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A mobile intervention to promote correct hand hygiene at key times to prevent COVID-19 in the Swiss adult general population: Study protocol of a multiphase optimization strategy

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Abstract

Introduction: Behavior change is key to public health measures that have been issued in many countries worldwide to contain COVID-19. Public health measures will only take preventive effect if people adhere to them. Interventions based on health psychology approaches may promote adherence to public health measures. However, evidence from randomized controlled behavior change trials during an ongoing pandemic are scarce. Based on the example of hand washing with soap, we aim to optimize and test a digital, theory- and evidence-based behavior change intervention to prevent COVID-19.

Methods and analysis: This protocol describes the Multiphase Optimization Strategy (MOST) for the preparation, optimization and evaluation of the app-based theory- and evidence-based intervention *soapp.* The app aims to promote correct hand hygiene at key times in the adult general population. The study will be conducted in German-speaking Switzerland. In the preparation phase, relevant behavioral determinants of hand hygiene during a pandemic were identified based on health behavior theories and formative research with focus groups (*N*=8). In the optimization phase, the most effective, and acceptable combination and sequence of three intervention modules will be identified in a parallel randomized trial (*N*=387) using ANOVA and regression analysis. Additionally, thematic analysis of qualitative interview data (*N*=15) will be used to gain insights on feasibility, usability and satisfaction of the intervention. In the evaluation phase, the optimized intervention will be tested against a control group (=treatment as usual) in a randomized controlled trial (*N*=205), analyzing pre-post differences and 6-month follow-up effects using ANOVA and regression analysis.

Ethics and dissemination: The Cantonal Ethics Commission Bern of the Swiss association of research ethics committees approved the study.

Trial registration number: This trial was prospectively registered at ClinicalTrials.gov: NCT04830761.

Keywords: MOST, Hand washing, behavior change intervention, randomized controlled trial, Smartphone applications, Everyday life; COVID-19

Introduction

Although scientists and international organizations had warned about the inevitability, proximity and severity of the next pandemic of infectious disease, the world was poorly prepared for the current coronavirus pandemic [1]. Starting in 2019, the coronavirus SARS-CoV-2 has been spreading rapidly worldwide, leading to a pandemic outbreak of coronavirus disease (COVID-19), which has caused a global health crisis resulting in 4 027 858 deaths worldwide to date [2]. Public health recommendations target a series of infection prevention behaviors that can contain the rapid spread and transmission of the virus, which in turn will alleviate the pressure on the health care system and save lives [3]. Behavior change interventions that aim to increase adherence to these preventive behaviors are highly recommended [4]. Besides other prevention behaviors such as isolation and wearing face masks, hands are the most common mode of transmission of pathogens [5], and correct hand washing is the most effective method for decreasing transmission of infection [6]. Besides COVID-19, a meta-analysis suggests that hand hygiene interventions may reduce rates of gastrointestinal illness by 31% and respiratory illness by 21% [6]. Hand hygiene includes correct hand washing or disinfection, performed at key times, e.g. when coming home [7]. However, the abrupt change of a habitual behavior such as hand hygiene can be challenging [8]. Thus, promoting correct hand hygiene at key times in the general population is important to prevent the spread of various diseases such as the SARS-CoV-2.

Health behavior change interventions based on key behavioral determinants can significantly augment the effectiveness of informational interventions [9,10]. For example, a web-based intervention for hand hygiene based on different behavioral determinants reduced the number and severity of respiratory infections [11]. However, as only a few handwashing interventions have included theory, little is known which behavioral determinant is most effective [12]. The present study focuses on behavioral determinants based on the theoretical

domains framework (TDF) [13]. The TDF combines different theories related to behavior change and defined 14 different domains, for example knowledge, beliefs about capabilities or intentions. The TDF has been suggested as a suitable theoretical framework to develop COVID-19 preventive behavior change interventions [14].

During an ongoing pandemic where social contact should be limited, app-based interventions have the advantage that no personal contact is needed, yet can be personalized and reach people in their daily lives. It has been postulated that health behavior interventions that are based on smartphone apps represent a potential pathway to deliver relevant behavior change techniques [15] in real life that could lead to substantial population-level impact and long-term health behavior change [16]. Therefore, app-based interventions applying a theoretical approach to promote health hygiene in everyday life are highly promising in the context of a pandemic.

Research aim

The current project "BECCCS - Behavior Change in Context to Contain the Spread of SARS-CoV-2" aims to develop, optimize and test an effective app-based behavior change intervention to promote hand hygiene at key times. In addition to arriving at robust conclusions, we aimed for timely results to contribute to the relief of the ongoing COVID-19 pandemic. We used the rigorous yet efficient MOST methodology (multiphase optimization strategy) [17] to develop the intervention based on theory and formative research. The MOST methodology provides an efficient methodology to develop an optimized multicomponent intervention in a systematic way in three distinct phases: preparation, optimization and evaluation. The MOST was deemed particularly suitable during a pandemic, because prior knowledge on the most effective behavior change strategy in this context was scarce. The available funding for our study allowed for the development and test of three distinct intervention modules. Next, we briefly

describe the preparation phase, where the intervention modules were developed. We will then focus on describing the study protocol for the optimization and evaluation phases.

Preparation Phase

In the preparation phase, we aimed at identifying the most promising behavioral determinants of hand washing behavior to tackle in the interventions. To this end, we conducted a rapid review of the hand washing behavior change literature as well as focus groups to obtain the target population's perspectives on hand washing with soap during the pandemic.

Our literature review indicated that interventions based on constructs such as intention or beliefs about capabilities, e.g. self-efficacy, have been found to be more successful to increase hand hygiene than interventions based on constructs such as knowledge alone [12,18]. In addition, there is evidence that hygiene behavior is reliably related to habit, defined as the mental association between a cue and a behavior [19], over and above other signification predictors such as intention and knowledge [20]. Intention can be fostered through higher self-efficacy, attitudes, risk perception and outcome expectancies, as these constructs can operate in concert with intention [13,21]. Self-efficacy is defined as a feeling of competency regarding a person's ability to overcome barriers in everyday life [22]. Attitudes is the person's subjective probability that performing a behavior of interest will lead to a certain outcome [23]. Risk perception is the perceived vulnerability to one's own health and outcome expectancies are influential beliefs in the motivation to change, e.g. a consideration of the pros and cons of behavior consequences [21]. Habit formation can be achieved through increased action planning and action control [8]. Action planning can help to initiate an action by specifying when, where and how to act and can be considered synonymous with implementation intentions [21,24]. Action

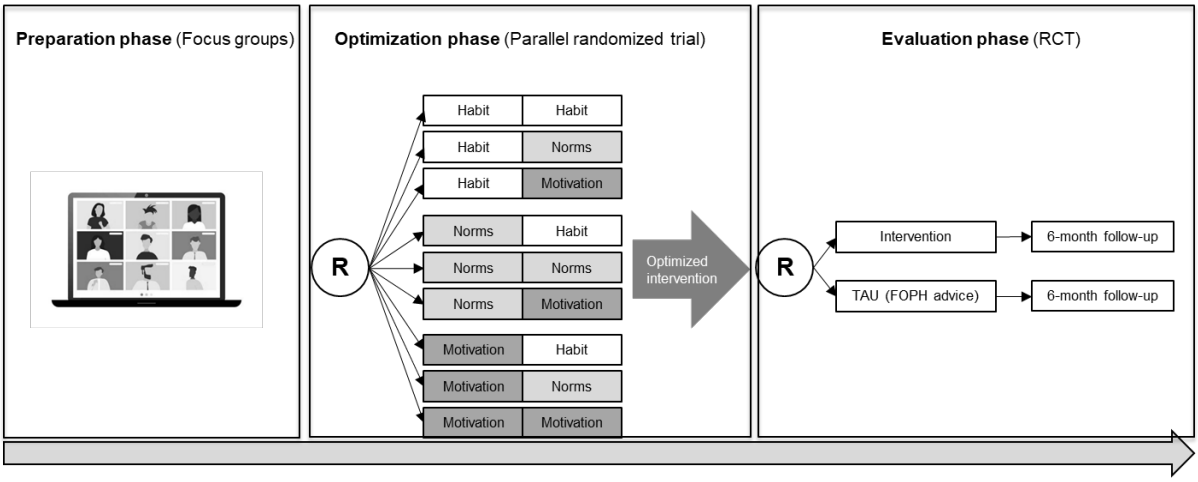
control is a self-regulatory strategy for promoting maintenance of an enacted behavior through the continual monitoring and evaluation of a behavior against a desired behavioral standard [21].

As the current project focus on intervention effects that are relevant during an ongoing pandemic, we additionally conducted focus groups to investigate how people from the Swiss general population experienced, perceived and implemented hand hygiene as a preventative measure to contain the spread of SARS-CoV-2. The aim was to examine relevant predictors for hand hygiene in everyday life specifically during an ongoing pandemic. The focused group discussions were analyzed with the mind-mapping approach for representing the key themes raised during the focus groups [43]. We subsequently allocated the themes to the categories of the TDF. The most frequently mentioned categories were social influences, motivation and goals. The literature review and the results of the focus groups are described in detail in the online supplementary file.

Overall, there was high convergence between the results of the literature review and the focus groups in that motivation and social influences emerged as important behavioral determinants in both sources. We therefore decided to dedicate one intervention module to promoting motivation for hand washing at key times (beliefs about consequences, self-efficacy, intention), whereas a second intervention module focused on social influences with the main focus on social norms including injunctive and descriptive norms [13,44]. Third, we decided to dedicate the third intervention module to habit processes due to strong theoretical and empirical evidence that habit is a key process in hand hygiene [20]. The intervention modules are explained in detail in the optimization phase, which is presented next.

Figure 1

Multiphase Optimization Strategy Design of the BECCCS Study (Behavior Change in Context to Prevent the Spread of SARS-CoV-2)



Note. Abbreviation: R = Randomization; RCT = Randomized controlled trial.

Optimization phase

Aim of the optimization phase

The aim of the optimization phase is to identify the most efficient, cost-effective and scalable combination and sequence of the three different intervention modules motivation, habit and social norms, and to assess usability and fidelity measures in order to optimize the intervention. The following hypotheses will be tested:

H1: The intervention groups show a significant increase in correct hand hygiene at key times after four weeks (T3) of intervention compared to baseline (T1).

H2: The intervention groups significantly differ in their effects on correct hand hygiene at key times (T1-T3).

If the groups significantly differ, the groups will be compared with post-hoc tests, to identify

the most effective intervention group. Further, we are interested whether a 4-week intervention is more effective than a 2-week intervention within the same module.

Secondary analyses will investigate the following hypotheses:

H3: The intervention groups show a significant increase in correct hand hygiene at key times after four weeks (T3) of intervention compared to baseline (T1).

H4: The groups attending a motivation module show a significant increase in a) intention, b) self-efficacy, c) outcome expectancies and d) attitude from the start of the intervention to the measures two (T2) and four weeks (T3) into the intervention compared to baseline (T1).

H5: The groups attending a habit module show a significant increase in a) habit strength, b) action control, and c) planning from the start of the intervention to the measures two (T2) and four weeks (T3) into the intervention compared to baseline (T1).

H6: The groups attending a social norms module show a significant increase in a) injunctive norms and b) descriptive norms from the start of the intervention to the measures two (T2) and four weeks (T3) into the intervention, compared to baseline (T1).

As exploratory research questions, the intervention effects on self-reported symptoms of infection or COVID-19 will be analyzed, and how the participants evaluate the intervention regarding perceived usability, satisfaction and other user experience evaluation scales. Additionally, to collect in-depth information about feasibility, usability and satisfaction of the intervention, a qualitative survey will be conducted with a small subsample.

Methods

Design

For the optimization phase, a parallel randomized trial will be conducted. All participants are randomized to one of nine intervention groups in a 1:1:1:1:1:1:1:1:1 ratio, and will complete two consecutive intervention modules accordingly (see Figure 1). An even randomization procedure is applied that has the advantage of increasing the comparability

between groups by keeping the number of subjects' ratio almost the same [45]. For a small subsample (n=15) in the optimization phase, qualitative interviews will be conducted to collect in-depth information about feasibility, usability, satisfaction of the intervention. The subsample was recruited according to the hand hygiene adherence at T3. The aim was to recruit five participants in each adherence group: low adherence, medium adherence and high adherence.

Population and participants

The study population for both the preparation and optimization phase is the interested Swiss general population. Persons participating in the optimization and evaluation phase must (1) be at least 18 years old, (2) own a smartphone with mobile access to the internet, (3) be proficient in the German language to the degree that they understand the contents and instructions of the study, (4) and have signed an informed consent form to participate in the study.

Sample size calculation. According to the main research question for the optimization phase, the sample size is calculated with a repeated measure ANOVA with a within-between-interaction. In the optimization phase, n = 387 subjects are to be randomized. This sample size was determined with an a priori power analysis with g*power [46]. The aim is that a statistical analysis using repeated-measure ANOVA with a within-between-interaction and with a power of β= .80 and α = .05, a small effect of f = 0.1 should be detectable. Accounting for 20% attrition, this leads to n = 465 for the enrolment in the optimization phase.

Outcome measures

The primary study outcome is the frequency of correct hand hygiene at key times. For this purpose, an electronic hand hygiene diary is administered. On diary days, participants indicate five times daily whether one of the 13 key hand hygiene situations occurred, defined by the Swiss Federal Office of Public Health (e.g. arriving home, after using the toilet, see

Table 2). For each situation that occurred, participants will be asked: How many times did you correctly wash or disinfect your hands [in key situation]? The response ranges from never (1) to always (4). The primary outcome correct hand hygiene at key times will be represented by the mean reported frequency of correct hand hygiene across all indicated key times and, ranging from 1-4.

Table 2

List of all key times, when to perform correct hand hygiene according to the Swiss Federal Office of Public Health.*

Number	Key times	Type
1	Before preparing the meal or before sitting down at the table	General
2	Before eating or before feeding the children	General
3	After blowing your nose, sneezing or coughing	General
4	Every time you come home	General
5	After using public transport	General
6	After visiting sick people or after close contact with material from sick people or with theirs personal effects	General
7	Before inserting and removing the contact lenses	General
8	After taking off the mask	General
9	After going to the toilet or accompanying a child to the toilet (including after changing diapers)	General
10	After handling waste	General
11	If you have dirty hands or if they are visibly dirty	General
12	After visiting public places	COVID-19 specific
13	After touching surfaces outside the home or money	COVID-19 specific

Note: The type General indicates key times that are recommended in general and before the COVID-19 pandemic occurred; * information from the Federal Office of Public Health of Switzerland [47].

To ensure that the intervention is delivered as expected and successfully implemented, intervention fidelity and further secondary outcomes will be assessed. Secondary outcomes are the frequency of incorrect hand hygiene at key times as well as the following behavioral determinants: (1) intention [48], (2) risk perception [49], (3) outcome-expectancies [49], (4) action and coping planning [48], (5) habit strength (Self-Report Behavioral Automaticity Index; SRBAI, [50], (6) injunctive and descriptive norm (Theory of Planned Behavior Questionnaire) [51], (7) attitude (TPB Questionnaire) [51], (8) action control [52], (9) self-reported flu-like infection symptoms, (10) self-reported statement of the occurrences of Covid-19, (11) user engagement [53], (12) intervention usability and satisfaction for trials and qualitative survey [54,55], and (13) intervention fidelity for trials and qualitative survey.

Additionally, intervention module-specific questions will be assessed after each module to assess the acceptance of the modules. For the motivation module e.g. “The instruction of the problem-solving steps task was comprehensible”, for the habit module e.g. “The majorities of my implementation intentions worked fine” and for the social norms module e.g. “I felt motivated from the other users for the behavior correct hand hygiene at key times”.

Procedures

For the optimization phase, the total study duration (recruitment and data collection) is six months (start: 26.3.2021) until a total sample size of 465 participants has been enrolled. In the optimization trial, the duration of the study for each participant is five weeks. Figure 2 illustrates the study procedure for the optimization phase. After downloading the study app, participants receive the baseline questionnaire T1. The day after T1, participants fill in a hand hygiene diary. The diary includes five 1-minute-questionnaires during one day to avoid retrospective bias in reporting hand hygiene [56]. The intervention will take four weeks and includes two modules of two weeks each. During the first module, participants will fill in another hand hygiene diary at the end of each week (two in total during one module). After the first module, participants will receive the second questionnaire (T2). After T2, the second intervention module follows within the same structure. After the second module, participants receive the last questionnaire (T3). Finally, participants who were given the option and volunteered for the qualitative study will be interviewed via telephone by a study team member. This 30-minutes-interview entails questions about the usability of the app and the overall experience with the intervention modules. This information will be used to optimize the study app before starting the evaluation phase.

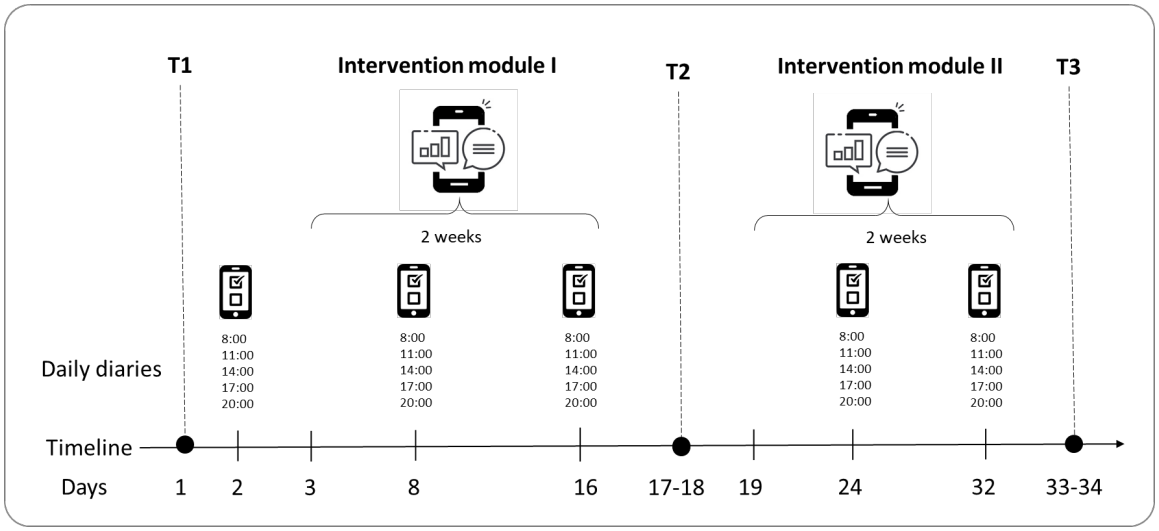
Enrolment

The sample will be recruited via social media, mailing lists and leaflets with the help of a recruitment company located in Bern, Switzerland. By posting advertisements on different sites such as Facebook and applying different recruitment channels by sending our online study flyer, the recruitment aims to collect a stratified sample, which is based on gender, socio-economic status and age to allow the generalizability of results to the adult Swiss population. Those who click on the link of the campaign will be led to a landing page with the relevant

study information. On this site, participants can enter their e-mail address to receive a link to the study.

Figure 2

Procedure study optimization phase



Note. This figure shows the study procedure in the optimization phase, which includes two consecutive intervention modules, three main surveys T1-T3 and five daily diaries with five short questionnaires at fixed times during the day.

The informed consent procedure takes place online, consistent with the safety measurements issued by the Swiss government concerning COVID-19. Participants access an online survey with detailed information about the study and an e-consent form to provide consent to the study electronically. Participants are not only provided with written study information, but are also informed orally about the study by means of an audio-visual presentation. Participants can download a copy of the online consent form at the end of the survey. An e-consent framework on mobile devices has been shown to be easy-to-use, satisfying, and engaging, allowing users to progress through the consent materials at their own pace [57].

The recruitment for the sub-sample is based on their adherence to correct hand hygiene at key times at T3. We aim to recruit five participants in three categories: low adherence, medium adherence, and high adherence. Recruitment of this subsample will be stopped when five participants in each of the three adherence groups have agreed to take part in the interview.

Data collection

Quantitative data collection. All quantitative measures will be collected using online questionnaires implemented in the app. As illustrated in Figure 2, participants receive a questionnaire at the beginning (T1), after the first module (T2) and after the second module (T3). The primary outcome the secondary outcome incorrect hand hygiene at key times will be assessed in the diary. All other secondary outcomes will be collected at T1, T2, and T3. An overview of all measures in the optimization phase can be found in the online supplementary file.

As an incentive, all participants who are participating in either the optimization phase or the evaluation phase will have the chance to win one of three iPhone 12 after both phases are conducted. Further, to prevent attrition, after two weeks, participants are offered to receive a small gift, which is a hand soap and a thank you card.

Qualitative data collection. Post intervention user engagement [53], acceptability [58], usability [54] and satisfaction will be explored using qualitative semi-structured telephone interviews. The interviews will be transcribed using a verbatim/denaturalized approach [59]. The pseudonymized transcripts will be analyzed using thematic analysis [60]. After the production of initial codes from the data, the codes will be grouped into themes. Conclusions will be drawn on possible improvement of *soapp* to optimize intervention effectiveness and usability.

Intervention

In the optimization phase, the three intervention modules motivation, habit and social norms will be tested against each other. They each take two weeks and are comparable in terms

of user time and extent of content. A basic module will provide information on hand hygiene to all participants. The modules will be delivered to participants via their personal smartphone through the study application *soapp,* allowing high reach of the general population. The *soapp* app contains all necessary information and no direct contact with the study team is required. Below, the content of each module is summarized. Table 4 outlines all details of the different modules and shows the allocated TDF domains and BCTs.

Basic module. The basic module entails the registration process (i.e., selecting a call name), general information about the study app and its purpose as well as specific information on correct hand hygiene at key times in the context of COVID-19. This information is available in the app for all participants during the entire intervention period. After reading the information, participants are prompted to make an implementation intention to organize disinfectant or soap to prepare for correct hand hygiene at key times.

Motivation module. The motivation module focuses on the construct intention, attitudes towards the target behavior, risk perception, outcome expectancies, and self-efficacy.

Participants receive information about bacteria, germs, and contamination processes and watch a video about the contamination process after using the toilet [61]. Further, participants are instructed to list all pros and cons for performing correct hand hygiene at key times. If they cannot generate more pros than cons, they will receive a list with more pros. In addition, participants are prompted to monitor challenges when performing hand hygiene in their daily lives, and to note these in a diary. After the monitoring phase, participants are guided through four problem-solving steps: describing the problem, finding alternative solutions, selecting a solution, implementing and evaluating the selected solution [62]. To boost self-efficacy [22] participants are advised to think about their previous successes in performing hand hygiene, and they receive push-notification as a reminder. Additionally, participants receive persuasive messages reinsuring them of their capabilities to perform the behavior.

Habit module. The aim of the habit module is to guide participants to perform correct hand hygiene at self-selected key times repeatedly based on a cue-action response and reach habit formation [63].

The habit module first includes a brief introductory video explaining the basic principles of habit formation. Then, participants are asked to identify suitable cues (situations in their daily routines, when hand hygiene is required) and keep them in a diary. Participants' notes will then be used to form an implementation intention for each identified cue. During the intervention period, participants are prompted with notifications to follow their implementation intentions, and to modify them if necessary. Additionally, participants will get information on how they can further support the process of habit formation by installing physical reminders (e.g., post-it notes). Finally, participants can activate automated push-messages, working as reminders for upcoming key situations to perform hand hygiene.

Social norms module. The social norms module aims to promote correct hand hygiene at key times by fostering injunctive and descriptive norms and social identification [44]. First, the social norms module presents instruction about the functionality of the module. As a key function, participants note their performance of correct hand hygiene at key times of a particular day in the evening (from 0% to 100%). Participants' performance scores are posted in a scoreboard in the Community Room, and are also shared in the daily newsfeed. On the score board, participants can compare their own hand hygiene with the behavior of the other group members. Participants can react to others' performance scores with emoticons or available standard comment options to endorse each other's behavior. Further, participants read quotes with phrases from healthcare professionals, who emphasize the importance of correct hand hygiene at key times. Another task is to interview a self-chosen significant other (e.g., romantic partner) about their positive attitudes towards hand hygiene. Participants can note the significant other's statement in *soapp* as a reminder. Further, participants are instructed to print

or draw eyes and put it above their sinks [64]. Finally, participants randomly receive push notifications throughout the intervention in order to further support the perception of norms, to emphasize social comparison or to remind participants to reward each other.

Data analysis

The comparative effects of the intervention will be determined as between-group differences in changes in primary and secondary outcomes from T1 to T3 using repeated-measure ANOVA with a within-between-interaction.

To select and optimize the intervention for the evaluation phase, two optimization criteria are defined that will be analyzed after the data in the optimization phase has been collected. The first optimization criteria to select the best intervention group is the primary study outcome. Therefore, the correct hand hygiene behavior at key times at T3 will be compared between all nine intervention groups. For the second optimization criteria, the quantitative and qualitative data of the constructs satisfaction, usability and engagement in regards of the different modules will be analyzed.

Data management, data security and quality control. All data for the intervention, the questionnaires T1-T3 and the diary are assessed using the Qualtrics services. The data for the consent forms are assessed using REDcap services. These services apply highest levels of data security. At the University of Bern, only members of the research team and an independent trial monitor have access to the system of Qualtrics. Data integrity will be enforced through a variety of mechanisms, i.e. referential data rules, valid values, range checks, and consistency checks. All questionnaires will be tested by members of the research team before employing them in the study. In the intervention, no data is collected that can identify participants. The qualitative data are recorded from the responsible team member and stored as a pseudonymized transcription for each participant on the protected server of the University of Bern.

Evaluation phase

Aim of the evaluation phase

In the evaluation phase, the optimized intervention will be tested against a control group (treatment as usual) to test short and long-term effects for correct hand hygiene at key times.

H7: The intervention group shows a greater increase in correct hand hygiene behavior at key times at the post measure (H7a) and at 6-month follow-up (H7b) compared to the control group.

H8: The intervention group shows a significant increase in the targeted behavioral determinants that are included compared to the control group at the post-intervention measure (H8a) and at 6-month follow-up (H8b). [the exact behavioral determinants depend on the results of the optimization phase].

Methods

Design

In the evaluation phase, the optimized intervention will be compared to treatment as usual in a randomized controlled trial. After random assignment, all participants will have access to the information of the Federal Office of Public Health [47] on infection prevention behaviors, specifically on hand hygiene (treatment as usual). The intervention group will additionally receive the optimized intervention.

Population and participants

The study population for both phases are the same and are described in the optimization phase above.

Sample size calculation

In the evaluation phase, 205 new subjects are to be randomized. The aim is that a statistical analysis using an independent samples t-test adopting an error probability and statistical power of $\alpha = .05$ and $\beta = .80$, at least a small to intermediate intervention effect of

Cohen's $d = 0.35$ should be detectable [65]. Accounting for 20% attrition, this leads to $n = 245$ for the enrolment in the evaluation phase.

Outcome measures

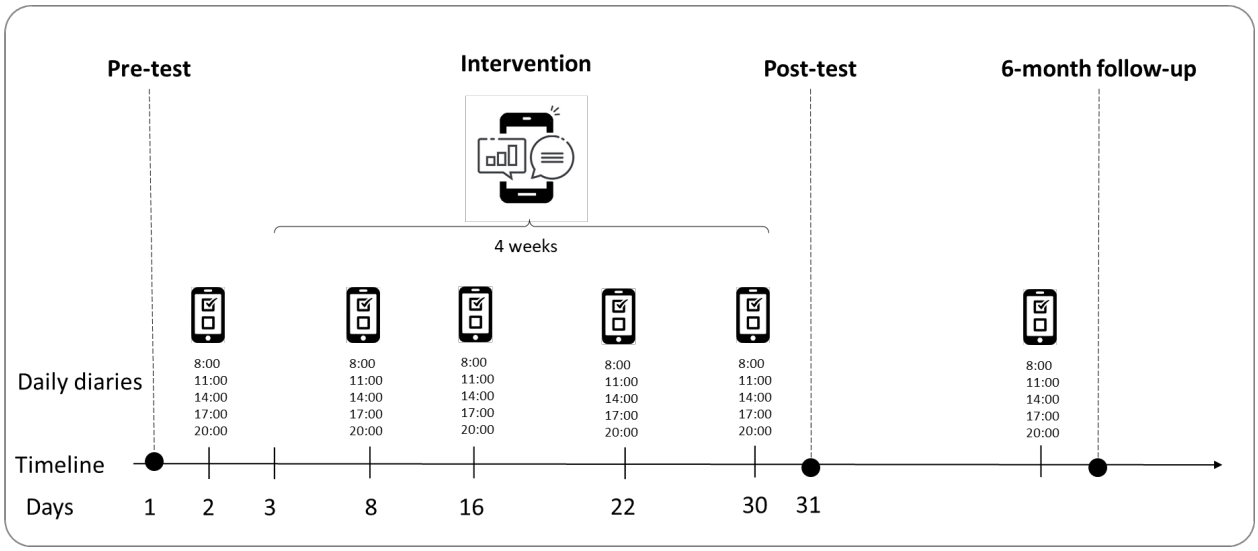
In the evaluation phase, the same primary and secondary outcomes will be investigated as in the optimization phase. Also, the same analyses for intervention fidelity will be applied as described in the optimization phase.

Procedures

For the evaluation phase, the total study duration (recruitment and data collection) is nine months (start 01.01.2022) until a total sample size of 245 participants has been enrolled. Figure 3 illustrates the study procedure for the evaluation phase. After downloading the study app, participants receive the baseline questionnaire and subsequently fill in the first hand hygiene diary. Afterwards, participants are invited to use a 4-week optimized intervention consisting of the content identified as most effective to promote correct hand hygiene at key times in the optimization phase. Again, participants fill in a hand hygiene diary at the end of each week during the intervention. After the intervention, participants are asked to fill in the post-test questionnaire. Finally, participants will receive a 6-month follow-up, which includes a diary day and the follow-up questionnaire. At the end of the study, all participants will be informed about the purpose and the aim of the study by email.

Figure 3

Procedure evaluation phase



Note. This figure shows the study procedure in the evaluation phase, which includes the final intervention, three main surveys (pre-test, post-test, 6-month follow-up) and six daily diaries with five short questionnaires at fixed times during the day

Enrolment

The evaluation phase includes the same enrolment procedure as described in the optimization phase

Data collection

Quantitative data collection. Data collection for all quantitative measures is the same as in the optimization phase using the study app *soapp*. As illustrated in Figure 3, participants receive a questionnaire at the beginning (pre-test), after the intervention (post-test) and after 6 months (follow-up). As in the optimization phase, all participants will have the chance to win one of three iPhone 12 and are offered to receive a small gift after two weeks.

Intervention

Based on the results of the optimization phase in accordance to the optimization criteria, the optimized intervention includes the most effective, and acceptable combination and sequence of the three intervention modules.

Data analysis

The effects of the intervention will be assessed as changes in primary and secondary outcomes from pre-test to post-test and follow-up using an independent samples t-test.

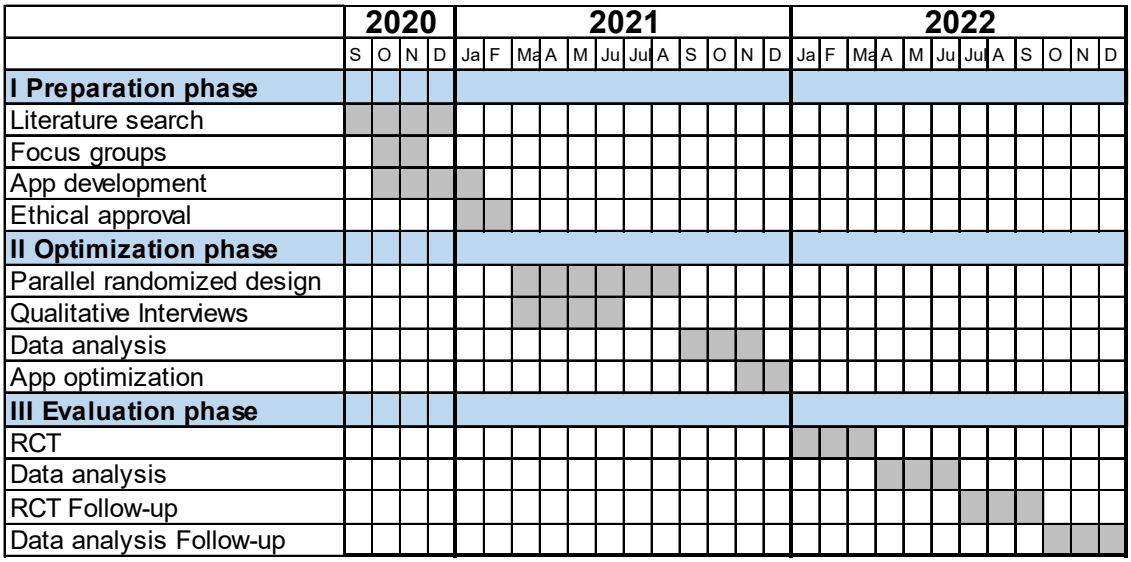
Data management, data security and quality control. The same data management, data security and quality control will be applied as described in the optimization phase.

Trial status

The preparation phase including the development of the intervention modules and the programming of the study app has already been completed on 9.7.2020 (cf. Figure 4). The ethical approval has been obtained (Cantonal Ethics Commission Bern from the Swiss association of research ethics committees; Protocol ID: 2021-00164). At the time of manuscript submission, 279 people have registered for participation in the study, and 127 participants have already completed the study. Recruitment for the optimization phase will continue until August 2021 and the enrolment for the evaluation phase will take from January to March 2022 and data collection ends in September 2022 (see Figure 4).

Figure 4

Study timetable with the preparation, optimization and evaluation phase from 2020-2022.



Note. S = September, O = October, N = November, D = December, Ja = January, F = February, Ma = March, A = April, M = May, Ju = June, Jul = July, A = August.

Ethics and dissemination

Consent to participate

All participants will provide online consent with an e-sign prior to any study procedures. Participants can download their consent directly after the registration is finished and receive the consent document signed by the PI by email after 1-2 weeks.

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Contributors

JI wrote the grant proposal and obtained funding; JI and MA developed the design and study procedures; JI, MA, GGR, CA and MB obtained ethical approval; JI and MA conceptualized the data monitoring procedures; All authors contributed to writing and revising this manuscript.

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Competing interests

There are no conflicts of interest. This study is conducted and the results are published independently of the funding agency. The intellectual property remains that of the study team.

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