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**Suggested citation referring to the original publication:**

Trials 23 (2022), Art. 1045

DOI: <https://doi.org/10.1186/s13063-022-06893-7>

ISSN: 1745-6215

**Journal article | Version of record**

Secondary publication archived on the Publication Server of the University of Potsdam:  
Zweitveröffentlichungen der Universität Potsdam : Reihe der Digital Engineering  
Fakultät 18

URN: <https://nbn-resolving.org/urn:nbn:de:kobv:517-opus4-589763>

DOI: <https://doi.org/10.25932/publishup-58976>

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METHODOLOGY

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# StudyMe: a new mobile app for user-centric N-of-1 trials

Alexander M. Zenner<sup>1,2</sup>, Erwin Böttinger<sup>1,2,3\*</sup> and Stefan Konigorski<sup>1,2,3\*</sup> 

## Abstract

N-of-1 trials are multi-crossover self-experiments that allow individuals to systematically evaluate the effect of interventions on their personal health goals. Although several tools for N-of-1 trials exist, there is a gap in supporting non-experts in conducting their own user-centric trials. In this study, we present StudyMe, an open-source mobile application that is freely available from <https://play.google.com/store/apps/details?id=health.studyu.me> and offers users flexibility and guidance in configuring every component of their trials. We also present research that informed the development of StudyMe, focusing on trial creation. Through an initial survey with 272 participants, we learned that individuals are interested in a variety of personal health aspects and have unique ideas on how to improve them. In an iterative, user-centered development process with intermediate user tests, we developed StudyMe that features an educational part to communicate N-of-1 trial concepts. A final empirical evaluation of StudyMe showed that all participants were able to create their own trials successfully using StudyMe and the app achieved a very good usability rating. Our findings suggest that StudyMe provides a significant step towards enabling individuals to apply a systematic science-oriented approach to personalize health-related interventions and behavior modifications in their everyday lives.

## Author summary

Information on how to improve personal health is widely available, but it can be difficult to know what works for oneself. One way to find out is by performing a scientific experiment called an N-of-1 trial, where a person tries out one or more things in a predefined schedule and collects data to see what helps him or her in reaching a health goal. In the first part of this study, we describe results from a survey including 272 participants, which revealed that individuals are interested in many different health aspects and things to try out. Afterwards, we developed our app StudyMe that we present here. StudyMe presents an app to guide users in creating and running their own fully personalized and customizable N-of-1 trials. An empirical evaluation with a focus on

trial creation showed that StudyMe has a very good usability and every participant successfully created a unique trial. The flexibility and guidance that StudyMe provides empower individuals to apply the scientific method of N-of-1 trials to their personal health in everyday life.

## Introduction

Self-experimentation is an intuitive approach whenever the best course of action to improve one's health is unknown [1, 2]. Yet, it is not available to everyone in a meaningful scientific and easy-to-use way. In clinical settings, N-of-1 trials have become the new gold standard for evaluating interventions on a personal level, when researchers or physicians design a systematic comparison of treatment options for individuals [3, 4]. In contrast to randomized controlled trials, which provide evidence of what likely works for the average person by evaluating treatments on a population level, N-of-1 trials provide a method to determine what works best for the individual

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directly. To do so, treatments are applied in a sequence of phases with cross-over.

In this study, we investigate how we can enable individuals without medical expertise to create their own N-of-1 trials. We aim to empower them with a new open-source mobile application, called StudyMe, that guides them in doing so. To give the users full control, we define the concept of *user-centric* N-of-1 trials, meaning trials in which each trial component is configurable by the user. We see four essential components that make up a trial: goal, interventions, measures, and schedule. The goal is what the user wants to achieve for his or her health, interventions are one or more behavioral modifications and/or treatments being evaluated, measures are the data collected to evaluate achievement of the goal, and the schedule concerns settings related to the trial's length and phases. We focus on two different designs for N-of-1 trials: evaluating a single intervention by switching between intervention and no-intervention phases (withdrawal design) and comparing two interventions (alternating-treatment design) [5]. We have a shared vision of a future in which individuals can and do conduct their own N-of-1 trials [1, 2], empowered by StudyMe, to explore ways to improve their health in a scientific and yet convenient way.

Several mobile applications exist that allow individuals to gain insights into their health. General self-tracking applications, such as Apple Health and Google Fit, can be used to gather data on various health aspects. More specific self-tracking applications are geared towards particular symptoms or diseases. Examples include apps such as SleepHealth [6] and mPower [7] that allow users to track factors and symptoms related to sleep and Parkinson's disease, respectively. However, none of these apps provide guidance on how to experimentally evaluate interventions [8]. Users are able to collect measures pertinent to their personal health goals in these apps and run their own N-of-1 trials. However, basic requirements to conduct a personal N-of-1 trial, data analysis, and interpretation are in general not supported.

More convenient is having an app that guides the user through an N-of-1 trial, by reminding them to follow an intervention or enter a measurement and then visualizing the results. The N1 app allows individuals to compare the effects of two supplements on their cognitive performance [9]. SleepCoacher evaluates sleep recommendations from clinicians through short experiments [10]. Trialist can compare different interventions and collect measures related to pain and treatment side-effects in trials set up together with a clinician [11]. TummyTrials, an app for irritable bowel syndrome-related N-of-1 trials, lets users choose from a list of dietary interventions and select measures and trial duration [12]. Besides these

apps with specific use cases, there are also N-of-1 trial platforms that can be used for different trials. QuantifyMe hosts trials created by researchers on a mobile app accessible by users to participate in various experiments with a fixed schedule [13]. StudyU, an N-of-1 trial platform that we developed in prior work [8], offers researchers more flexibility regarding the design of their trials, including participant eligibility, measurement collection, and scheduling. However, both these platforms are created to enable researchers, not individuals, to conduct trials and collect data.

In summary, the above-mentioned apps do not support users with the full flexibility and guidance to create and conduct their own user-centric trials in a single app. An advantage of N-of-1 trials is the focus on the individual, yet these tools don't allow users to tailor their trials to their needs and preferences. We believe this is a missed opportunity and aim to give individuals full control to create their own trials through the StudyMe app, without having to rely on access to clinicians and researchers. In the following, we present the StudyMe app and its features, followed by a description of the research we conducted to develop it. Finally, we present an empirical evaluation of StudyMe and a discussion of our methods and findings.

## The StudyMe app

### Overview

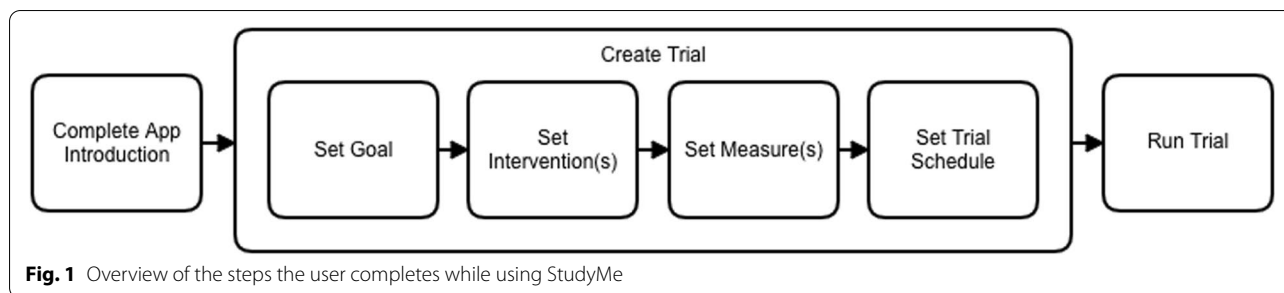
StudyMe was designed to enable users to create their own user-centric N-of-1 trials, and then run the created trial. The high-level steps a user completes are shown in Fig. 1 and illustrated in detail in Supplementary Video S1.

A selection of screenshots, covering the stages of the app, is shown in Fig. 2. They show a user's journey, from opening the app, to creating a trial, and running it. After finishing a trial, users can create a completely new trial or one based on their previous trial, allowing for sustained and versatile use of the app. Our focus in the development of the current version of StudyMe was on creating and running the trial. The trial results are displayed descriptively and as such, we did not set a main focus in this study on implementation of complex statistical methods and their communication to the user.

### Key features and design choices

#### Accessible language and asking questions

We reduced N-of-1 trial-related jargon in the StudyMe app, substituting technical terms with words we expect to be more commonly understood. A trial is referred to as "your experiment," the outcome as "your goal," interventions as "what/thing you want to try out," and measures as "data you want to collect." Additionally, during the trial creation, the app asks users for what is expected from



**Fig. 1** Overview of the steps the user completes while using StudyMe

**(a) App Introduction**: A welcome screen with the text: "Welcome to StudyMe. Have you ever tried something to improve your health or wellbeing but weren't sure if it worked? Or maybe you tried multiple things and didn't know which worked better?"

**(b) Trial Creation**: "Experiment Details" screen. "Your goal" is "Sleep better". "What you want to try out" is "Sleep early Daily at 22:00". "Compare to something else?" is "No". "Data collected to assess if what you are trying is helping you achieve your goal" includes "Mood Daily at 08:00, 14:00, 20:00" and "Hours slept Daily at 08:00". A green button says "Set Up Experiment".

**(c) Home Screen**: Shows trial progress for two phases: "A Without 'Sleep early'" and "B Sleep early". "Today" tasks include: 08:00 Log your Mood, 08:00 Log your Hours slept, 14:00 Log your Mood, 20:00 Log your Mood, and 22:00 Start to get ready for bed.

**(d) History Screen**: Shows "Average per Day" for "Mood" and "Hours slept" over 28 days. Mood is shown as a bar chart with smiley faces. Hours slept is shown as a bar chart.

**Fig. 2** Selection of screenshots from the StudyMe app. **a** Users are first introduced to the app’s purpose and the idea of using an experimental methodology. **b** Then users create their trials step-by-step, by specifying the different N-of-1 trial components (goal, interventions, measures, schedule). **c** Upon starting the trial, the app switches into the “run trial” stage, where trial progress and daily tasks are shown to the users on the Home screen. **d** While running the trial, users can view their results descriptively on the History screen and compare the data collected during each of the trial phases. The users can select different ways for the values to be aggregated and have the graphs show the values averaged by, e.g., day or phase

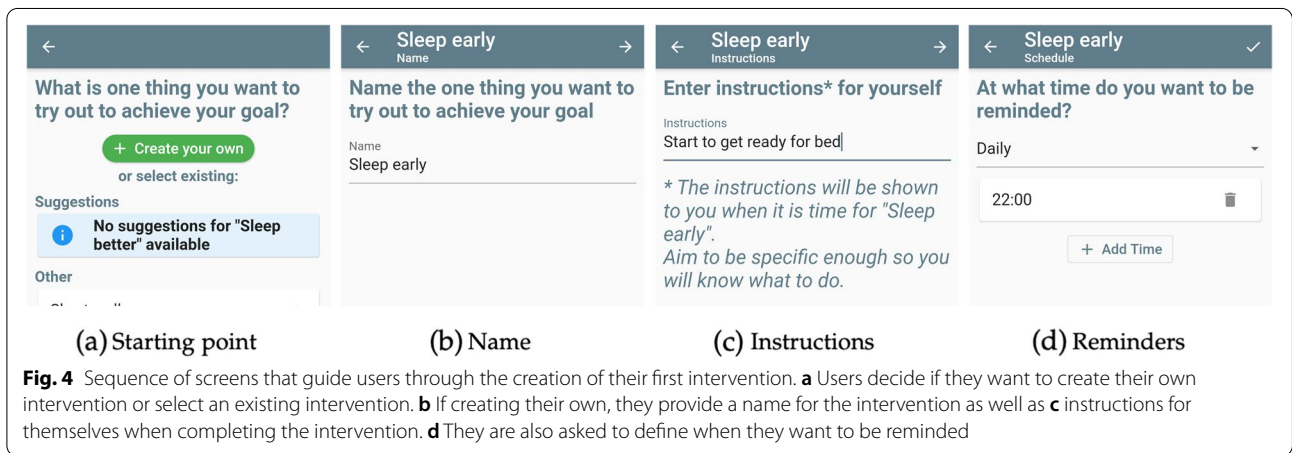
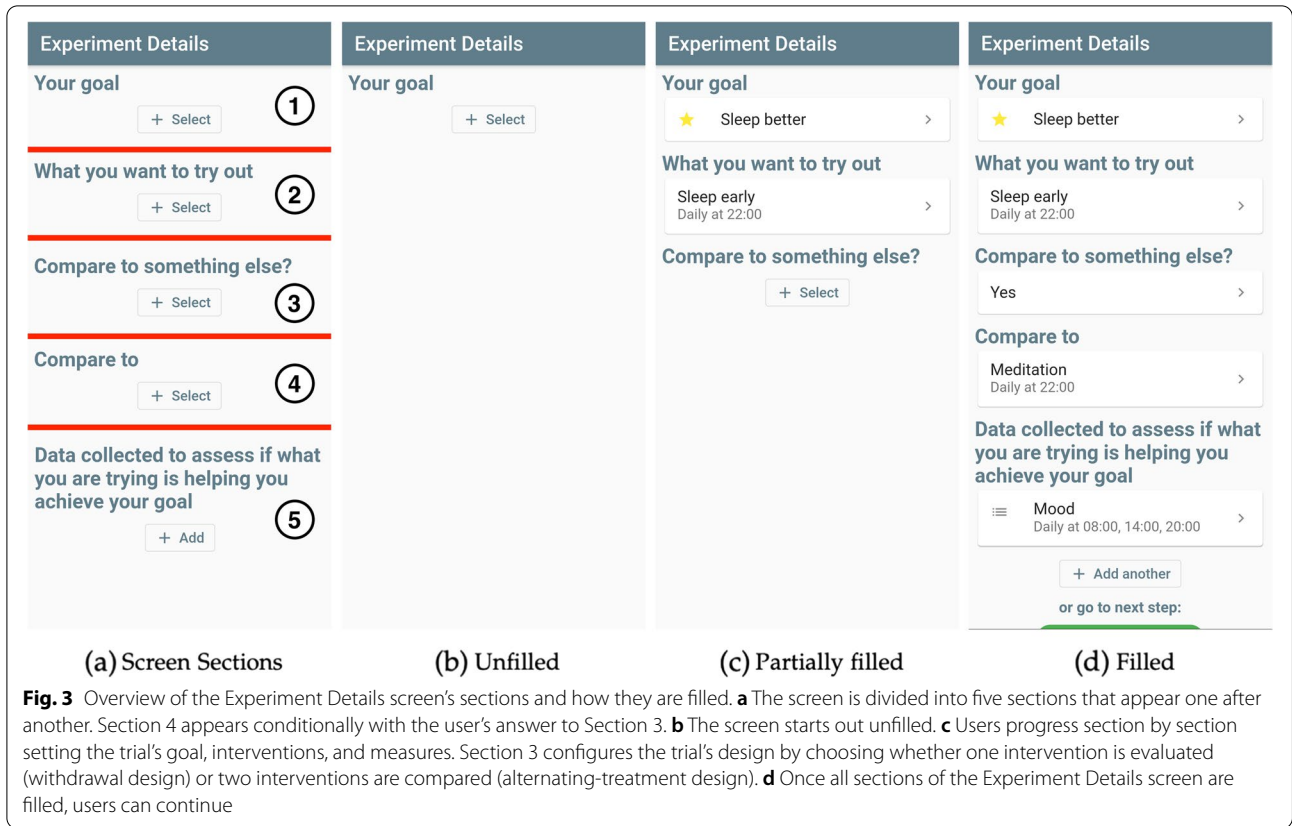
them. For example, when setting an intervention, the app asks: “What is one thing you want to try out to achieve your goal?”

**Step-by-step creation**

The centerpiece of trial creation in the StudyMe app is a questionnaire-like screen, called the Experiment Details screen, that guides users step by step through multiple sections, as shown in Fig. 3. In Fig. 4, we show an example for a sequence of screens when filling a section, in this case, Section 2 regarding interventions (“What you want to try out”). Users are taken to a similar sequence of screens for creating their goal as well as their measures.

**Different trial designs**

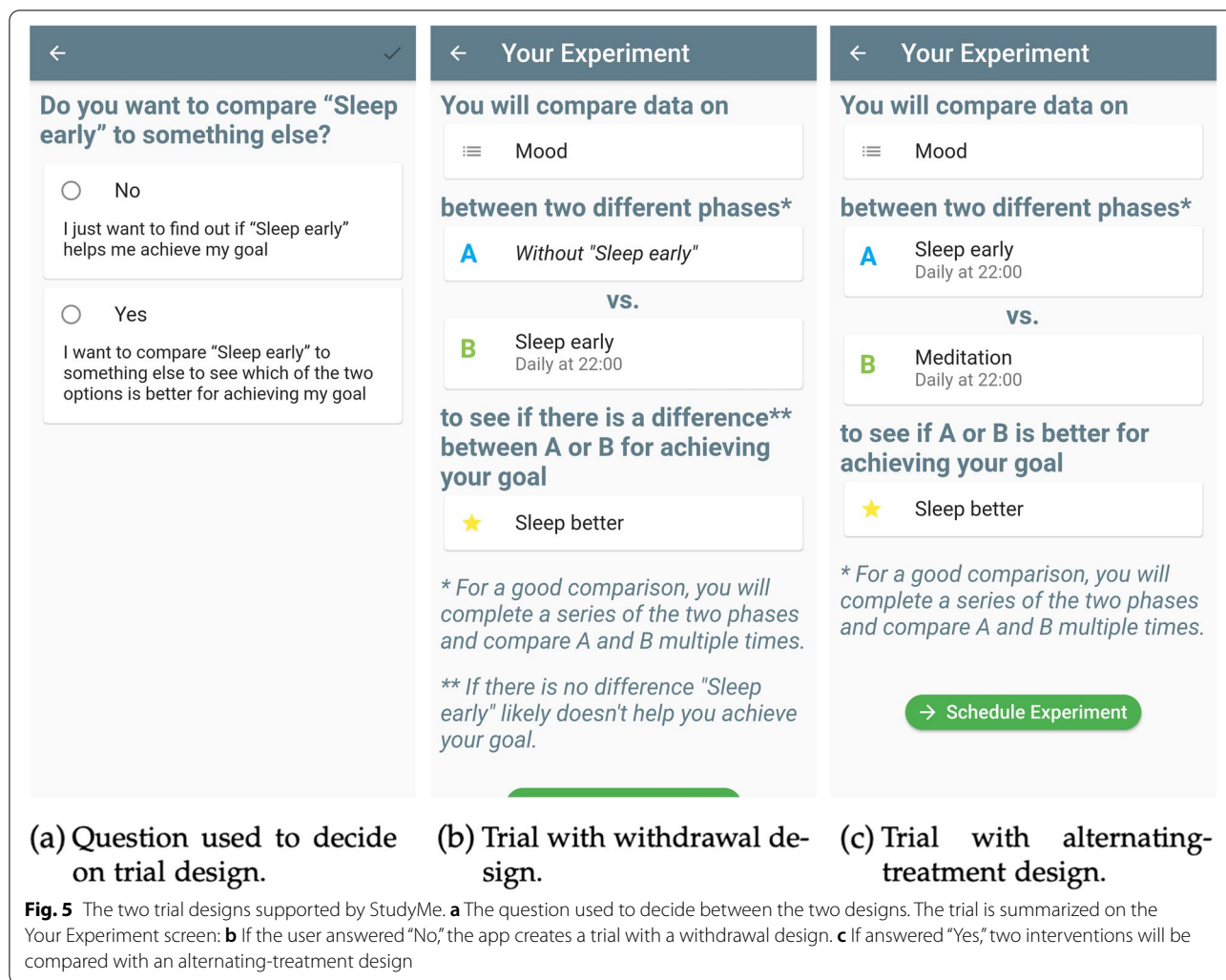
During trial creation, users are asked if they would like to compare the first intervention they entered to another one (see Fig. 3a). This determines which of the two trial designs will be used. In the withdrawal design, the intervention is evaluated by completing intervention and no-intervention phases. In the alternating-treatment design, a second intervention is entered and the two interventions are compared by completing phases in which either the first or second intervention is applied. In Fig. 5, we show this deciding question and how the two possible trial designs are explained to the user on the Your Experiment screen that follows the Experiment Details screen.



**Flexible scheduling**

The last step of creating a trial in StudyMe is defining its schedule. Once the users have filled and reviewed all the other settings, as described in the previous two sections, the app sets a default schedule that the users can edit as shown in Fig. 6. The default schedule is set to the phase sequence *ABAB*, with each phase lasting seven days, and the user can flexibly change this. We've followed

recommendations in the literature [14, 15] to maintain a balanced phase sequence, as an unbalanced sequence such as *AABB* can yield challenges in the statistical analysis when temporal effects are present. We do so by pairing phases (*AB* or *BA*) and setting the sequence so that the individual either alternates between phases (*ABAB*) or so that the phases are counterbalanced (*ABBA*).



**Flexible reminder settings**

In StudyMe, users set reminders for their interventions and measures. These reminders serve the purpose of assisting users in following interventions and taking measures consistently at the same time throughout their trials. As illustrated in Fig. 7, these reminders are set individually and independently for each intervention or measure component, providing high flexibility.

**Component Libraries**

Besides being able to create their own components, users can also select preconfigured components from goal, intervention, and measure libraries. Screenshots of these libraries are shown in Fig. 8. Users can gain orientation and inspiration for their own components by looking at the preconfigured ones. Additionally, preconfigured components are quick and easy to add to a trial. They can

be treated as templates, as users can further edit them to their liking.

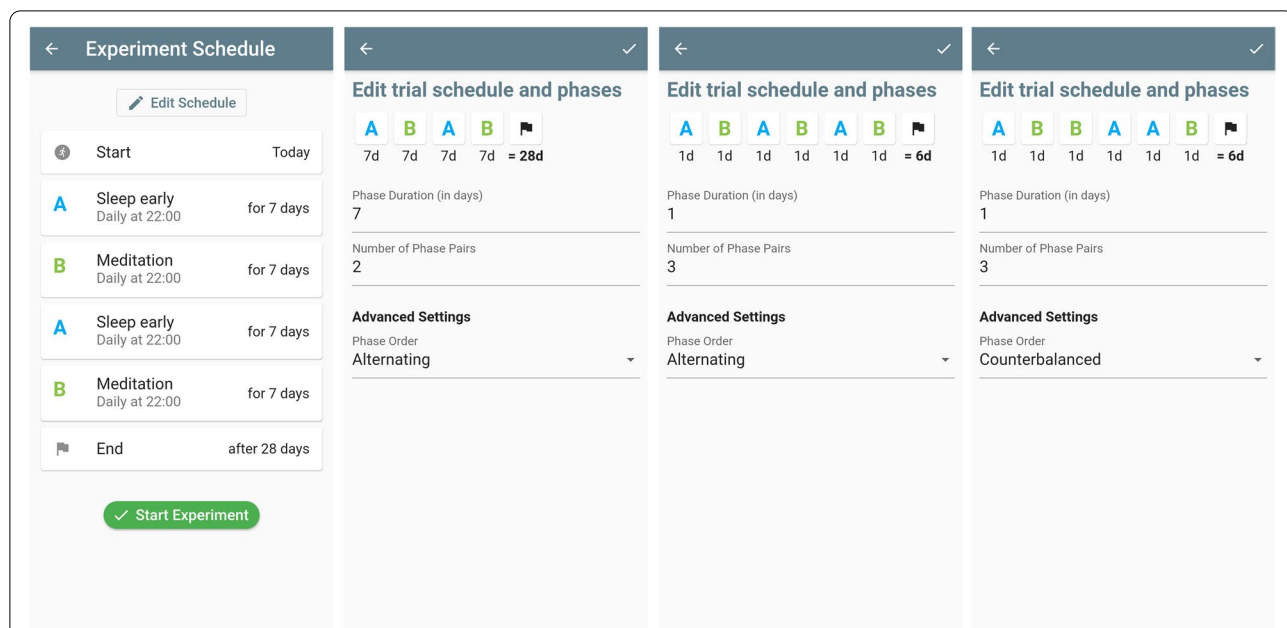
Within the libraries, preconfigured interventions are linked to preconfigured goals, allowing the app to provide specific suggestions together with the other more general examples. The ones currently linked in the app are shown in Table 1.

**Multiple measure input types**

Part of setting up a new measure in StudyMe is to define how the measurements will be inputted into the app. StudyMe provides three input types to offer variety on how measurements can be entered, as shown in Fig. 9.

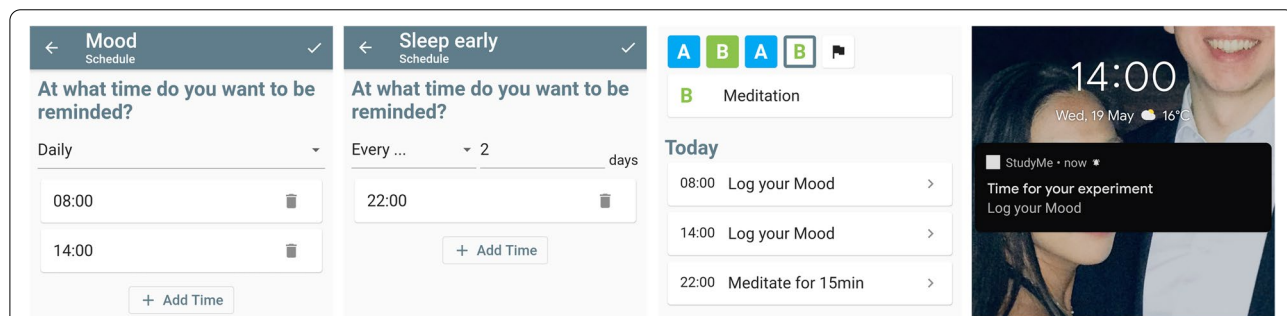
**Implementation and data privacy**

StudyMe was built with Flutter (<https://flutter.dev/>), an open-source user interface toolkit written in the Dart programming language. Both Flutter and Dart are



(a) Overview of the schedule (b) Default schedule settings (c) More, but shorter, phases (d) Different phase order

**Fig. 6** Different trial schedules in StudyMe. **a** An overview of the trial schedule on the Experiment Schedule screen, showing the order and length of the phases as well as the total duration of the trial. **b** Selecting “Edit Schedule” allows the user to change the phase duration and number of phase pairs and choose between two options for determining the phase order. The changes made are reflected dynamically in the minimized overview of the trial’s schedule at the top of the screen. **c** An example for a trial schedule where the phase duration has been reduced to one day and the number of phase pairs increased to three. **d** A schedule where additionally the phase order setting was changed from alternating to counterbalanced



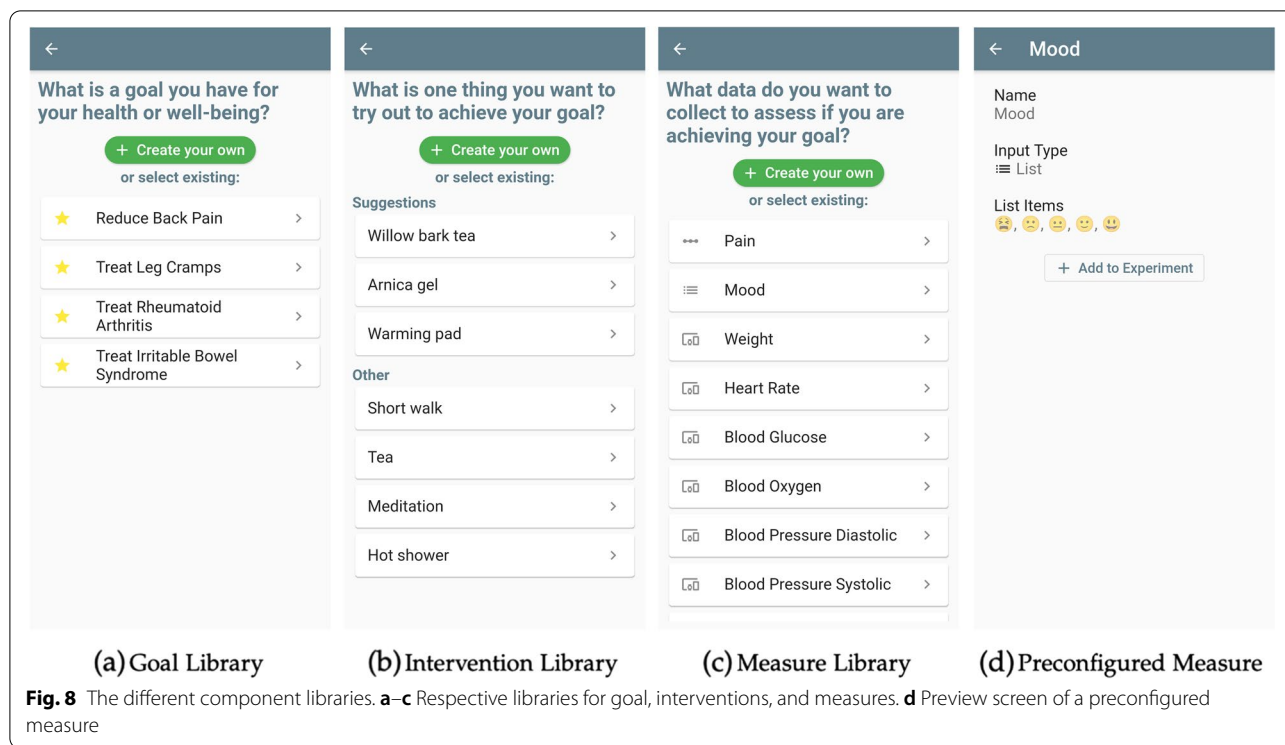
(a) Measure Reminder (b) Intervention Reminder (c) Generated Tasks (d) Notification

**Fig. 7** Example for the flexible setting of reminders, their generated tasks, and notifications. **a** Users can add multiple times in a day and choose if they want to get reminders daily or **b** every x days. **c** Based on the reminders defined in the trial creation stage, StudyMe generates the tasks to be completed each day and shows them on the home screen. **d** Additionally, StudyMe sends notifications to remind users to complete each task at the defined times

developed by Google and can be used to build cross-platform applications, meaning that a single codebase can be compiled to applications for different operating systems. In our case, we focused on developing StudyMe for Android and iOS. The StudyMe Health app is available on the Google Play Store at <https://play.google.com/store/apps/details?id=health.studyu>.

me and can be downloaded for free. No registration is required. The trials and all the other data in StudyMe are stored on the user’s device only, to alleviate potential privacy or data security concerns. For an illustration of the study model underlying each created trial, see Supplementary Fig. S1. The source code for the





**Table 1** Linked preconfigured goals and interventions, which are based on example studies developed during prior work on the StudyU platform [8]

Goal	Suggested Interventions
Reduce back pain	Willow bark tea; arnica gel; warming pad
Treat leg cramps	Magnesium; vitamin B12; massage
Treat rheumatoid arthritis	Omega-3 supplement; olive oil massage; cold patch
Treat irritable bowel syndrome	Gluten-free diet; fructose-free diet; low-fiber diet

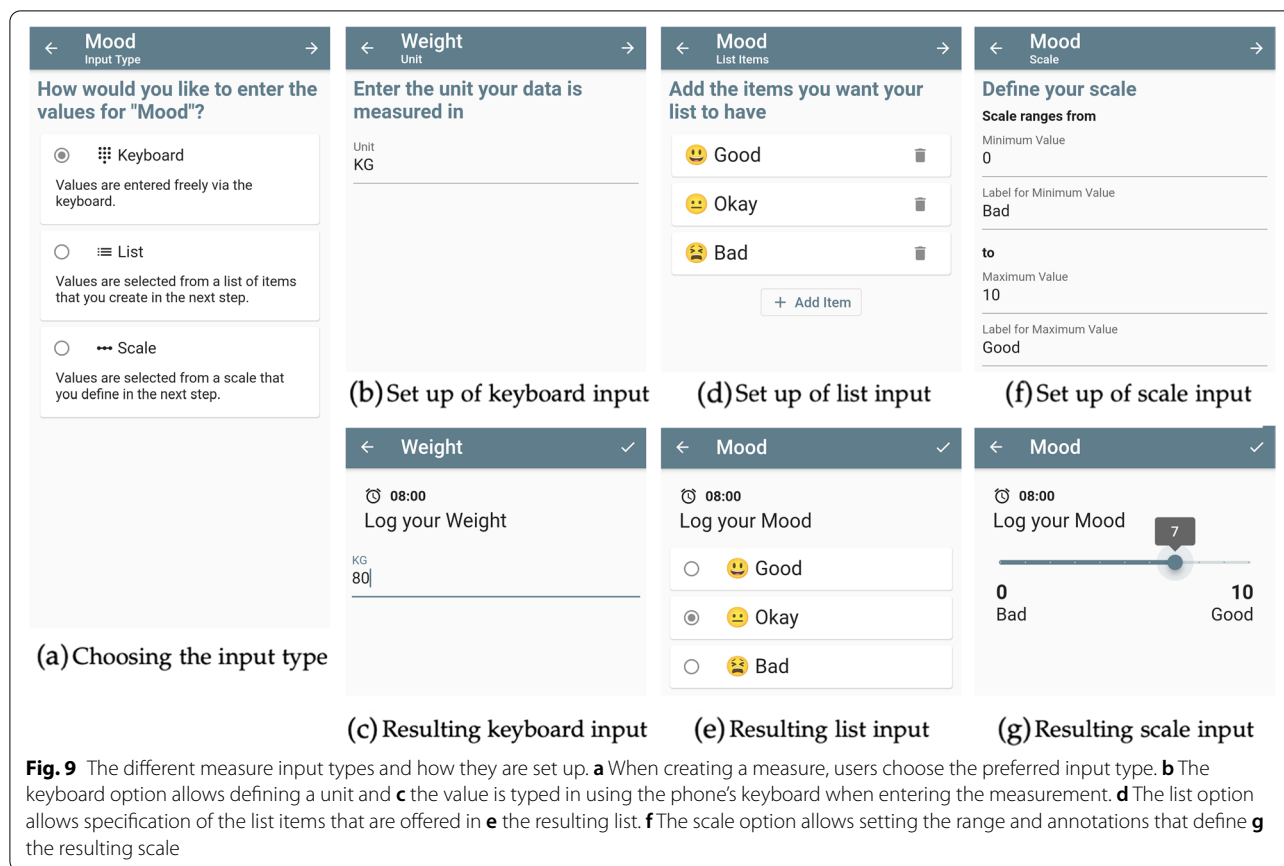
app is available on Github at <https://github.com/alexanderzenner/studyme>.

**Research and development of StudyMe**

We took a user-centered approach of developing StudyMe, with usability and trial creation as the main focus. StudyMe should help create useful N-of-1 trials for its users and also be straightforward and efficient to understand and interact with. To ensure that individuals that are not familiar with N-of-1 trials can successfully use the app, our process included multiple steps involving research, design, development, and user testing of the application, as shown in Supplementary Fig. S2. The iterations resulted in an adaptation of the language and design to improve the way N-of-1 trial concepts are introduced.

**Survey methods**

In the first stage of the development of StudyMe, we performed an empirical survey in order to get information about which health topics users are interested in and to better understand what trials individuals would want to create as well as what kind of guidance they might need. The survey contained demographic questions on age, sex, and country of residence, and four main questions are shown in Table 2. The survey was set up on Google Forms and distributed worldwide over various channels, including institutional email lists, LinkedIn posts, and printed handouts. We aimed for an international sample of survey participants representative of individuals’ personal health topics. The qualitative responses were manually coded, assigned to themes in an iterative process based on the concept of an inductive thematic analysis [16], and descriptive statistics were computed.



Participants received full information about the aims of the study before starting the survey and gave informed consent in the saving, analysis, processing, as well as the publication of their data. All data was saved anonymously without collecting any user-identifying information, the participants could stop the study at any point, and there was no direct interaction between the study participants and researchers. As such, we did not obtain formal approval from the ethics committee as this type of study is exempt from human subjects' research.

**Survey results**

Two hundred seventy-two participants of the survey gave valid responses. One hundred forty-six participants were








female, 125 male, and 1 person identified with 'other'. The mean age was 32 years and the participants were between 16 and 84 years old. We received responses from 22 countries with almost 60% of responses from Germany. Below we present the summarized themes of health aspects, interventions, and measures derived from the participants' responses (see Tables 3, 4, and 5). Responses that were not codeable due to lack of clarity or misinterpretation of the question asked were excluded, which applied to 8 answers to questions 1 and 2, 18 answers to question 3, and 42 answers to question 4.

One observation in the more detailed analysis of the answers was that some of the larger intervention and measure themes could be further divided into specific

**Table 2** The four main questions of the survey

No.	Question (additional instructions)	Aims to identify
1	Name the one aspect that you want to improve the most about your health or well-being	Health Aspects
2	Why do you want to improve it?	
3	In your case, what can you try to improve? (List one or multiple things. Please be as detailed as possible.)	Interventions
4	How would you assess if this improves the aspect you named? (Please be as detailed as possible.)	Measures

**Table 3** Absolute (# participants) and relative frequencies (% participants) of responses allocated to health aspect themes derived from responses for questions 1 and 2. “Lifestyle” includes mentions related to fitness, exercise, weight, diet, productivity, work, stress, and appearance. “Physical Symptom/Concern” includes mentions related to symptoms, body parts, and diseases. “Mental Health” includes depression, anxiety, different emotions and feelings, the mind, and cognitive abilities. Some individuals reported wanting to improve their overall health and some wanted to maintain it. The themes are not disjoint and some responses were assigned to multiple themes

Health Aspect Themes	# Participants	% Participants
Lifestyle	175	64,34 
Physical Symptom / Concern	95	34,93 
Mental Health	69	25,37 
Overall Health / Well-Being	65	23,90 
Maintain Health / Prevent Disease	43	15,81 
None	1	0,37 
Excluded	8	2,94 

sub-themes, while others were unspecific. For example, the intervention theme ‘Exercise’ contained 114 unspecific mentions such as “do more sports.” In comparison, only 55 participants specified the exercise activity and mentioned, e.g., going for a run or stretching. Another observation was that even if participants wanted to improve the same health aspect, they had different ideas which interventions to try or which measures to use. For example, several individuals wanted to improve their weight, but their responses how they would measure improvement varied, such as “if I lose weight,” “more confident when going to the beach,” “visually, looking at the mirror,” or “fit into my clothes better.” Also, different measures were proposed including Likert scales, counting something, or answering binary questions. We also counted how many responses mentioned frequencies, for both interventions and measures, such as “check in 3–4 times per day on computer” to measure one’s energy levels. Twenty-seven intervention responses (9.93%) and 31 measure responses (11.40%) included such frequencies.

**Implications for N-of-1 trial apps**
















With few exceptions, all participants identified a health aspect they wanted to improve as well as one or more interventions they could try out, highlighting the potential relevance of an app for N-of-1 trials. Based on our analysis, individuals want to improve a range of lifestyle-related, physical, and mental health topics. We also identified different themes for interventions and measures.

Furthermore, even if participants had stated the same health aspect, they wanted to try out or measure different things. To allow for this variety, StudyMe has to provide flexibility regarding the set-up of interventions and measures. On the other hand, several of the interventions and measures produced by the participants were unspecific. Only a few participants mentioned how often they would perform their intervention or take their measurement. StudyMe generates tasks based on what interventions and measures were set. Locke and Latham’s goal setting theory suggests that having more specific rather than unspecific task goals leads to better performance [17]. Considering this, we focused on providing guidance in StudyMe for creating specific interventions and measures and assisting users in setting reminders for when they want to conduct their interventions and measurements. A possible way to provide guidance is by using examples. Although we received a wide range of responses for each of the questions, certain interventions, such as those related to exercises and diets, and measures, such as those related to subjective feelings, were identified to be the most popular. Examples for those interventions and measures were included in StudyMe.

**Empirical evaluation of StudyMe**

The final version of StudyMe was evaluated empirically to (i) see how successful participants were in creating an N-of-1 trial by themselves, (ii) measure the usability of the app, and (iii) obtain further feedback on StudyMe.

**Table 4** Absolute and relative frequencies of responses allocated to intervention themes derived from responses for question 3. “Behavior Other” contains mentions related to activities that were not assigned to other themes, for example, improving habits, setting goals, turning off devices, reading, and journaling. “Thought Other” regards thought-related changes, such as reflecting, thinking happy things, and focusing. “Social” includes mentions of talking to or meeting friends or family. “Equipment” includes mentions of objects like “use of a sitting ball” and changes to work setups. The themes are not disjoint and some responses were assigned to multiple themes

Intervention Themes	# Participants	% Participants
Exercise	153	56,25 
Diet	93	34,19 
Behavior Other	30	11,03 
Meditation	29	10,66 
Sleep	26	9,56 
Thought Other	26	9,56 
Time/Work Management	24	8,82 
Pharmaceutics	17	6,25 
Professional Help	16	5,88 
Social	16	5,88 
Supplements	11	4,04 
Equipment	9	3,31 
Other	24	8,82 
None	3	1,10 
Excluded	18	6,62 

**Methods**

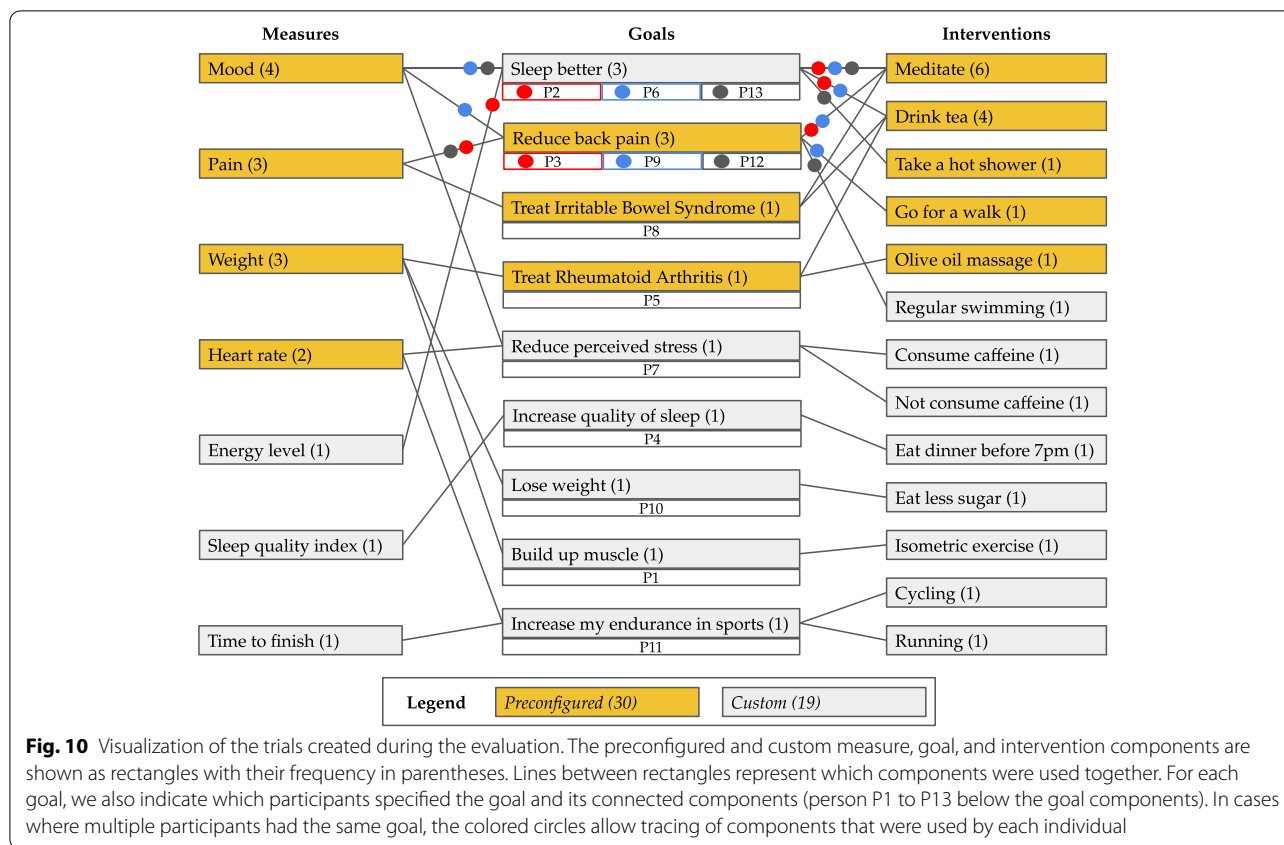
For the evaluation, we set up a survey on Google Forms with a link for participants to download the app onto their Android device, create a trial, and then answer a set of questions. Participants also reported their created trials, by copying a JavaScript Object Notation (JSON) string from the app and pasting it into the survey, allowing us to analyze the settings they selected. To determine the usability, we used the validated and popular System Usability Scale (SUS) [18] and asked open-ended questions about the app. Also, a few questions were asked

regarding the participants’ demographics. The survey was distributed through our professional network.

Participants received full information about the aims of the study before starting the survey and gave informed consent in the saving, analysis, processing, as well as the publication of their data. All data was saved anonymously without collecting any user-identifying information, the participants could stop the study at any point, and there was no direct interaction between the study participants and researchers. As such, we did not obtain formal approval from the ethics committee as this type of study is exempt from human subjects’ research.

**Table 5** Absolute and relative frequencies of responses allocated to measure themes derived from responses for question 4. “Track Consumption” includes counting consumption of certain types of meals, frequency of smoking, and tracking calories. Several codes did not fit into one of the other themes and were assigned to “Other,” including quality of relationships, posture, and general well-being. The themes are not disjoint and some responses were assigned to multiple themes

Measure Themes	# Participants	% Participants
Feeling	89	32,72
Physical Performance	49	18,01
Body Composition	42	15,44
Symptoms	26	9,56
Physiological	20	7,35
Productivity	16	5,88
Appearance	12	4,41
Sleep	10	3,68
Stress	9	3,31
Occurence of Sickness	7	2,57
Track Consumption	6	2,21
Other	44	16,18
None	9	3,31
Excluded	42	15,44



**Fig. 10** Visualization of the trials created during the evaluation. The preconfigured and custom measure, goal, and intervention components are shown as rectangles with their frequency in parentheses. Lines between rectangles represent which components were used together. For each goal, we also indicate which participants specified the goal and its connected components (person P1 to P13 below the goal components). In cases where multiple participants had the same goal, the colored circles allow tracing of components that were used by each individual

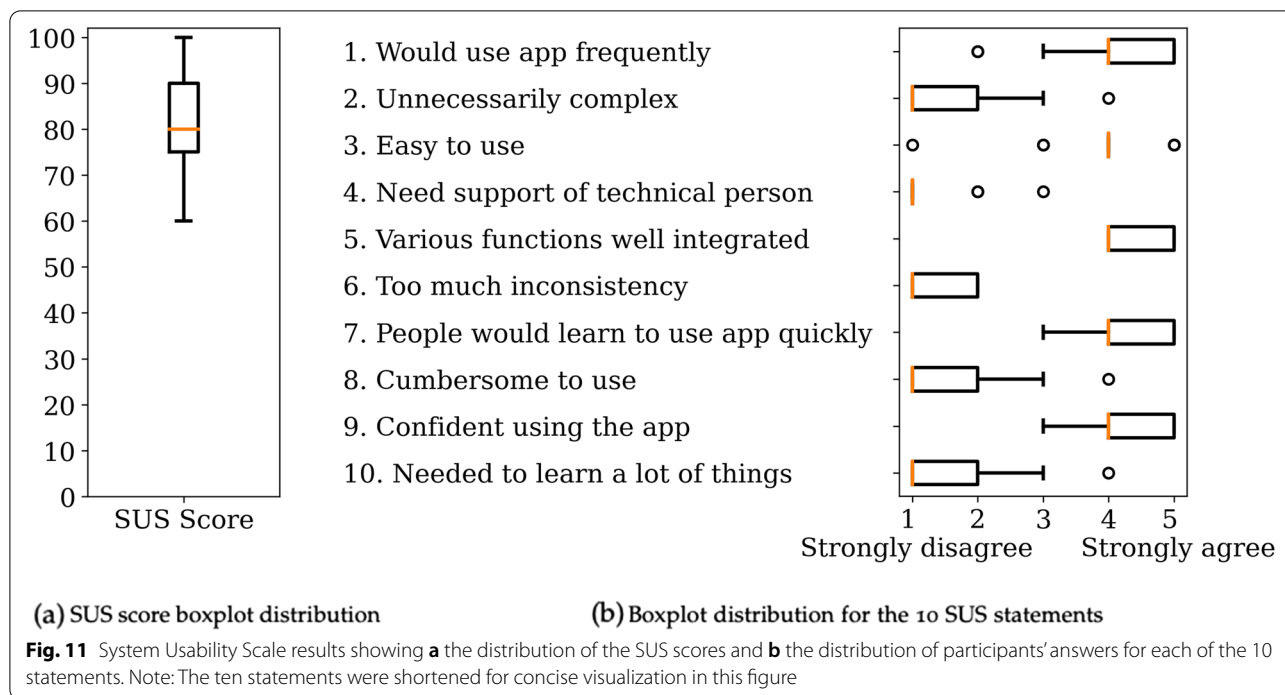
**Results**

Thirteen participants completed all parts of the evaluation; 1 participant was unable to install the app on her own device and was excluded from the evaluation. The participants had varying knowledge of how medical trials work, were generally interested in personal health topics, and had experience with smartphones and apps. They were aged between 21 and 57 years, nine were men and four were women. Two responses came from Canada and the other 11 responses from Germany. Figure 10 visualizes all the goal, intervention, and measure components that were created or used by the participants as well as how they were combined in each of the different trials. Four participants created trials that only consisted of preconfigured components chosen from the respective libraries and did not edit the default schedule that StudyMe suggests. None of the trials were completely customized, meaning everyone chose at least one of the preconfigured components and/or did not edit the default schedule. All the created trials were different from each other. Even if participants chose the same pre-configured goal, they still chose different interventions or measures. In all custom-specified trials, the interventions were clearly described, and the reminder features were used and correctly applied.

Figure 11 shows the SUS results. The app received a mean SUS score of 82, with 60 as the lowest and 100 as the highest individual SUS score. Overall, the participants mostly agreed with the positive statements and disagreed with the negative statements regarding StudyMe’s usability. For more information regarding the created trials, and regarding qualitative feedback on the usability of StudyMe, see Supplementary Text S1.

**Discussion**

In this study, we present StudyMe, a new mobile app for user-centric N-of-1 trials. StudyMe provides users with all the features to create a trial, from choosing pre-configured components or creating them freely, to defining reminders and customizing a trial’s schedule. The development of StudyMe was based on an empirical survey and multiple iterations of user testing, as well as a final evaluation. Throughout development, we focused on the app’s usability, as well as the flexibility and guidance it offers for creating N-of-1 trials. The empirical evaluation yielded a SUS score of 82, which is in the 90–95 percentile range and grants the StudyMe app an A grade [19]. The very good usability is further underlined by the qualitative feedback we received and the fact that all participants in the evaluation were



able to create their own trials, ranging from improving sleep, to building up muscles, to increasing endurance. As such, StudyMe provides a tool that empowers users to investigate their health. This is an exciting topic of research and during the time of publishing the present manuscript, one other study has been published with further interesting insights into user-based creation of N-of-1 trials [20].

One key aspect of StudyMe and user-centric apps in general is the set-up of the study design of the N-of-1 trial. In tests with a preliminary version of StudyMe, users struggled to specify an intervention schedule on their own. As a result, we restructured the app and included the default schedule that can be edited optionally. In the evaluation of the final version, only two users changed this default schedule. One person increased the length of each phase to 28 days, which is reasonable for evaluating the effects of regular swimming on his back pain, as they are likely to take time to become noticeable. The other person reduced the number of phase pairs to one (phase sequence AB), which was not an optimal design for his trial. In future iterations, we plan to provide scheduling suggestions based on automated statistical power calculations using the context of the other trial components.

Other important aspects of any app implementing N-of-1 trials are the suitability of the N-of-1 trial design for the respective study question, the lack of blinding and randomization in StudyMe, as well as potential ethical concerns. Regarding the applicability of StudyMe,

the most popular interventions participants mentioned in our survey were exercise and diet-related, which are well-suited for an N-of-1 trial study design [21–23]. We opted against limitations on which interventions can be specified in StudyMe (except for misuse and illegal or unethical studies, which are prohibited by the terms of use), as we aimed to find out what users are interested in. Blinding and randomization are important concepts for reducing the risk of bias in the statistical analysis of trial results [4, 14, 24]. We decided to not include any blinding or randomization functionalities in the current version of StudyMe, as they are challenging to execute in self-defined and self-administered trials, especially if interventions other than drugs are evaluated [25]. This is also true for exercises that were frequently mentioned in our survey and that usually requires conscious execution. Also, from an individual perspective, it might be less relevant to ensure whether an intervention actually has a causal effect or if it is due to a belief that it does, as long as there seemingly is an improvement. Regarding ethical aspects, we believe anything that involves individuals' health should be treated with caution, and StudyMe is purposely designed to help individuals in conducting experiments on themselves. For that reason, we only included preconfigured interventions that we expect to be safe, for example, going for a walk. Also, it should be noted that individuals can and do conduct self-experiments with or without being guided by a dedicated mobile application [1]. Ultimately, we do not see our app

as an alternative to professional health care, but instead envision that individuals use StudyMe after discussing the safety of their trials with their doctors or ideally create the trials together with them.

The reported empirical survey that served as a starting point for creating StudyMe as well as the final empirical evaluation carry some limitations. The sample of our survey on individuals' personal health topics was skewed towards a younger and predominantly German population. Due to the fact that a large part of participants were affiliated with universities, it can also be assumed that we reached a fairly tech-savvy and educated group of individuals. The final empirical evaluation was performed by 13 participants, which are likely not representative of a larger population. As such, StudyMe requires further evaluation with users of different backgrounds to ensure its broad applicability.

Our focus in this study was on creating and running trials using StudyMe. One important extension for future studies is to elaborate on the design of the to-be-created trial. Choosing an appropriate study design including the number of daily observations, study length, and structure of the trial is not trivial. We plan to develop automated and semi-automated recommendation systems beyond the traditional sample-size-calculation which requires an expert-in-the-loop for proposing optimal trial designs. Communicating these design suggestions to the user will require further user-centric developments. Next, we plan to implement analytical statistical methods for the automated analysis of the self-designed trials, including *t*-tests and Bayesian linear mixed models. If multiple outcomes are investigated in frequentist hypothesis tests, corrections for multiple testing have to be considered. Communicating such results to the user, including effect sizes, results from hypothesis tests or interpretations of the posterior distribution of the treatment effect, necessitates some adaptation and we are planning to employ a combination of explanations, step-by-step guidance, and sensible defaults. Based on these extensions, we next plan to apply StudyMe in long-term studies following individuals running their trials. Furthermore, we envision that the component libraries can be extended to include more preconfigured goals, interventions, and measures. To achieve this, we plan to integrate the StudyMe app with the StudyU platform [8] so that the vetted trials and components created by researchers on StudyU can be offered as inspiration to the users on StudyMe. Beyond that, including features that allow users to share their trials and components with each other would allow individuals to create and run their trials with their friends, family members, and a larger community. Part of this could be adding gaming aspects to

StudyMe's design, as gamification in mHealth applications has been shown to have a positive effect on individuals' behaviors, especially those involving physical activity [26]. We are looking forward to seeing the use of StudyMe in enabling individuals to reach their personal health goals, by testing interventions in a systematic way and contributing to a citizen-empowered transformation of healthcare.

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-022-06893-7>.

**Additional file 1: Supplementary Text S1.** Details on the empirical evaluation of StudyMe. **Supplementary Figure S1.** UML class diagram representing the data model of the Trial class and the classes it is composed of in StudyMe. The rectangles in the diagram represent classes and their properties. A line with a white triangle represents inheritance between classes, meaning the class below inherits the properties of the class above and that its objects are used in place of the upper class. A line with a black diamond at the end represents that the objects of the class on the end with a diamond are composed of objects of the class on the other end. Numbers on the lines, the multiplicities, represent how many objects are involved in the composition. One-to-one multiplicities are omitted from the diagram. **Supplementary Figure S2.** Overview of the steps of the iterative development process of StudyMe.

**Additional file 2: Supplementary Video S1.** Screen capture illustrating all steps in the StudyMe Health app in onboarding, generating, and running a trial.

## Acknowledgements

We thank all participants of the survey, intermediate tests, and app evaluation, as well as Stella Leowinata and Babajide Owoyele for their critical feedback and discussion of the app design and development.

## Authors' contributions

AZ and SK conceptualized the study with critical input from EB. AZ developed and implemented the StudyMe tool under supervision of SK and EB. AZ drafted the manuscript. All authors read, provided critical input, and approved the final manuscript.

## Funding

Open Access funding enabled and organized by Projekt DEAL. Funded by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) – Projektnummer 491466077.

## Availability of data and materials

All data underlying the empirical survey and empirical evaluation are publicly available in an anonymized format at <https://github.com/HIAlab/study-me-paper-data/>.

## Declarations

### Ethics approval and consent to participate

See the methods description in the manuscript for details.

### Consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

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Received: 10 January 2022 Accepted: 3 November 2022

Published online: 26 December 2022

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