Seminar for Nacrtovanje klinicnih in epidemioloskih raziskav, 2024/25.

Find a published paper describing an observational study for which the protocol of the study is avaialble (and was deposited in a public repository) and where there is enough information available to reproduce the sample size calculations performed to design the study. The study might have a separate document called Statistical analysis plan that describes in more detail the statistical analysis that were preplanned.

Prepare a short document that contains the following information.

1. Summary of a scientific paper. Shortly reply to the following questions. (1-2 pages)
   1. Description of the research question
   2. Has this question been answered before, if yes, what are the disagreements to be resolved with this paper
   3. Definition of the population, how satisfying is the sample
   4. Write down the main hypotheses
   5. Explain the study design (and how it helps answering the research question)
      1. Subjects
      2. Variables (outcomes and explanatory variables)
      3. Time frame
      4. Type of study
   6. Describe the statistical methods used and comment on why each of them was chosen
      1. Hypotheses
      2. Sample size
      3. Methods of analysis
   7. What are the main results? Are they statistically / clinically significant (max 1 paragraph)
   8. How is the discussion and the conclusions supported by the data
   9. Do you see any study limitations.
   10. Do you have any ideas what could be done next
2. Sample size calculation (Max 1 page + figures)
3. Copy the paragraph from the paper/protocol that describes how the sample size was determined.
4. Prepare a table where you summarize the assumptions made by the authors for the sample size justifications (the table might include: level of significance, desired power, assumed variability of the variables, assumed minimal difference, assumed OR or proporitions, type of planned statistical analysis,....). Indicate also if the authors justified their choices (references, justifications of different types).
5. Try to repeat the sample size calculation using PS (or manual calculations). Include the calculations, stating the values of the parameters that you choose. If you used a computer program, add a printscreen of the input values and of the results). If the sample size calculations cannot be repeated using simple methods as addressed in class, try using a simulation to evaluate the appropriateness of the sample size for the aims of the study.
6. Find the appropriate checklist for study reporting (for example, in the Equator web site) and fill it in.
7. Evaluate to which extent the statistical analysis plan (included in the protocol or described in a separate document) describes in sufficient detail the intended statistical analyses and to which extent the presented analyses deviate from the intended plan. Evalulate also if there were other possible deviations from the protocol, comparing in detail the protocol and the published paper.

Upload your seminar in a single (your name should be included in the file name) in the e-classroom.

Deadline is: May 29 uploading in the e-classroom. Presentation: June 2.

Language: Slovenian or English.

Sources: <https://www.amsterdamuas.com/uv-openscience/toolkit/planning/sap/sap.html>