## 임상연구 설계와 분석을 위한 통계 방법

Boncho Ku, Ph.D., Senior researcher

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KM Fundamental Research Division, Korea Institute of Oriental Medicine

# Chapter I: Overview of Statistics and Study Design

# Most researchers or people think

Statistics makes us insane...

#### However

Statistics sometimes gives us very useful information from data!!

So then, what is statistics??





 $<sup>^\</sup>dagger$  Each word cloud was cited from Trident University International and Augusta University, respectively.

#### 1. Data

- Investigation, experiment, and survey
- Gathering numbers (for quantitative analysis)

# 2. Description or Summarization

- Table, chart, and so on
- Based on summarized statistics (e.g. mean, standard deviation, median, ...)

#### 3. Inference

- · Numerous statistical tests and models based on probability theory
- e.g. two-sample t-test, ANOVA, ANCOVA, regression, and so on

Type of Studies

#### Overview

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Study or trial?

#### Study

자료의 수집과 분석 목적이 학술적 목적에 국한된 모든 종류의 연구 및 실험

#### Trial

자료의 수집과 분석 목적이 이윤추구 또는 허가에 목적이 있는 임상시험

#### Cross-sectional study (단면적 관찰연구)

- 1. prevalence study
- 2. Diagostic test
- 3. Ecological study
- 4. Validity, Reliability, and agreement study

## Longitudinal study (종단적 관찰연구)

- 1. Prospective study
- 2. Retrospective study

#### Experimental Study

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Randomized controlled trial

Pilot study

Exploratory study

Confirmative study

Type of outcome variables

## Primary outcomes

## Secondary outcomes

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## Surrogate variables

#### Global assessment variable

## Sample size calculation

#### Two approaches

- 1. Based on the marginal error rate  $\rightarrow$  population based observational study
- 2. Based on the effectiveness between concerning groups  $\rightarrow$  experimental study

Both approaches are based on previous studies

Is your study entirely new?

#### Observational study

#### Observational study: prevalence study

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#### Observational study: prevalence study

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## Parallel design

## $2 \times 2$ cross-over design

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## Factorial design

# Multiple comparison

#### What makes data significant?

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- $1. \ \, {\rm Data} \,\, {\rm themselves} \,\, {\rm contain} \,\, {\rm unexpected} \,\, {\rm errors}$
- 2. Bias
- 3. Just conincidence
- 4. Our hypothesis is working

## Torturing data

# Statistical Analysis

#### Overview

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#### Independent two sample t-test

1. Too easy, but very useful methodology for the comparison of sample means between two groups  $\,$ 

## Analysis of Variance (ANOVA)

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# Analysis of Covariance (ANCOVA)

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## Simple or multiple regression

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#### Repeated Measures ANOVA

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#### Linear mixed effects model

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#### Reliability analysis

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Cohen's  $\kappa$ 

Cronbach's  $\alpha$ 

Intra Class Correlation (ICC)