Part I: Participant information

Introduction

These multiple N-of-1 trials will be conducted by the course participants of the course "Digital N-of-1 trials and their application" at the Hasso-Plattner-Institute for Digital Engineering (HPI). All course participants have jointly planned this study and have created this document jointly, revised it, and agreed to its final form – and all these participants will also participate in the trials by reading on consenting to the below information.

With these information and consent form, we invite you to participate in this study. Please read this information sheet carefully before taking part in the study.

Aim of the research

The primary aim of the study is to examine the feasibility of designing and running N-of-1 trials in a classroom setting using the digital StudyU platform. The secondary aim is to investigate the effects of specified interventions on study participants' sleep on the individual level.

Type of investigation

Participants perform an intervention selected from a list with possible non-invasive and non-clinical interventions that were self-designed and agreed upon in the course. Additionally, participants will be provided with the publicly available StudyU app in which they can assess the effects of their selected intervention on their sleep. In the StudyU app, participants will get self-designed notifications about their chosen intervention and questions where they can assess their quality of sleep.

Participant selection/ voluntary participation

We invite all people to be part of the multiple N-of-1 trials for whom the following criteria all apply: Being between 20 and 35 years old, being enrolled at the HPI as a master student and being participant of the course "Digital N-of-1 trials and their application", use of a compatible smartphone (iOS or Android) and proficient in English. People with a serious illness (e.g. cancer, infectious diseases, acute major metabolic, kidney, or any other serious condition, etc.), or a current mental illness, pregnant women, as well as individuals with a comorbidity that could potentially be destabilised with the inability or difficulty sleeping are excluded from participation. Further exclusion criteria for participating in the study are showing any allergies/intolerances/sensitivities to the proposed interventions, in particular being lactose intolerant, having allergies or intolerance to animal-based proteins, plant-based proteins, herbal tea,Participation in this study is voluntary and can be terminated at any time during the study. Dropping out of the study does not affect the grade in the course and cannot be traced back to you.

Procedures and protocols

With the invitation to the study, you receive this information sheet and the consent form so that you have time to read it in preparation for participation. At the beginning of the study, you will receive further explanations and instructions and can clarify any questions. This will take place in person. The introduction also includes instructions on how to install the required StudyU app and how to use it.

Process description

1. After agreeing to participate in the study and sign the consent, you download the StudyU app on your mobile phone and enroll in the study "Self-designed N-of-1 trials on sleep", which has been created in the StudyU Designer at https://designer.studyu.health before.
2. When you accept the terms and conditions in the StudyU app an anonymous user ID is created.
3. Then, you receive a list of possible interventions, sleep outcome measures and potential covariates of interest such as your stress level on the previous day in the app and decide which ones you want to perform in an N-of-1 trial.
4. During the N-of-1 trial you will be asked every morning if you have done the intervention before going to bed. Furthermore, you will be asked your chosen questions to assess the quality of your sleep. The data is stored every time you answer a questionnaire. The anonymous data is stored directly on your device and is sent to a secure virtual machine at Hasso-Plattner-Institute.
5. Over the course of the trial, either four or eight treatment phases will take place. You are free to choose the rhythm of the interventions. For example, one period with the chosen intervention, or one period with intervention, two without, etc. It is recommended to plan each period with two to seven days.
6. After completion of participation, your data will be loaded and evaluated. The results and anonymized data will be made publicly available in the StudyU platform.

If you have any questions or encounter (technical) problems, you can reach us at any time via the stated contact channels.

Duration

The duration of participation is one month. The time required to answer the questions each morning is about 5-10 minutes. Depending on the choice of interventions, the required time varies. The amount of time allocated for the different interventions is recorded next to each on the list.

Risks and side effects

In the following we describe potential risks and side effects of the interventions. It should be noted that it was ensured in the joint planning of the study with all participants, that the exclusion criteria described on the previous page do not apply to any study participant, and that any allergies/lactose-intolerance or conditions posing a potential risk as described below do not apply. Therefore, risks and side effects in the narrower sense do not exist, as no potentially harmful interventions are carried out. In all interventions, prescribed times and instructions should be adhered to and that the StudyU app provided should not be used in situations where full attention is required (e.g. while driving).

- Two diet interventions. There are only minimal burdens, risks, and damages to the subjects for this intervention. Possible short-term consequences of consuming protein powder include irritation of the gestational system, and possible long-term consequences include the risk of the formation of kidney stones. However, the short-term consequences have only been described for people with lactose-intolerance or allergies or other known conditions that can cause irritations, and the long-term risks have been described for any consumption of protein that exceeds the daily suggestions. The suggested dose in our study is far below the suggested daily dose of about 2g per kg of body weight.
- Drinking herbal tea 1h before bedtime vs. not drinking any herbal tea. There are only minimal burdens, risks, and damages to the subjects for this intervention. In particular, as only side effects of drinking herbal tea, irritations of the gestational tract or other very seldom reactions have been described in rare cases, for people with allergies or other conditions that cause a reaction to herbal tea at high doses. Participants are advised to watch out for boiling water.

- Effect of drinking cold milk vs. warm milk. There are only minimal burdens, risks, and damages to the subjects for this intervention, most notably for participants who are lactose-intolerant. Participants are advised to watch out for boiling milk.
- Silence vs. noise. There are no burdens, risks, and damages to the subjects for this intervention. Any media consumption will be at noise level that cannot yield any damage or discomfort.
- Open window for the time of sleep. There are only minimal burdens, risks, and damages to the subjects for this intervention in the form of the risk of catching a cold if the temperature while sleeping is too low and people are freezing while sleeping. A requirement is that the apartment is not on the ground floor of the building to ensure general safety. Also, if the outside temperature will drop below 10° Celsius in the night, the intervention cannot be performed, and study participants are suggested to ensure sufficiently high temperature to avoid any risk of freezing in the night.
- Blue light glasses vs. without glasses. There are no burdens, risks, and damages to the subjects for this intervention.

Confidentiality, data processing and data storage

The study with the corresponding questions is implemented in StudyU and accessed by the participants. StudyU is a platform consisting of StudyU designer and StudyU app. With the web application StudyU designer it is possible to plan, publish and conduct N-of-1 trials. The StudyU app is an application for smartphones in which you can take part in the related trial and assess the effects of the various interventions on your health. When you accept the terms and conditions an anonymous user ID is created. The data is stored every time you complete a task or answer a questionnaire. The anonymous data is stored on a secure virtual machine at Hasso Plattner Institute. The anonymized data will continue to be stored for further analysis and for the preparation of scientific publications, and will be published openly through the platform.

In addition, anonymized information about your gender, age and living environment (urban or rural) will be assessed before the study, and questions about the app usage experience after the study. These will be provided through google forms, independently of the app, so that this information cannot be linked to the StudyU data. All data will be assessed in anonymized so that GDPR does not apply.

Right of refusal/ withdrawal

You are not obliged to participate in this study if you do not wish to do so. You can also end your participation in the study at any time. It is your decision and all your rights will continue to be respected. Not participating in the study after its implementation or dropping out of the study will not affect your grade in the course “Digital N-of-1 trials and their application”.

Use of data and publication of data and results

The anonymised data will be used to investigate the feasibility of conducting N-of-1 trials with StudyU and the feasibility of conducting a study in the setting of a lecture. Secondly, anonymised data will be used to investigate a relationship between the chosen interventions and the quality of sleep. It is planned to publish the results in a scientific publication.

Contacts

- Principal investigator: Dr. Stefan Konigorski (HPI), 0331-55094873, stefan.konigorski@hpi.de
- Data Protection Officer: Bernhard Rabe (HPI), 0331-55090, datenschutz@hpi.de

Part II: Declaration of Consent

I have read the above information. I had the opportunity to ask questions about it and all the questions I asked were answered to my satisfaction. I voluntarily agree to participate in this study as a participant.

Name: _____

Signature: _____

Date: _____