#### Mediation models and simple size calculation (Hugo Cogo-Moreira)

**Title:** Sample size calculation and mediation analysis: from the traditional and counterfactual based approach

#### **Course description:**

This course provides an in-depth exploration of sample size determination in the context of randomized controlled trial and mediation analysis techniques, focusing on both traditional and counterfactual-based approaches. For the sample size calculation, the students will learn the main parameters necessary for classical hypothesis testing when design a parallel randomized trial (i.e., power, alfa error probability, minimum detectable effect size and other). Students will learn the theoretical foundations of mediation analysis and their assumption when inferring causality. The course will cover both conceptual understanding and hands-on application through statistical software.

### Course Objectives for the sample size calculation and mediation analysis.

- Understand the conceptual framework of mediation analysis and its applications using data coming psychology and psychiatry.
- Gain proficiency in determining sample size requirements for RCTs.
- Compare and contrast traditional and counterfactual -based approaches to mediation analysis.
- Learn how to conduct mediation analysis using PROCESS, an add-on for SPSS.
- Interpret and communicate results from mediation analyses effectively (i.e., reporting effect sizes when possible).

#### Program for the sample size calculation.

- Basic statistical concepts: effect size, significance level, power
- Determining clinically meaningful effect sizes
- Hands-on using G\*power calculation
   <u>https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower</u> and
   <u>https://dimewiki.worldbank.org/Power\_Calculations\_in\_Optimal\_Design</u>
- Calculating sample size for continuous outcomes
  - Randomization at subject level
  - Randomization at cluster-level (for cluster randomized controlled trials)

#### Program for the mediation analysis.

- Basic mediation model,
- Estimating indirect and direct effects and significance testing
- Bootstrapping methods vs. Sobel test
- Introduction to counterfactual-based mediation analysis
- Potential outcomes framework
- Causal mediation analysis vs. traditional mediation analysis
- Introduction to statistical software for mediation analysis (in SPSS via PROCESS)

- Hands-on practice: conducting traditional mediation analysis using software
- Hands-on practice: conducting counterfactual-based mediation analysis using software

## Requirements

- For sample size calculation, student must come with G\*Power installed
  - <u>https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower</u>
- For the mediation analysis, the students must have a SPSS later than 22 version installed the PROCESS macro must be downloaded. The tutor will teach how to install PROCESS.
  - o <u>https://www.processmacro.org/download.html</u>

# Reference

Hayes, A. F., & Rockwood, N. J. (2017). Regression-based statistical mediation and moderation analysis in clinical research: Observations, recommendations, and implementation. *Behaviour research and therapy*, *98*, 39–57. https://doi.org/10.1016/j.brat.2016.11.001

VanderWeele T. J. (2016). Mediation Analysis: A Practitioner's Guide. *Annual review of public health*, *37*, 17–32. <u>https://doi.org/10.1146/annurev-publhealth-032315-021402</u>

VanderWeele T. J. (2009). Mediation and mechanism. *European journal of epidemiology*, *24*(5), 217–224. <u>https://doi.org/10.1007/s10654-009-9331-1</u>

Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G\*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods, 39, 175-191

Nordahl-Hansen, A., Cogo-Moreira, H., Panjeh, S., & Quintana, D. S. (2024). Redefining effect size interpretations for psychotherapy RCTs in depression. Journal of psychiatric research, 169, 38–41. https://doi.org/10.1016/j.jpsychires.2023.11.009