DEPARTMENT OF CLINICAL NEUROSCIENCE

K8F5638, Single Case Design (SCD) in Clinical Research and Data Driven Decision Processes for Individualized Health Care, 3 credits (hec)

Single case design för klinisk forskning och datadrivna beslutsprocesser i individanpassad vård, 3 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus is approved by the The Committee for Doctoral Education on 2023-12-21, and is valid from Spring semester 2024.

Responsible department

Department of Clinical Neuroscience, Faculty of Medicine

Prerequisite courses, or equivalent

Course in basic statistics or corresponding knowledge.

Purpose & Intended learning outcomes

Purpose

The course primarily targets PhD students and postdoctoral researchers involved in clinical research, with an interest in understanding individual change processes, including treatment effects.

The purpose of the course is to enhance clinical research in precision health and personalized interventions, and to facilitate a scientist-practitioner approach in health care with data driven decision processes. More specifically, the course will enable the student to:

1) understand the rationale for, and implications of using, Single Case Design (SCD) in relation to group-based designs such as randomized controlled trials (RCT) (e.g. research questions and conditions, validity of results)

2) acquire substantial knowledge about different types of SCDs

3) have a basic understanding of key statistical and visual/graphical analyses

4) follow guidelines for conducting and reporting SCD studies

Intended learning outcomes

The course contains intended learning outcomes (ILOs) in knowledge, skills and attitude. Below follows a presentation of ILOs in each of the course modules as well as for professionalism and overall course content, together with the form of assessment for each ILO.

KNOWLEDGE

Module 1. Introduction – why SCD?
- Understand limitations with group-based analytic approaches, such as RCTs (SBA, i.e. Single Best Answer)
- Understand when SCD is applicable (Seminar)

Module 2. Designing a single-case study
- Ability to contrast individual- and group level analyses, e.g. SCD vs RCT (SBA)
- Knowing the central types of SCD, including observational (SCOD) and experimental (SCED) designs

Module 3. Analyzing SCD data
- Knowing the basic statistical analyses for SCD data (Seminar)
- Knowing the visual/graphical analyses of SCD data (Seminar)

Module 4. Reporting SCD data
- Oriented in the guidelines for reporting SCD studies (SBA)

Professionalism
- Ability to critically appraise ethical concerns in using individual-level data (Brief report)

Overall course content
- Well oriented regarding the existing SCD resources, including data collection tools and networks (Final exam)
- Ability to apply guidelines for planning, conducting and reporting SCD studies (Seminar)

SKILLS

Module 1. Introduction – why SCD?
- Ability to describe the main SCED designs (Seminar)

Module 2. Designing a single-case study
- Ability to identify a SCD design suitable for analyzing the change process in a given clinical context (SBA)

Module 3. Analyzing SCD data
- Ability to apply digital tools for randomization, data collection and analyses (visual and statistical) (SBA)

Module 4. Reporting SCD data
- Ability to write a scientific report in accordance with guidelines (Seminar)

Professionalism
- Ability to communicate about SCD with a patient (e.g., why and how) (OSCE, i.e. Objective Structured Clinical Examination)

Overall
- Ability to apply SCD to investigate a clinically relevant question (Seminar)

ATTITUDE

Professionalism
- Ability to critically review and report strengths and concerns in own SCD studies (e.g., based on guidelines) (Brief report)

Overall
- Ability to critically evaluate the use of group-level designs, including RCTs (Final exam)

Course content

The course will cover the fundamentals of Single Case Design (SCD), and consists of four different modules covering:

1) what SCD is and what it is used for, different designs and key differences as compared to group-level designs (e.g. RCT)
2) design and implementation, including data collection with digital tools
3) how to analyze SCD data with visual and statistical methods
4) how SCD studies are reported based on international guidelines.

Forms of teaching and learning

To optimize learning of applied knowledge and skills, six different teaching-learning activities (TLA) are used:

1. Pre-recorded 45 min lectures by international SCD researchers followed by digital live 45 min ”question and answer (Q&A)” sessions with the presenter, covering different aspects of SCD.
2. Pre-recorded digital hands-on workshops on how to conduct a SCD study in practice.
3. Reading literature, including books and papers, on SCD.
4. Digital seminars, using a Flipped teaching/learning approach with a focus on questions that stem from the lectures, Q&A sessions and the literature.

5. Digital workgroup sessions, to provide and get peer feedback on practical exercises.
6. Asynchronous communication within the work group, on assignments related to each module.

Language of instruction

The course is given in English

Grading scale

Pass (G) /Fail (U)

Compulsory components & forms of assessment

Compulsory components

Attendance at the digital seminars is required, and therefore included in the summative assessment. Up to two seminars may be missed, and compensated by writing a brief report from the seminar.

Pre-recorded lectures and workshops are strongly recommended activities, and information from lectures will be included in both summative and formative assessments.

Forms of assessment

Examinations are designed to be in alignment with course objectives (ILOs) and learning activities (TLAs). Thus, there are assessments in each specific module (i.e., the building blocks of relevance for the overall skills, i.e., designing, analyzing and reporting SCD) for the three categories of ILOs (knowledge, skills, attitude), as well as an overall assessment of the course content, including professionalism. (Notably, summative assessments of professionalism are conducted on several occasions during the course, e.g., in two or more TLAs on ethics and methodology quality, for example “patient selection and informed consent”, and “confidentiality and anonymized data”.)

Examinations are designed to have summative and formative functions and include 1) single best answers (SBA), 2) seminar attendance, 3) Objective structured clinical examination (OSCE), 4) brief reports and a 5) final report.

Course literature

Recommended literature:

Books
1. Morley, S. (2017). Single Case Methods in Clinical Psychology. A Practical Guide.
2. Barlow, D. H., Nock, M. K., & Hersen, M. (2009). Single Case Experimental Designs: Strategies for Studying Behavior Change, 3rd Edition. New York: Pearson.

Scientific papers

1. Evans JG (1995). Evidence-based and evidence-biased medicine. Age Ageing, 24(6),
2. 461-463. doi:10.1093/ageing/24.6.461
3. Smith, L. S., & Wilkins, N. (2018). Mind the Gap: Approaches to Addressing the Research-to-Practice, Practice-to-Research Chasm. J Public Health Manag Pract, 24 Suppl 1 Suppl, Injury and Violence Prevention, S6-S11. doi:10.1097/PHH.0000000000000667
4. Grossman, J., & Mackenzie, F. J. (2005). The randomized controlled trial: gold standard, or merely standard? Perspect Biol Med, 48(4), 516-534. doi:10.1353/pbm.2005.009
5. Bulté, I., & Onghena, P. (2012). When the truth hits you between the eyes: A software tool for the visual analysis of single-case experimental data. Methodology, 8(3), 104-114.
6. Manolov, R., & Moeyaert, M. (2017). How Can Single-Case Data Be Analyzed? Software Resources, Tutorial, and Reflections on Analysis. Behav Modif, 41(2), 179-228. doi:10.1177/0145445516664307
7. Nikles J, Onghena P, Vlaeyen JWS, Wicksell RK, Simons LE, McGree JM, McDonald S. Establishment of an International Collaborative Network for N-of-1 Trials and Single-Case Designs. Contemp Clin Trials Commun. 2021Aug 2;23:100826. doi: 10.1016/j.conctc.2021.100826. PMID: 34401597; PMCID: PMC8350373.
8. Porcino, A. J., Shamseer, L., Chan, A. W., Kravitz, R. L., Orkin, A., Punja, S., Ravaud, P., Schmid, C. H., Vohra, S., & SPENT group (2020). SPIRIT extension and elaboration for n-of-1 trials: SPENT 2019 checklist. BMJ (Clinical research ed.), 368, m122. https://doi.org/10.1136/bmj.m122
9. Schork, N. J. (2015). Personalized medicine: Time for one-person trials. Nature, 520(7549), 609-611. doi:10.1038/520609a
10. Shamseer, L., Sampson, M., Bukutu, C., Schmid, C. H., Nikles, J., Tate, R., Johnston, B. C., Zucker, D., Shadish, W. R., Kravitz, R., Guyatt, G., Altman, D. G., Moher, D., Vohra, S., & CENT group (2016). CONSORT extension for reporting N-of-1 trials (CENT) 2015: explanation and elaboration. Journal of Clinical Epidemiology, 76, 18–46. https://doi.org/10.1016/j.jclinepi.2015.05.018
11. Tate, R.L., Perdices, M., Rosenkoetter, U., Shadish, W., Barlow, D.H., Horner, R., …. Wilson, B. (2016). The Single-Case Reporting guideline In BEhavioural Interventions (SCRIBE) 2016 Statement. Archives of Scientific Psychology. 4(1), 1-9.
12. Tate, R. L., Perdices, M., Rosenkoetter, U., Shadish, W., Vohra, S., Barlow, D. H., Horner, R., Kazdin, A., Kratochwill, T., McDonald, S., Sampson, M., Shamseer, L., Togher, L., Albin, R., Backman, C., Douglas, J., Evans, J. J., Gast, D., Manolov, R., Mitchell, G., … Wilson, B. (2016). The Single-Case Reporting Guideline In BEhavioural Interventions (SCRIBE) 2016 Statement. Journal of Clinical Epidemiology, 73, 142–152. https://doi.org/10.1016/j.jclinepi.2016.04.006
13. Vlaeyen, J., Onghena, P., Vannest, K., & Kratochwill, T. (2022). Single-Case Experimental Designs: Clinical Research and Practice. In G. Asmundson (Eds.), Comprehensive Clinical Psychology. Elsevier. ISBN: 9780128186978.
14. Vlayen JWS, Wicksell RK, Simons LE, Gentili C, Kumar De, T, Tate RL, Vohra S, Punja S, Linton SJ, Sniehotta FF, Onghena, P. From Boulder to Stockholm in 70 years: Single case experimental designs in health research. Under review
15. Vohra, S., Shamseer, L., Sampson, M., Bukutu, C., Schmid, C. H., Tate, R., Nikles, J., Zucker, D. R., Kravitz, R., Guyatt, G., Altman, D. G., Moher, D., & CENT Group (2016). CONSORT extension for reporting N-of-1 trials (CENT) 2015 Statement. Journal of Clinical Epidemiology, 76, 9–17. https://doi.org/10.1016/j.jclinepi.2015.05.004