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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 optimisation strategy

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ABSTRACT

Introduction Behaviour change is key to the 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 taking health psychology approaches may promote adherence to public health measures. However, evidence from randomised controlled behaviour change trials is scarce during an ongoing pandemic. We aim to use the example of hand washing with soap to optimise and test a digital, theory-based and evidence-based behaviour change intervention to prevent the spread of COVID-19.

Methods and analysis This protocol describes the multiphase optimisation strategy for the preparation, optimisation and evaluation of a theory-based and evidence-based intervention delivered via app. 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. The preparation phase has identified relevant behavioural determinants of hand hygiene during a pandemic from health behaviour theories and formative research with focus groups (n=8). The optimisation phase will identify the most effective and acceptable combination and sequence of three intervention modules in a parallel randomised trial (n=387) with analysis of variance (ANOVA) and regression analysis. Additionally, thematic analysis of qualitative interview data (n=15) will be used to gain insights on the feasibility, usability and satisfaction of the intervention. The evaluation phase will test the optimised intervention against an active control group in a randomised controlled trial (n=205), analysing pre-post differences and 6-month follow-up effects with ANOVA and regression analysis.

Ethics and dissemination The trial was approved by the Cantonal Ethics Commission Bern of the Swiss Association of Research Ethics Committees (protocol ID: 2021-00164). Final results will be presented in peer-reviewed journals and at conferences.

Trial registration number NCT04830761.

Strengths and limitations of this study

► Rigorous intervention development and evaluation using the multiphase optimisation strategy.
► Mixed methods approach to investigate the most effective intervention module sequence and combination.
► Randomised controlled trial to evaluate the app postintervention and its long-term effects at 6-month follow-up.
► The primary outcome, correct hand hygiene at key times, to be measured via a self-reported e-diary multiple times daily on selected days to minimise recall bias.

INTRODUCTION

Although scientists and international organisations 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] Since 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 behaviours that can contain the rapid spread and transmission of the virus, which in turn will alleviate the pressure on the healthcare system and save lives.[3] Behaviour change interventions that aim to increase adherence to these preventive behaviours are highly recommended.[4]

Hands are the most common mode of transmission of pathogens, and correct hand hygiene is the most effective method for decreasing transmission of infection alongside other prevention behaviours such as isolation and wearing face masks.[5] 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 and disinfection performed at key times, such as when coming home.[7] However, the abrupt change of a habitual behaviour 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 COVID-19.

Health behaviour change interventions based solely on information have been shown to be less effective than interventions based on key behavioural determinants.[9 10] For example, a web-based intervention for hand hygiene based on a range of behavioural determinants reduced the number and severity of respiratory infections.[11] Various determinants of hand hygiene behaviour, such as knowledge and risk, have been predominantly investigated.[12] In healthcare settings, an additional mechanism that has been examined to promote hand hygiene is nudging.[13] Overall, however, previous studies have only explored a narrow range of behavioural determinants, and evidence about determinants specifically in crises and outbreaks is lacking.[12] Therefore, the present study aims to include a wide range of behavioural determinants and thus uses the theoretical domains framework (TDF) as a theoretical basis.[14] The TDF combines various theories related to behaviour change and defines 14 domains that are related to behaviour change, for example, knowledge and beliefs about capabilities and intentions. The TDF has been suggested as a suitable theoretical framework for developing COVID-19 preventive behaviour change interventions.[15]

During an ongoing pandemic, in which social contact should be limited, app-based interventions have the advantage that no personal contact is needed, yet they can be personalised and reach people in their daily lives. It has been postulated that health behaviour interventions that are based on smartphone apps can deliver behaviour change techniques[16] in real life that could lead to substantial population-level impact and long-term health behaviour change.[17] Therefore, app-based interventions that apply a theoretical approach to promoting health hygiene in everyday life are highly promising in a pandemic.

Research aim

The current project named Behavior Change in Context to Contain the Spread of SARS-CoV-2 aims to develop, optimise and test an effective app-based behaviour change intervention to promote hand hygiene at key times. In addition to arriving at robust conclusions, we sought timely results to contribute to the relief of the ongoing COVID-19 pandemic. We used the rigorous yet efficient multiphase optimisation strategy (MOST)[18] to develop the intervention from theory and formative research. The MOST provides an efficient methodology to develop an optimised multicomponent intervention in a systematic way in three distinct phases: preparation, optimisation and evaluation. The MOST was deemed particularly suitable during this pandemic because prior knowledge on the most effective behaviour change strategy was scarce. The funding available for our study allowed the development and test of three distinct intervention modules. Next, we briefly describe the preparation phase, in which theory-based and evidence-based behaviour change intervention modules were developed. We then describe the study protocol for the optimisation and evaluation phases, in which, first, the effect of nine different sequences of the theory-based and evidence-based modules is tested (optimisation phase) and, subsequently, the optimised intervention will be tested against an active control group (evaluation phase).

PREPARATION PHASE

First, we aimed at identifying the most promising behavioural determinants of hand hygiene behaviour to tackle in the interventions. To this end, we conducted a rapid review of the hand hygiene behaviour change literature and focus groups to obtain the target population's perspectives on hand hygiene during the pandemic.

Our literature review indicated that interventions based on constructs such as intention and beliefs about capabilities, such as self-efficacy, have been found to be more successful in increasing hand hygiene than interventions based on knowledge alone.[19 20] In addition, hygiene behaviour is reliably related to habit, defined as the mental association between a cue and a behaviour,[21] over and above other signification predictors such as intention and knowledge.[22] Intention is predicted by self-efficacy, outcome expectancies, risk perception, attitude and social norms.[14 23 24] Self-efficacy is defined as a person's feeling of competence about their ability to overcome barriers in everyday life.[25] Outcome expectancies are the person's subjective assessment of the probability that performing a behaviour of interest will lead to a certain outcome.[23] Risk perception is the perceived vulnerability to one's own health.[23] Attitude is the evaluation of the behaviour along a dimension of favour or disfavour, good or bad, like or dislike.[24] Further, social norms include injunctive norms (the perceptions of what others approve of) and descriptive norms (others' behaviour).[23] Habit formation is achieved through repetition of a behaviour in a stable context. It can be facilitated through increased action planning and action control.[8] Action planning can help initiate an action by specifying when, where and how to act and can be considered synonymous with implementation intentions.[23 26] Action control is a self-regulatory strategy for promoting maintenance of an enacted behaviour through the continual monitoring and evaluation of a behaviour against a desired behavioural standard.[23]

Because the current project focuses on intervention effects that are relevant during an ongoing pandemic, we also conducted focus groups to investigate how people from the Swiss general population experienced, perceived and implemented hand hygiene as a preventive measure to contain the spread of SARS-CoV-2. The aim was to

examine predictors relevant to hand hygiene in everyday life during an ongoing pandemic. The focus group discussions were analysed with the mind-mapping approach for representing the key themes raised during the focus groups.[27] 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 supplemental file 1.

Overall, there was high convergence between the results of the literature review and the focus groups: motivation and social influences emerged as important behavioural determinants in both sources. We therefore decided to dedicate one intervention module to promoting motivation for hand hygiene at key times; this intervention focused on beliefs about consequences, self-efficacy and intention. A second intervention module focused on social influences and chiefly on social norms, including injunctive and descriptive norms.[14 28] 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.[22] The intervention modules are explained in detail in the optimisation phase, which is presented next.

OPTIMISATION PHASE
Aim of the optimisation phase

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

H1: The intervention groups show a significant increase in correct hand hygiene at key times after 4 weeks (T3) of intervention compared with baseline (T1).

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

If the groups differ significantly, they 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 incorrectly performed hand hygiene at key times after 4 weeks (T3) of intervention compared with 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 2 weeks (T2) and 4 weeks (T3) into the intervention compared with 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 2 weeks (T2) and 4 weeks (T3) into the intervention compared with 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 2 weeks (T2) and 4 weeks (T3) into the intervention compared with baseline (T1).

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

Methods
Design

The optimisation phase will include a double-blind parallel randomised trial. All participants are randomised 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 as shown in figure 1. In this way, the effect of different sequences of intervention modules can be tested. This is because both the combination and the sequence of
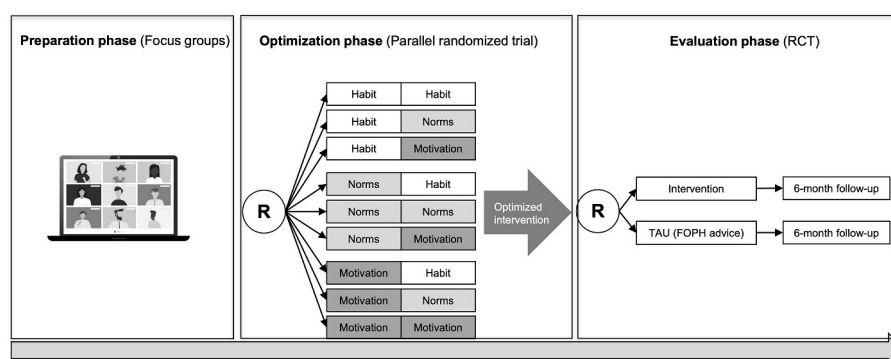
Figure 1 Multiphase optimisation strategy design of the Behavior Change in Context to Contain the Spread of SARS-CoV-2 (BECCCS) study. RCT, randomised controlled trial. TAU, Treatment as usual; FOPH, Federal office of public health.

intervention components can be relevant.[29] An even randomisation procedure is applied that has the advantage of increasing the comparability between groups by keeping the number of subjects' ratio almost equal.[30]

Qualitative interviews will be conducted with a small subsample (n=15) in the optimisation phase to collect in-depth information about the feasibility, usability and satisfaction of the intervention. The subsample will be recruited according to hand hygiene adherence at T3. The aim is to recruit five participants in each adherence group: low adherence, medium adherence and high adherence.

The current trial is registered at ClinicalTrials.gov. The study protocol was drafted and developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials 2013 checklist (see online supplemental file 2).

Population and participants

The study population for both the preparation phase and optimisation phase is the interested Swiss general population. Persons participating in the optimisation and evaluation phases 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; and (4) have signed an informed consent form to participate in the study.

Sample size calculation

According to the main research question for the optimisation phase, the sample size is calculated with a repeated measures analysis of variance (ANOVA) with a within–between interaction. In the optimisation phase, n=387

subjects are to be randomised. This sample size was determined with an a priori power analysis with g*power.[31] The intention is to use a statistical analysis with repeated measures ANOVA with a within–between interaction, a power of $\beta=0.80$ and $\alpha=0.05$ so that a small effect of $f=0.1$ should be detectable. Allowing for 20% attrition, this leads to n=465 for the enrolment in the optimisation 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 times occurred, defined by the Swiss Federal Office of Public Health (eg, arriving home, after using the toilet; see table 1). Therefore, the first question in the item is 'Which of the following key times has occurred at least once since the previous questionnaire?' For each situation that has occurred, participants will be asked the second question: 'How many times did you correctly wash or disinfect your hands [in this key situation]?' The 5-point response scale ranges from never (1) to always (5). The primary outcome, correct hand hygiene at key times, will be represented by the mean reported frequency of correct hand hygiene across all key times indicated and ranges from 1 to 5.

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 incorrectly performed hand hygiene behaviour at key times and the following behavioural determinants: self-reported behavioural

No	Key times	Type
Table 1	List of all key times, when to perform correct hand hygiene according to the Swiss Federal Office of Public Health*	
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 their personal effects.	General
7	Before inserting and removing the contact lenses.	General
8	After taking off the mask.	COVID-19 specific
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

General type indicates key times that are recommended in general and before the COVID-19 pandemic occurred.
*Information translated from the Federal Office of Public Health of Switzerland.[50]

intention[32]; mean score of five self-reported risk perception items[33]; mean score of eight self-reported outcome expectancy items[33]; mean score of four self-reported coping planning items[32]; mean score of three self-reported action planning items[32]; habit strength assessed with the Self-Report Behavioral Automaticity Index[34]; mean score of three self-reported injunctive norm items[35]; mean score of two self-reported descriptive norm items[35]; mean score of six self-reported attitude items[35]; mean score of three self-reported action control items[36]; user engagement assessed with the DBCI (Digital behavior change interventions) engagement scale[37]; intervention usability[38]; satisfaction using the ZUF-8 (=satisfaction with inpatient care)[39]; mean score of self-created intervention fidelity items such as 'The description in the soapp app was clear to me'; self-reported influenza-like infection symptoms; self-reported statement of the occurrences of COVID-19; and mean score of eight self-reported self-efficacy items.[33]

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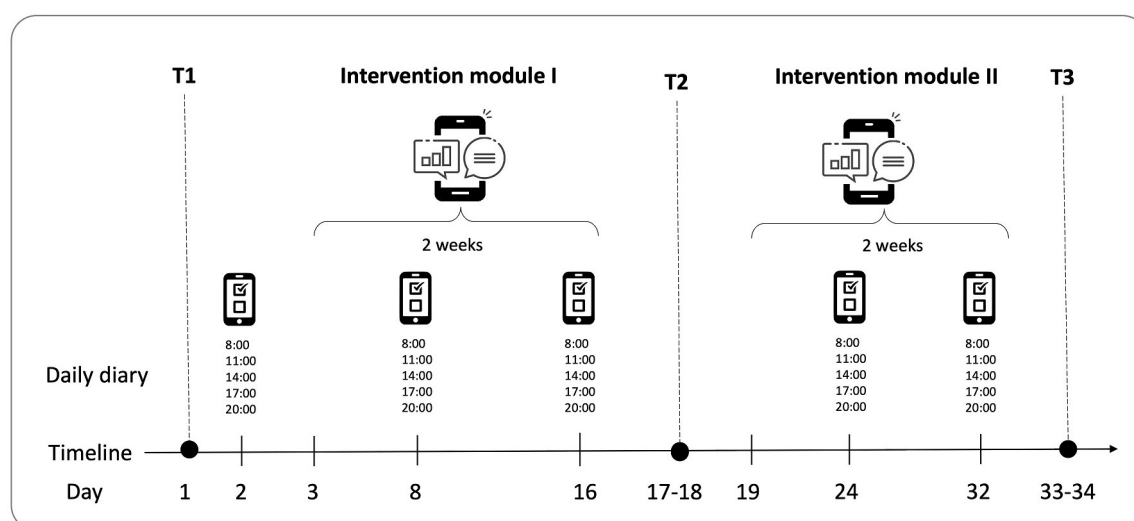
Procedures

The total duration of the optimisation phase, including recruitment and data collection, is 6 months (start: 26 March 2021) or until a total sample size of 465 participants have been enrolled. The duration of the optimisation trial for each participant is 5 weeks. Figure 2 illustrates the study procedure for the optimisation phase. After downloading the study app, participants receive the baseline questionnaire at T1. The day after T1, participants begin a hand hygiene diary. The diary includes five 1 min questionnaires per day to avoid retrospective bias in reporting

hand hygiene.[40] The intervention will take 4 weeks and includes two modules of 2 weeks each. During the first module, participants will begin 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 at T2. After T2, the second intervention module follows the same structure. After the second module, participants receive the final questionnaire at 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 min interview includes questions about the usability of the app and the overall experience with the intervention modules (see online supplemental file 3). This information will be used to optimise 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 in Bern, Switzerland. By posting advertisements on sites such as Facebook and accessing other recruitment channels with our online study flyer, the recruitment aims to collect a stratified sample, whose gender, socioeconomic status and age will allow the generalisability 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 study information. Participants can enter their email address to receive a link to the study.

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 with which to provide consent to the study electronically. Participants are provided with written study information and are informed orally about the study with an audiovisual presentation. Participants can download a copy of the online consent form at the end of the survey. An e-consent framework

Figure 2 Procedure study optimisation phase.

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.[41]

The recruitment for the subsample will depend on participants' 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. The categories are classified according to the percentile level of the main outcome. Participants on the 33rd percentile or lower are classified to the low adherence group, participants between the 34th and 66th percentiles are classified to the medium adherence group and participants on the 67th percentile or higher are classified to the high adherence group.

Data collection
Quantitative data collection
All quantitative measures will be collected using online questionnaires implemented in the app. Participants receive a questionnaire at T1, T2 and T3. The primary outcome, correct hand hygiene at key times, and 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 optimisation phase can be found in the online supplemental file 1.

All participants who participate in either the optimisation phase or the evaluation phase will have the chance to win one of three iPhone 12s after both phases are conducted. To prevent attrition, after 2 weeks, participants will be offered a small gift, which is a bar of hand soap and a thank you card.

Qualitative data collection
Postintervention user engagement,[37] acceptability,[42] usability[38] and satisfaction will be explored using qualitative semistructured telephone interviews. The interviews will be transcribed using a verbatim and denaturalised approach.[43] The pseudonymised transcripts will be analysed using thematic analysis.[44] 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 optimise intervention effectiveness and usability.

Intervention
In the optimisation phase, the three intervention modules, motivation, habit and social norms, will be tested against each other. They each take 2 weeks and are comparable in 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*, enabling high reach to the general population. The *soapp* app contains all the information needed to use it and no direct contact with the study team is required. The content of each module is summarised below. The content of the modules is described in detail in the online supplemental file 1.

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

Motivation module
The motivation module focuses on five constructs: intention, attitudes towards the target behaviour, risk perception, outcome expectancies and self-efficacy.

Participants receive information about bacteria, germs and contamination processes and watch a video about how toilets become contaminated after use.[45] Further, participants are instructed to list all the 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 and implementing and evaluating the selected solution.[46] To boost self-efficacy,[25] participants are advised to think about their previous successes in performing hand hygiene, and they receive push notifications as reminders. Additionally, participants receive persuasive messages reassuring them of their capability to perform the behaviour.

Habit module
The aim of the habit module is to guide participants to perform correct hand hygiene at self-selected key times repeatedly in a cue–action response and thus form a habit.[47]

The habit module first includes a brief introductory video explaining the basic principles of habit formation. Then, participants are asked to identify suitable cues, which are 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 cue identified. During the intervention period, participants are prompted with notifications to follow their implementation intentions and to modify them if necessary. Additionally, participants will receive information on how they can further support the process of habit formation by installing physical reminders such as post-it notes. Finally, participants can activate automated push messages, which remind them of 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.[28] First, the social norms module presents instructions about the functionality of the module. A key function is that 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. In the community room, all participants can see each other's scores that were shared. Participants' performance scores are also shared in the daily newsfeed. Participants can compare their own hand hygiene with the behaviour of the other group members. Participants can react to others' performance scores with emoticons or standard comment options to endorse each other's behaviour. Further, participants read quotes with phrases from healthcare professionals, who emphasise the importance of correct hand hygiene at key times. Another task is to interview a self-chosen significant other, such as their 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 a picture of two unisex eyes and put it above their handbasins.[48 49] Finally, participants randomly receive push notifications throughout the intervention to further support the perception of norms, to emphasise social comparison and 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 measures ANOVA with a within–between interaction.

To select and optimise the intervention for the evaluation phase, two optimisation criteria are defined; these will be analysed after the data have been collected in the optimisation phase. The first optimisation criterion to select the best intervention group is the primary study outcome. Therefore, correct hand hygiene behaviour at key times at T3 will be compared between all nine intervention groups. For the second optimisation criterion, the quantitative and qualitative data for satisfaction, usability and engagement will be analysed for each of the modules.

No interim analyses or safety analyses are planned. Deviations from the planned analyses will be described in the final report. Missing data and dropouts will be handled according to the intention-to-treat (ITT) principle. The ITT analysis includes every subject who is randomised according to randomised study group. It ignores noncompliance, protocol deviations from the intervention modules and anything that happens after randomisation. Participants who withdrew consent are excluded from ITT analysis. ITT analysis avoids overoptimistic estimates of the efficacy of an intervention resulting from the removal of non-compliers by accepting that non-compliance and protocol deviations are likely to occur in practice.

Data management, data security and quality control

All data for the intervention, 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 the 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 Qualtrics system. Data integrity will be enforced through a variety of mechanisms: referential data rules, valid values, range check and consistency checks. All questionnaires will be tested by members of the research team before employing them in the study. During the intervention, no data are collected that can identify participants. The qualitative data are recorded by the team member responsible and stored as a pseudonymised transcription for each participant on the protected server of the University of Bern.

EVALUATION PHASE

Aim of the evaluation phase

The evaluation phase will test the optimised intervention against an active control group (basic app content including advice of the federal office of public health) to test the intervention's short-term and long-term effects on correct hand hygiene at key times.

H7: The intervention group shows a greater increase in correct hand hygiene behaviour at key times at the postmeasure (H7a) and at 6-month follow-up (H7b) than the control group.

H8: The intervention group shows a significant increase in the targeted behavioural determinants that are included compared with the control group at the postintervention measure (H8a) and at 6-month follow-up (H8b). The exact behavioural determinants depend on the results of the optimisation phase.

Methods

Design

In the evaluation phase, the optimised intervention group will be compared with an active control group in a double-blind randomised controlled trial. The control group has access to the app and receives the basic module to test the effect of the final intervention. After random assignment, all participants will have access to the information from the Federal Office of Public Health[50] on infection prevention behaviours, specifically on hand hygiene. The intervention group will additionally receive the optimised intervention.

Population and participants

The study population for both phases is described in the optimisation phase above. In the evaluation phase, participants are excluded if they have already attended the optimisation trial.

Sample size calculation

In the evaluation phase, 205 new subjects are to be randomised. The intention is to use a statistical analysis

with an independent samples t-test adopting an error probability and statistical power of α=0.05 and β=0.80 so that at least a small to intermediate intervention effect of Cohen's d=0.35 should be detectable.[51] Allowing 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 optimisation phase. Furthermore, the same analyses for intervention fidelity will be applied as described in the optimisation phase.

Procedures

The total duration of the evaluation phase, including recruitment and data collection, is 9 months (start: 1 January 2022) or until a total sample size of 245 participants have been enrolled. First, participants give informed consent online and receive information to download the study app. Then, participants will receive the baseline questionnaire and subsequently begin the first hand hygiene diary. Afterwards, participants will be invited to use a 4-week optimised intervention consisting of the content identified as most effective in promoting correct hand hygiene at key times in the optimisation phase. Again, participants will begin a hand hygiene diary at the end of each week during the intervention. After the intervention, participants will be asked to complete the post-test questionnaire. Finally, participants will receive a 6-month follow-up, which includes a diary day and the follow-up questionnaire (see figure 3). At the end of the study, all participants will be informed about the purpose and the aim of the study by email.

Enrolment

The evaluation phase includes the same enrolment procedure as described in the optimisation phase. In addition, interested people will be asked in the informed consent procedure whether they have already participated in the optimisation trial.

Data collection

Quantitative data collection

Data collection for all quantitative measures is the same as in the optimisation phase and uses the study app *soapp*. Participants receive a questionnaire at the beginning (pretest), after the intervention (post-test) and after 6 months (follow-up). As in the optimisation phase, all participants will have the chance to win one of three iPhone 12s and are offered a small gift after 2 weeks.

Intervention

Based on the results of the optimisation phase in accordance with the optimisation criteria, the optimised intervention includes the most effective and acceptable combination and sequence of the three intervention modules.
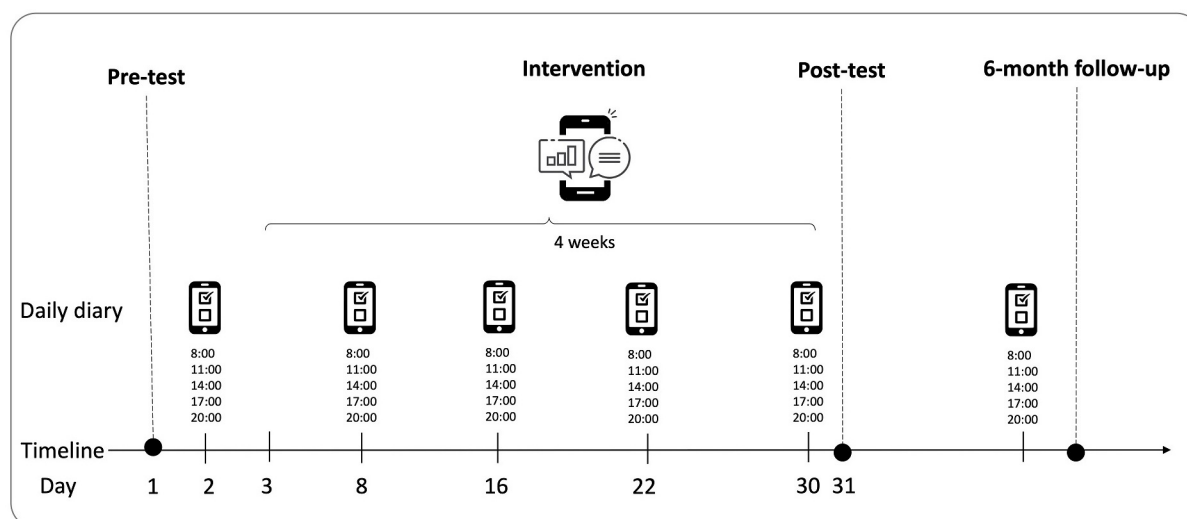
Data analysis

The effects of the intervention will be assessed as changes in primary and secondary outcomes from pretest to post-test and follow-up using an independent samples t-test. The analyses will be controlled for participants, who already attended the optimisation trial.

Data management, data security and quality control

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

TRIAL STATUS

At the time of manuscript submission on 5 August 2021, the preparation phase, including the development of the intervention modules and the programming of the study app, was completed (cf figure 4). Two hundred and seventy-nine people have registered for participation in

Figure 3 Procedure evaluation phase.

Figure 4 Study timetable with the preparation, optimisation and evaluation phases from 2020 to 2022. RCT, randomised controlled trial.

the study, and 127 participants have already completed the study. Recruitment for the optimisation phase continued until August 2021, the enrolment for the evaluation phase will take from January to March 2022 and data collection ends in September 2022 (figure 4).

ETHICS AND DISSEMINATION

Ethical approval was obtained from the Cantonal Ethics Commission Bern of the Swiss Association of Research Ethics Committees (Protocol ID: 2021-00164). Final results will be presented in peer-reviewed journals and at conferences. Good Clinical Practice regulations will be followed, and written informed consent will be obtained from all participants.

Results will be disseminated through peer-reviewed publications, presented at conferences and published on ClinicalTrials.gov. First, the results of the optimisation trial, including the final decision on the optimisation criteria, will be submitted to a peer-reviewed journal. At the end of the trial, the results of the evaluation phase will be published. Requests for data access should be sent to JI (ORCID: 0000-0002-7884-3222).

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 principal investigator by email after 1–2 weeks (see online supplemental file 4).

Provenance and peer review Not commissioned; externally peer reviewed.

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