Promoting hand hygiene during the COVID-19 pandemic: A parallel randomized trial for the optimization of the Soapp app

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Abstract

Background: Hand hygiene is an effective behavior for preventing the spread of the respiratory disease COVID-19, and was included in public health guidelines worldwide. Behavior change interventions addressing hand hygiene have the potential to support the adherence to public health recommendations and thereby prevent the spread of COVID-19. However, randomized trials during a pandemic are largely absent, wherefore there is little knowledge about the most effective strategies to promote hand hygiene during an ongoing pandemic. The present study addresses this gap by presenting the results of the optimization phase of a Multiphase Optimization Strategy of Soapp, a smartphone app to promote hand hygiene in the context of the COVID-19 pandemic.

Objective: The goal was to identify the most effective combination and sequence of three theory- and evidence-based intervention modules (Habit, Motivation, Social Norms) to promote hand hygiene. To this aim, nine versions of Soapp were developed (conditions) and two optimization criteria were defined: i) condition with largest increase in hand hygiene at follow-up and ii) condition with highest engagement, usability and satisfaction based on quantitative and qualitative analyses.

Methods: The study design was a parallel randomized trial with nine intervention conditions defined by the combination of two intervention modules and their sequence. The trial was conducted from March to August 2021 with interested participants of the Swiss general population (N = 232 randomized). Randomization was performed by Qualtrics and blinding was ensured. The duration of the intervention was 34 days. The primary outcome was self-reported hand hygiene at follow-up, assessed via an electronic diary. Secondary outcomes were user engagement, usability and satisfaction, assessed at follow-up. Participants were further invited for semi-structured exit interviews (n = 9). A set of Anovas was performed to test the main hypotheses while thematic analysis was performed to analyze the qualitative data.

Results: Results showed a significant increase in hand hygiene over time across all conditions. There was no interaction effect of time and intervention condition. Likewise, no between-group difference in engagement, usability and satisfaction emerged. Seven themes (e.g., “variety and timeliness of the workload”, “social interaction”) were found in the thematic analysis.

Conclusions: The current findings evidenced no effect of intervention condition of a habit, motivation and social norms module on hand hygiene, engagement, usability and satisfaction. In the absence of quantitative differences, we relied on the results from the thematic analysis to select the best version of Soapp for the evaluation phase. Clinical Trial: NCT04830761

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Abstract

Background: Hand hygiene is an effective behavior for preventing the spread of the respiratory disease COVID-19, and was included in public health guidelines worldwide. Behavior change interventions addressing hand hygiene have the potential to support the adherence to public health recommendations and thereby prevent the spread of COVID-19. However, randomized trials during a pandemic are largely absent, wherefore there is little knowledge about the most effective strategies to promote hand hygiene during an ongoing pandemic. The present study addresses this gap by presenting the results of the optimization phase of a Multiphase Optimization Strategy of *Soapp*, a smartphone app to promote hand hygiene in the context of the COVID-19 pandemic. **Objective:** The goal was to identify the most effective combination and sequence of three theory- and evidence-based intervention modules (Habit, Motivation, Social Norms) to promote hand hygiene. To this aim, nine versions of *Soapp* were developed (conditions) and two optimization criteria were defined: *i)* condition with largest increase in hand hygiene at follow-up and *ii)* condition with highest engagement, usability and satisfaction based on quantitative and qualitative analyses. **Methods:** The study design was a parallel randomized trial with nine intervention conditions defined by the combination of two intervention modules and their sequence. The trial was conducted from March to August 2021 with interested participants of the Swiss general population (N = 232 randomized). Randomization was performed by Qualtrics and blinding was ensured. The duration of the intervention was 34 days. The primary outcome was self-reported hand hygiene at follow-up, assessed via an electronic diary. Secondary outcomes were user engagement, usability and satisfaction, assessed at follow-up. Participants were further invited for semi-structured exit interviews (n = 9). A set of Anovas was performed to test the main hypotheses while thematic analysis was performed to analyze the qualitative data. **Results:** Results showed a significant increase in hand hygiene over time across all conditions. There was no interaction effect of time and intervention condition. Likewise, no between-group difference in engagement, usability and satisfaction emerged. Seven themes (e.g., “variety and timeliness of the workload”, “social interaction”) were found in the thematic analysis. **Conclusions:** The current findings evidenced no effect of intervention condition of a habit, motivation and social norms module on hand hygiene, engagement, usability and satisfaction. In the absence of quantitative differences, we relied on the results from the thematic analysis to select the best version of Soapp for the evaluation phase. **Trial registration:** ClinicalTrials.gov: NCT04830761. **Funding:** Ursula-Wirz Stiftung

Keywords: COVID-19, hand hygiene, behavior change intervention, MOST, Smartphone applications, Motivation, Habit, Social norm

Introduction

Hand hygiene is an effective behavior for decreasing the transmission of respiratory illnesses [1,2], including Coronavirus disease 2019 (COVID-19)[3]. Therefore, recommendations to perform correct hand hygiene at key times have been included in public health guidelines worldwide to counter the spread of COVID-19 [4]. To facilitate the adoption of public health guidelines, the development and evaluation of effective behavior change interventions was identified as a priority of the COVID-19 research agenda [5]. Particularly due to the fact that limited or no contextualized evidence was available on the effectiveness of behavior change interventions during pandemics[5]. Even though evidence synthesis reports became available during the COVID-19 pandemic (July-December 2020) showing a medium, positive effect of hand hygiene interventions developed to counter the spread of various respiratory viruses (e.g., influenza, respiratory syncytial virus, adenovirus) [6], their validity and relevance to the COVID-19 pandemic can be questioned. For example, the reviewed studies included interventions targeted at diverse respiratory infections which were not pandemics (e.g., influenza, flu, colds) or did not lead to the spread of a pandemic of the magnitude of COVID-19 (e.g., pandemic influenza A H1N1).

The need for research on effective behavior change interventions to promote hand hygiene during a pandemic was further confirmed by the fluctuation in hand hygiene over the course of the COVID-19 pandemic. At first, results indicated high adherence by the public. During the first wave of the pandemic (i.e., between March and May 2020) studies suggested that *i*) hand hygiene was one of the most adopted protective behavior against the spread of the COVID-19 [7], and *ii)* the frequency and correctness of hand hygiene behavior in key situations (i.e., after coughing/sneezing/blowing one's nose and when getting home or into work) improved compared to the period before the pandemic outbreak [8,9]. However, research including longer periods of the pandemic showed decreasing hand hygiene over time. For example, a study conducted from May 2020 to August 2021 showed that almost one third of adults from the general population did not comply with hand hygiene recommendations and some of them had no intention to change their behavior [10]. Additionally, there is evidence of significant associations between hand hygiene and indicators of the pandemic trajectory (e.g., the increase in recent cases of COVID-19 morbidity is associated with an increase in frequency of self-reported hand hygiene) [11]. Taken together, the literature suggests that hand hygiene is not consistently performed throughout a pandemic and is prone to variations over time. Therefore, fostering sustained hand hygiene by the means of effective behavior change interventions represented a public health priority to contrast the spread of COVID-19 and future pandemics.

During an ongoing pandemic, in which social contact should be limited, digital interventions have the advantage that no personal contact is needed, yet they can be personalized and potentially reach an unlimited number of people in their daily lives. Interventions based on smartphone apps can deliver behavior change techniques (BCTs) [12] in real life that could lead to substantial population-level impact and long-term health behavior change [13]. However, recent reviews pointed out that there is limited knowledge about how to effectively promote hand hygiene using digital interventions in the general population [6,14].

The present study

To address these research gaps, we devised a multiphase optimization strategy [15] to develop and test Soapp, an effective smartphone-based behavior change intervention to promote hand hygiene during the ongoing COVID-19 pandemic [16]. The MOST provides a rigorous and efficient methodology to develop a multicomponent intervention in a systematic way in three distinct phases: preparation, optimization, and evaluation. The MOST was deemed particularly suitable during the COVID-19 pandemic because prior knowledge on the most effective behavior change strategy in a similar context was scarce[5,6]. In the preparation phase, we developed three intervention modules, tackling habit, motivation, and social norms, based on behavior change theory and empirical evidence[16].

The current paper focuses on the optimization phase of Soapp, which aims to identify the most effective combination and sequence of the developed intervention modules to be included in the subsequent evaluation phase. As described in the study protocol [16], in the optimization phase, we compared nine

different combinations of the three developed modules (i.e., habit, motivation, social norms). Two optimization criteria were defined in order to select the best intervention for the subsequent evaluation phase. The optimization criteria were to select *i)* the condition with largest increase in hand hygiene at key times at follow-up and *ii)* with highest engagement, usability and satisfaction. Regarding the first criterion, we tested the following pre-registered hypotheses [16]:

- H1: The intervention groups show a significant increase in correct hand hygiene at key times after 4 weeks (T3) of intervention compared to baseline (T1).
- H2: The intervention groups significantly differ in their effects on correct hand hygiene behavior at key times (T1-T3).

In case of significant between-group differences in hand hygiene at key times, post-hoc tests were performed to determine the most effective condition. Additionally, we investigated the unique contribution of each module by testing the following, not pre-registered hypotheses:

- H3: The intervention groups containing the *habit* module show a significant increase in correct hand hygiene behavior at key times (T1-T3) compared to the groups without the *habit* module.
- H4: The intervention groups containing the *motivation* module show a significant increase in correct hand hygiene behavior at key times (T1-T3) compared to the groups without the *motivation* module.
- H5: The intervention groups containing the *social* module show a significant increase in correct hand hygiene behavior at key times (T1-T3) compared to the groups without the *social* module.

The second optimization criterion leveraged a combination of quantitative and qualitative methods to explore participants' engagement and satisfaction with the app as well as the usability. This criterion was tested with the following hypotheses:

- The intervention groups significantly differ regarding engagement (H6), usability (H7), satisfaction (H8) with the intervention (T3).
- Additionally, semi-structured interviews were conducted to explore what aspects and features of Soapp were perceived as more usable and more important for supporting engagement and satisfactory experiences after 34 days of usage of the app.

As secondary outcomes, we had pre-registered a series of hypotheses regarding the psychological mechanisms and health impact of the intervention that did not inform the optimization decision. We reported them in the appendix for completion (see Multimedia Appendix 1).

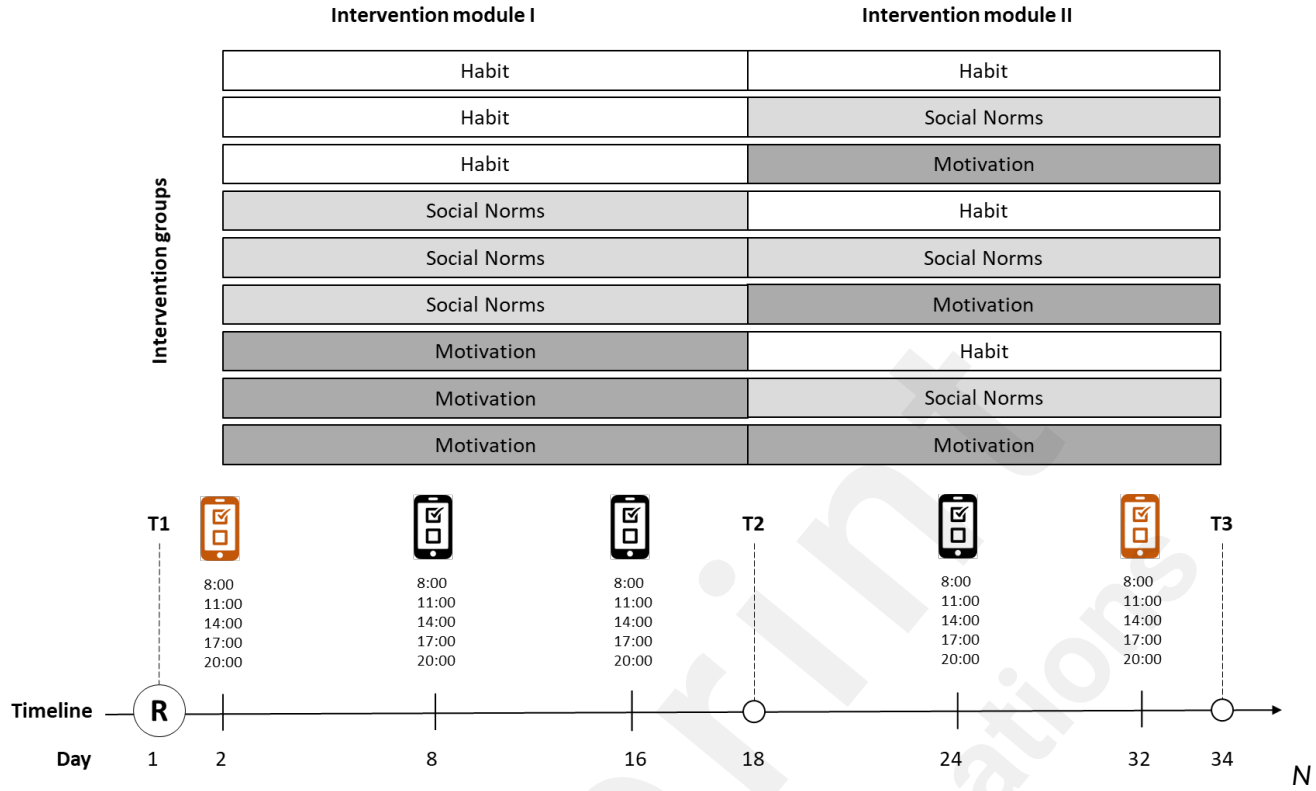
Methods

Study design

The study design for the optimization phase was a double-blind parallel randomized trial. Participants were randomized to one of nine intervention groups in a 1:1:1:1:1:1:1:1:1 ratio and completed two consecutive intervention modules, as shown in Figure 1. The total duration of the optimization study (i.e., recruitment, data collection) was set to six months (start: 26 March 2021) or until a total sample size of 465 participants was enrolled, whichever came first. The duration of the optimization trial for each participant (i.e., time between T1-T3) was 34 days.

At the end of the study, as part of the second optimization criterion, qualitative interviews were conducted with a subsample, to collect in-depth information about the engagement, usability and satisfaction with the intervention. The current trial is registered at ClinicalTrials.gov (NCT04830761) and the reporting is in line with the CONSORT guidelines [17] (see supplemental materials).

Figure 1. Intervention optimization



ote. R = Randomization; Red diaries represent baseline (T1) and follow-up (T3) assessments for the primary outcome (hand hygiene).

Participants

The target population for the Soapp app were German speaking adults from the Swiss population interested in using an app to improve hand hygiene behavior. Inclusion criteria were: i) being at least 18 years old, ii) owning a smartphone with mobile access to the internet, iii) being proficient in the German language, and iv) having signed an electronically informed consent form to participate in the study. As presented in the study protocol [16], the initial target sample size for the optimization phase was 387 participants. The sample size was calculated in order to perform a repeated-measures ANOVA with a within (time: T1-T3) – between (intervention group) interaction. The sample size was determined with an a priori power analysis with g*power[18] (β= .80, α = .05, f = 0.1). Assuming a 20% attrition during the course of the intervention, the target sample size was raised to 465 participants for the enrolment into the study. However, due to both trial and project timeline, we stopped recruiting after five months, for a total study duration of six months.

A subsample (n = 9) took part in the qualitative interviews. The recruitment was based on participants' willingness to take part in semi-structured interviews as assessed at the end of last survey (T3). For the qualitative interview, the aim was to recruit an even number of participants per intervention module and according to hand hygiene adherence: low adherence, medium adherence and high adherence to hand hygiene. Participants in the 33rd percentile or lower were assigned to the low adherence group (n = 3), participants between the 34th and 66th percentiles were classified to the medium adherence group (n = 3), and participants on the 67th percentile or higher were classified to the high adherence group (n = 3). The sample size (n = 9) was smaller than the one reported in the study protocol (n=15) because the recruitment stopped when theoretical saturation was achieved (i.e., no new themes emerged) [19].

Outcomes

Primary outcome

The primary outcome of the study (i.e., the first optimization criterion), was the frequency of correct hand hygiene at key times at follow-up, assessed via Ecological Momentary Assessment with the support of an electronic diary embedded in Soapp. On diary days (day 2, 8, 16, 24, 32), participants were prompted five times per day to indicate whether each of 13 key times to perform hand hygiene defined by the Swiss Federal Office of Public Health occurred (e.g., arriving home, after using the toilet; see Table 3). For each situation that occurred, participants were asked how often they correctly washed or disinfected their hands in that specific situation. The 5-point response scale ranged from never (1) to always (5). The main outcome was operationalized as the mean reported frequency of correct hand hygiene across all the indicated key times and ranged from 1 to 5. In order to test the first and second hypotheses, the assessment points considered for hand hygiene behavior were the first diary at day 2 (T1) and the last diary day at day 32 (T3).

Table 2. List of all key times when to perform correct hand hygiene according to the Swiss Federal Office of Public Health [20].

Item	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 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

Note. Type = 'General' indicates key times that are recommended in general and before the COVID-19 pandemic occurred.

Secondary outcomes

Engagement, usability and satisfaction (i.e., second optimization criterion) were measured at T3. User engagement was assessed with the DBCI Engagement Scale[21], a 7-point Likert scale ranging from *not at all* (1) to *extremely* (7) (Cronbach's Alpha = .78). Intervention usability was assessed with the System Usability Scale (SUS) [22], a 6-point Likert scale ranging from *I don't agree at all* (1) to *I agree completely* (6) (Cronbach's Alpha = .80). Satisfaction was assessed using the ZUF-8[23], a 4-point Likert scale ranging from (0) to (3) (Cronbach's Alpha = .89).

Other variables assessed during the study but not relevant to the current report are described in the

clinical trial registration and the corresponding results are presented in the supplemental materials (see Multimedia Appendix 1).

Procedure

Participants were recruited via social media (e.g., Facebook, Instagram), mailing lists, and leaflets with the help of a market research company, aiming to recruit a broad range of people from the German speaking adult Swiss general population in terms of gender, age and socio-economic status. Interested people who clicked on the link of the campaign were led to a landing page with the study information. Those who chose to continue were redirected to the study page on RedCap[24] where they could read and watch a video of the study information, fill out an eligibility and consent survey, and sign the e-consent form. After providing electronically informed consent to participate in the study, participants received a registration code via email and were guided to download the Soapp app from iTunes or Google Play Store and register to it. The day after the registration, participants received the baseline questionnaire (T1) and were then randomized to one of the intervention groups. Randomization was implemented in Qualtrics, which preserved the allocation concealment. Additionally, the researchers involved in the study were blinded to intervention assignment because the participant identifier was pseudo-anonymized before randomization. The day after the randomization, participants filled out the first hand hygiene diary. The diary included five 1-minute questionnaires per day to avoid retrospective bias in reporting hand hygiene [25].

The study took 34 days and included two intervention modules of two weeks each (see Figure 1). During the first module, participants completed the hand hygiene diary on day 2, 8 and 16. After the first module, participants received the second questionnaire (T2) and a second intervention module which followed the same structure as the first one. After completing T2, participants were offered a small gift (i.e., a bar of hand-soap and a thank you card) in order to prevent attrition, that was sent to their homes. During the second intervention module, they filled out the hand hygiene diaries at day 24 and day 32. At the end of the second module, participants received the final questionnaire (T3). Participants were given the chance to win one of three iPhone 12s after both optimization and evaluation phases of the study were completed. Questionnaires and the diaries were integrated in Qualtrics services using Soapp's API, and the participants' data were stored on Qualtrics.

Participants who were given the option and volunteered for the qualitative study were interviewed via telephone by a study team member (CB). This 30 min interview was recorded and included questions about the usability of the app as well as the overall experience with the intervention modules in terms of satisfaction and engagement (see multimedia appendix 2).

Intervention

In the optimization phase, each arm of the parallel randomized trial was characterized by a unique combination and sequence of two of three intervention modules: motivation, habit, and social norms (Figure 1). The definition of the modules was the outcome of the preparation phase in which a theory- and evidence-based approach was followed. The resulting content is synthesized in Table 1 and detailed in the supplemental material 1 of the protocol paper [16].

The modules were delivered to participants via their personal smartphone through the study application Soapp. They were comparable in user time and extent of content, and each module took two weeks to be completed. Each intervention condition also included a basic module that provided information on hand hygiene to all participants. During the configuration process, the Soapp app went through various iterative testing cycles to refine the content of each module and improve the usability. The Soapp app contained all the information needed to use it and there was no direct contact with the study team.

Table 1. Content of the modules

Module	TDF domain	Behavioral predictor	Behavior Change Technique
Basic	Goals	Intention	1.1 Goal setting (behavior)
	Skills	Skills	4.1 Instruction on how to perform behavior
	Knowledge	Knowledge	5.1 Information about health consequences
	Environmental context and resources	Resources/material resources (availability and management)	1.4 Action planning
Motivation	Goals	Intention	1.1 Goal setting (behavior)
	Beliefs about consequences	Risk perception	5.1 Information about health consequences
		Attitude	5.2 Salience of consequences
		Outcome expectancies	9.2 Pros and cons
		Intention	5.2 Salience of consequences
	Beliefs about capabilities	Self-efficacy	1.2 Problem solving 15.1 Verbal persuasion about capabilities 15.3 Focus on past success
	Reinforcement	Intention	10.9 Self-reward
Habit	Knowledge	Knowledge	4.2. Information about antecedents
	Memory, attention, and decision processes	Action control	2.3 Self-monitoring of behavior
	Goals	Action planning	1.4 Action planning 7.1. Prompts/cues
	Skills, Goals	Habit strength	8.1 Behavioral practice/ rehearsal 8.3 Habit formation
	Behavioral regulation	Habit strength	7.1 Prompts/cues (physical cue)
Social Norms	Social Influences	Descriptive norm	2.1 Monitoring of behavior by others without feedback 2.2 Feedback on behavior 6.2 Social comparison 10.4 Social reward 10.5 Social incentive

		Injunctive norm	5.1 Information about health consequences 6.3 Information about others' approval 9.1 Credible source 10.5 Social incentive 12.1 Restructuring the physical environment

Data analysis

Handling of missing data

Missing data were handled according to the intention-to-treat (ITT) principle[26]. The ITT analysis includes every participant who was randomized. It ignores noncompliance, protocol deviations from the intervention modules, and anything that happens after randomization. ITT analysis avoids overoptimistic estimates of the efficacy of an intervention resulting from the removal of noncompliers by accepting that noncompliance and protocol deviations that are likely to occur in practice. In line with previous research[27], missing data for hand hygiene behavior were replaced using the last observation carried forward (LOCF) approach.

Hypothesis testing

To test the hypotheses related to the first optimization criterion, a repeated-measures ANOVA with a within-between interaction was used. The *within* effect is represented by the difference in hand hygiene between T1 and T3 (H1), while the *within-between* interaction was represented by the change in correct hand hygiene behavior between T1 and T3 across all nine intervention groups (H2). If the groups differed significantly, post hoc tests were performed to identify the most effective intervention group. To test hypotheses H3, H4 and H5, three dummy variables were created: *habit exposure*, *motivation exposure*, and *social exposure*. These variables indicate whether a participant was exposed to the corresponding module during the intervention. Then, three repeated-measures ANOVAs, one for each dummy variable, with a within-between interaction were performed. Each ANOVA tested the interaction between time and the exposure to a specific module (see Table 3). Eventually, for the second optimization criterion, three one-way ANOVAs were performed to test differences across conditions at T3 in terms of engagement (H6), usability (H7), and satisfaction (H8). For all the hypotheses, a set of sensitivity analyses with robust and non-parametric (i.e., Kruskal–Wallis test) ANOVAs was performed to account for potential unequal sample sizes and non-normal distribution of the data.

Analytical software

The packages *ez* and *WRS2* from the statistical software R (Version 4.1.2) were used to perform parametric and robust Anovas respectively. The data and R code used for the main analyses are available on the Open Science Framework repository platform (https://osf.io/pzhqx/).

Table 3. Summary of hypothesis tests

Hypotheses	Pre-registered	Dependent variable	Within Factor	Between factor
First optimization criterion based on primary outcomes				
H1	Yes	Hand hygiene	Time: T1-T3	-
H2	Yes	Hand hygiene	Time: T1-T3	Intervention groups
H3	No	Hand hygiene	Time: T1-T3	Habit exposure
H4	No	Hand hygiene	Time: T1-T3	Motivation exposure
H5	No	Hand hygiene	Time: T1-T3	Social exposure
Second optimization criterion based on secondary outcomes				
H6	No	Engagement	-	Intervention groups

H7	No	Usability	-	Intervention groups
H8	No	Satisfaction	-	Intervention groups

Qualitative analysis

Post-intervention user engagement, usability and satisfaction were explored using semi-structured interviews. The interviews were transcribed verbatim and transcripts were analyzed using thematic analysis [28]. Thematic analysis is characterized by 6 phases: (1) familiarizing with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report. Data and repeated patterns that were considered pertinent to the aims of the study were coded by a co-author (CR). New inductive codes were labeled as they were identified during the coding process and the results of the coding were iteratively discussed by 2 co-authors (CR and JI). The next stage involved searching for themes; CR reviewed the codes one-by-one, organizing the findings to combine different codes that focus on similar aspects. The ordered data were reviewed and revised in discussion among three co-authors (CR, JI and DB) and were subsequently organized into themes. Resolution of disagreements and agreement on the final themes was reached through discussion among CR, JI and DB. After having defined and named themes, examples of relevant transcripts were selected to illustrate themes. Data were analyzed in their original language to preserve original meanings. Illustrative quotes were translated by CR. Conclusions were drawn on possible improvement of Soapp to optimize the intervention effectiveness and usability for the evaluation phase.

Results

The recruitment for the optimization trial began on 27th March 2021 and ended on 28th July 2021. Follow-up data were collected between 29th April and 25th August 2021. Due to both trial and project timeline, we stopped the trial six months after the start of the study, with the recruitment lasting five months. Two hundred thirty-two participants were recruited and randomized into one of the nine intervention conditions. Among these, 14 participants never filled out any of the five hand hygiene diaries while other 27 participants didn't complete the first diary at T1. A further participant completed the first diary but didn't encounter any of the key situations to perform hand hygiene during that day. Therefore, these participants (n = 42) were excluded from the analysis because the main outcome (i.e., hand hygiene) at T1 was missing. Out of the 232 participants who were randomized, 190 (82%) filled out the hand hygiene diary at T1 and 118 of these (51% of the randomized participants) completed the hand hygiene diary at T3. Figure 2 shows the participants' flow through randomization, T1 diary assessment and T3 diary assessment for each intervention group. For the secondary analysis we included only those participants who filled out the T3 panel assessment because the dependent variables were assessed at T3 only.

Baseline characteristics

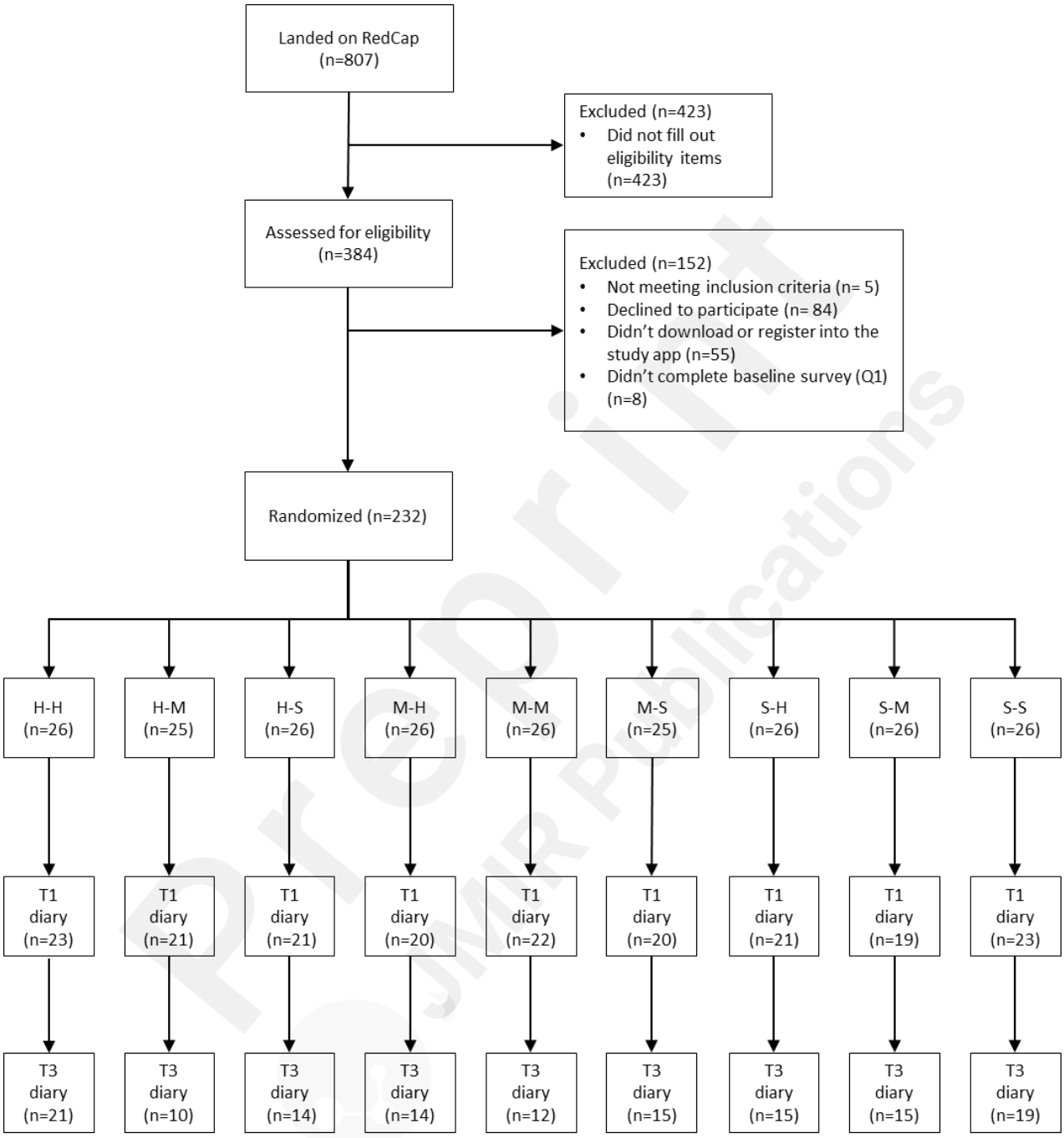
Socio-demographic and hand hygiene behavior at baseline are reported in Table 4. The figures refer to the 190 participants who filled out the first diary at T1. Participants' mean age was 39.9 years, 73% were women, 66% had high-school qualifications, 54% were employed and 23% were living alone. Descriptive statistics in hand hygiene behavior (mean = 4.11; median = 4.22; skewness = -.96) suggested that hand hygiene behavior was already high at baseline, with a moderate left tailed distribution.

Dropout analysis was performed to investigate baseline differences between participants who finished the study and those who dropped out at any point during the intervention. We analyzed all the 232 randomized participants and the ones who didn't complete the last panel assessment at T3 were categorized as dropouts (n = 83). The results suggested no baseline differences between dropouts and retainers regarding age ($F(1, 230) = 2.17$, $p = .142$), sex ($X^2(1) = .36$, $p = .546$), hand hygiene ($F(1, 229) = .24$, $p = .625$), or intention to increase hand hygiene behavior ($F(1, 230) = .72$, $p = .396$).

First optimization criterion: Change in hand hygiene behavior

Main effects of time, and interaction between time and intervention group are reported in Table 5. The main effect of time (F = 10.95, p < .01) was statistically significant (H1) while the interaction between intervention group and time was not (H2). Results referring to H3, H4, and H5 suggested no effect of the exposure to a specific module during the course of the intervention. Sensitivity analysis with robust approach confirmed the same results. As part of sensitivity analysis, the main hypotheses were also tested without applying any missing value imputation algorithm. Results are available in Multimedia Appendix 3 and confirm the time effect and the null findings for the interaction effect.

Figure 2. Participant recruitment flow



Note. Intervention groups are specified as follows: H-H = Habit-Habit; H-M = Habit-Motivation; H-S = Habit-Social; M-H = Motivation-Habit; M-M = Motivation-Motivation; M-S = Motivation-Social; S-H = Social-Habit; S-M = Social-Motivation; S-S = Social-Social

Table 4. Participant characteristics and descriptive statistics on hand hygiene, engagement, usability and satisfaction

	All	H-H	H-M	H-S	M-H	M-M	M-S	S-H	S-M	S-S
Baseline										
Sample size	190	23	21	21	20	22	20	21	19	23
Mean age (SD)	39.9 (15.9)	38.6 (16.8)	37.0 (14.6)	42.6 (15.8)	34.6 (13.2)	41.1 (16.2)	44.3 (17.0)	41.2 (16.1)	39.5 (17.8)	39.8 (16.4)
Women (%)	139 (73)	16 (70)	17 (81)	18 (86)	15 (75)	14 (64)	14 (70)	13 (62)	16 (84)	16 (70)
High school education (%)	129 (68)	16 (70)	12 (58)	14 (67)	16 (80)	16 (73)	14 (70)	14 (67)	15 (79)	12 (52)
Employed (%)	101 (53)	12 (52)	13 (62)	11 (52)	11 (55)	12 (55)	11 (55)	11 (52)	8 (42)	12 (52)
Living alone (%)	49 (23)	8 (35)	4 (19)	6 (29)	4 (20)	7 (32)	7 (35)	5 (24)	3 (16)	5 (22)
Mean HH (SD)	4.01 (.82)	3.88 (.83)	4.03 (.69)	3.95 (.83)	3.91 (.80)	4.09 (.73)	4.12 (.76)	4.13 (.89)	4.08 (.98)	3.92 (.96)
Follow-up										
Mean HH (SD) with NA imputation	4.18 (.85)	4.17 (.87)	4.23 (.71)	4.10 (.78)	3.91 (.73)	4.13 (1.00)	4.35 (.76)	4.10 (.01)	4.21 (.94)	4.42 (.79)
Mean HH (SD) without NA imputation	4.21 (.91)	4.36 (.69)	4.52 (.52)	4.27 (.79)	3.86 (.72)	3.99 (1.29)	4.61 (.42)	3.77 (1.23)	4.03 (1.17)	4.42 (.89)
Mean Engagement (SD)	4.42 (.94)	4.67 (.91)	4.76 (.73)	4.82 (.92)	3.86 (1.04)	3.95 (.90)	4.46 (.75)	4.29 (.68)	4.53 (1.00)	4.41 (1.10)
Mean Usability (SD)	4.89 (.72)	5.16 (.66)	5.07 (.66)	5.15 (.59)	4.68 (.71)	4.70 (.79)	4.61 (.81)	4.49 (.85)	5.14 (.41)	4.98 (.69)
Mean Satisfaction (SD)	2.01 (.55)	2.13 (.44)	2.12 (.59)	2.24 (.42)	1.75 (.69)	1.75 (.61)	2.05 (.43)	1.80 (.69)	2.18 (.46)	2.09 (.43)

Note. SD = Standard deviation; HH = Hand Hygiene. Intervention groups are specified as it follows: H-H = Habit-Habit; H-M = Habit-Motivation; H-S = Habit-Social; M-H = Motivation-Habit; M-M = Motivation-Motivation; M-S = Motivation-Social; S-H = Social-Habit; S-M = Social-Motivation; S-S = Social-Social.

Table 5. Main effects and interactions between modules on hand hygiene behavior at key times

				Parametric ANOVA					Robust ANOVA	
Hp	**Outcome**	**Factor**	**N**	**F**	**df**	***P* value**	**Part Eta Sq[2]**	**95% CI[3]**	**coefficient[4]**	**p-value**
H1 - H2	Hand Hygiene	Group[1]	190	.33	8	.954	.01	[0.00, 1.00]	.75	.646
		Time (T1-T3)		**10.95**	**1**	**.001**	**.06**	**[0.01, 1.00]**	**11.71**	**.001**
		Time*Group		1.19	8	.306	.05	[0.00, 1.00]	.95	.487
H3	Hand Hygiene	Habit	190	1.25	1	.265	.01	[0.00, 1.00]	3.03	.085
		Time (T1-T3)		**10.87**	**1**	**.001**	**.05**	**[0.01, 1.00]**	**16.12**	**<.001**
		Time*habit		1.07	1	.301	.01	[0.00, 1.00]	1.33	.251
H4	Hand Hygiene	Motivation	190	.00	1	.995	.00	[0.00, 1.00]	.75	.387
		Time (T1-T3)		**10.86**	**1**	**.001**	**.05**	**[0.01, 1.00]**	**14.80**	**<.001**
		Time*Motivation		.94	1	.332	.00	[0.00, 1.00]	.58	.446
H5	Hand Hygiene	Social	190	.75	1	.387	.00	[0.00, 1.00]	2.21	.140
		Time (T1-T3)		**10.83**	**1**	**.001**	**.05**	**[0.01, 1.00]**	**14.87**	**<.001**
		Time*Social		.41	1	.522	.00	[0.00, 1.00]	.34	.559
				F	**df**	**p-value**	**Eta Sq[2]**	**95% CI**	**chi-squared[5]**	**p-value**
H6	Engagement	Group (T3)	148	**2.19**	**8**	**.03**	**.11**	**[0.01, 1.00]**	15.40	.051
H7	Usability	Group (T3)	148	**2.46**	**8**	**.02**	**.12**	**[0.01, 1.00]**	**16.05**	**.04**
H8	Satisfaction	Group (T3)	148	1.46	8	.176	.11	[0.00, 1.00]	12.38	.135

Note. [1]Group = Intervention group; [2]Part Eta Sq = Partial Eta Squared corresponds to the proportion of variance that a variable explains that is not explained by other variables; [3]CI = Confidence Intervals; [4]robust coefficients from WRS2 R package; [5]chi-squared value from Kruskasl-Wallis test.

Second optimization criterion: Participants engagament, usability and satisfaction

The effects of intervention group on engagement, usability and satisfaction are reported in Table 5. Results from parametric ANOVA suggested that the self-reported measures of engagement (F = 2.18, p < .05) and usability (F = 2.46, p < .05) differed across the nine intervention groups. Non-parametric ANOVA with Kruskasl-Wallis test showed significant differences across intervention groups only for usability (X^2 = 16.05, p-value < .05). However, both parametric and non-parametric post hoc comparisons with Bonferroni adjustment indicated no mean score differences in engagement and usability between any pair of intervention groups.

Qualitative analysis

Across nine interviews, seven themes emerged in relation to the research question (see Multimedia Appendix 4 for a summary of the themes and for additional extracts illustrating each theme). The themes were named “user experience and app functionality”, “importance of guidance”, “variety and timeliness of the workload”, “reasons for participation”, “change in awareness of hand hygiene and its implications”, “social interaction”, and “personal relevance”. Additionally, the following two subthemes were identified as part of the “social interaction” theme: “personal communication and connectedness”, and “social comparison”.

User Experience and App Functionality

A first theme that emerged concerns the user experience with the general aesthetic and functionalities of the app. Overall, satisfaction concerning the intuitive and simple handling of the app was high. Participants considered the usability to be pleasant. Regarding the app aesthetics, some participants were very satisfied with the simplicity of the layout; however, the majority would have preferred more visual structure.

> *What I liked in particular? Actually, how things were presented. Just the simplicity - all in all it was very simple.* [P7, Habit-Habit, Moderate Adherence [general comment about the app]]

> *Because it is a simple app. It is easy to use for everyone and everything is always nicely described.* [P4, Habit-Motivation, High Adherence [general comment about the app]]

Another point on which most participants agreed was that certain features of the app showed technical flaws, which negatively impacted their motivation.

> *So, when this annoying technical problem occurred - if you were to draw a curve now, it [my motivation] went up quite steadily at the beginning, and then slowly decreased due to this technical problem, and then when it was resolved it [my motivation] got back up again.* [P5, Motivation-Social, High Adherence]

> *In the beginning, I participated pretty motivated, but then my motivation actually dropped quite a bit after these technical problems I had when I could not manage to download these images.* [P8, Social-Habit, Low Adherence]

Importance of Guidance

Throughout the interviews, participants regularly highlighted the importance of receiving guidance within the app. Specifically, they mentioned the importance of clarity and meaning regarding the tasks the app was asking them to do.

> *I also thought it was nice that you kind of knew in the morning “ah today is a day with a big survey”, so that you could already plan “okay, today there are maybe a little bit more push messages coming in and I have to pay a little bit more attention”.* [P2, Habit-Habit, High Adherence]

> *It [the app] has certainly made you feel secure. Just in the sense that at certain - at certain points, where you perhaps did not even think of it yourself, when you had to do something, it*

provided you with input or ideas like "perhaps this is something you could do as well" - I have not even thought of that - or "there are still times when you should stick to it more often" and so. That was certainly a great benefit for me. [P7, Habit-Habit, Moderate Adherence]

The importance of guidance was also manifested as the need for a better overview of the participants' journey along the study. For instance, some participants would have liked more background information about the study to better understand the timeline or the reasons behind receiving certain tasks.

And otherwise maybe somehow a little bit more background information about what - why am I being asked these questions, so that I can see even more behind this algorithm and behind this concept and then it would become clearer to me why the same questions keep coming. So, a little bit, so even more background knowledge. [P3, Social, Habit, Low Adherence]

Although guidance was acknowledged as something important, too much direction was also perceived as overwhelming, for example too frequent push notifications.

Was that now at 10 o'clock, at 12 o'clock or at 2 o'clock, I do not remember any more in which intervals the push messages came in. At the end, I no longer knew at what point I had I received the last push notification - there, I lost overview. [P2, Habit, Habit, High Adherence]

Variety and Timeliness of the Task Load

Variety in daily engagement with the content of the app emerged as a central topic from the interviews. A few participants were satisfied with the degree of variety in the task load and timing of the content that the intervention offered. The majority, however, wished for significantly more variety in the task load and timing, particularly towards the end of the intervention.

Sometimes, it was just quiet, nothing happened. But later, once again it came "today something is happening", yes, I liked that. [P2, Habit-Habit, High Adherence]

Towards the end, when there were fewer and fewer exercises, I found it almost a bit boring. [P7, Habit-Habit, Moderate Adherence]

It is funny, my motivation dropped relatively quickly. It was on a high level - because I like to try out new things, I had the feeling that I was very motivated when I started. But then I felt like it was probably always going to be the same now, and there is never anything new. So, then my motivation sank. [P3, Social-Habit, Low Adherence]

Reasons for participation

In most interviews, participants mentioned their initial reasons for participating in the study. One of the most frequently reported motives was curiosity and interest in learning something new.

I thought, "yeah, sure, I can wash my hands. But do I know everything when they do a study? I could still learn something at the end, I'm not omniscient". And that's actually what mainly motivated me, this openness, I'm curious to see what else there is to learn. [P1, Habit-Habit, Moderate Adherence]

I am generally very interested in trying out new things and see what is new on the market, or what different things are currently being tested. And so, I was very curious. [P3, Social-Habit, Low Adherence]

Participants also expanded on why they kept using the app. One cited motive was the perceived obligation to complete the study.

Well, it [my motivation] certainly did not increase, it was more a matter of persevering - in the sense of whoever says A must also say B. It was said that you could drop out at any time, but still. [P9, Motivation, Motivation, Low Adherence]

Change in Awareness of Hand Hygiene and its Implications

A further theme was represented by the increase in participants' hand hygiene awareness due to the use of the app. The change in awareness seemed to have been generated by the fact that participants paid more attention to self-monitoring the target behavior.

> *That was simply my observation of my reaction then - you observe yourself during these four weeks incredibly - I do not know if you have also heard this from other people, but you start watching yourself.* [P5, Motivation-Social, High Adherence]

> *There were moments in between when I thought, "hey, I can still wash my hands without writing it down," but afterwards it hit me – I realized "now you have not done it three times"* [P6, Social-Social, Moderate Adherence]

The change in awareness generated a positive loop which led to an increase in frequency of hand hygiene behavior together with a shift in perception of the issue of hand hygiene and its implications.

> *I certainly washed my hands more than I had before. And therefore, I have the feeling that I have certainly benefitted from it [the intervention].* [P4, Habit-Motivation, High Adherence]

Social Interaction

The theme of social interaction was found several times during most interviews. Two subthemes contribute to defining the main theme according to the different social aspects that came to light during the interviews: personal communication and connectedness, and social comparison.

Subtheme 1: Personal Communication and Connectedness

Some participants particularly appreciated that the app communicated with them in a personal way. This led to a feeling of authenticity, so these participants had no longer the impression of interacting with a machine when using the app.

> *You can say that there is someone behind it. I never felt alone, it was not a one-way kind of communication. I always knew that behind these tasks was indeed a computer, but I still felt connected in a way.* [P2, Habit-Habit, High Adherence]

In contrast, other participants would have preferred an even more human-centered mode of delivery of the app content, for example, getting direct motivational support from other humans.

> *Maybe, despite everything, a video or something like that - or actually, as is often the case nowadays: a small video with other participants who motivate you. Because reading statistics and news is something else than when someone speaks directly to you.* [P8, Social-Habit, Low Adherence]

Some participants described having developed a feeling of connectedness with other app users over time. This led to a sense of community, which made them feel supported.

> *And then I think I had to answer this question three times. And at the end, I think that was at the final question, I thought "yes, I think it is cool that they are taking part, I do not know them, but I think it is cool that they are taking part, and I feel connected to them. [P2, Habit-Habit, High Adherence]*

Subtheme 2: Social Comparison

Participants who were exposed to the social module shared different opinions regarding the opportunity to compare their own behavior with that of other participants, which was a feature of the social module only. Indeed, while some participants expressed avoidance of social comparison and fatigue with the competition it created for them, others were pleased about the comparison with other users.

> *For me, personally, it was too much with the community and otherwise, because others cannot motivate me. Whether someone somehow achieved 100% or 50%, that is actually relatively indifferent to me. And it does not encourage me to become more or less active or whatever.* [P8,

Social-Habit, Low Adherence]

What did you like most about the app? [Interviewer] *That there were more who participated, and you could see how they were doing*. [P6, Social-Social, Moderate Adherence]

Wish for Personalization

One issue raised by almost every participant was the lack of personal relevance that the list of key moments for hand hygiene entailed. Being regularly asked about key situations that never occurred for them (e.g., not having children or not wearing contact lenses) led to a decrease in motivation to fill out the hand hygiene diaries.

So, for example, that when I am asked regularly over the course of four weeks if I washed my hands before I take my contact lenses out - if I am no lens wearer, then that question starts to annoy me over time. [P5, Motivation-Social, High Adherence]

Things are asked again and again, which do not concern you at all. This leads to a decrease in motivation. Now, I have to spend five minutes filling out the form again, even though it does not apply. [P3, Social-Habit, Low Adherence]

The desire to personalize the app also came up concerning other intervention content, for example the number of push notifications.

But maybe in the beginning you should be able to specify "I would rather have a little more [push notifications] or a little less". But what I have received, however, has been right for me. [P2, Habit, Habit, High Adherence]

Discussion

As part of a multiphase optimization strategy to develop and test a smartphone-based hand hygiene intervention during the COVID-19 pandemic, this intervention optimization parallel randomized trial aimed at identifying the best combination of intervention modules to be included in the subsequent evaluation phase of Soapp. Results from the main analyses confirmed that participants who took part in the study increased the frequency of correct hand hygiene at key times over time (H1). However, the intervention groups didn't differ in their effects on correct hand hygiene at key times (H2). Similarly, the exposure to specific modules was not associated with an increased hand hygiene over time (H3, H4, H5). Taken together, the findings related to the first optimization criterion suggest a promising increase in hand hygiene during the intervention, but didn't provide scientific evidence to prefer one version of Soapp or a specific module over the others. Similarly, the quantitative results from the second optimization criterion (H6, H7, H8) didn't show any difference in engagement, usability and satisfaction among the nine intervention modules at T3.

On the other hand, qualitative results revealed participants' perspectives about what characteristics and features of Soapp were perceived as supportive or, conversely, detrimental in terms of engagement, usability and satisfaction. The finding that the aesthetic and design of the app is important for participants to better enjoy their interaction with Soapp is in line with a previous study on health-related behavior change [29]. Participants expressed the desire for an app that is simple to use, intuitive, not cognitively demanding and that allows a smooth use of its functionalities. Such fundamental characteristics are deemed to guarantee satisfactory and engaging user experiences with Soapp. A second relevant aspect raised by the interviewed participants refers to the wish for receiving clear guidance about the tasks that the app proposes and the rationale behind. Participants also appreciated when they received *i)* information regarding the behavior change intervention they committed to and *ii)* suggestions (e.g., tips, problem solving strategies) on how to adhere to correct hand hygiene. However, to prevent declining engagement, the delivery of guiding content should be balanced and not overwhelming (e.g., push notifications). Such findings are in line with what found in a previous systematic review and empirical research on engagement with digital behavior change interventions[30–32]. A further topic is represented by the variety in the daily interaction with the app and the proposed tasks and activities. A task load that varies daily (i.e., days with more tasks and days with

fewer tasks) seems important to sustain engagement with Soapp. Additionally, regular provision of content over the course of the intervention was considered an important aspect of the app that might require some improvements. This aspect is of particular relevance as the receipt of an optimal dose of engagement may increase the effectiveness of digital interventions[30]. Another theme that emerged during the interviews concerned the reasons that led participants to join and remain engaged with the study. While curiosity and interest to learn new things were important to trigger initial engagement, perceived obligation was a reason to maintain it over time. This result provides further support to participants' demand for a better distributed workload and content over the course of the usage of Soapp. On the content side, as emerged in a previous study about adults' perspectives on health behavior change apps[33], participants appreciated those features that foster an increase sense of awareness around the target health-related behavior (i.e., hand hygiene) and what are the resulting benefits. Such results are in line with recent research conducted during the COVID-19 pandemic suggesting that self-monitoring is positively associated with hand washing [34]. Interestingly, participants reported that the awareness formed mostly because of filling out hand hygiene diaries which were included in the study as assessment tools and not as behavior change technique (i.e., self-monitoring). This aspect underlines how assessment tools and intervention strategies were not distinguished one from the other by participants but were perceived as part of a same user experience. A further theme that was at the center of participants' comments regarding social interaction. Consistent with previous findings[30–32,35], features supporting a sense of relatedness due to both a human-centered communication style (i.e., tone of voice) and the feeling of connectedness were considered necessary to create social commitment and, ultimately, for engagement and satisfactory interactions with Soapp. Such sense of relatedness was generated by the general user experience provide by the app (e.g., communication style) and not related to the features delivered by the social norm module. On the other hand, in line with previous findings regarding health-related digital interventions[29,31–33,35], a dual perspective emerged in relation to the features that purposefully provide opportunities for social comparison and were part of the social norms module. Indeed, while some participants expressed avoidance of social comparison because they considered their behavior change journey as a personal dimension of their life, others were pleased about the comparison with other users. For this reason, social comparison features can be seen as a two-edged sword for engagement as preference or aversion for such features are expected to vary across individuals. Eventually, participants believed that receiving more personally relevant content would strengthen their engagement with Soapp. Such comments were partially generated by participants' experiences in filling out hand hygiene diaries that refer to not applicable key times.

Implications for the evaluation phase of Soapp

Due to the null findings of the first optimization criterion, we were not able to identify the best intervention group based on the quantitative analysis of the primary outcome. Similarly, no between group differences emerged in relation to the second optimization criterion (i.e., engagement, usability, satisfaction). For these reasons, we relied on the results from the thematic analysis to derive the implications for the evaluation phase of Soapp. The resulting intervention design decisions based on this optimization study are summarized in Table 7.

Table 7. Intervention design recommendations for the evaluation phase of Soapp

Recommendation	Rationale
The social module is excluded from the next evaluation phase.	Habit and motivation modules seem best suited to leverage some of the themes emerged during the thematic analysis. For instance, themes like change in awareness and guidance can be better supported by the app features that characterize such modules (i.e., action planning tasks, self-monitoring,

	opportunity to schedule custom reminder, video on health implication). In addition, the social module might be detrimental for engagement since it embeds social comparison features that were perceived as counterproductive by some users.
A parallel delivery of modules is preferrable over a sequential one.	The specific sequence of intervention modules (i.e., habit-motivation VS motivation-habit) wasn't associated with differences in hand hygiene. Therefore, following the participants' needs identified as part of the theme 'Variety and Timeliness of the Workload', a parallel delivery of the selected intervention modules is preferable.
Define a more even distribution of the intervention content and notifications over the course of the study.	A parallel delivery of the modules would allow to distribute each module's content and tasks over 32 days instead of 16 days, as done during the optimization phase. Therefore, there is more flexibility to define the timeline of the intervention with the aim of balancing the daily task load and, ultimately, guaranteeing a more suited dose of content over the course of the intervention.

Limitations

This study is not without limitations. A main weakness is about the achieved sample size for testing the main hypotheses. Indeed, an a posteriori achieved power of .44 (n = 190, α = .05, partial η^2 = .01) suggests that the probability of detecting a true effect of the intervention groups was lower than the recommended standard (i.e., .80). Different factors contributed to collect data from a limited sample of 190 participants. First, we stopped the recruitment after five months from the start of the study even though the target sample size was not achieved. As specified in the study protocol, the criterion of discontinuing the participants' enrollment after five months was based on the constraints of the project timeline [16]. This led to a sample of 232 randomized participants. A second reason is due to the drop-outs between randomization and baseline assessment. Indeed, the baseline assessment was scheduled for the day after the randomization and some participants who had been randomized (n = 42) did not filled it out. Therefore, they were excluded from the main analyses.

A further limitation that has impacted the analysis of the primary outcome is the attrition. Out of the 190 participants who filled out the baseline diary, 118 completed the follow-up diary at T3, leading to a 38% and 49% of attrition compared to the baseline and randomization figures respectively. The attrition was higher than estimated (i.e., 20%). A possible explanation might be due to the longitudinal study design with five diary days and further quasi daily tasks that might have generated an interaction fatigue. Additionally, the pandemic trajectory during the enrollment period flattened in Switzerland, which may have made hand hygiene less of a priority for potential participants. To overcome this issue and in line with the ITT approach, we used the LOCF method to replace the missing observations in the T3 diary with the latest available diary assessment. It should be noted though that this method is based on the assumption that behavior is stable and, therefore, it might

have introduced bias.

Finally, the self-report measurement of hand hygiene may be biased. Using an electronic diary to measure hand hygiene behavior at key times should have limited retrospective bias. However, social desirability cannot be ruled out. Additionally, the thematic analysis indicated that the diary may have worked as unintentional BCT (i.e., self-monitoring).

Conclusions

The present study described the optimization phase of Soapp, a smartphone app to promote hand hygiene in the context of the COVID-19 pandemic. By leveraging the MOST approach, we addressed the call raised by public health experts for developing evidence-based behavior change interventions that are designed and optimized to be effective in a pandemic context[5]. Therefore, our findings contributed to fill an existing research gap and improve the scientific knowledge on the most effective behavior change strategies to promote hand hygiene during a pandemic.

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Conflicts of Interest

We have no conflicts of interest to disclose.

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Supplementary Files

Multimedia Appendixes

Secondary hypotheses testing.
URL: http://asset.jmir.pub/assets/62ed24285a53880b311badca74456a22.docx

Qualitative interview guide.
URL: http://asset.jmir.pub/assets/ae45098977e4c1adb32ffdbb7cc27b26.docx

Sensitivity analysis without NA imputation.
URL: http://asset.jmir.pub/assets/390503a672da3df38c4006800fee21dc.docx

Summary and quotes from thematic analysis.
URL: http://asset.jmir.pub/assets/25afa043cf7d064cb27aea47fe2d988f.docx

CONSORT (or other) checklists

Consort checklist.
URL: http://asset.jmir.pub/assets/849cbb008615c40ada076deb7f39462a.pdf