## Laboratory activities. Exposed-unexposed study

### Aim and utility of this practical session

1. Realize the research protocol of the exposed-unexposed study based on a proposed scenario
2. Data analysis and presentation of the obtained results
3. Statistical and clinical interpretation of the obtained results

### Proposed scenario:

It was aim to test the hypothesis that oral breathing during early childhood favors the occurrence of maxillary compression syndrome.

To test the hypothesis, a study was initiated in Cluj-Napoca. Aged 3-4 years children from 5 kindergartens in Cluj were included in the study.

51 children were identify to be exposed to the risk factor: with oral breathing due to upper airways obstruction (CAS) or adenoid vegetation or nasal septal deviations whose surgery was denied by parents or rhinitis allergic refractory to treatment. Children in the group not exposed to the risk factor (73) did not have oral respiration at rest, having C.A.S. permeability within normal limits.

The facial growth and development of the jaw of the two groups of children was followed periodically for **4 years**, as well as the onset of jaw compression.

Data recording was done in the **lp03bd\_chen.xls** file. Save your files locally.

**Definition.** In the early years of growth, a child may develop **dental maxillary abnormalities** called maxillary compression syndrome. The three main groups of muscles involved in the development of the jaw: the tongue, cheeks and the muscles of the lips allow harmonious lining up of the teeth. If a nonphysiological position occurs or a hypotonicity develops on one of these muscles, it may lead to the appearance of various dental maxillary abnormalities by altering the growth directions.

**Research Protocol**

1. Aim and objectives of the research:

**Aim:**

**Objectives:**

1. Domain of research:

### Domain of research:

1. Study type:

**Based on study objectives (Descriptive / Analytical):**

**Based on the researchers role (Observational / Experimental) :**

**Based on the technique used in the choice of groups (With matching / No matching):**

### Target population and study sample

### What was the accessible population of this study?

#### **Accessible population:**

#### Describe the study sample:

##### **Study sample:**

##### • Inclusion criteria:

Clinical characteristics:

Demographic characteristics:

#### • Exclusion criteria (applied only to subjects who comply with the above inclusion criteria; if not relevant, some or all exclusion criteria may be missing):

####  Biasing factors (e.g. coexistent diseases/coexistent treatments):

####  Adverse effects:

####  Factors that make data collection difficult or impossible:

####  Ethic issues:

#### Sample size – is your sample large enough?

#### **Is the size of the sample sufficient? (Yes/No):**

1. Data collection method

**Based on the studied population (Exhaustive / sample):**

**Based on the duration of data collection (transversal / longitudinal prospective or retrospective):**

**Based on the grouping method (case-control, exposed-not exposed):**

### Defining variables (open the Excel database and fill in the names of all collected variables in the correct textboxes below):

|  |
| --- |
| 1. **Qualitative variables**
 |
| Nominal | Nominal dichotomial | Ordinal |
| 1. **Quantitative**
 |
| Continuous | Discrete |

1. Data description and analysis plan:

|  |
| --- |
| What kind of charts, table can be use to describe the research data? |
|  |
| What kind of charts, table can be use to describe the association between oral breathing and maxillary compression syndrome? |
|  |
| Which inferential statistical method can be use to test the association between oral breath and maxillary compression syndrome? |
|  |
| Which measures can be use to quantify the association between oral breath and maxillary compression syndrome? |
|  |

## Results. Data analysis and presentation

### Make the frequency table for oral breathing (use Jamovi):

Table 1. Distribution of oral breath in the study sample

**Make a Bar chart for oral breathing** (**use Jamovi**)**:**

Fig.1. Distribution of oral breath in the study sample

**Table of contingency between risk factor and disease** (**use Jamovi**)**:**

Table 2. Distribution of oral maxillary compression syndrome at exposed versus unexposed

**Column chart for the relationship between risk factor and illness** (**use Jamovi**)**:**

Fig.2. The distribution of maxillary compression syndrome at exposed versus unexposed

**Compute Relative Risk (RR), Attributable Risk (RA), and associated 95% confidence intervals copy** (**use Jamovi**)

*in the follwing format: punctual estimator (95% CI lower limit-upper limit)*

*RR=*

*AR=RD=*

**Identify the value of p (use Jamovi write down this result** *in the following format: p=value – name of the Test the has been used- with maximum 3 decimals. if p<0.001 than write p<0.001***):**

## Interpret the results:

**Interpreting the results from statistic point of view:**

Null Hypothesis:

Alternative hypothesis:

Rejected null hypothesis (yes / no). Argument:

Interpretation of punctual estimators:

 RR:

 RA:

Interpretation of 95% confidence intervals for:

 RR:

 RA:

**Interpreting the results from statistic point of view:**

The size of RR and RA indicators in clinical context (very important / moderate / minor)

Result accuracy based on confidence interval width (imprecise results / accurate results)

Interpretation of 95% confidence intervals (clinically relevant relationship / relatively little clinically relevant / clinically unclear link).

Specify whether a study like this (observational) is sufficient to draw a firm conclusion about a causal relationship between the risk factor and the disease:

• Yes No

## To remember

How an exposed-unexposed (cohort) study can be recognize?

- All individuals are free from the disease we want to study when they are included in the study,

- There are two patient groups involved: a group exposed to the factor we want to evaluate and a group that is not exposed to the factor

- Is a prospective study