

Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 4. November 2025, 17:00 – 18:30 Uhr

Wo: [Campus Charité Mitte, Raum 02.002, Virchowweg 10, 10117 Berlin](#)

Online-Übertragung: der Link wird auf der [Website](#) zur Verfügung gestellt

Vortragssprache: Englisch

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Design and Analysis of Digital N-of-1 Trials

Personalized health is of increasing interest both in clinical practice and for healthy citizens that want to reach health goals. For inference on individual-level treatment effects, N-of-1 trials can be employed, which are multi-crossover trials in one person where health interventions are applied sequentially to derive individual-level treatment effects. There may be carryover effects or time trends, and intervention allocation may or may not be randomized, creating challenges for inference on intervention effects. If data from series of N-of-1 trials is available, where multiple participants perform the same trial, then population-level treatment effects can be estimated more efficiently compared to standard randomized controlled trials (RCTs). There has been increased recent interest in N-of-1 trials with the development of novel causal inference frameworks, novel statistical methods, extensions to new designs, integration of multimodal data, and development of computational platforms. These approaches integrate methods from causal inference, reinforcement learning and deep learning and allow more applications to different interventions, drugs, diseases, integration of different data sources and scalability to a large number of study participants. With the possibility to link research and clinical care, an important part of N-of-1 trials is also on showing and explaining the results of the trials to the individual participants. In this talk, I will first review the main principles of N-of-1 trials and contrast the similarities and differences to standard population-level RCTs, both regarding study design and statistical inference. Next, I will define estimands of interest in a potential outcomes framework. Examples of different clinical N-of-1 trials based on the open-source StudyU platform (<https://www.studyu.health>) will be described, also highlighting ethical and data privacy aspects. Finally, I will outline recent work on adaptive and multimodal N-of-1 trials.

Literature

1. Piccininni M, Shahn Z, Stensrud MR, Konigorski S (2024). Causal inference for N-of-1 trials. *ArXiv*. <https://arxiv.org/pdf/2406.10360v2>
2. Konigorski S, Schmid CH (2024). Digital N-of-1 trials and their application in experimental physiology. *ArXiv*. <https://arxiv.org/pdf/2412.15076>
3. Konigorski S, Wernicke S, Slosarek T, Zenner AM, Strelow N, Ruether FD, Henschel F, Manaswini M, Pottbäcker F, Edelman JA, Owoyele B, Danieleto M, Golden E, Zweig M, Nadkarni G, Böttinger E (2022). StudyU: a platform for designing and conducting innovative digital N-of-1 trials. *J Med Internet Res* 24(6): e35884. <https://doi.org/10.2196/35884>.
4. Vetter VM, Kurth T, Konigorski S (2025). Evaluation of two easy-to-implement digital breathing interventions in the context of daily stress levels in a series of N-of-1 trials: results from the Anti-Stress Intervention Among Physicians (ASIP) study. *medRxiv*. <https://doi.org/10.1101/2025.04.09.25325513>