Study design, sampling, statistical analysis plan and power calculation for protocol writing in biomedical research.

Synopsis

This course will be held by blend in-person and remote modality, it will be in English (with a specific part dedicated to protocol writing in Italian) and will consist of a total of 50 hours to be held in four consecutive weeks by five days each with two hours a day for the first three weeks and 4 hours a day for the fourth week. The first three weeks will be held in a remote mode and are dedicated to the most theoretical aspects and the use of softwares. The fourth week (in presence) is dedicated to practical aspects of protocol writing and foresees the direct interaction with students aimed at the setting up of their protocols. The course will be carried on during the period 2-27 September 2024.

This training has three aims. Firstly, to create awareness about the theoretical concepts and practical aspects of scientific protocol drafting in quantitative observational and experimental biomedical research. Secondly, to teach the use of software for statistical analyses and power calculations. Finally, the course aim to improve protocol writing skills. To facilitate the software use, the course will be based on the use of graphical interface software (SPSS and G*Power). The approach will not be theoretically based being centred on most practical aspects of study design, statistical analyses and power calculations. The skills verification will be carried out through a test consisting in the drafting of a protocol reporting the study design and the sampling plan, the statistical analysis plan, and the assessments of adequacy of the sample size and power analysis.

Week 1 -Preparatory theoretical aspects

From 30/9 to 4/10 (Remote) from 12.00 to 14.00

Introduction to quantitative research in the biomedical field

- Formulation of statistical hypothesis and statistical testing of scientific hypothesis
- Type-I and type-II errors, P-value and statistical tests
- Parametric and non-parametric analysis
- ANOVA, linear regression and correlation, ANCOVA and R-ANOVA analysis
- Logistic regression
- Survival analyses using nonparametric and semi-parametric approaches
- Multivariate space reduction and related techniques

Theoretical elements of study design for observational and experimental studies

- Bias types
- Sampling and study design for bias control

- Observational studies (cross sectional, retrospective and prospective)
- Experimental studies with parallel arms and cross-over design

Week 2-Data management and Statistical analyses in practice

From 7/10 to 11/10 (Remote) from 12.00 to 14.00

- Use of software for data storage, data analysis and power calculations Hints to systems for data capturing (REDcap, EPI info and access)
- SPSS: Nonparametric and parametric univariate tests
- SPSS: ANOVA, linear regression and correlation, ANCOVA and R-ANOVA analysis
- SPSS: Logistic regression
- SPSS: Survival analyses using nonparametric and semi-parametric approaches
- SPSS: Multivariate space reduction and related techniques
- SAS and R and coding of statistical analyses (hints)

Week 3-Power Calculation

From 14/10 to 18/10 (Remote) from 12.00 to 14.00

- G*Power: Nonparametric and parametric univariate tests
- G*Power: ANOVA, ANCOVA and RANOVA analysis
- G*Power: logistic regression
- G*Power: Survival analysis (hints)
- Power calculation with SAS and R (hints)
- Simulation and power calculation for the mixed model analysis (hints)

Week 4-Scientific writing and protocol preparation

From 21/10 to 25/10 (In presence) (4 hours a day to be defined)

- Basics of scientific writing and general rules for the writing of a scientific protocol
- Reporting and justification of the study design and sample strategy
- Reporting and justification of the sample size adequacy and power calculations
- Drafting of the statistical analysis plan
- Bibliographic aspects (hints)
- Extension to scientific protocols in Italian language
- Vis a vis interaction with students for their protocol writing

Contact for didactic info: cristian.ricci@nwu.ac.za