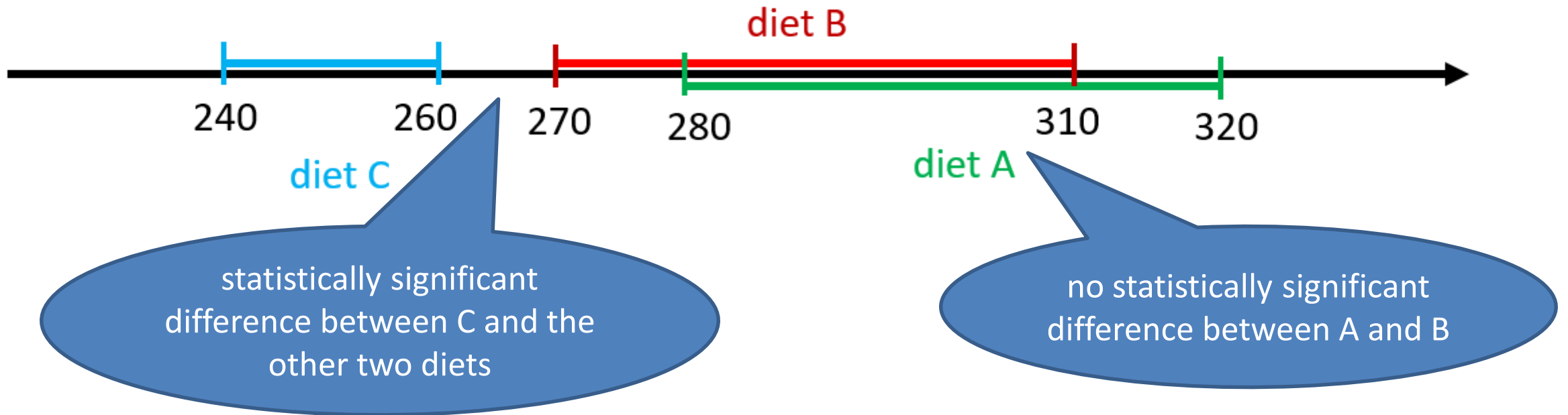
- In the worst case average cholesterol can be 260mg/dl, in the best case 240mg/dl



- 95% CI 270-310

Interpretation: if we measure the whole population of subjects following mediteranean diet than average cholesterol will be somewhere between 270mg/dl and 310mg/dl with 5% error, we do not know where exactly in this interval is.

- In the worst case it can be 310mg/dl, in the best case can be 270mg/dl



- Conclusion 1: this study demonstrate that subjects that follow diet C have low cholesterol than those who follow diet B (with 10mg/dl) and diet A (with 20mg/dl) (95% CI of diet C did not overlap the 95% CI of diet B and A. Any value in the 95% CI of diet C < any value in the 95% CI of diet B and A)
- Conclusion 2: we fail to demonstrate that there is a significant statistically difference between cholesterol in diet B compare with diet A (95% CIs of diet A and B overlap. Observation: The difference between diet A and B is less than 10mg/dl, if we want to know the difference we should repeat the study with more subjects to have a better precision)

# Compare two groups arithmetic means with statistical tests

steps of a statistical test exemplified with t test for independent samples in case of unequal variances

# Comparing two means

- General:

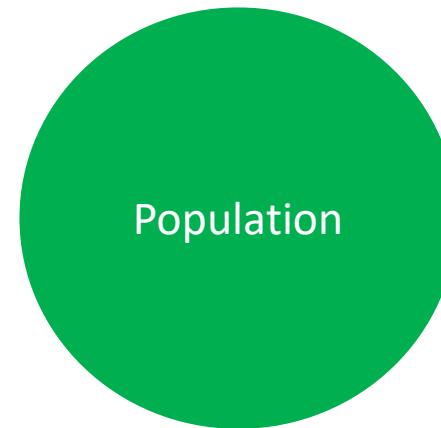
population  $P_1$

population  $P_2$

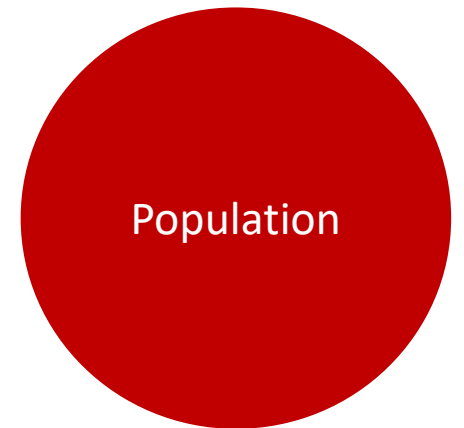
- Example:

patients with

- diet A
- diet B;



diet A



diet B

# Comparing two means

- General:

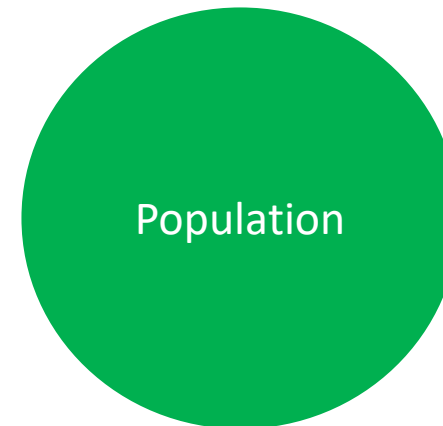
population  $P_1$

population  $P_2$

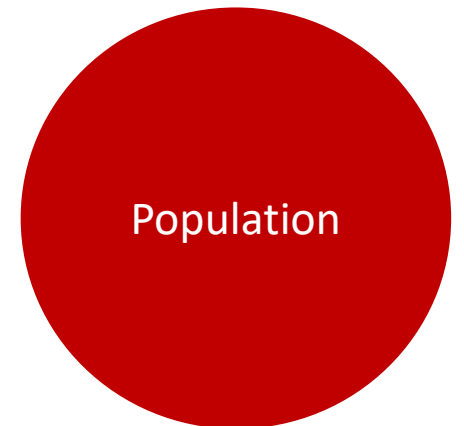
- Example:

patients with

- diet A
- diet B;



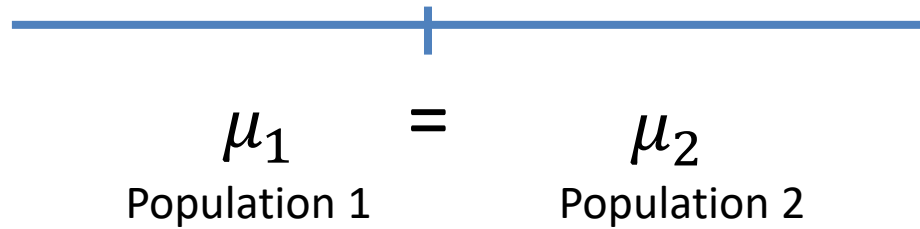
diet A



diet B

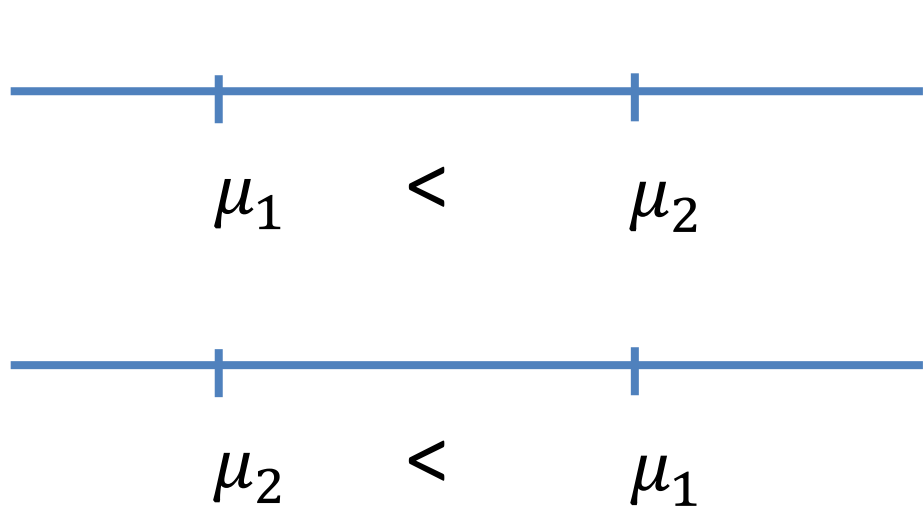
# Possible results

Arithmetic means



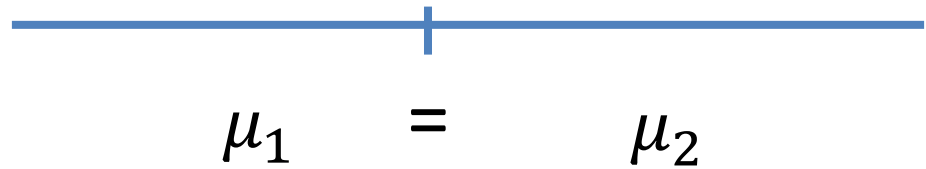
$$\mu_1 = \mu_2 \text{ (or near equal)}$$

OR



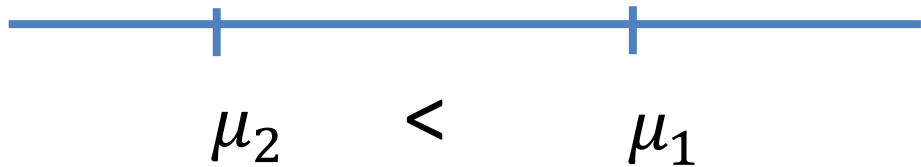
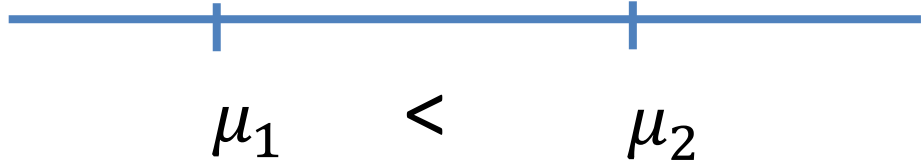
$$\mu_1 \neq \mu_2$$

# Possible results



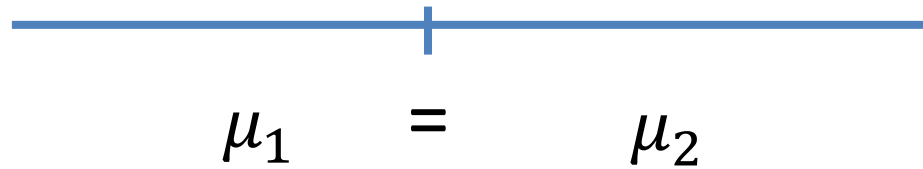
$\mu_1 = \mu_2$  H0: there is no difference

OR



$\mu_1 \neq \mu_2$  H1: there is difference

# Possible results

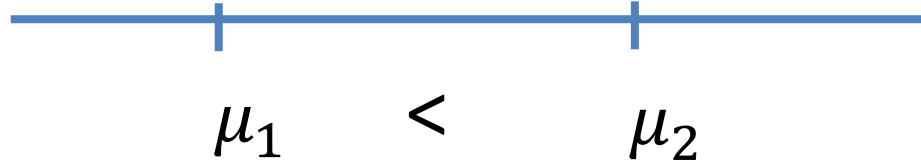


$\mu_1 = \mu_2$  H0: there is no difference

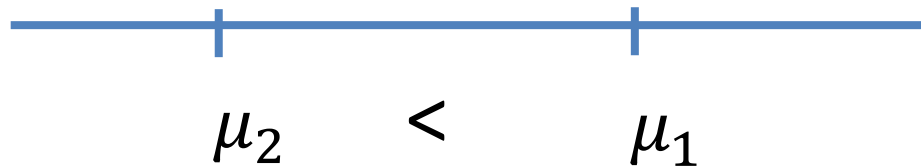
OR

Which one is true?

we will choose H0 or H1 based on a probability



$\mu_1 \neq \mu_2$  H1: there is difference



# Select samples, make the study, obtain the results on the samples

- General:

population  $P_1$

population  $P_2$

$\bar{X}_1$  = average for first sample,

$\bar{X}_2$  = average for second sample,

$s_1^2$  = variances for first sample

$s_2^2$  = variances for second sample

- Example:

patients with

- diet A

- diet B;

= cholesterol  $\bar{X}_1$  for first sample 300mg/dl,

= cholesterol  $\bar{X}_2$  for second sample 290mg/dl,

= cholesterol  $s_1^2$  for first sample 100

= cholesterol  $s_2^2$  for second sample 100



diet A



diet B

# Select samples, make the study, obtain the results on the samples

- General:

population  $P_1$

population  $P_2$

$\bar{X}_1$  = average for first sample,

$\bar{X}_2$  = average for second sample,

$s_1^2$  = variances for first sample

$s_2^2$  = variances for second sample

- Example:

patients with

- diet A
- diet B;

= cholesterol  $\bar{X}_1$  for first sample 300mg/dl,

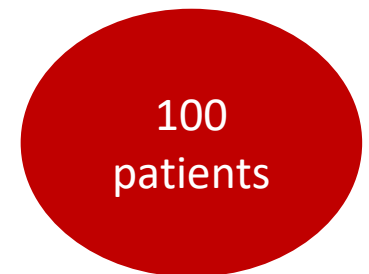
= cholesterol  $\bar{X}_2$  for second sample 290mg/dl,

= cholesterol  $s_1^2$  for first sample 100

= cholesterol  $s_2^2$  for second sample 100



diet A



diet B

# Step 1 of a statistical test: Formulating Hypothesis

## General:

- H0 - null hypothesis: at the population level, there is no statistical significant difference between group 1 average and group 2 average
- H1 - alternative hypothesis: at the population level, there is statistical significant difference between group 1 average and group 2 average

## Example:

- H0 - null hypothesis: at the population level there is no statistically significant difference between the averages of cholesterol for patients with diet A versus diet B
- H1 - alternative hypothesis: at the population level there is statistically significant difference between the averages of cholesterol for patients with diet A versus diet B

# Step 1 of a statistical test: Formulating Hypothesis

## General:

- H0 - null hypothesis: at the population level, there is **no** statistical significant difference between group 1 average and group 2 average
- H1 - alternative hypothesis: at the population level, there is statistical significant difference between group 1 average and group 2 average

## Example:

- H0 - null hypothesis: at the population level there is **no** statistically significant difference between the averages of cholesterol for patients with diet A versus diet B
- H1 - alternative hypothesis: at the population level there is statistically significant difference between the averages of cholesterol for patients with diet A versus diet B

# Step 1 of a statistical test: Formulating Hypothesis

- H0 - null hypothesis: to demonstrate there is no statistically significant difference between the averages of cholesterol for patients with diet A versus diet B

“statistically significant” = suggest that is at the population level, so the term “population level” is redundant

- H1 - alternative hypothesis: there is no statistically significant difference between the averages of cholesterol for patients with diet A versus diet B

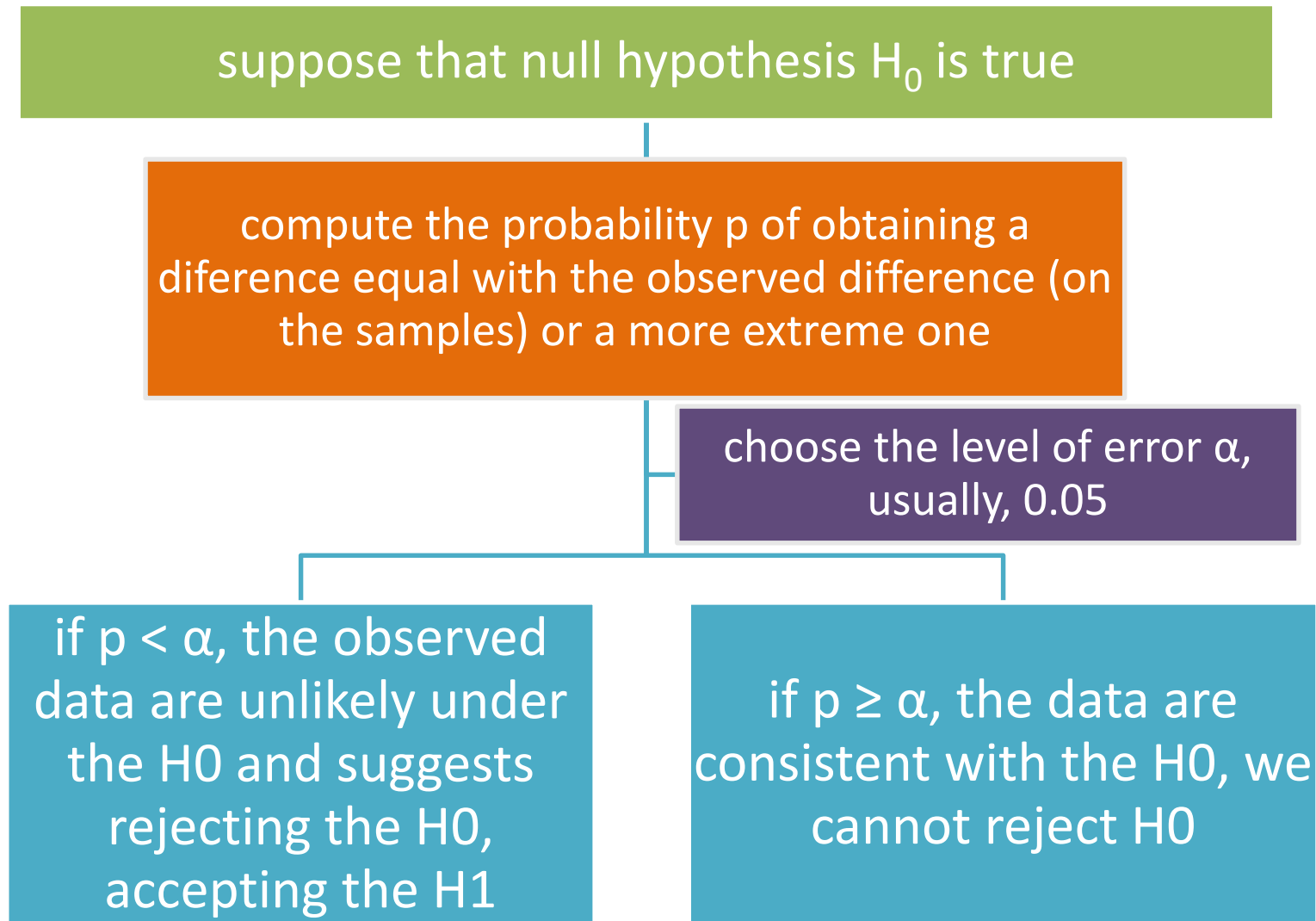
“statistically” – we estimate statistically the cholesterol average in the population of subjects with diet A with the cholesterol average from the sample with diet B

“significant” – we will choose a level of significance, i.e. a probability level for the confidence

Alternative=the other possible situation, when null hypothesis is not true

# Method:

absurd assumption



# p-value interpretation

$p < \alpha$  (small p-value)

- the observed data are unlikely under the null hypothesis and suggests rejecting the  $H_0$ , accepting the  $H_1$
- suggests that the observed result is statistically significant and unlikely to have occurred by chance. We reject  $H_0$ , we are in favor of  $H_1$
- the result is considered statistically significant
- the obtain difference does not automatically mean is a medical relevant result

- $p \geq \alpha$
- the data are consistent with the null hypothesis, we cannot reject  $H_0$
- suggests that the observed result is not statistically significant and is likely to have occurred by chance. We cannot reject  $H_0$
- the result is considered statistically not significant
- the obtain difference does not automatically mean that is no medical relevant result

# Step 2 of a statistical test – Finding the proper statistical test to apply by answering to the questions:

## General:

- What we compare?
  - means,
  - variances,
  - percentages
  - ....
- How is the distribution?
  - normal
  - non-normal,
  - binomial
  - ...
- How are the samples?
  - independent
  - dependent
- How is the sample size?
  - small (<30)
  - large
- How are the variances?
  - equal
  - unequal
- How many samples we want to compare?
  - one,
  - two,
  - three
  - many

- Example:

- normal distributions

- we should check the distribution,
      - Result: stress is normally distributed in both groups,

- unequal variances

- we should check (not the subject of this lecture, see next lecture),
      - Result: variances are not equal,

- two arithmetic means are compared,

- groups are independent

- between groups - within the sample there are no subjects that are extremely similar to the others (repeated observations on the same subjects, measurements on the left hand and on the right hand of the same subject, ...)
    - not the case - between the subjects in the same group

- we will choose:

- **Student t-test for independent samples in the case of unequal variances**

# Step 3. Select the level of significance

## General:

- $\alpha$  - level of significance
  - probability of incorrectly rejecting the null hypothesis when it is actually true
- **Usually,  $\alpha$  is choose to be 0.05**
  - (corresponding to  $Z_{\alpha}=1.96$ )
- p-value or p
  - probability to obtain a result more extreme than the result obtained from the observed data.
  - If  $p < \alpha$ , then we will **reject the null hypothesis**: we demonstrate that there is difference between the arithmetic means and say that the test is statistically significant: we have difference between the means

## Example:

- we choose  $\alpha = 0.05$

# Step 4. Determine the value the test parameter must attain to be declared significant

## General:

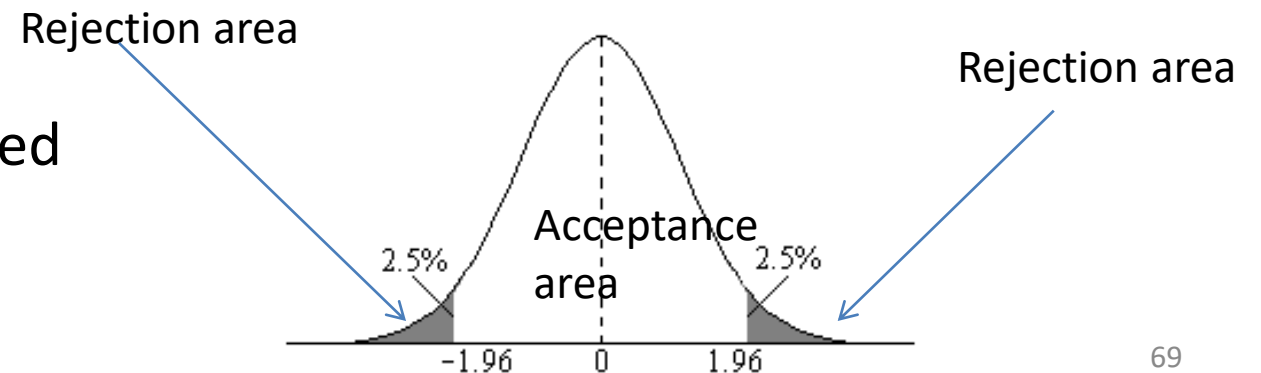
- **critical value**
  - ex. for t-test  $t_{\alpha}$ , for Z test  $Z_{\alpha}$
- Rejection area – critical interval
  - interval where  $H_0$  should be rejected
  - the interval depend on the distribution of the test and sometimes degrees of freedom
  - ex.  $(-\infty, -Z_{\alpha}) \cup (Z_{\alpha}, \infty)$
- Acceptance interval:
  - interval where  $H_0$  should be accepted
  - ex.  $[-Z_{\alpha}, Z_{\alpha}]$
  - for  $\alpha=0.05$ ,  $Z_{\alpha}=1.96$

## Example:

t test – Student distribution – critical value is different for each degree of freedom

- $t_{\alpha} = 1.97 =$  critical value for 100+100-2 degree of freedom
- rejection interval  $(-\infty, -t_{\alpha}) \cup (t_{\alpha}, \infty) = (-\infty, -1.97) \cup (1.97, \infty)$
- acceptance interval:  $[-t_{\alpha}, t_{\alpha}] = [-1.97, 1.97]$

= an interval around 0, if we found a difference in this interval it means is a small difference and  $H_0$  will be accepted (there is no difference)



# Step 4. Determine the value the test parameter must attain to be declared significant

## General:

- **critical value**
  - ex. for t-test  $t_{\alpha}$ , for Z test  $Z_{\alpha}$ )
- Rejection area – critical interval
  - interval where  $H_0$  should be rejected
  - different depending on the distribution of the test and sometimes degrees of freedom
  - ex.  $(-\infty, -Z_{\alpha}] \cup [Z_{\alpha}, \infty)$
- Acceptance interval:
  - interval where  $H_0$  should be accepted
  - ex.  $(-Z_{\alpha}, Z_{\alpha})$
  - for  $\alpha=0.05$ ,  $Z_{\alpha}=1.96$

## Example:

t test – Student distribution – **critical value** is different for each degree of freedom

- $t_{\alpha} = 1.97 = \text{critical value for } 100+100-2 \text{ degree of freedom}$
- rejection interval  $(-\infty, -t_{\alpha}) \cup (t_{\alpha}, \infty) = (-\infty, -1.97) \cup (1.97, \infty)$
- acceptance interval:  $[-t_{\alpha}, t_{\alpha}] = [-1.97, 1.97]$

= an interval around 0, if we found a difference in this interval it means is a small difference and  $H_0$  will be accepted (there is no difference)

# Step 5: computing the formula for test parameter

## General:

- any statistical test have a test parameter
- test two means, then  $\bar{X}_1 - \bar{X}_2$  should be in the formula, divided by standard errors

if parameter of the test is small, then the difference between  $\bar{X}_1$  and  $\bar{X}_2$  is small, near 0.

## Example:

- the parameter of the test:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{s_1^2}{N_1} + \frac{s_2^2}{N_2}}}$$

difference between averages.

material A:  $\bar{X}_1 = 300\text{MPa}$ ,  $s = 100\text{MPa}$

material B:  $\bar{X}_2 = 290\text{MPa}$ ,  $s = 100\text{MPa}$

$$t = \frac{300-290}{\sqrt{\frac{100^2}{100} + \frac{100^2}{100}}} = \frac{10}{\sqrt{200}} = \frac{10}{14.14} = 0.71,$$

p=0.48

p can be computed only by computers – have a very complicated formula

# Step 5: computing the formula for test parameter

## General:

any statistical test have a test parameter based on the difference between what we test

test two means than  $\bar{X}_1 - \bar{X}_2$  should be in the formula, divided by standard errors

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## Example:

- the parameter of the test:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{s_1^2}{N_1} + \frac{s_2^2}{N_2}}}$$

difference between averages.

diet A:  $\bar{X}_1 = 300\text{mg/dl}$ ,  $s = 100\text{mg/dl}$

diet B:  $\bar{X}_2 = 290\text{mg/dl}$ ,  $s = 100\text{mg/dl}$

$$t = \frac{300-290}{\sqrt{\frac{100^2}{100} + \frac{100^2}{100}}} = \frac{10}{\sqrt{200}} = \frac{10}{14.14} = 0.71,$$

p=0.48

p can be computed only by computers – have a very complicated formula

# Step 6. Draw and state the conclusion

## General:

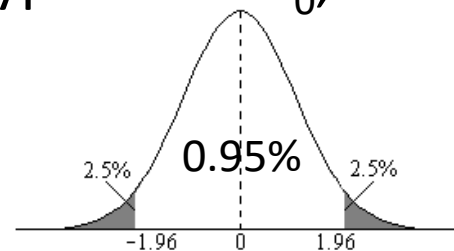
If parameter of the test  $\in$  acceptance interval  $\rightarrow$  we fail to reject null hypothesis  $H_0$

If parameter of the test  $\in$  rejection interval  $\rightarrow$  we reject null hypothesis  $H_0$ , accept  $H_1$

**the same as**

If  $p \geq 0.05$  we fail to reject null hypothesis  $H_0$

If  $p < 0.05$  we reject null hypothesis  $H_0$ , accept  $H_1$



## Example:

if  $t \in [-t_\alpha, t_\alpha]$  – acceptance interval = small differences.

if  $t \in (-\infty, -t_\alpha) \cup (t_\alpha, \infty)$  – rejection interval = high differences.

**the same as**

If  $p \geq 0.05$ , then  $H_0$  is in favor – fail to reject  $H_0$

If  $p < 0.05$  than  $H_0$  is false, we reject  $H_0$  – accept  $H_1$

# Step 6. Draw and state the conclusion

## General:

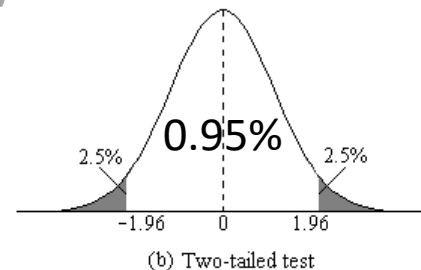
If parameter of the test  $\in$  acceptance interval  $\rightarrow$  we fail to reject null hypothesis  $H_0$

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**the same as**

If  $p \geq 0.05$  we fail to reject null hypothesis  $H_0$

If  $p < 0.05$  we reject null hypothesis  $H_0$ , accept  $H_1$



## Example:

if  $t \in [-t_\alpha, t_\alpha]$  – acceptance interval = small differences.

if  $t \in (-\infty, -t_\alpha) \cup (t_\alpha, \infty)$  – rejection interval = high differences.

**the same as**

If  $p \geq 0.05$ , then  $H_0$  is in favor – fail to reject  $H_0$

If  $p < 0.05$  than  $H_0$  is false, we reject  $H_0$  – accept  $H_1$

## Example:

$$-1.97 \leq t = 0.71 \leq 1.97$$

we fail to reject null hypothesis,

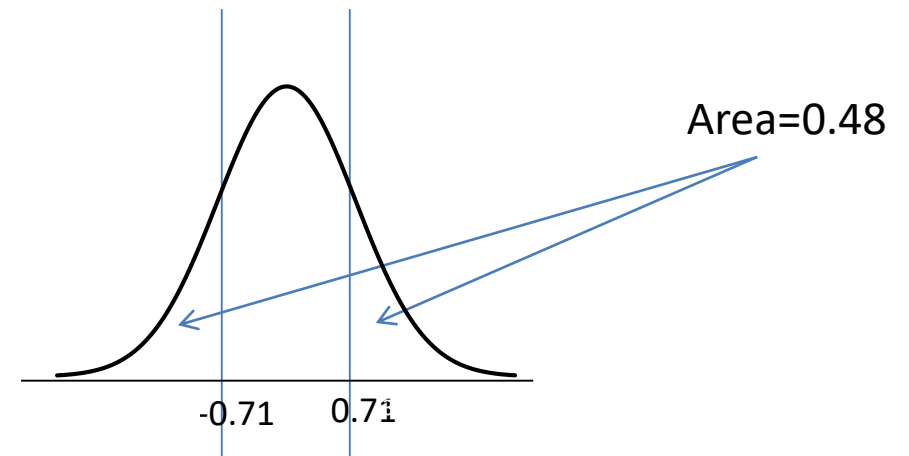
the average cholesterol in people who have diet A did not differ statistically significant from the average cholesterol in people who have diet B

Area under the curve for  $t = 0.71$  is 0.48,  $p = 0.48 > 0.05$  we fail to reject null hypothesis,

the average cholesterol in people who have diet A did not differ statistically significant from the average cholesterol in people who have diet B

~~We accept the null hypothesis~~

We fail to reject the null hypothesis



# Example 2

diet C compare with B

# Comparing two means

- General:

population  $P_1$

population  $P_2$

$\bar{X}_1$  = average for first sample,

$\bar{X}_2$  = average for second sample,

$s_1^2$  = variances for first sample

$s_2^2$  = variances for second sample

- Example:

= subjects with diet C

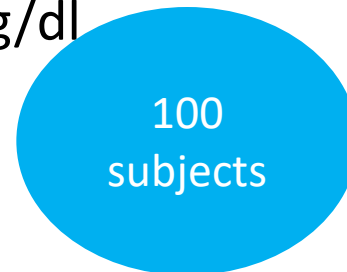
= subjects with diet B;

= average cholesterol for first sample 250mg/dl,

= average cholesterol for second sample 290 mg/dl,

= cholesterol variances for first sample 50mg/dl

= cholesterol variances for second sample 100 mg/dl



diet C



diet B

# Step 1 of a statistical test: Formulating Hypothesis

## General:

- H0 - null hypothesis: there is **no** statistically significant difference between group 1 average and group 2 average
- H1 - alternative hypothesis: there is statistically significant difference between group 1 average and group 2 average

## Example:

- H0 - null hypothesis: there is **no** statistically significant difference between the averages of cholesterol for subjects with **diet C** versus diet B
- H1 - alternative hypothesis: there is statistically significant difference between the averages of cholesterol for subjects with diet C versus diet B

# Step 2 of a statistical test – Finding the proper statistical test to apply after answering to the questions:

## General:

- What we compare?
  - means,
  - variances,
  - percentages
  - ....
- How is the distribution?
  - normal
  - non-normal,
  - binomial
  - ...
- How are the samples?
  - independent
  - dependent
- How is the sample size?
  - small (<30)
  - large
- How are the variances?
  - equal
  - unequal
- How many samples we want to compare?
  - one,
  - two,
  - three
  - many

- Example:

- normal distribution

- usually we should check the distribution,
      - Result: cholesterol is normally distributed in both groups,

- unequal variances

- usually we should check,
      - Result: unequal variances,

- two arithmetic means are compared,

- groups are independent

- subjects are independent in the groups

- we will choose:

- t-test for independent samples in the case of unequal variances

# Step 3. Select the level of significance of the statistic test

## General:

- $\alpha$  - level of significance
  - probability of incorrectly rejecting the null hypothesis when it is actually true
- **Usually,  $\alpha$  is choose to be 0.05**
  - (corresponding to  $Z_{\alpha}=1.96$ )
- p-value or p
  - the probability to obtain a result more extreme than the result obtained from the observed data.
  - If  $p < \alpha$ , then we will reject the null hypothesis: we demonstrate that there is difference between the arithmetic means and say that the test is significant: we have difference between the means

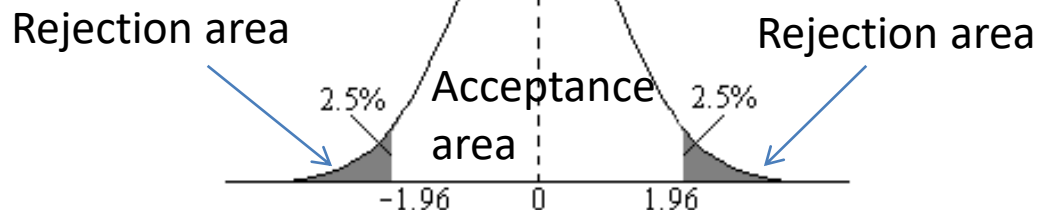
## Example:

- we choose  $\alpha = 0.05$

# Step 4. Determine the value the test parameter must attain to be declared significant

## General:

- **critical value**
  - for Z test  $Z_\alpha$
- Rejection area – critical interval
  - different depending on the distribution of the test and sometimes degrees of freedom
  - interval where  $H_0$  should be rejected
  - ex.  $(-\infty, -Z_\alpha) \cup (Z_\alpha, \infty)$
- Acceptance interval:
  - interval where  $H_0$  should be rejected
  - ex.  $[-Z_\alpha, Z_\alpha]$
  - $\alpha=0.05, Z_\alpha=1.96$



## Example:

t test – Student distribution – different for each degree of freedom

- $t_\alpha = 1.97 =$  **critical value for 100+100-2 degree of freedom**
- rejection interval  $(-\infty, -t_\alpha) \cup (t_\alpha, \infty) = (-\infty, -1.97) \cup (1.97, \infty)$
- acceptance interval:  $[-t_\alpha, t_\alpha] = [-1.97, 1.97]$

# Step 5: computing the formula for test parameter

## General:

any statistical test have a test parameter based on the difference between what we test

test two means, then  $\bar{X}_1 - \bar{X}_2$  should be in the formula, divided by standard errors

## Example:

- the parameter of the test:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{s_1^2}{N_1} + \frac{s_2^2}{N_2}}}$$

diet C:  $\bar{X}_1 = 250$ mg/dl,  $s = 50$ mg/dl

diet B:  $\bar{X}_2 = 290$ mg/dl,  $s = 100$ mg/dl

$$t = \frac{250 - 290}{\sqrt{\frac{50^2}{100} + \frac{100^2}{100}}} = -\frac{40}{\sqrt{125}} = -\frac{40}{11.18} = 3.58,$$

$p=0.0004$

# Step 6. Draw and state the conclusion

## General:

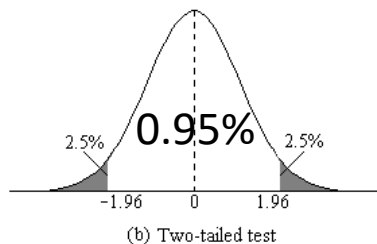
If parameter of the test  $\in$  acceptance interval  $\rightarrow$  we fail to reject null hypothesis  $H_0$

If parameter of the test  $\in$  rejection interval  $\rightarrow$  we reject null hypothesis  $H_0$ , accept  $H_1$

**the same as**

If  $p \geq 0.05$  we fail to reject null hypothesis  $H_0$

If  $p < 0.05$  we reject null hypothesis  $H_0$ , accept  $H_1$



## Example:

if  $t \in [-t_\alpha, t_\alpha]$  – acceptance interval = small differences.

if  $t \in (-\infty, -t_\alpha) \cup (t_\alpha, \infty)$  – rejection interval = high differences.

**the same as**

If  $p \geq 0.05$ , then  $H_0$  is in favor – fail to reject  $H_0$

If  $p < 0.05$  then  $H_0$  is false, we reject  $H_0$  – accept  $H_1$

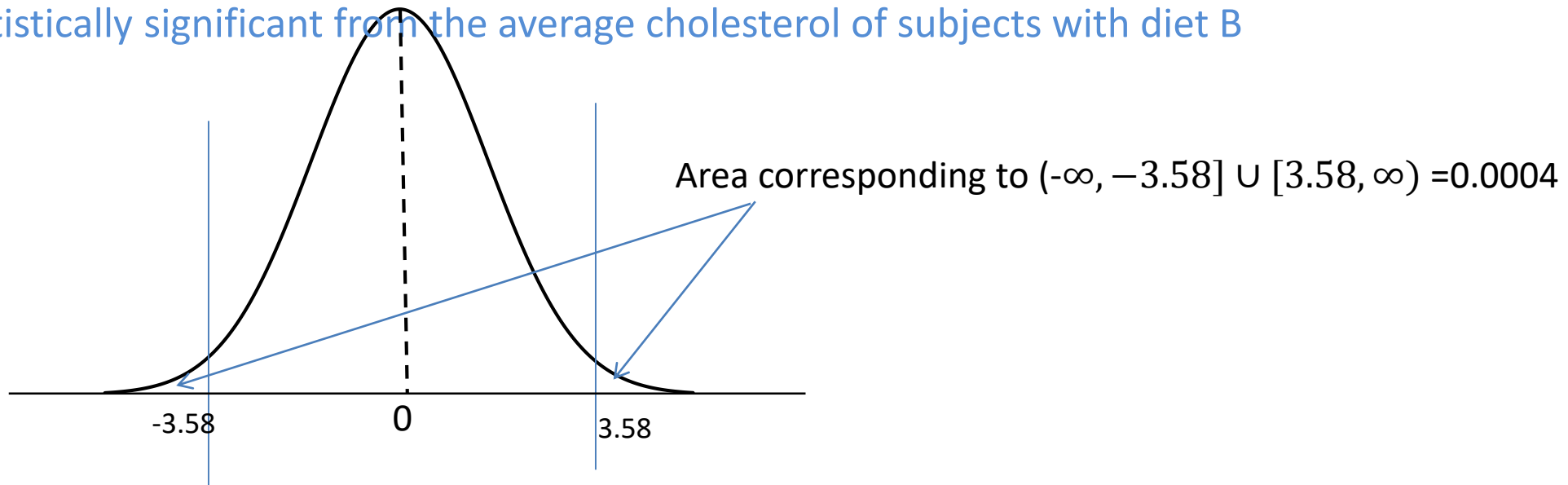
Step 6. Draw and state the conclusion

**Example:**

$3.58 \in (-\infty, -1.97) \cup (1.97, \infty)$  Rejection area

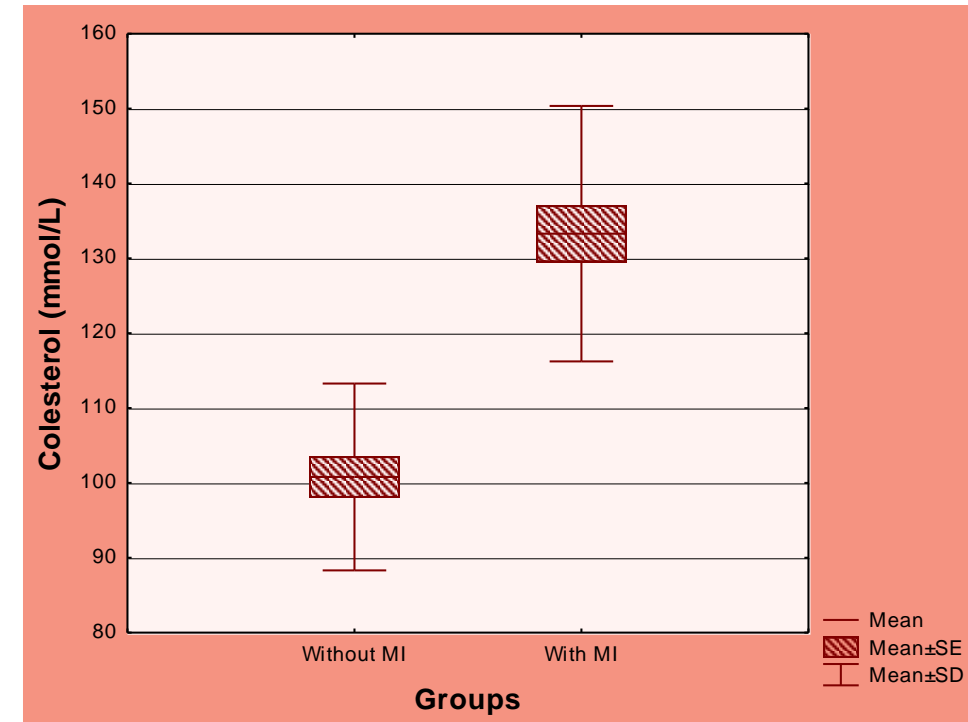
We reject the null hypothesis  $H_0$ , we accept the alternative hypothesis  $H_1$ : The average cholesterol of subjects with diet C differ statistically significant from the average cholesterol of subjects with diet B

Area under the curve for  $t = 3.58$  is  $0.0004$ ,  $p = 0.0004 < 0.05$  we reject the null hypothesis  $H_0$ , we accept the alternative hypothesis  $H_1$ : The average cholesterol of subjects with diet C differ statistically significant from the average cholesterol of subjects with diet B



# Scenario

- Question: Higher cholesterol in people with myocardial infarction is related with relapse of myocardial infarction?



- We randomly select 40 people with myocardial infarction.
- Cholesterol for the patients **with relapse** ( $n_1=20$ ) was  $133 \pm 17$  mmol/L ( $\bar{X}_1 \pm s_1$ )
- Cholesterol for the patients **without relapse** ( $n_2=20$ ) was  $101 \pm 12$  mmol/L ( $\bar{X}_2 \pm s_2$ )

Two samples,  
need  
inference:  
statistical test

# T test (Student) for independent samples assuming unequal variances

- Step 1:
  - H0 - null hypothesis: there is no statistical significant difference between the averages of cholesterol for patients with and without relapse
  - H1 - alternative hypothesis: there is statistical significant difference between the averages of cholesterol for patients with and without relapse
- Step 2: assumptions: normal distributions, equal variances
  - t-test for independent samples in the case of equal variances
- Step 3:  $\alpha = 0.05$ ,
- Step 4: degree of freedom =  $20 + 20 - 2$ ,  
rejection area  $(-\infty, -t_\alpha] \cup [t_\alpha, \infty) = (-\infty, -2.02] \cup [2.02, \infty)$   
acceptance area:  $(-t_\alpha, t_\alpha) = (-2.02, 2.02)$

# T test (Student) for independent samples assuming equal variances

- Step 5: compute p and the parameter of the test:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{s_p \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}, \text{ where } s_p = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}} \text{ (pooled standard deviation)}$$

$$s_p = \sqrt{\frac{(20 - 1) \cdot 17^2 + (20 - 1) \cdot 12^2}{20 + 20 - 2}} = \sqrt{216.5} = 14.71$$

$$t = \frac{133 - 101}{14.71 \sqrt{\frac{1}{20} + \frac{1}{20}}} = \frac{32}{4.65} = 6.88, p = 0.000000003$$

# T test (Student) for independent samples assuming equal variances

- Step 6: conclusion:

- **$t=6.88 \in (-\infty, -2.02] \cup [2.02, \infty)$**  reject null hypothesis, **accept alternative hypothesis**: there is statistical significant difference between the averages of cholesterol for patients with and without relapse

**Or**

- **$p=0.000000003 < 0.05$**  reject null hypothesis, **accept alternative hypothesis**: there is statistical significant difference between the averages of cholesterol for patients with and without relapse

# Normal distribution?

Normal distribution



- Shapiro-Wilk test (small and large samples),  
**or**
- Lilliefors test (large samples),  
**or**
- Kolmogorov-Smirnov test (small samples)

# How are the variances?

- Two independent samples
  - Two **variances** to compare
- 

Test Fisher for variances

Or

Test Levene for variances

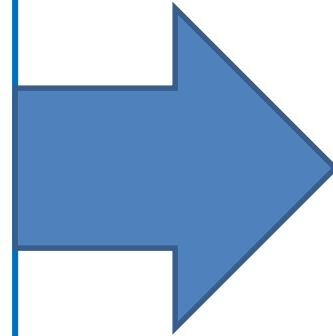
Or

Test Bartlett for variances

Result: variances are equal or unequal

# If variances are equal, how are the means?

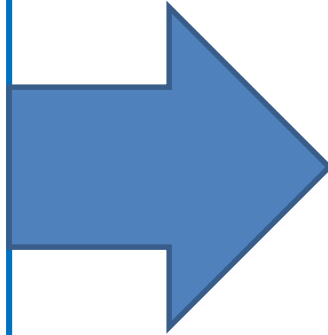
- Two independent samples
- Two means to compare
- **Equal** variances
- Normal distributions ( $n_1$  or  $n_2 < 30$ )



T test (Student) for  
**equal** variances

# If variances are unequal, how are the means?

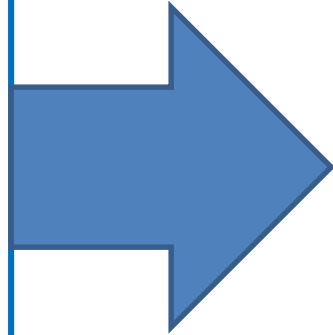
- Two independent samples
- Two means to compare
- **Unequal** variances
- Normal distributions ( $n_1$  or  $n_2 < 30$ )



T test (Student) for  
**unequal** variances

# If the distribution is not normal

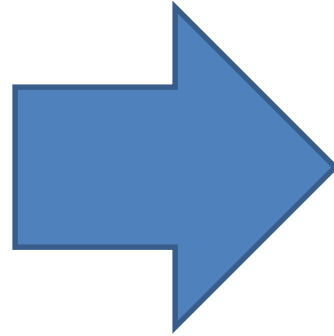
- Two independent samples
- Two means to compare
- **Non-normal** distributions  
( $n_1$  or  $n_2 < 30$ )



Mann-Whitney test

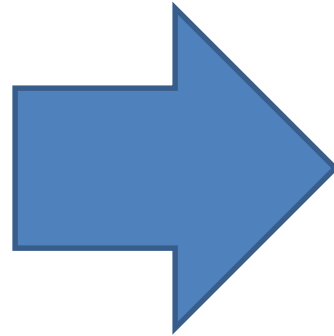
# If we have **dependent** samples?

- Two dependent samples
- Two means to compare
- **Normal** distribution



T test (Student) for **paired** samples

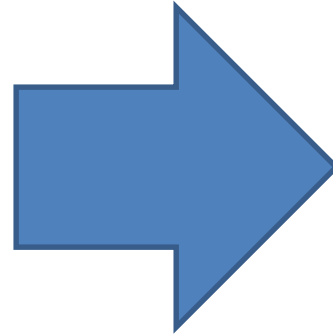
- Two dependent samples
- Two means to compare
- **Non-normal** distribution



Wilcoxon rank sum test for **paired** samples

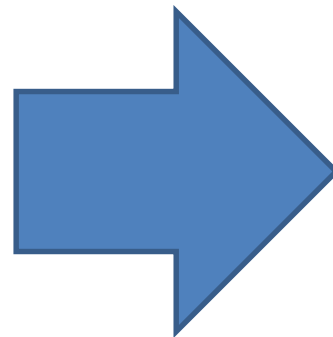
## If >2 samples?

- 3 or >3 **independent** samples
- 3 or >3 means to compare
- Equal variances
- Normal distribution or  $n_1 > 30$  and  $n_2 > 30$



Anova test

- 3 or >3 independent samples
- 3 or >3 means to compare
- Unequal variances or non-normal distribution and ( $n_1 > 30$  or  $n_2 > 30$ )



Kruskal-Wallis test

## Low-Calorie Vegetarian Versus Mediterranean Diets for Reducing Body Weight and Improving Cardiovascular Risk Profile: CARDIVEG Study (Cardiovascular Prevention With Vegetarian Diet)

Francesco Sofi<sup>1 2 3</sup>, Monica Dinu<sup>4</sup>, Giuditta Pagliai<sup>4</sup>, Francesca Cesari<sup>5</sup>, Anna Maria Gori<sup>4 6</sup>, Alice Sereni<sup>4 6</sup>, Matteo Becatti<sup>7</sup>, Claudia Fiorillo<sup>7</sup>, Rossella Marcucci<sup>4 6</sup>, Alessandro Casini<sup>4 2</sup>

Affiliations + expand

PMID: 29483085 DOI: [10.1161/CIRCULATIONAHA.117.030088](https://doi.org/10.1161/CIRCULATIONAHA.117.030088)

### Abstract

**Background:** Only a few randomized dietary intervention studies that investigated the effects of lacto-ovo vegetarian diet (Vd) in clinically healthy omnivorous subjects are available.

**Methods:** We randomly assigned to overweight omnivores with a low-to-moderate cardiovascular risk profile a low-calorie Vd compared with a low-calorie Mediterranean diet (MD), each lasting 3 months, with a crossover design. The primary outcome was the difference in body weight, body mass index, and fat mass changes between the 2 groups. Secondary outcomes were differences in circulating cardiovascular disease risk parameters changes between the 2 groups.

**Results:** One hundred eighteen subjects (mean age: 51.1 years, females: 78%) were enrolled. The total participation rate at the end of the study was 84.7%. No differences between the 2 diets in body weight were observed, as reported by similar and significant reductions obtained by both Vd (-1.88 kg) and MD (-1.77 kg). Similar results were observed for body mass index and fat mass. In contrast, significant differences between the 2 interventions were obtained for low-density lipoprotein cholesterol, triglycerides, and vitamin B<sub>12</sub> levels. The difference between the Vd and MD groups, in terms of end-of-diet values, was recorded at 9.10 mg/dL for low-density lipoprotein cholesterol ( $P=0.01$ ), 12.70 mg/dL for triglycerides ( $P<0.01$ ), and 32.32 pg/mL for vitamin B<sub>12</sub> ( $P<0.01$ ). Finally, no significant difference was found between Vd and MD interventions in oxidative stress markers and inflammatory cytokines, except for interleukin-17, which improved only in the MD group. Forty-six participants during the Vd period and 35 during the MD period reached the target values for  $\geq 1$  cardiovascular risk factor.

**Conclusions:** Both Vd and MD were effective in reducing body weight, body mass index, and fat mass, with no significant differences between them. However, Vd was more effective in reducing low-density lipoprotein cholesterol levels, whereas MD led to a greater reduction in triglyceride levels.

**Clinical trial registration:** URL: <https://www.clinicaltrials.gov>. Unique identifier: [NCT02641834](https://www.clinicaltrials.gov/ct2/show/study/NCT02641834).

- Italy
- vegetarian versus Mediterranean diet in obese people
- 118 subjects were randomly assigning in groups
- 3 months
- after 3 months change the diets (cross-over design)
- trial was registrated

## Low-Calorie Vegetarian Versus Mediterranean Diets for Reducing Body Weight and Improving Cardiovascular Risk Profile: CALDIET Study

**Table 1.** Baseline Characteristics of the Study Population According to the First Randomization

Characteristic	All (n=118)	Vegetarian Diet (n=60)	Mediterranean Diet (n=58)	P Value
Total cholesterol, mg/d (mean±SD)	202.7±109.2	198.8±94.5	206.8±124.9	0.96

index, and fat mass changes between the 2 groups. Secondary outcomes were differences in circulating cardiovascular disease risk parameters changes between the 2 groups.

**Results:** One hundred eighteen subjects (mean age: 51.1 years, females: 78%) were enrolled. The total participation rate at the end of the study was 84.7%. No differences between the 2 diets in body weight were observed, as reported by similar and significant reductions obtained by both Vd (-1.88 kg) and MD (-1.77 kg). Similar results were observed for body mass index and fat mass. In contrast, significant differences between the 2 interventions were obtained for low-density lipoprotein cholesterol, triglycerides, and vitamin B<sub>12</sub> levels. The difference between the Vd and MD groups, in terms of end-of-diet values, was recorded at 9.10 mg/dL for low-density lipoprotein cholesterol (*P*=0.01), 12.70 mg/dL for triglycerides (*P*<0.01), and 32.32 pg/mL for vitamin B<sub>12</sub> (*P*<0.01). Finally, no significant difference was found between Vd and MD interventions in oxidative stress markers and inflammatory cytokines, except for interleukin-17, which improved only in the MD group. Forty-six participants during the Vd period and 35 during the MD period reached the target values for ≥1 cardiovascular risk factor.

**Conclusions:** Both Vd and MD were effective in reducing body weight, body mass index, and fat mass, with no significant differences between them. However, Vd was more effective in reducing low-density lipoprotein cholesterol levels, whereas MD led to a greater reduction in triglyceride levels.

**Clinical trial registration:** URL: <https://www.clinicaltrials.gov>. Unique identifier: [NCT02641834](https://www.clinicaltrials.gov/ct2/show/study/NCT02641834).

- 198.8 compare with 206.8
- *p*=0.96 >0.05 we cannot reject H<sub>0</sub>: there are no significant difference between baseline cholesterol between groups (i.e. in the population from where they select this samples)

	Vegetarian Diet: Before (n=104)	Vegetarian Diet: After (n=104)	Mediterranean Diet: Before (n=103)	Mediterranean Diet: After (n=103)	<i>P</i> ( $\Delta_{VD}$ Versus $\Delta_{MD}$ ) <sup>‡</sup>
TC, mg/dL	207.89 (200.74–215.29)	202.55 (195.98–209.56)*	205.41 (197.95–212.94)	205.30 (198.34–212.72)	0.15

- they compare the difference (delta) between baseline and final cholesterol (TC=total cholesterol) between groups
- $p=0.15 > 0.05$  we cannot reject  $H_0$ : there are no significant difference between the decrease of the cholesterol between vegetarian and Mediterranean diet (i.e. there is no difference in cholesterol decrease between the population which adopt 3 months period a vegetarian and a population who adopt a Mediterranean diet)

# A Mediterranean Diet and Low-Fat Vegan Diet to Improve Body Weight and Cardiometabolic Risk Factors: A Randomized, Cross-over Trial

Neal D. Barnard, Jihad Alwarith, Emilie Rembert, Liz Brandon, Minh Nguyen, Andrea Goergen, ...show all  
Pages 127-139 | Received 23 Nov 2020, Accepted 22 Dec 2020, Published online: 05 Feb 2021

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## Abstract

**Objective:** Evidence suggests that both Mediterranean and vegan diets improve body weight and cardiometabolic risk factors, but their relative efficacy has not been compared in a randomized trial.

**Methods:** In a randomized crossover trial, 62 overweight adults were randomly assigned to a Mediterranean or vegan diet for a 16-week period. Body weight, plasma lipids, blood pressure, and body composition (dual X-ray absorptiometry) were measured. Secondary measures included insulin resistance (Homeostasis Model Assessment, HOMA-IR), oral glucose insulin sensitivity (OGIS), and predicted insulin sensitivity (PREDIM) indices. Thereafter, participants were asked to return to their baseline diets for 4 weeks, after which they began the opposite diet for 16 weeks. The same parameters were measured before and after this 2<sup>nd</sup> 16-week period.

**Results:** Overall net weight changes were 0.0 (Mediterranean) and -6.0 kg (vegan), (treatment effect -6.0 kg [95% CI -7.5 to -4.5];  $p < 0.001$ ). HOMA-IR decreased and OGIS increased on the vegan diet with no significant change on the Mediterranean diet (treatment effect -0.7 [95% CI, -1.8 to +0.4];  $p = 0.21$ ; and +35.8 mL/min/m<sup>2</sup> [95% CI, +13.2 to +58.3];  $p = 0.003$ , respectively). PREDIM did not change significantly in either group. Among participants with no medication changes, total and LDL-cholesterol decreased 18.7 mg/dL (0.5 mmol/L) and 15.3 mg/dL (0.4 mmol/L), respectively, on the vegan diet, compared with no significant change on the Mediterranean diet (treatment effect -15.6 [-24.6 to -6.6];  $p = 0.001$  and -14.8 [-23.5 to -6.2];  $p = 0.001$ , respectively); systolic and diastolic blood pressure decreased 9.3 and 7.3 mmHg on the Mediterranean diet, compared with 3.4 and 4.1 mmHg on the vegan diet (treatment effect +5.9 [95% CI +1.0 to +10.9];  $p = 0.02$ ; and +1.8 [95% CI -4.6 to +8.1];  $p = 0.58$ , respectively).

**Conclusions:** A low-fat vegan diet improved body weight, lipid concentrations, and insulin sensitivity, both from baseline and compared with a Mediterranean diet. Blood pressure decreased on both diets, more on the Mediterranean diet.

**Clinical trial registration:** ClinicalTrials.gov number, NCT03698955

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- USA
- 62 obese
- randomly assign to Mediteranean or Vegan diet
- trial was registered

# A Mediterranean Diet and Low-Fat Vegan Diet to Improve Body

## Weigh Cross-

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### Abstract

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95% confidence interval between -24.6 to -6.6

vegan diet versus mediteranean diet in population best: -24.6mg/dl, worst -6.6mg/dl

# The OMNIVEG STUDY: Health outcomes of shifting from a traditional to a vegan Mediterranean diet in healthy men. A controlled crossover trial

Miguel López-Moreno <sup>a,b</sup> · Ujué Fresán <sup>c</sup> · Juan Del Coso <sup>d</sup> · ... · Javier Pena-Fernández <sup>e</sup> · Alejandro Muñoz <sup>e</sup> · Jorge Gutiérrez-Hellín <sup>e</sup>  
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## » Abstract

Show Outline

### Background and aim

The Mediterranean diet is a plant-based dietary pattern with well-established health benefits such as the reduced risk of cardiovascular disease. Additionally, incorporating more plant-based foods into a Mediterranean diet may provide further health benefits. The study aimed to assess the effect of shifting from a traditional Mediterranean diet to a vegan Mediterranean diet on cardiorespiratory fitness and lipid profile in physically active and healthy men.

### Methods and Results

Participants underwent a baseline period with adherence to the general patterns of the Mediterranean diet for three weeks and then they changed to an isocaloric vegan version of the Mediterranean diet for four weeks, with a 7-day washout period between diets. The shift from the traditional Mediterranean diet to the vegan Mediterranean diet required substituting animal-based foods with plant-based foods that contain comparable amounts of protein and fat. Fourteen participants with a mean age of  $24.6 \pm 7.0$  years (range: 18–37 years), completed the study protocol. The change from the traditional to the vegan Mediterranean diet reduced blood concentration of total cholesterol ( $-22.6$  mg/dl,  $p < 0.01$ , Effect size [ES] = 1.07) and low-density lipoprotein cholesterol ( $-12.8$  mg/dl,  $p < 0.01$ , ES = 0.72). An inverse correlation was observed between the intake of dietary fibre and LDL-C (partial rho =  $-0.43$ ,  $p = 0.040$ ).

### Conclusions

The adoption of a vegan Mediterranean diet with plant-based proteins and fats instead of the traditional Mediterranean diet improved several cardiometabolic health outcomes in physically active and healthy men.

### Clinical Trial Registry

NCT06008886. ←

- Spain
- vegetarian versus Mediterranean diet
- 14 subjects
- 3 weeks
- after 3 weeks change the diets (cross-over design)
- trial was registered

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## Abstract Methods and Results

Show Outline

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Thank you !!!