

Promoting hand hygiene during the COVID-19 pandemic: A randomized controlled trial of the optimized Soapp+ app

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Abstract

Background: The adoption of protective behaviors represents a crucial measure to counter the spread of infectious diseases. The development of effective behavior change interventions therefore emerged as public health priority during the COVID-19 pandemic, but randomized controlled trials testing such interventions during the pandemic were scarce. We conducted a Multiphase Optimization Strategy (MOST) to develop, optimize and evaluate a smartphone app, Soapp+, to promote hand hygiene during the COVID-19 pandemic.

Objective: In this paper, we present the results of the evaluation phase of Soapp+ that tested the app's efficacy in promoting hand hygiene in comparison to an active control group that used a simplified version of the same app.

Methods: We conducted a randomized controlled trial from March 2022 to April 2023 involving 193 participants. After baseline, the Soapp+ intervention lasted 32 days, followed by a post-intervention assessment and a 6-month follow-up. The primary outcome was the difference in hand hygiene behavior pre-post, and pre-follow-up. Hand hygiene was assessed with electronic diaries. Group differences were tested intention-to-treat with the Student's t-test and the non-parametric Wilcoxon Rank Sum test.

Results: Pre-registered t-tests didn't show significant differences between groups. Differently, non-parametric analyses evidenced significant group differences in hand hygiene between pre-post and pre-follow-up in favor of the group using the full version of Soapp+.

Conclusions: Soapp+ was developed through a rigorous experimental method during the ongoing COVID-19 pandemic. The randomized controlled trial provided mixed but encouraging evidence for the efficacy of Soapp+ to promote hand hygiene in the context of a pandemic. Clinical Trial: ClinicalTrials.gov: NCT04830761

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Original Manuscript

Original paper

Promoting hand hygiene during the COVID-19 pandemic: A randomized controlled trial of the optimized Soapp+ app

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Abstract

Background: The adoption of protective behaviors represents a crucial measure to counter the spread of infectious diseases. The development of effective behavior change interventions therefore emerged as public health priority during the COVID-19 pandemic, but randomized controlled trials (RCTs) testing such interventions during the pandemic were scarce. We conducted a Multiphase Optimization Strategy (MOST) to develop, optimize and evaluate a smartphone app, *Soapp+*, to promote hand hygiene during the COVID-19 pandemic. **Objective:** This RCT aimed to evaluate the efficacy of the *Soapp+* app (intervention group) targeting motivation and habit compared to a simplified version of the app mainly delivering hand hygiene information (active control group). We hypothesized that, compared to the control group, the intervention group would show greater improvements in hand hygiene behavior and behavioral determinants at post-intervention and 6-month follow-up. **Methods:** We conducted a RCT from March 2022 to April 2023, recruiting 193 adults living in Switzerland online. Following baseline assessment, the intervention lasted 32 days, followed by a post-intervention assessment and a 6-month follow-up. The primary outcome was the change in hand hygiene behavior from pre- to post-intervention and pre-intervention to follow-up. Hand hygiene was assessed with electronic diaries. The intervention group received content incorporating various behavior change techniques designed to address key motivational and volitional determinants of hand hygiene behavior (e.g., skills, knowledge, intention, attitudes toward hand hygiene, risk perception, outcome expectancies, self-efficacy, action planning, coping planning, action control, and habit). In contrast, the active control group was exposed to behavior change techniques targeting only a subset of these determinants (i.e., skills, knowledge, and intention). The delivery of the intervention content was fully automated. Group differences were tested using an intention-to-treat approach with the non-parametric Wilcoxon Rank Sum test. **Results:** Of the 193 randomized participants, 146 completed the first hand hygiene diary pre-intervention and were included in the main analysis. The mean age was 41 years, and 69% were women. The main analysis revealed significant superiority of the intervention compared to controls in the change in hand hygiene pre-post-intervention ($W = 2034$, $P < .04$, effect size $r = .17$) and between pre-intervention and follow-up ($W = 2005$, $P < .03$, effect size $r = .18$). Regarding behavioral determinants, the change in coping planning pre-post-intervention ($W = 3840$, $P = .03$, effect size $r = .16$) was significantly greater in the intervention group using *Soapp+* compared to controls. **Conclusions:** *Soapp+* was developed through a rigorous experimental method during the ongoing COVID-19 pandemic. The randomized controlled trial provided evidence for the efficacy of *Soapp+* to promote hand hygiene in the context of a pandemic. **Trial registration:** ClinicalTrials.gov: NCT04830761. **Funding:** Ursula-Wirz Stiftung

Keywords: COVID-19, hand hygiene, behavior change intervention, MOST, RCT, Smartphone applications

Introduction

The spread of the Coronavirus disease 2019 (COVID-19) pandemic represented an exceptional threat to human health worldwide. In that context, the collective adoption of protective behaviors (e.g., hand hygiene, physical distancing, mask wearing) became an essential measure to prevent the transmission of the virus, especially during the pandemic outbreak when there was no vaccine available [1,2]. Consequently, the development of effective behavior change interventions aiming at supporting the uptake and adoption of such behaviors emerged as public health priority [3]. However, during the course of the pandemic outbreak there was limited or no contextualized knowledge about how to effectively promote protective behaviors in the general population [4,5].

During the early stages of the pandemic, we addressed the call for applying principles of behavior change to reduce the transmission of COVID-19 [2,3] and devised a multiphase optimization strategy (MOST) [6] to develop, optimize and evaluate a smartphone-based behavior change intervention to promote hand hygiene during the COVID-19 pandemic [7,8]. We opted for a digital intervention to avoid in-person interaction, which is crucial for preventing virus transmission. Additionally, digital interventions can be tailored to individual needs and have the potential to reach a large number of users. The MOST framework was deemed highly suitable for rigorously contextualizing the intervention to the pandemic through optimization. We targeted correct hand hygiene (i.e., hand washing or sanitizing) at key times because it represents an effective strategy in preventing the transmission of respiratory illnesses, including COVID-19 [9,10] and was therefore included in public health guidelines [11].

Following the MOST framework [12], the project included three phases: *preparation*, *optimization*, and *evaluation*. In the preparation phase [7], we developed a set of intervention modules and defined the optimization criteria. The development of intervention modules was guided by the Theoretical Domain Framework (TDF) [13]. First, we identified behavioral determinants of hand hygiene through a literature review, and through two focus group discussions with the target population [7]. Then, we mapped behavior change techniques (BCTs; Michie et al., 2013) to the behavioral determinants. Specifically, three intervention modules were developed targeting *i*) motivation, *ii*) habit formation and *iii*) social influence. The identified modules were paired and sequenced, resulting in nine different intervention conditions. Each intervention condition was hosted in the developed smartphone app *Soapp*. During the subsequent optimization phase, we devised a mixed-method double-blind parallel randomized trial between March and August 2021, which lasted 34 days. The trial aimed at identifying the intervention condition that met our optimization criteria: superiority regarding change in hand hygiene pre-post intervention, and regarding user satisfaction, usability, and engagement [8]. The results of the trial showed that hand hygiene improved while using the *Soapp* app. However, no superiority was found for any of the versions of the app. The qualitative results indicated that participants preferred the motivation and habit formation modules over the social influence one. A further emerging theme pointed out the need for better distribution of intervention content over time. Thus, in the optimized version of the *Soapp* app, named *Soapp+*, we selected the motivation and habit formation modules and delivered them in a parallel fashion rather than sequentially.

Soapp+ comprises BCTs aimed at targeting key motivational and volitional behavioral determinants including, intention, attitudes towards hand hygiene, risk perception, outcome expectancies, self-efficacy, action planning, coping planning, action control, and habit. These determinants represent fundamental psychological constructs in prominent behavior change

theories [15], addressing both reflective and automatic processes. Reflective processes are deliberate and conscious, involving setting intended goals, planning, and monitoring progress [16,17]. In contrast, automatic processes, such as habit, operate unconsciously, enabling individuals to perform behaviors without deliberate thought once learned through repetition. These automatic processes help sustain behavior change by reducing the cognitive load associated with decision-making and promoting consistency in behavior performance [18,19].

Aim of the study

The current paper focuses on the evaluation phase of the MOST in which we tested the efficacy of *Soapp+* (intervention group) by comparison to an active control group in a randomized controlled trial (RCT). As presented in the study protocol [7], we tested the following preregistered hypotheses:

- H1: The intervention group shows a greater increase in correct hand hygiene behavior at key times at the post-measure (H1a) and at 6-month follow-up (H1b) than the control group.
- H2: The intervention group shows a significant increase in the targeted behavioral determinants compared with the control group at the post-intervention measure (H2a) and at 6-month follow-up (H2b). Specifically, the target behavioral determinants were intention, attitude, risk perception, outcome expectancies, self-efficacy, action planning, coping planning, action control, and habit strength.

As secondary aim, we examined between group differences in flu-like infection symptoms and occurrences of Covid-19 (secondary outcomes). The corresponding results are reported in the Multimedia Appendix 1.

Methods

The study design for the evaluation phase was a double-blind RCT (1:1 ratio) comparing the optimized app *Soapp+* with an active control group using a simplified version of the app that focused on providing information on hand hygiene. The trial was carried out from March 9th, 2022 to April 18th, 2023, a few days before the World Health Organization (WHO) declared the end of global health emergency [20].

Participants

The target population were German speaking adults from the Swiss population interested in using an app to improve hand hygiene. 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 informed consent form to participate in the study. Additionally, smartphone proficiency was an implicit eligibility criterion, as participants needed to perform various tasks on their smartphones prior to the study's commencement (e.g., downloading the app and registering). As per protocol [7], the initial target sample size was 205 participants. The sample size was calculated a priori for an independent samples t-test ($\beta = .80$, $\alpha = .05$, Cohen's $d = 0.35$). The target sample size was raised to 245 participants to account for a 20% dropout rate.

Measures

Primary outcome

The frequency of correct hand hygiene at key times was assessed using ecological momentary assessment with an electronic diary embedded in the study apps (i.e., *Soapp+* and active control apps). This approach was used to avoid retrospective bias in reporting hand hygiene [21]. On study days 2, 8, 16, 24, and 32, participants were prompted five times per day to indicate whether each of the 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

Multimedia Appendix 1, Table 1.2.). For each key situation that occurred, participants were asked how often they correctly washed or disinfected their hands. The 5-point response scale ranged from never (0) to always (4). For each diary day, the hand hygiene score was calculated by (1) computing the mean frequency of correct hand hygiene across all indicated key times in a single diary, and then (2) averaging the hand hygiene frequency across the five diaries.

Secondary outcomes

Targeted behavioral determinants. The following behavioral determinants were assessed at T1, T2, and follow-up. These variables were selected based on the results of the optimization phase and represented the determinants targeted by the *Soapp+* intervention.

Behavioral intention. One self-reported item adapted from [22] asking: "To what extent do you intend to correctly perform your hand hygiene behavior at key times?". The response options ranged from 1 "not at all" to 6 "very strongly".

Action planning. Mean score of three self-reported items [23] such as: "I have made a detailed plan about when I am going to wash and disinfect my hands." The response options ranged from 1 "not at all" to 6 "very strongly." The scale was reliable (Cronbach's Alpha = .90 at T1).

Coping planning. Mean score of four self-reported items such as: "I have made a detailed plan about how I can perform correct hand hygiene behavior at key times, when soap and water are not available" The response options ranged from 1 "not at all" to 6 "very strongly". (Cronbach's Alpha = .84 at T1).

Habit strength. Assessed with the 'Self-Report Behavioural Automaticity Index' (SRBAI) [24] with four items such as: "Correct hand hygiene behavior at key times is something that I do automatically." The response options ranged from 1 "strongly disagree" to 7 "strongly agree". (Cronbach's Alpha = .93 at T1).

Action control. Mean score of three self-reported items such as "During the last two weeks I have constantly monitored myself whether I washed or disinfected my hands according to my plans" The response options were adapted from [25] and ranged from 1 "not at all" to 6 "very strongly". (Cronbach's Alpha = .91 at T1).

Self-efficacy. Mean score of eight self-reported items such as "How confident are you that you correctly wash/disinfect your hands at key times, when you are on the way" The response options ranged from 1 "not at all" to 6 "very strongly." Self-efficacy items were adapted from [23]. (Cronbach's Alpha = .91 at T1).

Attitude. Mean score of six self-reported bipolar items [26] introduced by the wording "Correct hand hygiene behavior at key times is..." and followed by pairs of bipolar adjectives (e.g., useless VS useful). (Cronbach's Alpha = .81 at T1).

Outcome expectancies. Mean score of eight self-reported items [27] such as "If I engage in correct hand hygiene, then then the risk drops that I contract pathogens". The response options ranged from 1 "this doesn't apply at all" to 6 "this applies very precisely". (Cronbach's Alpha = .72 at T1).

Risk perception. Mean score of five self-reported items [27] such as "to what extent do you think that you could contract corona, if you don't engage in correct hand hygiene in key situations?". The response options ranged from 1 "this doesn't apply at all" to 6 "this applies very precisely". (Cronbach's Alpha = .90 at T1).

Flu-like infection symptoms and occurrences of Covid-19. Participants reported on these secondary outcomes by answering the items "In the last two weeks, did you have flu-like infection symptoms?" and "In the last two weeks, did you have a positive corona test?".

Finally, social desirability was assessed at T1 using the German Short Scale for the Two-Dimensional Measurement of Social Desirability [28]

Procedure

Participants were recruited via social media (e.g., Facebook, Instagram), mailing lists, and leaflets with the support of a market research company. We aimed at recruiting a broad range of people from the German speaking adult Swiss general population in terms of gender, age, and socio-economic status. The content of the recruitment materials targeted individuals interested in forming new hand-hygiene habits and learning how to correctly wash or disinfect their hands to counter the spread of the virus. Interested people were redirected to the study page on RedCap [29] where they could go through the study information, fill out an eligibility and consent survey, and sign the e-consent form. Afterwards, participants received a registration code via email and were guided to download the *Soapp+* app from Apple App Store or Google Play Store and register to it. The day after the registration, participants received the baseline questionnaire (T1) and were then randomized to intervention or active control group. A simple 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 (see Figure 1.1 in Multimedia Appendix 1). During the intervention phase, participants completed the hand hygiene diary on day 2, 8, 16, 24 and day 32. At the end of intervention phase (day 34), participants received a second questionnaire (T2). Six months (182 days) after T1, participants received the last follow-up questionnaire. Questionnaires and diaries were integrated in Qualtrics services using *Soapp+*'s API, and the participants' data were stored on Qualtrics. The recruitment for the evaluation trial began on March 9th, 2022, and ended on October 20th, 2022. Follow-up data were collected between September 5th, 2022, and April 18th, 2023.

Intervention

The content of the intervention was delivered to participants via their personal smartphone through the study application *Soapp+*. The intervention group received the optimized *Soapp+* app while the active control group was exposed to a simplified version of *Soapp+*. Table 1 shows the content delivered. The exact wording of the intervention messages and the intervention timeline can be found in the Multimedia Appendix 1, Table 1.3 and Figure 1.2.

Active control group. The active control group received information on how to perform correct hand hygiene (both in written and video formats), the key times to perform hand hygiene, and a statement of the goal of the app (basic module). This content was accessible throughout the intervention phase. Based on the results of the optimization phase, we also added a list of fun facts that were delivered to the participants via push notifications throughout the intervention phase. Finally, quizzes on hand hygiene aimed at ensuring that the active control group interacted with the app throughout the intervention phase.

Intervention group. Like the control group, the intervention group received the basic module. They additionally received the content targeting motivation and habit. Based on results of the optimization phase (i.e., request for better distributed content/tasks), this content was delivered in parallel instead of sequentially as done during the optimization trial.

Table 1. Intervention content overview

Condition	Module	TDF domain	Behavioral determinant	Behavior Change Technique
Intervention and active control group				
	Basic	Goals	Intention	1.1 Goal setting (behavior)
	Basic	Skills	Skills	4.1 Instruction on how to perform behavior
	Basic	Knowledge	Knowledge	5.1 Information about health consequences
Active control group				
	Quizzes	Knowledge	Knowledge	5.1 Information about health consequences
	Quizzes	Skills	Skills	4.1 Instruction on how to perform behavior
Intervention group				
	Motivation	Goals	Intention	1.1 Goal setting (behavior)
	Motivation	Beliefs about consequences	Risk perception	5.1 Information about health consequences
	Motivation	Beliefs about consequences	Attitude	5.2 Salience of consequences
	Motivation	Beliefs about consequences	Outcome expectancies	9.2 Pros and cons
	Motivation	Beliefs about consequences	Intention	5.2 Salience of consequences
	Motivation	Beliefs about capabilities	Self-efficacy	1.2 Problem solving 15.1 Verbal persuasion about capabilities 15.3 Focus on past success
	Motivation	Beliefs about capabilities	Coping planning	1.2 Problem solving
	Motivation	Reinforcement	Intention	10.9 Self-reward
	Habit	Knowledge	Knowledge	4.2. Information about antecedents
	Habit	Memory, attention, and decision processes	Action control	2.3 Self-monitoring of behavior
	Habit	Goals	Action planning	1.4 Action planning 7.1. Prompts/cues
	Habit	Skills, Goals	Habit strength	8.1 Behavioral practice/rehearsal 8.3 Habit formation
	Habit	Behavioral regulation	Habit strength	7.1 Prompts/cues (physical cue)

Note. TDF = theoretical domains framework [29].

Data analysis

Handling of missing data

To handle missing data, the intention-to-treat (ITT) principle was adopted [30]. According to the ITT principle, all the randomized participants are included in the analysis, regardless of what happens after randomization (e.g., noncompliance, protocol deviations). Therefore, the ITT approach avoids overoptimistic estimates of the efficacy of an intervention resulting from the removal of noncompliers. Missing data and dropouts were addressed using the last observation carried forward approach (LOCF). LOCF represents a parsimonious yet effective method to maintain appropriate Type 1 error protection [31]. This approach has been used in previous behavior change research [e.g., 31], including the optimization trial of the *Soapp* app [8]. This methodological choice was reinforced by the results of a secondary analysis conducted on the optimization trial [33]. The analysis revealed a noteworthy intra-class correlation (ICC) of 0.60 in hand hygiene, signifying that a substantial portion of the observed behavior can be attributed to individual differences between persons. This implies that the behavior tends to be more consistent or less variable within individuals over time. Finally, we also conducted a set of sensitivity analyses without missing value imputation; results are available in the Multimedia Appendix 1.

Hypothesis testing

In order to test the hypotheses, the assessment points considered for hand hygiene behavior were the first diary at day 2 (T1), the diary day at day 32 (T2, post-intervention), and the last diary day at day 181 (follow-up). The difference in hand hygiene between T2 and T1 and follow-up and T1 was compared between the intervention and the active control group using the non-parametric Wilcoxon Rank Sum test. A positive value in hand hygiene difference over assessments indicated an increase in hand hygiene. Likewise, positive values in the targeted behavioral determinants over assessments indicated an increasing trend. The Wilcoxon Rank Sum test was chosen over the pre-registered Student's t-test due to the non-normal distribution of the data, as assessed by the Shapiro-Wilk normality test, representing a deviation from the registered protocol. Results of the analysis with the Student's t-test are available in Table 2.1 in the Multimedia Appendix 1.

Analytical software

The *Soapp+* app was developed by the study authors using technological resources provided by the Faculty of Human Sciences at the University of Bern, with support from an internal software engineer. The statistical software R (version 4.3.0) was used to process the data and run the analyses. The data and R code used for the main analyses are available on the Open Science Framework repository platform <https://osf.io/pzhqx/> [34].

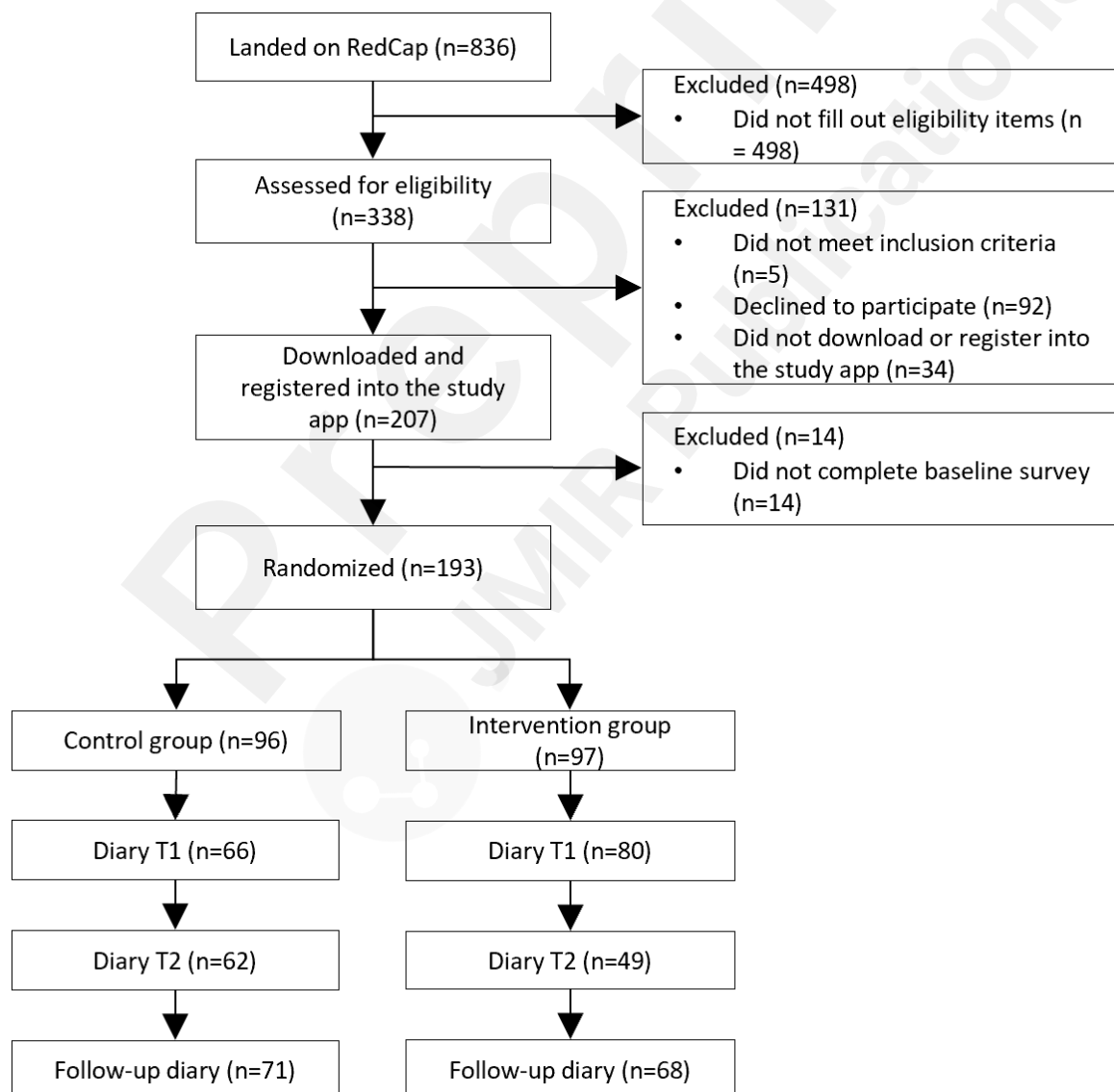
Ethical considerations

The trial received ethical approval from the Swiss Ethics Committee of the canton of Bern (ID: 2021-00164). The reporting of the trial is in line with the CONSORT guidelines [35] (Multimedia Appendix 2). Informed consent was obtained from all participants, who were also informed of their right to opt out at any stage of the study. To protect privacy and confidentiality, data were de-identified through pseudonymization. As compensation, participants had the opportunity to win one of three iPhone 12s as an incentive for their participation. Additionally, 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 dropout, that was sent to their homes.

Results

We stopped the trial 13 months after the start of the study due to the end of the project timeline. One hundred ninety-three participants were recruited and randomized into one of the two experimental conditions. Among these, 12 participants did not complete any of the six hand hygiene diary days while other 35 participants did not fill out the first diary at T1. Further three participants completed the first diary but did not encounter any of the key situations to perform hand hygiene during that day. These participants ($n = 50$) were excluded from the analysis because the main outcome (i.e., hand hygiene) at T1 was missing. Out of the 193 participants who were randomized, 146 (76%) filled out the hand hygiene diary at T1, 91 of these (47% of the randomized participants) completed the hand hygiene diary at T2, and 109 (56% of the randomized participants) completed the hand hygiene diary at the six-month follow-up. Figure 1 shows the participants' flow through randomization, T1 diary assessment, T3 diary assessment, and follow-up for each intervention group.

Figure 1. Participant recruitment flow



Baseline characteristics

Socio-demographics and hand hygiene behavior at baseline are reported in Table 2 (see Table

1.1 in Multimedia Appendix 1 for comparison with the socio-demographic characteristics of the Swiss population). The figures refer to the 146 participants who completed the first diary at T1. Participants' mean age was 41 years, 69% were women, 70% had high-school qualifications, 46% were employed, and 24% were living alone. Descriptive statistics in hand hygiene behavior (mean = 3.05; median = 3.15; skewness = -1.24) suggested that hand hygiene behavior was already high at baseline and characterized by a moderate left tailed distribution. No significant differences in social desirability were found between the intervention and the control group ($M_1 = 4.72$, $M_2 = 4.79$, $F(1, 189) = 0.44$, $P = .51$).

Table 2. Socio demographic characteristics at baseline (T1)

Variable	Overall, N = 146 ¹	Experimental group		p-value ²
		control, N = 66 ¹	intervention, N = 80 ¹	
Age	41 (17)	42 (17)	40 (17)	.56
Sex				.49
Diverse	3(2.1%)	1(1.5%)	2(2.5%)	
Male	42(29%)	16(24%)	26(33%)	
Female	101(69%)	49(74%)	52(65%)	
Marital status				.01
Divorced	12(8.2%)	8(12%)	4(5.0%)	
Single	88(60%)	32(48%)	56(70%)	
Married	44(30%)	26(39%)	18(23%)	
Widowed	2(1.4%)	0(0%)	2(2.5%)	
Have children				.047
Yes	43(29%)	25(38%)	18(23%)	
No	103(71%)	41(62%)	62(78%)	
Education				.15
High school diploma	102(70%)	42(64%)	60(75%)	
Completed primary school	2(1.4%)	2(3.0%)	0(0%)	
Completed secondary school	42(29%)	22(33%)	20(25%)	
Higher education				.20
Completed vocational training (apprenticeship)	35(24%)	21(32%)	14(18%)	
Completed (applied) university degree	59(40%)	26(39%)	33(41%)	
Other educational or vocational qualification	14(9.6%)	5(7.6%)	9(11%)	
No educational or vocational training	38(26%)	14(21%)	24(30%)	
Profession				.59
Unemployed	4(2.7%)	1(1.5%)	3(3.8%)	
Employed	67(46%)	35(53%)	32(40%)	

Homemaker	8(5.5%)	4(6.1%)	4(5.0%)	
In training / retraining	2(1.4%)	1(1.5%)	1(1.3%)	
Retired	18(12%)	8(12%)	10(13%)	
Student	47(32%)	17(26%)	30(38%)	
Monthly income³				.25
Less than 2'000 Fr	11(7.5%)	3(4.5%)	8(10%)	
Between 2'000 and 4'000 Fr	17(12%)	12(18%)	5(6.3%)	
Between 4'001 and 6'000 Fr	29(20%)	13(20%)	16(20%)	
Between 6'001 and 8'000 Fr	23(16%)	7(11%)	16(20%)	
Between 8'001 and 10'000 Fr	23(16%)	11(17%)	12(15%)	
More than 10'000 Fr	26(18%)	12(18%)	14(18%)	
I don't know	17(12%)	8(12%)	9(11%)	
Living situation				.42
Living by themselves	35(24%)	15(23%)	20(25%)	
Living with family	67(46%)	35(53%)	32(40%)	
Living in a shared apartment	33(23%)	12(18%)	21(26%)	
Other	11(7.5%)	4(6.1%)	7(8.8%)	

Note. ¹Mean (SD); n(%). ²Welch Two Sample t-test; Fisher's exact test. ³Swiss Francs

Dropout analysis

Dropout analysis was performed to investigate baseline differences between participants who reached the end of the intervention phase and those who dropped out at any point during the intervention. We analyzed all the 193 randomized participants and the ones who did not complete the T2 panel assessment were categorized as dropouts (n = 120). The results suggested that participants who dropped out were significantly younger than retainers ($M_1 = 39$, $M_2 = 46$, $F(1, 191) = 7.06$, $P = .009$). Dropouts and retainers did not differ regarding sex (male vs female) ($\chi^2(1) = 1.72$, $P = .188$), hand hygiene ($F(1, 190) = .12$, $P = .730$), intention to increase hand hygiene behavior ($F(1, 191) = 2.36$, $P = .126$), or intervention group allocation ($\chi^2(1) = 2.04$, $P = .153$).

Hand hygiene behavior

Hand hygiene behavior at T1, T2 and follow-up is summarized in Table 3. The whole sample exhibited a non-significant increase in hand hygiene behavior from T1 (Median = 3.25, IQR = [2.63, 3.60]) to T2 (Median = 3.42, IQR = [2.62, 3.88]; $W = 8904$, $P = .059$, $r = .11$). This was followed by a significant decrease between T2 and the 6-month follow-up (Median = 3.25, IQR = [2.50, 3.65]; $W = 11655$, $P = .040$, $r = .12$). When looking at changes in hand hygiene

within each experimental group, the data shows that hand hygiene between T1 and T2 remained almost stable for the active control group ($W = 2050$, $P = .771$, $r = .03$) while the intervention group showed a significant increase in hand hygiene after the intervention phase ($W = 2386$, $P = .020$, $r = .19$). At follow-up, both the active control group ($W = 2313$, $P = .352$, $r = .08$) and the intervention group ($W = 2924$, $P = .677$, $r = .03$) exhibited a non-significant decrease in hand hygiene compared to T1.

Table 3. Hand hygiene and targeted behavioral determinants mean values at each assessment point and Shapiro-Wilk normality test.

Variable	Assessment point	N				Shapiro-Wilk normality test	
			Overall ¹	Active control group ¹	Intervention group ¹	Statistic	p-value
Target behavior							
Hand hygiene	T1	14 3	3.25 (2.63, 3.60)	3.23 (2.56, 3.57)	3.25 (2.71, 3.61)	0.897	<.001
Hand hygiene	T2	14 3	3.42 (2.62, 3.88)	3.29 (2.55, 3.71)	3.58 (3.00, 3.94)	0.852	<.001
Hand hygiene	Follow-up	14 3	3.25 (2.50, 3.65)	3.14 (2.33, 3.55)	3.29 (2.57, 3.77)	0.894	<.001
Behavioral determinants							
Intention	T1	19 3	5.00 (5.00, 6.00)	5.00 (5.00, 5.25)	5.00 (5.00, 6.00)	0.823	<.001
Intention	T2	19 3	5.00 (5.00, 6.00)	5.00 (5.00, 6.00)	5.00 (5.00, 6.00)	0.796	<.001
Intention	Follow-up	19 3	.00 (4.00, 6.00)	5.00 (4.00, 5.00)	5.00 (4.00, 6.00)	0.841	<.001
Action planning	T1	19 3	4.33 (4.00, 5.00)	4.33 (3.67, 5.00)	4.67 (4.00, 5.00)	0.922	<.001
Action planning	T2	19 3	4.67 (4.00, 5.00)	4.67 (4.00, 5.00)	5.00 (4.00, 5.00)	0.890	<.001
Action planning	Follow-up	19 3	4.67 (3.67, 5.00)	4.33 (3.67, 5.00)	4.67 (3.67, 5.00)	0.916	<.001
Coping planning	T1	19 3	3.75 (2.75, 4.25)	3.50 (2.75, 4.25)	3.75 (2.75, 4.50)	0.974	.001
Coping planning	T2	19 3	4.00 (3.25, 4.75)	3.75 (2.94, 4.50)	4.25 (3.50, 5.00)	0.971	<.001
Coping planning	Follow-up	19 3	4.00 (2.75, 4.75)	3.75 (2.69, 4.50)	4.00 (3.00, 5.00)	0.966	<.001
Habit strength	T1	18 7	5.25 (4.00, 6.25)	5.00 (3.50, 6.00)	5.75 (4.19, 6.25)	0.933	<.001
Habit strength	T2	18 7	5.25 (4.25, 6.00)	5.25 (4.00, 6.00)	5.25 (4.50, 6.25)	0.940	<.001
Habit strength	Follow-up	18 7	5.25 (4.00, 6.00)	5.00 (3.75, 6.00)	5.25 (4.63, 6.00)	0.932	<.001
Action	T1	15	4.00 (3.33, 4.00)	4.00 (3.58, 4.00)	4.00 (3.33, 4.00)	0.947	<.001

control		2	5.00)	5.00)	5.00)		
Action control	T2	15	4.67 (4.00, 5.00)	4.33 (4.00, 5.00)	4.67 (4.00, 5.33)	0.938	<.001
Action control	Follow-up	15	4.33 (3.33, 5.00)	4.33 (3.33, 5.00)	4.33 (3.58, 5.00)	0.955	<.001
Self-efficacy	T1	19	4.25 (3.63, 4.88)	4.13 (3.50, 4.75)	4.38 (3.63, 5.00)	0.986	.049
Self-efficacy	T2	19	4.38 (3.75, 5.00)	4.25 (3.75, 4.88)	4.38 (3.88, 5.00)	0.979	.005
Self-efficacy	Follow-up	19	4.25 (3.63, 4.88)	4.13 (3.59, 4.88)	4.25 (3.63, 4.88)	0.984	.03
Attitudes	T1	18	5.17 (4.67, 5.62)	5.17 (4.67, 5.50)	5.17 (4.67, 5.67)	0.932	<.001
Attitudes	T2	18	5.17 (4.67, 5.50)	5.17 (4.50, 5.50)	5.08 (4.67, 5.67)	0.885	<.001
Attitudes	Follow-up	18	5.00 (4.33, 5.50)	5.00 (4.46, 5.38)	5.08 (4.33, 5.67)	0.880	<.001
Outcome expectancies	T1	19	4.63 (4.25, 5.13)	4.63 (4.25, 5.00)	4.75 (4.25, 5.13)	0.979	.005
Outcome expectancies	T2	19	4.75 (4.25, 5.13)	4.75 (4.25, 5.13)	4.75 (4.25, 5.13)	0.987	.08
Outcome expectancies	Follow-up	19	4.63 (4.13, 5.13)	4.63 (4.13, 5.13)	4.63 (4.25, 5.13)	0.987	.07
Risk perception	T1	19	4.60 (4.00, 5.00)	4.60 (4.00, 5.00)	4.60 (3.80, 5.00)	0.942	<.001
Risk perception	T2	19	4.60 (4.00, 5.00)	4.60 (4.00, 5.00)	4.60 (4.00, 5.00)	0.953	<.001
Risk perception	Follow-up	19	4.60 (3.60, 5.00)	4.60 (3.60, 5.00)	4.60 (3.80, 5.00)	0.950	<.001

Note. ¹Median (IQR)

The between group differences in hand hygiene behavior between T1 and T2 and T1 and follow-up are reported in Table 4. Non-parametric analysis with the Wilcoxon rank-sum test showed that the change in hand hygiene behavior between T1 and T2 ($W=2034$, $P < .04$, effect size $r = .17$) and between T1 and follow-up ($W=2005$, $P < .03$, effect size $r = .18$) significantly differed between the groups, indicating better hand hygiene in the intervention group.

Targeted behavioral determinants

Behavioral determinants values at T1, T2 and follow up are summarized in Table 3 while results from the paired Wilcoxon tests between T1 and T2 and T1 and follow-up are reported in Multimedia Appendix 1 (Table 2.2). Shapiro-Wilk normality test showed that almost all the behavioral determinants were not normally distributed at all assessment points, with the exception of outcome expectancies at T2 and follow-up (see Table 3). The variables that increased the most in the whole sample between T1 and T2 were coping planning ($W = 1474$, $P < .001$) and action control ($W = 611$, $P < .001$), followed by action planning ($W = 1338$, $P = .006$) and self-efficacy ($W = 2115$, $P = .011$). The change in behavioral determinants between T1 and follow-up was less pronounced and sometimes negative (i.e., intention, self-efficacy, attitudes, outcome expectancies, and risk perception). The between group differences in the targeted behavioral determinants between T1 and T2 and T1 and follow-up

are reported in Table 4. Results showed that the change in coping planning between T1 and T2 ($W = 3840$, $P = .03$, effect size $r = .16$) significantly differed between the intervention groups.

Sensitivity analysis

All the hypotheses were also tested without applying any missing value imputation algorithm. Results are available in the supplementary materials (Multimedia Appendix 1) and confirm most of the findings. Additionally, Wilcoxon tests without missing values imputation showed between group differences in coping planning between T1 and T2, and in risk perception between T1 and follow-up in favor of the intervention group.

Table 4. Differences in changes in hand hygiene and behavioral determinants between intervention group and active control group with the Wilcoxon rank-sum test.

Variables	Change	N	Overall ¹	Active control group ¹	Intervention group ¹	W-Statistic	p-value	Effect size r^2
Target behavior								
Hand hygiene	T1-T2	143	0.00 (-0.11, 0.38)	0.00 (-0.23, 0.35)	0.00 (0.00, 0.41)	2034	.04	.17
Hand hygiene	T1-Follow-up	143	0.00 (-0.41, 0.23)	-0.04 (-0.52, 0.05)	0.00 (-0.23, 0.32)	2005	.03	.18
Behavioral determinants								
Intention	T1-T2	193	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	4560	.75	.02
Intention	T1-Follow-up	193	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (-1.00, 0.00)	4845	.57	.04
Action planning	T1-T2	193	0.00 (0.00, 0.33)	0.00 (0.00, 0.33)	0.00 (0.00, 0.33)	4395	.47	.05
Action planning	T1-Follow-up	193	0.00 (-0.33, 0.33)	0.00 (0.00, 0.33)	0.00 (-0.33, 0.33)	4917	.49	.05
Coping planning	T1-T2	193	0.00 (0.00, 0.75)	0.00 (-0.25, 0.50)	0.00 (0.00, 1.00)	3840	.03	.16
Coping planning	T1-Follow-up	193	0.00 (-0.25, 0.75)	0.00 (-0.31, 0.56)	0.00 (0.00, 0.75)	4388	.48	.05
Habit strength	T1-T2	187	0.00 (0.00, 0.25)	0.00 (-0.13, 0.25)	0.00 (0.00, 0.25)	4585	.54	.04
Habit strength	T1-Follow-up	187	0.00 (-0.50, 0.38)	0.00 (-0.63, 0.38)	0.00 (-0.31, 0.31)	4469	.79	.02
Action control	T1-T2	152	0.00 (0.00, 0.67)	0.00 (0.00, 0.67)	0.00 (0.00, 0.42)	2996	.68	.03
Action control	T1-Follow-up	152	0.00 (-0.33, 0.33)	0.00 (-0.33, 0.33)	0.00 (-0.33, 0.08)	3075	.48	.06
Self-efficacy	T1-T2	193	0.00 (0.00, 0.25)	0.00 (0.00, 0.25)	0.00 (0.00, 0.25)	4824	.65	.03
Self-efficacy	T1-Follow-up	193	0.00 (-0.38, 0.25)	0.00 (-0.25, 0.38)	0.00 (-0.38, 0.25)	4881	.56	.04
Attitudes	T1-T2	188	0.00 (0.00, 0.00)	0.00 (0.00, 0.17)	0.00 (0.00, 0.00)	4650	.50	.05

Attitudes	T1-Follow-up	188	0.00 (-0.33, 0.17)	0.00 (-0.25, 0.17)	0.00 (-0.33, 0.00)	4747	.37	.07
Outcome expectancies	T1-T2	193	0.00 (0.00, 0.25)	0.00 (0.00, 0.25)	0.00 (0.00, 0.13)	5059	.28	.08
Outcome expectancies	T1-Follow-up	193	0.00 (-0.25, 0.13)	0.00 (-0.25, 0.25)	0.00 (-0.25, 0.13)	5125	.22	.09
Risk Perception	T1-T2	193	0.00 (-0.20, 0.00)	0.00 (-0.20, 0.00)	0.00 (0.00, 0.00)	4300	.33	.07
Risk Perception	T1-Follow-up	193	0.00 (-0.40, 0.20)	0.00 (-0.60, 0.20)	0.00 (-0.20, 0.40)	3971	.07	.13

Note. ¹Median (IQR). ² The following guidelines are used to interpret the effect size (r): a large effect is defined as $r \geq .50$, a medium effect as $r \approx .30$, and a small effect as $r \approx .10$ [36]

Discussion

As part of a MOST to develop, optimize, and test a smartphone-based hand hygiene intervention during the COVID-19 pandemic, this RCT aimed at evaluating the efficacy of the *Soapp+* app intervention against an active control group. Results showed that hand hygiene can be increased short and long-term using the *Soapp+* app intervention compared to active controls towards the end of the COVID-19 pandemic. Specifically, we observed small but stable effect sizes ($r = 0.17$ between pre-post intervention, and $r = 0.18$ between pre-intervention and follow-up) for increase in hand hygiene among the intervention group compared to the control group. The current results contribute to the notion that simultaneously targeting both reflective and automatic processes is an effective strategy for promoting and sustaining behavior change, even in challenging contexts such as a pandemic.

Discussing the clinical relevance of the effect size is challenging due to the limited evidence available regarding the necessary target effect size for a hand hygiene intervention to prevent the acquisition or transmission of COVID-19 [37]. However, we can note that the effect sizes we observed were smaller than the average effect size typically reported in previous interventions, primarily RCTs, aimed at promoting hand hygiene to mitigate the transmission of respiratory viruses (Cohen's $d = .62$) [4]. One plausible reason for this difference is that the study's target population consists of individuals who are already inclined towards hand hygiene behavior. This is evident from the fact that the frequency of hand hygiene in key situations was already relatively high in our sample at baseline with median values of 3.25 and 3.23 out of 4 for intervention and active control group respectively, where a value of 3 indicates that hand hygiene was performed 'often'. In spite of such a ceiling effect, participants in the intervention group still managed to increase the frequency of correct hand hygiene compared to those in the active control group.

Additionally, even though between-group differences in hand hygiene were small, we saw a trend that they resulted in fewer self-reported flu-like symptoms at post-intervention and follow-up for the intervention group (Multimedia Appendix 1, table 2.5). Although this difference was not statistically significant due to the small sample size and claims about the clinical significance of the intervention cannot be made, it does indicate a tendency toward an intervention effect on flu-like symptoms. Finally, it should be noted that digital interventions like *Soapp+* offer the advantage of scalability and the potential to reach a broader segment of the population. This is especially relevant in a pandemic context, where the diffusion of the virus's transmission grows exponentially, and even small changes in the individual behavior, but enacted on a larger scale, have the potential to significantly contribute to counter the pandemic's spread at the community level.

Targeted behavioral determinants

Regarding our second hypothesis, results evidenced significant group differences pre-post intervention in coping planning in favor of the intervention group (see table 4). The fact that coping planning was the only behavioral determinant associated with group differences pre-post intervention aligns well with the intervention content targeting coping planning skills (i.e., problem solving) delivered towards the end of the intervention and close to the post intervention assessment (see Multimedia Appendix 1). A possible explanation is that coping planning was a determinant with a low baseline value. Therefore, the intervention content might have played a significant role on this variable as there were more margins for improvement compared to the other targeted determinants.

Strengths and limitations

To the best of our knowledge (based on a search on clinicaltrial.gov with the following key terms: Condition or disease = 'COVID 19', Age = 'Adult (18 - 64)', Study type = 'Interventional', Outcome measure = 'Hand hygiene'), the current is one of the few registered RCTs testing the effectiveness of a behavior change intervention targeting hand hygiene in the general population during the COVID-19 pandemic. Additionally, this RCT study is a third of a series where we have employed the MOST approach for intervention development. This feature of our project stands as a significant strength, given that the MOST places strong emphasis on a rigorous, evidence-based approach to developing, refining, and evaluating interventions. Moreover, the mixed but overall encouraging evidence for the efficacy of *Soapp+* points to the potential value of this app as an effective tool to address the next pandemics. This aspect is of primary relevance as before the pandemic there was only limited or no contextualized knowledge about how to effectively promote hand hygiene during an outbreak [3,4]. In case of future epidemics, the *Soapp+* is a contextualized intervention that is readily available to be tested at larger scale.

This study is not without limitations. First, the achieved sample size ($N = 143$) was smaller than planned. Therefore, the probability of detecting a true effect of the intervention was below standard (i.e., .80) and some small effect sizes might have been missed. The decision to stop the recruitment even though the target sample size was not reached was due to the project timeline [7], but also considering that the pandemic situation was developing towards better scenarios till the point where the WHO declared the end of the global health emergency [20]. Based on the found effect size, future efficacy trials should be powered to detect small effects.

A second limitation is related to the dropouts between randomization and the first diary assessment. Indeed, the first diary was scheduled for the day after the randomization and some participants who had been randomized ($n = 47$) did not complete it. Other participants dropped out through the course of the study without filling out the assessment at T2 and follow-up. A possible explanation for the attrition might be due to the longitudinal study design with multiple diaries and other daily tasks that might have generated some fatigue. To address potential differences between dropouts and retainers, we conducted a dropout analysis, indicating a higher likelihood of younger participants dropping out. Thus, when extending the current results to young adults, caution is advised.

Another limitation is the high prevalence of women in the trial (69%), resulting in a sex ratio that does not mirror the target population. This ratio aligns with the sample characteristics of the optimization trial [8] and other COVID-19 hand hygiene research [38]. This imbalance can be explained in light of empirical evidence suggesting that women were more worried about the COVID-19 pandemic and keener to adopt hand hygiene behavior [39].

Last, the primary outcome of the study was self-reported, which can be biased by social desirability and recall issues [21]. The latter were minimized using the electronic hand hygiene diary. Nevertheless, social desirability might still have played a role.

Implications, challenges, and considerations

A key practical implication is that the *Soapp+* app, a behavior change intervention contextualized to a pandemic, is now available and can be readily offered to the general public at the emergence of a future infectious disease outbreak (e.g., via public health institutions). However, since the app's efficacy has not yet been robustly demonstrated due to sample size, we recommend conducting a larger-scale RCT in a future outbreak. It is also important to note that testing behavior change interventions like *Soapp+* during a pandemic remains challenging due to the constantly evolving context, including shifts in the pandemic trajectory, public health policies, government regulations, and medical advancements such as vaccine availability. These multifaceted and evolving factors likely contributed to the observed temporal variations in the adoption of hand hygiene behaviors, with implications for the evaluation of behavior change interventions [33,38]. For this reason, we believe that further testing of *Soapp+* could extend beyond pandemic contexts and be conducted in more feasible settings, provided that the BCTs specifically referring to the Covid-19 pandemic (e.g., the ones targeting risk perception and outcome expectancies, see Table 1.3 in Multimedia Appendix 1) are adapted to the specific characteristics of the new context. Upon confirmation of the current positive effect of *Soapp+* on hand hygiene, this further testing beyond the pandemic context would also pave the way for a broader application of *Soapp+*, particularly in settings where there is a demand for hand hygiene interventions (e.g., healthcare settings, during regular flu seasons, and to prevent the transmission of other viruses).

A methodological lesson learned regards the suitability of the MOST as reference framework to intervention development in a pandemic context. The sequential decision-making process unique to the MOST may be too rigid for dealing with a continuously changing context. Indeed, the contextual conditions under which the intervention is developed may differ from those in which the intervention is later optimized and evaluated. Therefore, we foresee a validity risk when using the results from one phase to inform the implementation of the upcoming phase. Additionally, the pandemic context has amplified the already known challenges in completing the full MOST cycle – preparation, optimization, and evaluation – within the project timeline [40], as evidenced by the slow recruitment pace and the high dropout rates we saw in this study.

One strategy to enhance the feasibility of RCTs in future pandemics is to join forces and contribute to large-scale multicenter trials [41]. This approach was successfully adopted by observational studies investigating protective behaviors during the COVID-19 pandemic [38,42] but was less commonly used in behavior change interventions for protective behaviors, which saw fewer collaborative efforts [43]. Another strategy is represented by adaptive clinical trials [44], whose adaptive design aims to decrease the time needed to complete a trial and increase the likelihood of detecting intervention effects. Specifically, they allow for interim analysis, which are used to enhance the efficiency of the trials by adapting the original study design. Examples include response-adaptive randomization (i.e., decreasing the allocation ratio to less promising arms), sample size reassessment (i.e., redefining the target sample size), or seamless trials (i.e., discontinuing the most unpromising arms of the trial).

Conclusions

The present study described the evaluation phase of *Soapp+*, a smartphone app to

promote hand hygiene in the context of the COVID-19 pandemic. We leveraged digital technology and the MOST approach to address the call raised by public health experts for developing evidence-based behavior change interventions that are built to be used in a pandemic context [3]. Our findings provided tentative support for the efficacy of *Soapp+*, and of targeting reflective and automatic behavior change processes more broadly, in promoting hand hygiene during an ongoing pandemic. Beyond our individual results, the trial has provided important learnings for conducting rigorous trials of contextualized behavior change interventions during a pandemic, which can be further developed in the next outbreak.

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Authors' contributions. DB: Conceptualization, Resources, Data Curation; Methodology, Formal analysis, Discussion, Writing – Original Draft; CR: Resources, Data Curation; MAA: Conceptualization, Resources; Methodology; JI: Funding acquisition, Conceptualization, Methodology, Formal analysis, Supervision; Discussion, Writing – Original Draft. All authors: Writing – Review & Editing.

Conflicts of interest. We have no conflicts of interest to disclose.

Multimedia appendix 1: Supplemental materials

Multimedia appendix 2: CONSORT guidelines checklist

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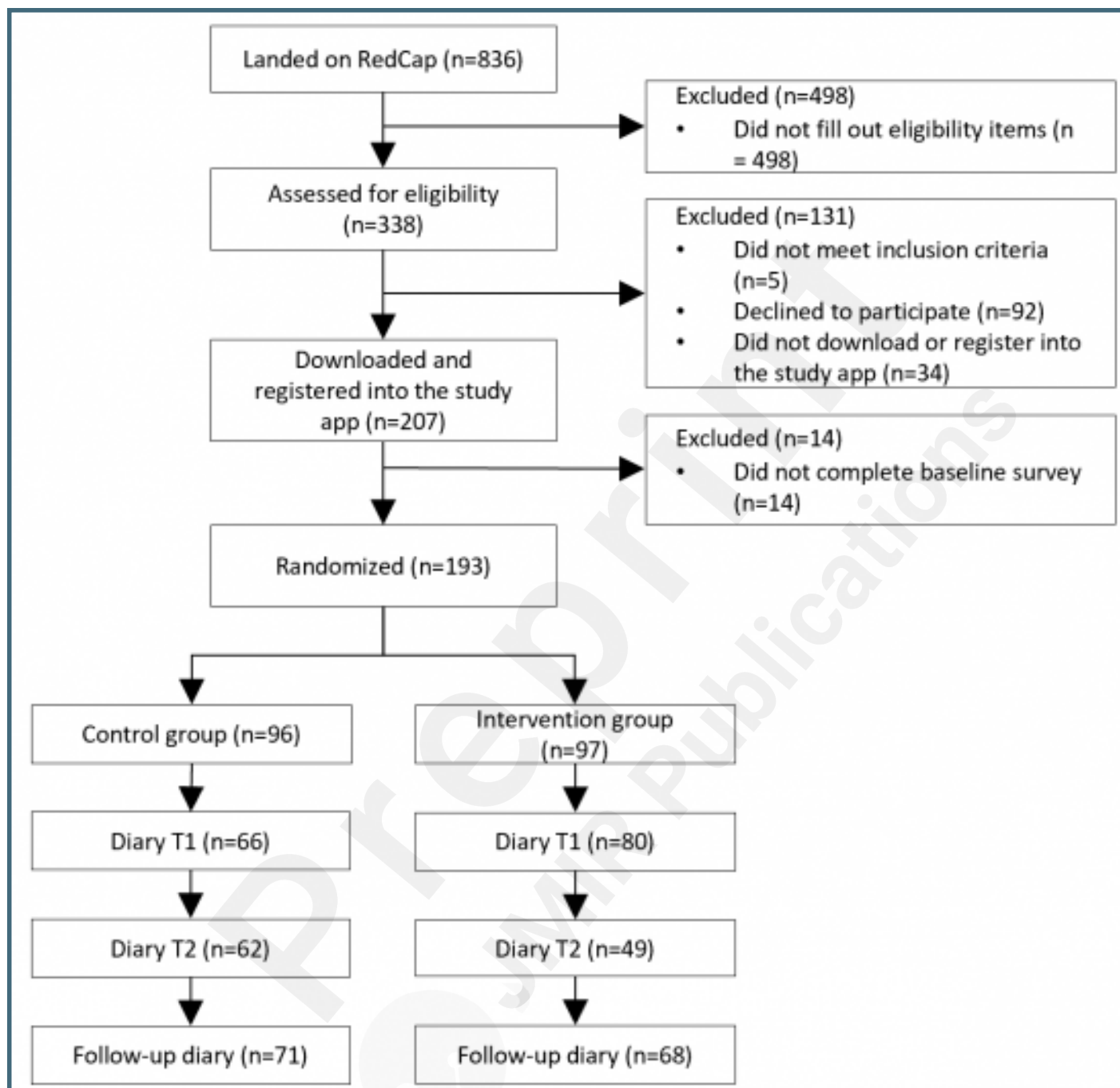
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Supplementary Files

Figures

Participant recruitment flow.



Multimedia Appendixes

Supplemental materials.

URL: <http://asset.jmir.pub/assets/1bd3ef6f85efb4d7511d8809149b28fe.docx>

CONSORT checklist.

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