

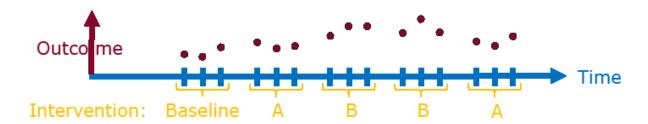
Multimodal N-of-1 trials – designing the future of personalized healthcare

What is our motivation?

What can you do if you want to know whether this new diet app really helps you to eat healthier? Or if you want to know which dose of drug xyz helps you better to control your high blood pressure, given that your physician is not sure either? You could look at medical research studies that have investigated this on the population level. But they typically do not tell you whether it will work for you, they will tell you at best that the drug works in maybe 60% of the population. You could just try out whether the app helps you or which dose is best? Sure! And if you want to do this systematically to avoid biases, you can perform an experiment called N-of-1 trial to evaluate it scientifically with valid statistical inference.

What are N-of-1 trials?

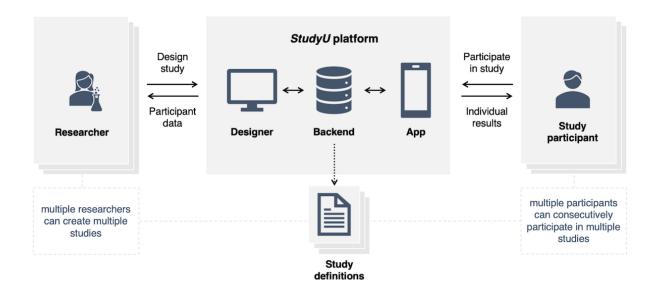
More formally, N-of-1 trials are cross-over randomized controlled trials where one or more health interventions are applied sequentially in one person over time. This is illustrated below, where two interventions A and B are administered in blocks, and the outcome is measured at all time points. And actually, if multiple people perform such N-of-1 trials you can make efficient statistical inference what might help others in the population.



What have we already developed?

In recent work, we have developed the StudyU platform (https://www.doi.org/10.2196/35884), which consists of a study designer web app (https://designer.studyu.health/) that allows researchers to design and implement N-of-1 trials, and a study app that allows study participants and patients to take part in these studies (https://app.studyu.health/). StudyU is open source (https://github.com/HIAlab/studyu) and free, the participant app is available in Android and Apple app stores and first clinical studies are running using StudyU. We have the vision to build a free resource that contains a repository of anonymized data of personalized trials and can empower users in their health behavior. StudyU has been developed and improved in two master projects, and students from the last project recently won the Best Idea Award 2022 at the HPI! The current tech stack of StudyU is Flutter/Dart, PostgreSQL/Supabase, Git/Gitlab, Jupyter Notebooks and there is ongoing work on its design. Clinical studies are ongoing or planned with UKE Hamburg, Mount Sinai, Weill Cornell, and University of Queensland that can be leveraged for clinical insights.





Description of the Master project

Currently, you can use StudyU to design and perform N-of-1 trials for health outcomes assessed through binary questions, multiple choice questions or some one-dimensional scale. But wouldn't it be nice if you could investigate multimodal health outcomes that you can easily capture using your smartphone such as pictures, audio and video? For example, that could let you (i) study changes of your skin injury by taking pictures or (ii) correct your pose or gait when you walk by taking videos or (iii) evaluate your pronunciation after taking language classes or check which medication helps best in your coughing if you have long-COVID by recording audio.

In order to be able to conduct such multimodal N-of-1 trials, you need infrastructure, machine learning models and statistical inference tools for dealing with pictures, audio or video. We have some work in the early stages on the machine learning models, and collected some imaging data, but overall, all above points do not exist yet and will be your project!

This master project will contain 2 main work packages, and combine aspects of machine learning, app development, user-centered design, and implementation for clinical applications:

(1) Models and infrastructure for multimodal N-of-1 trials

Implement and try out different machine learning models and deep learning models. Either use our existing pilot data from imaging N-of-1 trials, or collect your own data. Pretrained models? Unsupervised learning? Transfer learning? Implement statistical tests to make inference on whether there was an effect of your health intervention on your health outcome. You can start with simple baseline models and can go as far as developing hypothesis tests for complex dependent longitudinal data.



• Investigate how such models can be integrated into the StudyU platform (where would they run, how implemented, where would data be stored ...?). Implement one approach (e.g., provide API) so that researchers can design and run such trials using StudyU.

(2) Visualization of results and communication to study participants

- When you perform multimodal N-of-1 trials, but also more generally N-of-1 trials, what are the best ways to summarize, visualize, and present them in the StudyU app back to the participant during and after the study?
- How do you interpret the findings from multimodal N-of-1 trials in the first place?
- Think about what is a good visualization and communication of the results to the study participants, and implement those in StudyU.

What you should bring with you

The project is open to students from IT Systems Engineering, Software Systems Engineering, Digital Health, Data Engineering and Cybersecurity. To carry out this project successfully, you will need expertise in at least one of the following areas to contribute to the team:

- 1. App development (front end, back end)
- 2. Programming skills (e.g. mobile app development, web development, Python/R)
- 3. Interest in learning about study designs and the evaluation of interventions for personalized medicine
- 4. Machine learning or statistics
- 5. Data visualization

References

- 1. Konigorski S, Wernicke S, Slosarek T, Zenner AM, Strelow N, Ruether FD, Henschel F, Manaswini M, Pottbäcker F, Edelman JA, Owoyele B, Danieletto M, Golden E, Zweig M, Nadkarni G, Böttinger E (2022). StudyU: a platform for designing and conducting innovative digital N-of-1 trials. *JMIR* 24(7):e35884.
- 2. Kravitz RL, Duan N (eds), and the DEcIDE Methods Center N-of-1 Guidance Panel (2014). *Design and implementation of N-of-1 trials: a user's guide*. AHRQ Publication No. 13(14)-EHC122-EF. Rockville, MD: Agency for Healthcare Research and Quality.
- 3. Nikles J, Mitchell G (eds) (2015). *The essential guide to N-of-1 trials in health*. Dordrecht: Springer.



Contact

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