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A brief mindfulness-based intervention of "STOP (Stop, Take a Breath, Observe, Proceed) touching your face": a study protocol of a randomized controlled trial

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Abstract

Introduction Face-touching behavior often happens frequently and automatically, and poses potential risk for spreading infectious disease. Mindfulness-based interventions (MBIs) have shown its efficacy in the treatment of behavior disorders. This study aims to evaluate an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face" in reducing face-touching behavior.

Methods and analysis This will be a single-blind, randomized, controlled, trial. We will recruit 1,000 participants, and will randomize and allocate participants 1:1 to the "STOP touching your face" intervention group (n=500) and the control group (n=500). All participants will be asked to monitor and record their face-touching behavior. The intervention group will receive the brief online mindfulness-based "STOP touching your face" program, and the control group will receive control intervention. Primary outcome will be the efficacy of short-term mindfulness-based "STOP touching your face" intervention for reducing the frequency of face-touching. The secondary outcomes will be the reduction of the duration of face-touching after intervention; the correlation between the psychological traits of mindfulness and face-touching behavior; and the differences of face-touching behavior between left-handers and right-handers. We will recruit 1000 participants from April to June 2020 or until the recruitment process is complete. The follow-up will be completed in June 2020. We expect all trial results to be available by the end of June 2020.

Ethics and dissemination The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32). Study results will be disseminated via social media and peer-reviewed publications.

Trial registration number NCT04330352.

Strengths and limitations of this study

- This is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior.
- This is a theoretical framework guided (mindfulness-based cognitive behavior theory) large sample size RCT to evaluate the efficacy of "STOP touching your face" during the outbreak of COVID-19.
- "STOP touching your face" program is a free, brief, simple and widely accessible mindfulness-based behavior change intervention.
- There is no digital videotape recording for the behavior of face-touching by researchers. Alternatively, it will be self-monitored.
- This is only a brief intervention by internet. A face to face long-term mindfulness intervention will help participants gain the maximum benefits of practice.

Introduction

Nonverbal behavior plays an important role in interpersonal relations and constitutes a large amount of all communication. But self-touching is usually not used to communicate with others and is often done automatically without thinking about it at all in our daily life[1]. It might be one of the so called "autistic" gestures when they have no evident meaning[2]. Spontaneous facial self-touching or face-touching has been defined as *the use of the hand to touch the individual's own face* to scratch, rub, groom, or caress it. Research shows that the average face-touching frequency ranges from approximately 16[3] to 23[4] times per hour. Furthermore, research of face-touching across handedness showed that left-handed individuals more frequently touch their face than their counterparts[5].

An increase in face-touching frequency may result in increased risk of transmissible infections, defined as self-inoculation or auto-inoculation (a type of contact transmission occurs when a person transfers an infectious disease from one part of the body to another, e.g., when a contaminated hand makes subsequent contact with the nose and introduces contaminated material to those areas)[3 4]. Of all face-touching behaviors, touching the T-zones will pose a potential risk for transmission and acquisition of a range of infectious diseases. Unfortunately, research found that 42.2%[6] to 44%[4] of face-touching involved in contacting with a mucous membrane. Even clinicians touch their T-zones (the mucus membranes of the eyes, nose, and mouth) as frequently as 19 times on average within 2 hours[7]. Many diseases can be spread by self-inoculation in this way, including coronavirus disease 2019 ("COVID-19") [8 9]. Thus, the

Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have been telling people to stop touching their faces.

However, even we all know that stop touching our faces will minimize spread of coronavirus and other germs. The question is how to stop this behavior? Although face-touching is often an automatic behavior without conscious thought or decision, research indicates that the frequency of self-touching and the duration of touch and contact are associated with cognitive and emotional demands[10 11]. In addition to emotional states, especially negative affect states, self-touching also has been linked to information processing and production[12].

Raising self-awareness of face-touching behavior may be effective in reducing or avoiding this behavior. For example, every time when you touch your face, be mindful, notice how you touched your face, check what you are thinking, physical and psychological feeling or your sensation that preceded it. This process or skill is similar to "mindfulness practice" developed by Jon Kabat Zinn[13]. Mindfulness can be defined as *"Mindful Awareness is the moment-by-moment process of actively and openly observing one's physical, mental and emotional experiences"* (Mindful Awareness Research Center at the University of California at Los Angeles). Mindfulness-based interventions (MBIs) are proven to be clinically efficacious in treatment of behavioral disorders, such as alcohol drinking, smoking, gambling[14 15], attention deficit/hyperactivity disorder (ADHD)[16], eating disorders[17 18], as well as in enhancing the emotional health of Chinese long-term male prison inmates[19]. Increasing peoples' awareness of their habituated face-touching behavior may help individuals to avoid touching their face by contaminated hands, and

decrease the risk of spreading infectious diseases. The structured MBIs, such as mindfulness-based stress reduction (MBRS) and mindfulness-based cognitive therapy (MBCT) program, are 8 to 10 weeks course[20-23], but brief MBIs can also produce numerous health-related outcomes, even only with one session intervention and as brief as 5 minutes[24 25]. Randomized controlled trials (RCT) of a brief mindfulness-based intervention further suggested the feasibility and effectiveness of short- term, self-guided, internet or smartphone-based interventions[26 27].

The primary objective of this proposed project is to identify a simple but effective practice to reduce or avoid face-touching to low people's chances of catching infectious diseases like COVID-19. Based on the efficacy of MBIs in treatment of some behavioral disorders and the efficacy of short-term MBIs, we here propose a RCT of an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face". It is hypothesized that this skill will be an effective, feasible, accessible skill in reducing or avoiding face-touching for people in the general population. To be specific, the primary hypothesis of this brief behavioral intervention is that, compared with a control intervention, the intervention would result in greater reduction of frequency of face-touching. We also hypothesize that the length of face-touching behavior will also be reduced. Based on the theory that both face-touching behavior and mindfulness link to cognitive or emotional process[10 22], we hypothesize that people with higher levels of self-reported mindfulness will touch their face less frequently. Given left-handed individuals more frequently touch their face than their counterparts[5], It is hypothesized that, compared with right-handed participants, left-handed individuals will touch their face more frequently during their self-monitoring of face-touching.

Methods and analysis

Patient and public involvement

Neither participants nor the public were involved in the design, recruitment or conduct of the study.

Study design and participants

In this single-blind, randomized, parallel-group trial, undertaken in China by internet, about 1,000 participants willing to participate in "STOP touching your face" training program and provide electronic consent, will be randomly allocated to mindfulness-based "STOP touching your face" intervention group or a control group at a 1:1 ratio. A 2 × 2 (practice group and control group × pre–post measurements) experimental design will be used. All participants who are allocated to the control group will have the opportunity to practice this skill after the end of the study period. An overview of participant eligibility criteria is given in **Table1.**

Sample size and power calculation

This study aims to recruit 1000 participants, with 500 in each group. The sample size assessment and power calculations are mainly on the basis of the results of RCTs of different types of behavioral intervention--stop smoking behavior[28], as well as smartphone-based mindfulness intervention[27] and the "Learning Mindfulness Online" intervention[26]. The RCT of mindfulness training for smoking cessation screened 757 participants, assessed 134 eligible participants, randomized 88 participants with more than 70% participants completed all follow-up interviews.

Individuals who received mindfulness intervention showed a trend toward greater 1-week point prevalence abstinence (stop smoking behavior) at the end of treatment (36% vs. 15%). It is estimated that, for assessing stop face-touching behavior, a total of 128 participants (64 participants in each group) are required to achieve 80% power (1-beta=0.8), as significant at the 5% level (alpha=0.05), an increase in the primary outcome measure from 15% in the control group to 36% in the intervention group. However, online interventions often have much higher dropout rate than face to face intervention. The smartphone-based RCT assessed 537 participants with only 194 participants had been randomized to intervention group (n=97) or control group(n=97). There were only 13 participants partially completed follow up measures in the intervention and 11 participants in the control group. The overall loss to follow-up rate was as high as more than 80% in this RCT. The online program invited 111 participants and randomized 104 participants (50 participants in the Wait-list control group and 54 participants in the intervention group). 70% (n=35) from control group and 43%(n=23) from the intervention group completed post-intervention measures. Considering the high loss to follow-up rate, this study will have a final target sample size of 1000 participants (500 in each arm), which will have sufficient power to detect a significant difference.

Recruitment

As in other similar research, we will advertise this program online using websites, social media (such as WeChat, QQ). to recruit potential participants. Potential participants will register their interest by sending messages by social media, email or sending text messages, or making a call to research assistants (by Dr. Y Wang and Dr. Z Wu). Then, research assistants will contact

respondents to assess their eligibility and explain the study to each participant and inform them that they would be allocated to either a control group or to a group that receives the Mindfulness-based "STOP touching your face" program. Before collecting baseline data, electronically informed consent will be obtained from each participant. Participants who enrolled in this study could withdraw at any time. They will also be asked to provide contact information (will not be shared with any third party), in case any problems arise.

Baseline data

Prior to randomization, demographic information and self-reported questionnaires will be obtained from all participants at baseline (assessed by Dr. Y Liao, Dr. C Pan and Dr. Q Luo). The demographic information of participants will be gender, age, years of education, marital status, occupation by the International Standard Classification of Occupations (ISCO), living in rural or urban region, smoker types (nonsmoker or current smoker and former smoker). The Five Facets Mindfulness Questionnaire (FFMQ) will be applied to measure the dispositional tendency to be mindful in daily life. The Edinburgh Handedness Inventory (EHI) will be used to assess handedness. Frequency and length of face-touching will be assessed at baseline and after intervention.

Randomization and group allocation

Participants will be randomized and assigned (by Dr. Y Liu) to the intervention or control group. Randomization will be run by randomizeR, (https://CRAN.R-project.org/package=randomizeR). All Investigators will be masked to participants' treatment assignment until all data have been

collected. The investigators (by Dr. J Tang and Dr. Y Liu) who will analyze the data for evaluating outcomes will still be blinded to participants' treatment allocations until the entire analysis has been completed.

Development of "STOP touching your face" training program

Theory

Face-touching behavior is often an automatic behavior that could potentially disseminate respiratory infections (eg, influenza, coronavirus), yet can be changed. However, changing the behavior of face-touching is "easier said than done", as there is only limited evidence for the neuropsychological basis or physiological fundamentals of this behavior. Research shows that the frequency of self-touching increases when attention is distracted[10], as well as under stressful situations or with negative affect[11]. Cognitive behavioral theory-based mindfulness intervention (mindfulness-based cognitive therapy, MBCT[23]) has been used as a psychological intervention for people with mental or behavior problems, targeting both cognitive and behavioral problems. Mindfulness-based interventions (MBIs)[13] can help people cultivate positive affect, increase self-awareness and concentration that are associated with reducing frequency of face-touching.

Practice

STOP[29] is an acronym that stands for four action: "Stop", "Take a breath", "Observe", "Proceed". It is a helpful aid in becoming more mindful of our body, behavior and emotion on a daily basis. The following is the instruction for how to practice STOP:

S = Stop

Remind yourself to STOP. Whatever you are doing in this moment (e.g. touching your month,

pinching your nose, rubbing your eyes, resting your chin on your hands), pause for a minute.

T = Take

Take a deep breath. This reconnects you with your body. Pay attention to your breathing and just allow yourself to continue to breathe normally and naturally.

O = Observe

OBSERVE what is happening for you in this moment—including thoughts, feelings, and emotions (e.g. feel distracted, anxious or nervous?). What do you notice in your body (e.g. feel itchy or tingling on any part of your face)? You can be aware of anything: posture, sensations, tension in your body, or, once again, your breath. You might notice the sound around you. You might even notice your thoughts or emotions

P = Proceed

Proceed with whatever you were doing before you came to a STOP or something that you want to do in the moment (e.g. proceed with touching your face, or stop face-touching and take an alternative behavior).

The STOP Practice is very short, simple, and the acronym (STOP) makes it easy to remember as well. Thus, it has become one of the most popular mindfulness-based practices. The practice of STOP may cultivate a space between stimulus and response, which could help avoid the mostly spontaneous behavior of facial self-touching. The “STOP touching your face” training program in Chinese was already developed by Dr. Y Liao, Dr. Q Luo and Dr. C Pan. Both text and audio description (see Supplementary Material) will be available.

Intervention

Intervention group

Eligible participants who are allocated to the intervention group will be required to find a time to monitor and record their behavior of hand-to-face contacts, including the frequency and length (in second) of face-touching in any of the mucosal area (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) during a 60-minute period. Then, they will receive the online mindfulness-based "STOP touching your face" program. Each participant will be required to practice this technique until they feel confident and natural. The systematic review showed the efficacy of single session of brief MBIs, the average length of which was 15 minutes, ranged from less than 5 to 25 min[24]. Thus, the requirement practice time will be 15 minutes. Later (with a one-hour interval), they will be asked to self-monitor and report their one-hour face-touching behavior again by send them messages via social media app (mainly WeChat). This online mindfulness-based intervention will not have face-to-face interaction between the experimenter and participants throughout the entire study.

Control group

Participants who allocate to the control group will only receive information to thank them and encourage them to complete the study. They will receive "STOP touching your face" program after the end of this study. The repeat measurement of the face-touching behavior will be done in a one-hour interval.

Both groups

Participants from both groups will be required to provide information about face-touching behavior before and after intervention. The self-monitoring behavior of face-touching will be

asked to be recorded before and after "STOP touching your face" or control intervention. All participants will be encouraged to practice it regularly after the end of the study.

Follow-up

In order to measure the changes of face-touching behavior before and after intervention, frequency and length of face-touching in a 60-minute period will also be self-monitored and reported after intervention for groups with or without "STOP touching your face" practice, with a one-hour interval between the repeated measures. All outcomes will be collected by an online survey through the Chinese professional survey software WenJuanXing (Sojump, Shanghai, China, www.sojump.com). For non-responders, a reminding message will be sent to them by their provided contact information for reporting the outcomes.

Outcomes

Primary outcome: the efficacy of short-term mindfulness-based "STOP touching your face" intervention for reducing the frequency of face-touching.

Secondary outcomes: the reduction of the duration of face-touching after intervention; the correlation between the psychological traits of mindfulness and face-touching behavior; the differences of face-touching behavior between left-handers and right-handers.

Measures

1. Frequency and length of face-touching: Self-observation or self-monitoring of face-touching behavior will be required to report from each participant. A standardized scoring sheet will be

provided to tally the frequency of hand-to-face contacts, the touched area of the face, including the mucosal area (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) , and the time in seconds of each contact will be recorded in a 60-minute period [4].

2. Five Facet Mindfulness Questionnaire (FFMQ)[30-32]: this self-report scale is currently the most frequently used mindfulness questionnaire to measure changes in participant's tendency to be mindful in daily life by the following five related facets: observing(noticing, attending to sensations, perceptions, thoughts, feelings; 8 items), describing (labeling feelings, thoughts with words), acting with awareness (automatic pilot, concentration, non-distraction), non-judging internal experience, and non-reactivity to internal experience. Participants will be asked to what extent each of the statements are true of them. Each item is on a 1 to 5 Likert scale, ranging from 1 (never or very rarely true) to 5 (very often or always true). The scores represent a spectrum of mindfulness with no cut-off points, higher scores indicate higher levels of mindfulness. The factor structure of the short version (FFMQ-15) will be used in this study, which has been consistent with that of the FFMQ-39[33].

3. The Edinburgh Handedness Inventory (EHI) [34 35]: EHI is the most widely used 10-item self-report inventory to assess handedness. It is comprised of the following 10 activities: (1) writing, (2) drawing, (3) throwing, (4) using scissors, (5) a toothbrush (6) knife (without fork), (7) spoon, and such activities involving both hands as (8) using a broom (upper hand), (9) striking a match, and (10) unscrewing the lid of a bottle. To complete the EHI, one or two check marks are placed under “left (L)” or “right (R)” columns, indicating strength of preference for each activity. Participants will be asked write “2”, ”1” or ”0” in the appropriate corresponding column. If the preference is very strong that they would never try to use the other hand unless absolutely forced

to, then they will mark this column as “2” and the other column as “0”. If they are really indifferent, they will mark it as “1” in both columns. A laterality quotient (LQ = R − L/R + L × 100) can be calculated, where a score of 100 reflects complete right-handedness, and a score of −100 reflects complete left-handedness.

Procedures

After advertising, participants who are interested in this study will be assessed for eligibility by making a call or communicating with social media (mainly WeChat). Then, eligible participants will complete baseline information, and information about frequency and length of face-touching in a 60-minute period by self-monitoring. Afterwards, one group will receive a brief mindfulness-based "STOP touching your face" intervention and other control intervention. With a one-hour interval, a follow-up assessment of face-touching behavior will be taken for both groups. The schedule of enrolment and one follow-up assessment summarizes in **Figure 1.**

Withdrawal from the Program

Every participant will feel free to withdraw from the study at any time and without giving any reason. On the basis of the intention-to-treat (ITT) principle[36], participants who fail to respond to follow-up assessment will be retained in the analysis and classified as those who continued the same behavior. Only participants who request withdrawal from the study will be excluded from the analysis, and reasons for withdrawal will be noted if they are available.

Data collection

Data will be collected on line by WenJuanXing, a Chinese online market research Web site that provides professional online questionnaire survey or data collection for RCTs[37]. Data will be monitored by data monitoring committee of the hospital. Personal data will be de-identified.

Data analysis

All data will be automatically collected by internet. A user-specified Excel file will be downloaded from the database. There will be no interim analyses. When all data have been obtained, they will be analyzed and blinded to intervention assignment by the trial statistician using R software (R Foundation for Statistical Computing, Vienna, Austria. https://www.r-project.org/) and SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Descriptive statistics will be performed to determine the frequency of touches in a 60-minute period. In order to determine if the intervention group showed a reduction of face-touching behavior than the control group, pre- and posttest mean scores by group and "STOP touching your face" intervention effects will be analyzed with 2 (group) × 2 (time), repeated measures ANACOVAs (analysis of covariance) (controlling for handedness and prior mindfulness meditation experience); χ^2 test will be applied to rates of none face-touching behavior between intervention and control groups, and between left-handers and right-handers; T-test will be applied to assess the differences of face-touching behavior duration between intervention and control groups, and between left-handers and right-hander; Pearson's correlations will be used to explore the correlation between the psychological traits of mindfulness and face-touching behavior; intention-to-treat (ITT) basis will be applied in this study to handle incomplete or missing data. All tests will be 2-tailed. A two-sided $P<0.05$ will be used to determine statistical significance.

Safety

Throughout the "STOP touching your face" program, participants will be encouraged to communicate with us if they experience any mindfulness practice relative issues. Adverse events will be monitored during the study. The MBIs are regarded as relatively safe interventions[38].

Research showed that even highly vulnerable participants (such as patients with major depressive disorder[39]) can safely practice mindfulness, but if participants experience any health-related issues, they will be encouraged to contact with us or a health care provider.

Ethics and dissemination

The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32). All activities associated with this protocol will be conducted in full compliance with the approved policies and procedures. Electronically Informed consent (this e-consent is a form of written consent) will be communicated and obtained from each participant prior to participation. All participant will be explained about the purpose, procedures and assessments, potential risks and benefits of the trial before recruitment. After fully understanding the study, participants will be informed that their participation in this research study is total voluntary. They can choose to (sign the electronic consent form by selecting “agree to participant”) or not to participate (sign the electronic consent form by selecting “disagree to participant”). Participation can withdrawal at any time without reasons. Contact information (phone number and social media contact like WeChat contact ID) of the study coordinator for any future questions and concerns will be provided and informed to each participant. We will recruit 1000 participants from April to June 2020 or until the recruitment process is complete. The follow-up will be completed in June 2020. We expect all trial results to be available by the end of June 2020. Any results from this trial (publications, conference presentations) will be disseminated via social media and be published in peer-reviewed journals and conference proceedings.

Discussion

This RCT is to investigate the efficacy of brief mindfulness-based intervention of "STOP touching your face" for people from general population in China. To our knowledge, this will be the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior on the basis of mindfulness and cognitive behavioral principles.

The strength of this study is that this is a theoretical framework guided (mindfulness-based cognitive behavior theory) large sample size RCT to evaluate the efficacy of "STOP touching your face" during the outbreak of COVID-19. If "STOP touching your face" program is proved to be effective, it opens up its potential application worldwide at the population level. As "STOP touching your face" program is a free, brief, simple and widely accessible mindfulness-based behavior change intervention, the public health impact of its expansion world-wide could be enormous, helping us to manage any face-touching spread infectious diseases, like COVID-19.

There are some limitations in this study. First, there is no digital videotape recording for the behavior of face-touching by researchers. Alternatively, it will be self-monitored. Self-monitoring of physical (such as blood pressure), and mental health (such as anger or frustration that comes from daily life) has been used as a strategy for improving the treatment of a number of chronic conditions or reducing unhealth behaviors including smoking, drinking, gambling and so on[40]. Thus, self-monitoring itself may change participants face-touching behavior by creating a more active role in observing this behavior. Second, this is only an online intervention, participants may

be more likely to drop out from the study. Thus, we will encourage participants contact with us if they have any questions or concerns. We will also apply an intention-to-treat principle to prevent potential bias caused by missing data from loss to follow-up. Third, this is only a brief intervention by internet. A face to face long-term mindfulness intervention will help participants gain the maximum benefits of practice. However, neuroimaging study demonstrates that both long and short-term mindfulness practice can improve automatic emotion regulation[41], and RCT shows that brief online mindfulness-based intervention can also increase mindfulness and decrease perceived stress and symptoms of anxiety or depression[26].

In conclusion, this is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior. If "STOP touching your face", a brief and simple skill, is proven effective, the public health impact of its expansion world-wide could be enormous, its dissemination will help us to manage any face-touching spread infectious diseases, like Coronavirus disease 2019 (COVID-19).

Availability of data and materials

All data in the current study will be available from the corresponding author on reasonable request and with completion of data user agreement.

Authors' Contributions

YLiao and JT developed and designed the study. YLiao took the lead in drafting the manuscript protocol with contributions by JT, LW, WC, CP, QL, JC and XG advised the study design, and

coordinated study approval. All authors read and proposed critical comments, as well as approved the manuscript for publication.

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Competing interests statement

No potential conflicts of interest to declare.

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References

1. Harrigan JA, Kues JR, Weber JG. Impressions of hand movements: Self-touching and gestures. *Perceptual and motor skills* 1986;63(2):503-16.

2. Krout MH. Autistic gestures: An experimental study in symbolic movement. *Psychological Monographs* 1935;46(4):i.
3. Nicas M, Best D. A study quantifying the hand-to-face contact rate and its potential application to predicting respiratory tract infection. *Journal of occupational and environmental hygiene* 2008;5(6):347-52.
4. Kwok YLA, Gralton J, McLaws M-L. Face touching: A frequent habit that has implications for hand hygiene. *American journal of infection control* 2015;43(2):112-14.
5. Dimond S, Harries R. Face touching in monkeys, apes and man: Evolutionary origins and cerebral asymmetry. *Neuropsychologia* 1984;22(2):227-33.
6. Measurement of Face-touching Frequency in a Simulated Train. E3S Web of Conferences; 2019. EDP Sciences.
7. Elder NC, Sawyer W, Pallerla H, et al. Hand hygiene and face touching in family medicine offices: a Cincinnati Area Research and Improvement Group (CARInG) network study. *The Journal of the American Board of Family Medicine* 2014;27(3):339-46.
8. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *The Lancet* 2020;395(10223):497-506.
9. Ong SWX, Tan YK, Chia PY, et al. Air, surface environmental, and personal protective equipment contamination by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from a symptomatic patient. *Jama* 2020
10. Mueller SM, Martin S, Grunwald M. Self-touch: Contact durations and point of touch of spontaneous facial self-touches differ depending on cognitive and emotional load. *PloS one* 2019;14(3)
11. Grunwald M, Weiss T, Mueller S, et al. EEG changes caused by spontaneous facial self-touch may represent emotion regulating processes and working memory maintenance. *brain research* 2014;1557:111-26.
12. Harrigan JA. Self-touching as an indicator of underlying affect and language processes. *Social science & medicine* 1985;20(11):1161-68.
13. Kabat-Zinn J. Mindfulness-based interventions in context: past, present, and future. *Clinical psychology: Science and practice* 2003;10(2):144-56.
14. Cavicchioli M, Movalli M, Maffei C. The Clinical Efficacy of Mindfulness-Based Treatments for Alcohol and Drugs Use Disorders: A Meta-Analytic Review of Randomized and Nonrandomized Controlled Trials. *European addiction research* 2018;24(3):137-62. doi: 10.1159/000490762 [published Online First: 2018/07/18]
15. Sancho M, De Gracia M, Rodríguez RC, et al. Mindfulness-based interventions for the treatment of substance and behavioral addictions: a systematic review. *Frontiers in psychiatry* 2018;9:95.
16. Haydicky J, Wiener J, Badali P, et al. Evaluation of a mindfulness-based intervention for adolescents with learning disabilities and co-occurring ADHD and anxiety. *Mindfulness* 2012;3(2):151-64.
17. Kristeller JL, Wolever RQ. Mindfulness-based eating awareness training for treating binge eating disorder: the conceptual foundation. *Eating disorders* 2010;19(1):49-61.
18. Wanden-Berghe RG, Sanz-Valero J, Wanden-Berghe C. The application of mindfulness to eating disorders treatment: a systematic review. *Eating disorders* 2010;19(1):34-48.
19. Xu W, Jia K, Liu X, et al. The effects of mindfulness training on emotional health in Chinese long-term male prison inmates. *Mindfulness* 2016;7(5):1044-51.
20. Shonin E, Van Gordon W, Griffiths M. Mindfulness-based interventions: Towards mindful clinical integration. *Frontiers in Psychology* 2013;4:194.
21. Carmody J, Baer RA. Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of behavioral medicine* 2008;31(1):23-33.

22. Grossman P, Niemann L, Schmidt S, et al. Mindfulness-based stress reduction and health benefits: A meta-analysis. *Journal of psychosomatic research* 2004;57(1):35-43.
23. Segal ZV, Teasdale J. Mindfulness-based cognitive therapy for depression: Guilford Publications 2018.
24. Howarth A, Smith JG, Perkins-Porras L, et al. Effects of Brief Mindfulness-Based Interventions on Health-Related Outcomes: a Systematic Review. *Mindfulness* 2019:1-12.
25. Chen Y, Yang X, Wang L, et al. A randomized controlled trial of the effects of brief mindfulness meditation on anxiety symptoms and systolic blood pressure in Chinese nursing students. *Nurse education today* 2013;33(10):1166-72.
26. Cavanagh K, Strauss C, Cicconi F, et al. A randomised controlled trial of a brief online mindfulness-based intervention. *Behaviour research and therapy* 2013;51(9):573-78.
27. Howells A, Ivtzan I, Eiroa-Orosa FJ. Putting the 'app'in happiness: a randomised controlled trial of a smartphone-based mindfulness intervention to enhance wellbeing. *Journal of Happiness Studies* 2016;17(1):163-85.
28. Brewer JA, Mallik S, Babuscio TA, et al. Mindfulness training for smoking cessation: results from a randomized controlled trial. *Drug and alcohol dependence* 2011;119(1-2):72-80.
29. Smalley SL, Winston D. Fully present: The science, art, and practice of mindfulness: Da Capo Lifelong Books 2010.
30. Deng Y-Q, Liu X-H, Rodriguez MA, et al. The five facet mindfulness questionnaire: psychometric properties of the Chinese version. *Mindfulness* 2011;2(2):123-28.
31. de Bruin EI, Topper M, Muskens JG, et al. Psychometric properties of the Five Facets Mindfulness Questionnaire (FFMQ) in a meditating and a non-meditating sample. *Assessment* 2012;19(2):187-97.
32. Baer RA, Smith GT, Hopkins J, et al. Using self-report assessment methods to explore facets of mindfulness. *Assessment* 2006;13(1):27-45.
33. Gu J, Strauss C, Crane C, et al. Examining the factor structure of the 39-item and 15-item versions of the Five Facet Mindfulness Questionnaire before and after mindfulness-based cognitive therapy for people with recurrent depression. *Psychological assessment* 2016;28(7):791.
34. Yang N, Waddington G, Adams R, et al. Translation, cultural adaption, and test–retest reliability of Chinese versions of the Edinburgh Handedness Inventory and Waterloo Footedness Questionnaire. *Laterality: Asymmetries of Body, Brain and Cognition* 2018;23(3):255-73.
35. Oldfield RC. The assessment and analysis of handedness: the Edinburgh inventory. *Neuropsychologia* 1971;9(1):97-113.
36. Montori VM, Guyatt GH. Intention-to-treat principle. *Cmaj* 2001;165(10):1339-41.
37. Fitzpatrick T, Zhou K, Cheng Y, et al. A crowdsourced intervention to promote hepatitis B and C testing among men who have sex with men in China: study protocol for a nationwide online randomized controlled trial. *BMC infectious diseases* 2018;18(1):489.
38. Wong SY, Chan JY, Zhang D, et al. The safety of mindfulness-based interventions: a systematic review of randomized controlled trials. *Mindfulness* 2018;9(5):1344-57.
39. Piet J, Hougaard E. The effect of mindfulness-based cognitive therapy for prevention of relapse in recurrent major depressive disorder: a systematic review and meta-analysis. *Clinical psychology review* 2011;31(6):1032-40.
40. Kim JY, Wineinger NE, Steinhubl SR. The influence of wireless self-monitoring program on the relationship between patient activation and health behaviors, medication adherence, and blood pressure levels in hypertensive patients: a substudy of a randomized controlled trial. *Journal of medical Internet research* 2016;18(6):e116.
41. Kral TR, Schuyler BS, Mumford JA, et al. Impact of short-and long-term mindfulness meditation training on amygdala reactivity to emotional stimuli. *Neuroimage* 2018;181:301-13.

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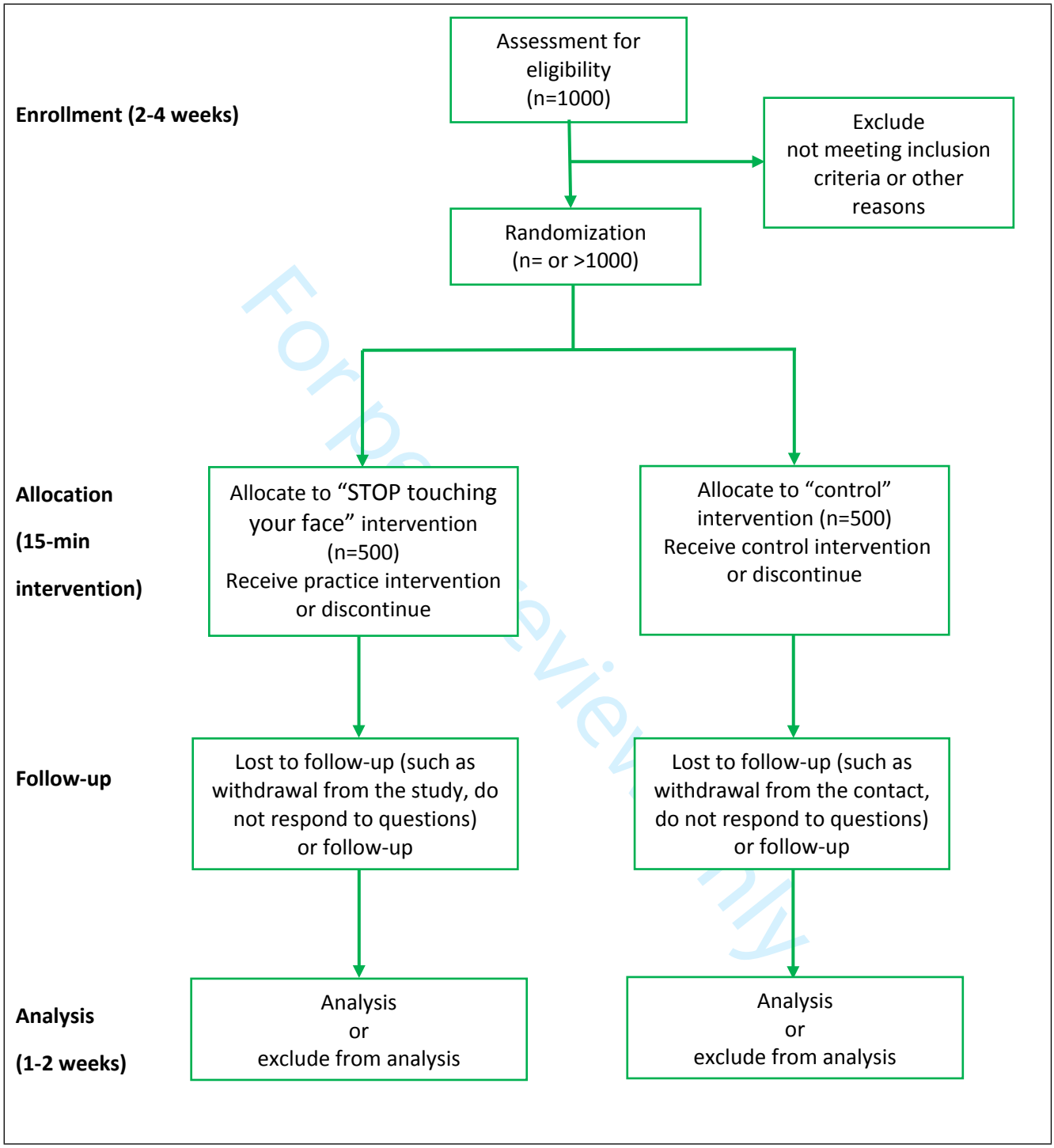
Figure Legend

Figure 1 Study Flow Diagram

Table1 study inclusion and exclusion criteria

Inclusion Criteria:
1. 18 years of age or older
2. Being able to access online services
3. Being able to read and write in Chinese
4. Expressing an interest in participant this study
5. Willing to provide informed consent to participate in the study
Exclusion Criteria:
1. Under 18 years of age
2. Unable to access online services
3. Unable to read and write in Chinese

Figure 1



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
P1,1-3 Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
P4, 54 Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Not applicable, Protocol version	3	Date and version identifier
P21,427-432 Funding	4	Sources and types of financial, material, and other support
P1-2, 5-31; P22, 437-442 Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
P5-7, 69-117 Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
P7 119-133 Objectives	7	Specific objectives or hypotheses

P8, 141-145 Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
P8, 141 Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
P8, 147 P26, 546-547 Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
P13-14, 243-266 Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
P14, 277-282 Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
P19, 375-377; P16, 314-321 Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
P8-9, 149-171 Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

P10, 197-198 Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
P10-11, 199-200 Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
P10, 197 Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
P10, 200-202 Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
P17, 330-333 Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
P17, 335-340 Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
P17-18, 341-352 Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods: Monitoring

P17, 332-333 Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
P18, 354-360 Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

P21, 429-431 Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
P18-19, 362-375 Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
P10, 182-183 P17, 333 Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
P21, 434-435 Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
P11, 200-202 Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
P8, 145-147 Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

P19, 377-379 Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
In supplementary file, Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Not applicable, Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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A brief mindfulness-based intervention of "STOP (Stop, Take a Breath, Observe, Proceed) touching your face": a study protocol of a randomized controlled trial

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Primary Subject Heading:	Public health

Secondary Subject Heading:	Mental health, Infectious diseases
Keywords:	EDUCATION & TRAINING (see Medical Education & Training), MENTAL HEALTH, PUBLIC HEALTH, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT
Note: The following files were submitted by the author for peer review, but cannot be converted to PDF. You must view these files (e.g. movies) online.	
Supplementary file 1_STOP_practice.mp3	

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A brief mindfulness-based intervention of "STOP (Stop, Take a Breath, Observe, Proceed) touching your face": a study protocol of a randomized controlled trial

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Abstract

Introduction Face-touching behavior often happens frequently and automatically, and poses potential risk for spreading infectious disease. Mindfulness-based interventions (MBIs) have shown its efficacy in the treatment of behavior disorders. This study aims to evaluate an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face" in reducing face-touching behavior.

Methods and analysis This will be a single-blind, randomized, controlled, trial. We will recruit 1,000 participants, and will randomize and allocate participants 1:1 to the "STOP touching your face" (both 750-word text and 5-min audio description by online) intervention group (n=500) and the wait-list control group (n=500). All participants will be asked to monitor and record their face-touching behavior during a 60-minute period before and after the intervention. Primary outcome will be the efficacy of short-term mindfulness-based "STOP touching your face" intervention for reducing the frequency of face-touching. The secondary outcomes will be the reduction of the duration of face-touching after intervention; the correlation between the psychological traits of mindfulness and face-touching behavior; and the differences of face-touching behavior between left-handers and right-handers. Analysis of covariance, regression analysis, χ^2 test, T-test, Pearson's correlations will be applied in data analysis. We will recruit 1000 participants from April to July 2020 or until the recruitment process is complete. The follow-up will be completed in July 2020. We expect all trial results to be available by the end of July 2020.

Ethics and dissemination The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32). Study results will be disseminated via social media and peer-reviewed publications.

Trial registration number NCT04330352.

Strengths and limitations of this study

- This is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior.
- This is a theoretical framework guided (mindfulness-based cognitive behavior theory) large sample size RCT to evaluate the efficacy of "STOP touching your face" during the outbreak of COVID-19.
- "STOP touching your face" program is a free, brief, simple and widely accessible mindfulness-based behavior change intervention.
- There is no digital videotape recording for the behavior of face-touching by researchers. Alternatively, it will be self-monitored.
- This is only a brief intervention by internet. A face to face long-term mindfulness intervention will help participants gain the maximum benefits of practice.

Introduction

Nonverbal behavior plays an important role in interpersonal relations and constitutes a large amount of all communication. But self-touching is usually not used to communicate with others and is often done automatically without thinking about it at all in our daily life[1]. It might be one of the so called "autistic" gestures when they have no evident meaning[2]. Spontaneous facial self-touching or face-touching has been defined as *the use of the hand to touch the individual's own face* to scratch, rub, groom, or caress it. Research shows that the average face-touching frequency ranges from approximately 16[3] to 23[4] times per hour. Furthermore, research of face-touching across handedness showed that left-handed individuals more frequently touch their face than their counterparts[5].

An increase in face-touching frequency may result in increased risk of transmissible infections, defined as self-inoculation or auto-inoculation (a type of contact transmission occurs when a person transfers an infectious disease from one part of the body to another, e.g., when a contaminated hand makes subsequent contact with the nose and introduces contaminated material to those areas)[3 4]. Of all face-touching behaviors, touching the T-zones will pose a potential risk for transmission and acquisition of a range of infectious diseases. Unfortunately, research found that 42.2%[6] to 44%[4] of face-touching involved in contacting with a mucous membrane. Even clinicians touch their T-zones (the mucus membranes of the eyes, nose, and mouth) as frequently as 19 times on average within 2 hours[7]. Many diseases can be spread by self-inoculation in this way, including coronavirus disease 2019 ("COVID-19") [8 9]. Thus, the

Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have been telling people to stop touching their faces.

However, even we all know that stop touching our faces will minimize spread of coronavirus and other germs. The question is how to stop this behavior? Although face-touching is often an automatic behavior without conscious thought or decision, research indicates that the frequency of self-touching and the duration of touch and contact are associated with cognitive and emotional demands[10 11]. In addition to emotional states, especially negative affect states, self-touching also has been linked to information processing and production[12].

Raising self-awareness of face-touching behavior may be effective in reducing or avoiding this behavior. For example, every time when you touch your face, be mindful, notice how you touched your face, check what you are thinking, physical and psychological feeling or your sensation that preceded it. This process or skill is similar to "mindfulness practice" developed by Jon Kabat Zinn[13]. Mindfulness can be defined as *"Mindful Awareness is the moment-by-moment process of actively and openly observing one's physical, mental and emotional experiences"* (Mindful Awareness Research Center at the University of California at Los Angeles). Mindfulness-based interventions (MBIs) are proven to be clinically efficacious in treatment of behavioral disorders, such as alcohol drinking, smoking, gambling[14-16], attention deficit/hyperactivity disorder (ADHD)[17], eating disorders[18 19], as well as in enhancing the emotional health of Chinese long-term male prison inmates[20]. Increasing peoples' awareness of their habituated face-touching behavior may help individuals to avoid touching their face by contaminated hands, and

decrease the risk of spreading infectious diseases. The structured MBIs, such as mindfulness-based stress reduction (MBRS) and mindfulness-based cognitive therapy (MBCT) program, are 8 to 10 weeks course[21-24], but brief MBIs can also produce numerous health-related outcomes, even only with one session intervention and as brief as 5 minutes[25 26]. Randomized controlled trials (RCT) of a brief mindfulness-based intervention further suggested the feasibility and effectiveness of short- term, self-guided, internet or smartphone-based interventions[27 28].

The primary objective of this proposed project is to identify a simple but effective practice to reduce or avoid face-touching to low people's chances of catching infectious diseases like COVID-19. Based on the efficacy of MBIs in treatment of some behavioral disorders and the efficacy of short-term MBIs, we here propose a RCT of an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face". It is hypothesized that this skill will be an effective, feasible, accessible skill in reducing or avoiding face-touching for people in the general population. To be specific, the primary hypothesis of this brief behavioral intervention is that, compared with a control intervention, the intervention would result in greater reduction of face-touching behavior. We also hypothesize that the frequency of face-touching behavior will also be reduced. Based on the theory that both face-touching behavior and mindfulness link to cognitive or emotional process[10 23], we hypothesize that people with higher levels of self-reported mindfulness will touch their face less frequently. Given left-handed individuals more frequently touch their face than their counterparts[5], It is hypothesized that, compared with right-handed participants, left-handed individuals will touch their face more frequently during their self-monitoring of face-touching.

Methods and analysis

Patient and public involvement

Neither participants nor the public were involved in the design, recruitment or conduct of the study.

Study design and participants

In this single-blind, randomized, parallel-group trial, undertaken in China by internet, about 1,000 participants willing to participate in "STOP touching your face" training program and provide electronic consent (e-consent), will be randomly allocated to mindfulness-based "STOP touching your face" intervention group or a control group at a 1:1 ratio. A 2 × 2 (practice group and control group × pre–post measurements) experimental design will be used. All participants who are allocated to the control group will have the opportunity to practice this skill after the end of the study period. An overview of participant eligibility criteria is given in **Table1.**

Sample size and power calculation

This study aims to recruit 1000 participants, with 500 in each group. The sample size assessment and power calculations are mainly on the basis of the results of RCTs of different types of online short-term mindfulness intervention for behavioral changes, such as for alcohol consumption[16] and stopping smoking or decreasing smoking craving[29], or for positive psychological changes, such as enhancing wellbeing[28] and reducing perceived stress and anxiety/depression symptoms[27]. A single brief session of mindfulness of 11-minutes (n=34) detected a significant reduction in

alcohol consumption compared with a relaxation control intervention (n=34)[16]. It is estimated that, for assessing stop face-touching behavior, individuals who received mindfulness intervention will at least twice likely to reduce the chance of touching T-Zone than the control group (5 to 10% vs. 2 to 4%). Thus, a total of 562 participants (281 participants in each group) are required to achieve 80% power (1-beta=0.8), as significant at the 5% level (alpha=0.05), an increase in the primary outcome measure from 4% in the control group to 10% in the intervention group. However, online interventions often have much higher dropout rate than face to face intervention. A web-based guided self-help intervention for preventing depression reported about 20% dropout rate at 6-month follow-up[30], but a brief online mindfulness-based intervention for reducing stress, anxiety and depression reported 30% dropout rate in the intervention group and more than a half in the waiting list control group[27] Considering the high loss to follow-up rate, this study will have a final target sample size of 1000 participants (500 in each arm), which will have sufficient power to detect a significant difference.

Recruitment

As in other similar research, we will advertise this program online using social media (such as WeChat and QQ) to recruit potential participants. Potential participants will register their interest by sending messages by social media, email or sending text messages, or making a call to research assistants (by Dr. Y Wang and Dr. Z Wu). Then, research assistants will contact respondents to assess their eligibility and explain the study to each participant and inform them that they would be allocated to either a control group or to a group that receives the Mindfulness-based “STOP touching your face” program. Before collecting baseline data, electronically informed consent

will be obtained from each participant. Participants who enrolled in this study could withdraw at any time. They will also be asked to provide contact information (will not be shared with any third party), in case any problems arise.

Baseline data

Prior to randomization, demographic information and self-reported questionnaires will be obtained from all participants at baseline (assessed by Dr. Y Liao, Dr. C Pan and Dr. Q Luo). The demographic information of participants will be gender, age, years of education, marital status, occupation by the International Standard Classification of Occupations (ISCO), living in rural or urban region, smoker types (nonsmoker or current smoker and former smoker). The Five Facets Mindfulness Questionnaire (FFMQ) will be applied to measure the dispositional tendency to be mindful in daily life. The Edinburgh Handedness Inventory (EHI) will be used to assess handedness. Frequency of face-touching will be assessed at baseline and after intervention.

Randomization and group allocation

After reporting the first 60-min self-monitoring face-touching behavior, participants will be randomized and assigned (by Dr. Y Liu) to either start the intervention immediately (intervention condition) or to a wait-list control condition (who will be offered the intervention immediately after reporting the second 60-min self-monitoring face-touching behavior). Randomization will be run by randomizeR, (https://CRAN.R-project.org/package=randomizeR). All participants will report the first self-monitoring by the same link (the same Excel file will be downloaded), and the second will be reported by two different links (two separated Excel files will be downloaded) to

detect group allocation. Group allocation will not be concealed to investigators who will provide interventions. But the investigators (by Dr. J Tang and Dr. Y Liu) who will analyze the data for evaluating outcomes will be blinded to participants' treatment allocations until the entire analysis has been completed.

Development of "STOP touching your face" training program

Theory

Face-touching behavior is often an automatic behavior that could potentially disseminate respiratory infections (eg, influenza, coronavirus), yet can be changed. However, changing the behavior of face-touching is "easier said than done", as there is only limited evidence for the neuropsychological basis or physiological fundamentals of this behavior. Research shows that the frequency of self-touching increases when attention is distracted[10], as well as under stressful situations or with negative affect[11]. Cognitive behavioral theory-based mindfulness intervention (mindfulness-based cognitive therapy, MBCT[24]) has been used as a psychological intervention for people with mental or behavior problems, targeting both cognitive and behavioral problems. Mindfulness-based interventions (MBIs)[13] can help people cultivate positive affect, increase self-awareness and concentration that are associated with reducing frequency of face-touching.

Practice

STOP[31] is an acronym that stands for four action: "Stop", "Take a breath", "Observe", "Proceed". It is a helpful aid in becoming more mindful of our body, behavior and emotion on a daily basis. The following is the instruction for how to practice STOP:

S = Stop

Remind yourself to STOP. Whatever you are doing in this moment (e.g. touching your month, pinching your nose, rubbing your eyes, resting your chin on your hands), pause for a minute.

T = Take

Take a deep breath. This reconnects you with your body. Pay attention to your breathing and just allow yourself to continue to breathe normally and naturally.

O = Observe

OBSERVE what is happening for you in this moment—including thoughts, feelings, and emotions (e.g. feel distracted, anxious or nervous?). What do you notice in your body (e.g. feel itchy or tingling on any part of your face)? You can be aware of anything: posture, sensations, tension in your body, or, once again, your breath. You might notice the sound around you. You might even notice your thoughts or emotions

P = Proceed

Proceed with whatever you were doing before you came to a STOP or something that you want to do in the moment (e.g. proceed with touching your face, or stop face-touching and take an alternative behavior).

The STOP Practice is very short, simple, and the acronym (STOP) makes it easy to remember as well. Thus, it has become one of the most popular mindfulness-based practices. The practice of STOP may cultivate a space between stimulus and response, which could help avoid the mostly spontaneous behavior of facial self-touching. The “STOP touching your face” training program in Chinese was already developed by Dr. Y Liao, Dr. Q Luo and Dr. C Pan. Both 750-word text and 5-min audio description (see **Supplementary file 1**) will be available by online.

Procedures

After advertising, participants who are interested in this study will be assessed for eligibility by making a call or communicating with social media (mainly WeChat). Then, eligible participants will sign a e-consent form (**Supplementary file 2**), and complete baseline information and the first self-monitoring of frequency of face-touching in a 60-minute period by online. Afterwards, participants will receive a brief mindfulness-based "STOP touching your face" intervention or control intervention. For both groups, the second self-monitoring of frequency of face-touching behavior will be taken at least 1 hour apart from the first one. The schedule of study procedures summarizes in **Figure 1.** The details of the procedure will include the following 3 steps:

Step 1. The first self-monitoring of face-touching behavior (before intervention)

In order to measure the changes of face-touching behavior before and after intervention, all eligible participants will receive the instruction (in Chinese) of how to self-monitored and reported the frequency of face-touching in any of the mucosal area (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) during a 60-minute period. All participants will be required to monitor their face-touching behavior during a 60-minute period, and be encouraged to do it in a manageable situation. Wearing facial mask will not be permitted during the time of self-monitoring face-touching. All participants will be provided with the same link to complete their baseline information and the first self-monitoring of face-touching behavior, and be encouraged to complete this questionnaire immediately after completion of self-monitoring.

Instruction: *"1. Please find a convenient time, no need to deliberately change your routine life (such as working or studying at the desk, watching TV), observe and record how many times you touched your hair, forehead, eyes, nose, mouth, ears, cheeks , Chin and neck in one-hour period (if you touched your mouth and nose at one time, you should count one time for month-touching and one time for nose-touching). If there is any information that you cannot understand, please contact with me at any time; 2. fill in the following content immediately after completion of self-monitoring (with a link to "hand-to-face contacts" behavior monitoring record 1); 3. please contact with me to send the information about intervention to you when you completed the link. 4. You will repeat another one-hour period self-monitoring after your receiving another information (either "STOP touching your face" program or just thanks words)."*

Step 2. Intervention

The intervention group: Participants from the intervention group will receive the online mindfulness-based "STOP touching your face" program (both 750-word text and 5-min audio description). Each participant will be required to read the text of the program first and then listen to the audio. They will be encouraged to practice this technique until they feel confident and natural. The systematic review showed the efficacy of single session of brief MBIs, the average length of which was 15 minutes, ranged from less than 5 to 25 min[25]. Thus, the requirement practice time will be at least 15 minutes (excluding the time of reading the text and the first time of listening to the audio). This online mindfulness-based intervention will not have face-to-face interaction between the experimenter and participants throughout the entire study.

The control group: Participants who allocate to the control group will only receive information

to thank them and encourage them to complete the study. They will be reminded to receive "STOP touching your face" program after the end of this study.

Both groups: Participants from both groups will be reminded to contact with us to provide the instruction of another self-monitoring behavior of face-touching.

Step 3. The second self-monitoring of face-touching behavior (after intervention)

After intervention, all participants will be required to monitor their face-touching behavior during a 60-minute period again. When participants tell us *"I am ready to do another self-monitoring"*, they will receive instruction of how to complete the second self-monitoring of face-touching behavior during a 60-minute period. The repeat measurement of the face-touching behavior will be done at least 1 hour apart from the first self-monitoring. All participants will be encouraged to monitor their face-touching behavior in two similar situations.

Instruction: *"1. Again, please find a convenient time, no need to deliberately change your routine life (such as working or studying at the desk, watching TV), observe and record how many times you touched your hair, forehead, eyes, nose, mouth, ears, cheeks , Chin and neck in one-hour period (if you touched your mouth and nose at one time, you should count one time for month-touching and one time for nose-touching). It is better to find a similar situation (the similar time if not in the same day, same place, and when you are doing the same thing). You need to do it at least 1 hour apart from the last observation. If there is any information that you cannot understand, please contact with me at any time; 2. fill in the following content immediately after completing self-monitoring (with a link to "hand-to-face contacts" behavior monitoring record 2, the two groups will receive different links); 3. please let me known when you completed the link*

(the intervention group); please contact with me to send the program to you when you completed the link (the control group).”

All participants will be thanked and encouraged to practice “STOP touching your face” regularly after the end of the study. All outcomes will be collected by an online survey through the Chinese professional survey software WenJuanXing (Sojump, Shanghai, China, www.sojump.com). For non-responders, a reminding message will be sent to them by their provided contact information for reporting the outcomes.

Outcomes

Primary outcome: the efficacy of short-term mindfulness-based “STOP touching your face” intervention ($\geq$ 15min) for reducing face-touching behavior, measuring by reduction of percentage of the T-Zone touching during a 60-minute period by intervention.

Secondary outcomes: the reduction of the frequency of face-touching after intervention; the factors (demographic characteristics, psychological traits of mindfulness) that would be associated with reduction of frequency of face-touching; the differences of face-touching behavior between left-handers and right-handers.

Measures

1. Frequency of face-touching: Self-observation or self-monitoring of face-touching behavior will be required to report from each participant. A standardized scoring sheet will be provided to tally the frequency of hand-to-face contacts, the touched area of the face, including the mucosal area

(eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) , and the time in seconds of each contact will be recorded in a 60-minute period [4].

2. Reduction of frequency of face-touching behavior: this will be calculated as the total times of face-touching (including the eyes, nose, mouth, ears, cheeks, chin, neck, forehead, hair) during a 60-minute period before the intervention minus the total times of face-touching after the intervention.

3. Five Facet Mindfulness Questionnaire (FFMQ)[32-34]: this self-report scale is currently the most frequently used mindfulness questionnaire to measure changes in participant's tendency to be mindful in daily life by the following five related facets: observing(noticing, attending to sensations, perceptions, thoughts, feelings; 8 items), describing (labeling feelings, thoughts with words), acting with awareness (automatic pilot, concentration, non-distraction), non-judging internal experience, and non-reactivity to internal experience. Participants will be asked to what extent each of the statements are true of them. Each item is on a 1 to 5 Likert scale, ranging from 1 (never or very rarely true) to 5 (very often or always true). The scores represent a spectrum of mindfulness with no cut-off points, higher scores indicate higher levels of mindfulness. The factor structure of the short version (FFMQ-15) will be used in this study, which has been consistent with that of the FFMQ-39[35].

4. The Edinburgh Handedness Inventory (EHI) [36 37]: EHI is the most widely used 10-item self-report inventory to assess handedness. It is comprised of the following 10 activities: (1) writing, (2) drawing, (3) throwing, (4) using scissors, (5) a toothbrush (6) knife (without fork), (7) spoon, and such activities involving both hands as (8) using a broom (upper hand), (9) striking a match, and (10) unscrewing the lid of a bottle. To complete the EHI, one or two check marks are placed

under “left (L)” or “right (R)” columns, indicating strength of preference for each activity. Participants will be asked write “2”, ”1” or ”0” in the appropriate corresponding column. If the preference is very strong that they would never try to use the other hand unless absolutely forced to, then they will mark this column as “2” and the other column as “0”. If they are really indifferent, they will mark it as “1” in both columns. A laterality quotient ($LQ = R - L/R + L \times 100$) can be calculated, where a score of 100 reflects complete right-handedness, and a score of −100 reflects complete left-handedness.

Withdrawal from the Program

Every participant will feel free to withdraw from the study at any time and without giving any reason. On the basis of the intention-to-treat (ITT) principle[38], participants who fail to respond to follow-up assessment will be retained in the analysis and classified as those who continued the same behavior. Only participants who request withdrawal from the study will be excluded from the analysis, and reasons for withdrawal will be noted if they are available. However, self-monitoring itself may increase the awareness of face-touching behavior, then consequently increase or decrease the frequency of face-touching behavior in the second time of observation. Alternatively, a complete case analysis will also be performed in which any participant withdrew from the study in the second observation will be excluded.

Data collection

Data will be collected on line by WenJuanXing, a Chinese online market research Web site that provides professional online questionnaire survey or data collection for RCTs[39]. Data will be

monitored by data monitoring committee of the hospital. Personal data will be de-identified.

Data analysis

All data will be automatically collected by internet. A user-specified Excel file will be downloaded from the database. There will be no interim analyses. When all data have been obtained, they will be analyzed and blinded to intervention assignment by the trial statistician using R software (R Foundation for Statistical Computing, Vienna, Austria. https://www.r-project.org/) and SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Descriptive statistics will be applied for demographic and face-touching-related characteristics at baseline; two sample T-test or Mann-Whitney U test (for continuous variables) and $\chi 2$ test (for categorical variables) will be applied to compare the demographic information and face-touching behavior at baseline between the STOP intervention group and control group. Percentage of touching the T-Zone participants between pre- and post- intervention in the STOP group and the control group will be compared by χ^2 test. In order to determine if the "STOP touching your face" intervention group showed a reduction of face-touching behavior than the control group, two sample T-test or Mann-Whitney U test will first be applied to compared group differences in reduction of the frequency of face-touching. Then, analysis of covariance (ANCOVA) will be applied with controlling for demographic information (such age, handedness and prior mindfulness meditation experience). In ANCOVA model, the dependent variable will be the reduction of face-touching behavior. The pre-intervention measure of the total times of face-touching will be controlled as a covariate, and intervention will be a fix factor. This model will assess the differences in the post-intervention means after accounting for pre-intervention

values; Pearson's correlations or regression analysis (linear and binary regression model) will be used to explore the any factor that associated with face-touching behavior at baseline and reduction of face-touching behavior in the intervention group and in the control group. Intention-to-treat (ITT) basis will be applied in this study to handle incomplete or missing data (assuming for no reduction of the frequency of face-touching). In addition, a complete case analysis will be performed in which any participant with missing information on the follow-up will be excluded. All tests will be 2-tailed. A two-sided $P<0.05$ will be used to determine statistical significance.

Safety

Throughout the "STOP touching your face" program, participants will be encouraged to communicate with us if they experience any mindfulness practice relative issues. Adverse events will be monitored during the study. The MBIs are regarded as relatively safe interventions[40]. Research showed that even highly vulnerable participants (such as patients with major depressive disorder[41]) can safely practice mindfulness, but if participants experience any health-related issues, they will be encouraged to contact with us, or we will refer a health care provider. This study is not clinical-facilitated and may have very low risk of any safety issue. We will send a message to each participant to check whether they have any safety issues after providing them with intervention instruction.

Ethics and dissemination

The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32). All activities associated with this protocol will be conducted in full compliance with the approved policies and procedures. Electronically Informed consent (this e-consent is a form of written consent) will be communicated and obtained from each participant prior to participation. All participant will be explained about the purpose, procedures and assessments, potential risks and benefits of the trial before recruitment. After fully understanding the study, participants will be informed that their participation in this research study is total voluntary. They can choose to (sign the electronic consent form by selecting "agree to participant") or not to participate (sign the electronic consent form by selecting "disagree to participant"). Participation can withdrawal at any time without reasons. Contact information (phone number and social media contact like WeChat contact ID) of the study coordinator for any future questions and concerns will be provided and informed to each participant. We will recruit 1000 participants from April to July 2020 or until the recruitment process is complete. The follow-up will be completed in July 2020. We expect all trial results to be available by the end of July 2020. Any results from this trial (publications, conference presentations) will be disseminated via social media and be published in peer-reviewed journals and conference proceedings.

Discussion

This RCT is to investigate the efficacy of brief mindfulness-based intervention of "STOP touching your face" for people from general population in China. To our knowledge, this will be the first

RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior on the basis of mindfulness and cognitive behavioral principles.

The strength of this study is that this is a theoretical framework guided (mindfulness-based cognitive behavior theory) large sample size RCT to evaluate the efficacy of "STOP touching your face" during the outbreak of COVID-19. If "STOP touching your face" program is proved to be effective, it opens up its potential application worldwide at the population level. As "STOP touching your face" program is a free, brief, simple and widely accessible mindfulness-based behavior change intervention, the public health impact of its expansion world-wide could be enormous, helping us to manage any face-touching spread infectious diseases, like COVID-19.

There are some limitations in this study. First, there is no digital videotape recording for the behavior of face-touching by researchers. Alternatively, it will be self-monitored. Self-monitoring of physical (such as blood pressure), and mental health (such as anger or frustration that comes from daily life) has been used as a strategy for improving the treatment of a number of chronic conditions or reducing unhealth behaviors including smoking, drinking, gambling and so on[42]. Thus, self-monitoring itself may change participants face-touching behavior by creating a more active role in observing this behavior. Also, self-reported results of self-monitored times of face touching may be overestimated or underestimated. The results will be more accurate under lab conditions. In order to reduce the bias, we will invite a sub-group of participants with video record by another person to confirm the consistency of these results. Second, this is only an online intervention, participants may be more likely to drop out from the study. Thus, we will

encourage participants contact with us if they have any questions or concerns. We will also apply an intention-to-treat principle to prevent potential bias caused by missing data from loss to follow-up, as well as a complete case analysis. Third, this is only a brief intervention by internet. A face to face long-term mindfulness intervention will help participants gain the maximum benefits of practice. However, neuroimaging study demonstrates that both long and short-term mindfulness practice can improve automatic emotion regulation[43], and RCT shows that brief online mindfulness-based intervention can also increase mindfulness and decrease perceived stress and symptoms of anxiety or depression[27]. Last, this is a mindfulness-based intervention, and mindfulness could make participants better at catching themselves touching their faces, so participants from the intervention group may report higher frequency than the control group in the second self-monitoring of face-touching behavior.

In conclusion, this is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior. If "STOP touching your face", a brief and simple skill, is proven effective, the public health impact of its expansion world-wide could be enormous, its dissemination will help us to manage any face-touching spread infectious diseases, like Coronavirus disease 2019 (COVID-19).

Availability of data and materials

All data in the current study will be available from the corresponding author on reasonable request and with completion of data user agreement.

Authors' Contributions

YLiao and JT developed and designed the study. Yliao, CP and QL developed the "STOP touching your face" training program. Yliao discussed with LW and WC on the planning and conduct of the study, and discussed with YLiu and JT on the acquisition of data and the planning of data analysis. YLiao took the lead in drafting the manuscript protocol with contributions by JT and JC. TL, SW, ZW, YW, XG, LX and JZ advised the study design, and coordinated study approval. All authors read and proposed critical comments, as well as approved the manuscript for publication.

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Competing interests statement

No potential conflicts of interest to declare.

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References

1. Harrigan JA, Kues JR, Weber JG. Impressions of hand movements: Self-touching and gestures. *Perceptual and motor skills* 1986;63(2):503-16.
2. Krout MH. Autistic gestures: An experimental study in symbolic movement. *Psychological Monographs* 1935;46(4):i.
3. Nicas M, Best D. A study quantifying the hand-to-face contact rate and its potential application to predicting respiratory tract infection. *Journal of occupational and environmental hygiene* 2008;5(6):347-52.
4. Kwok YLA, Gralton J, McLaws M-L. Face touching: A frequent habit that has implications for hand hygiene. *American journal of infection control* 2015;43(2):112-14.
5. Dimond S, Harries R. Face touching in monkeys, apes and man: Evolutionary origins and cerebral asymmetry. *Neuropsychologia* 1984;22(2):227-33.
6. Measurement of Face-touching Frequency in a Simulated Train. E3S Web of Conferences; 2019. EDP Sciences.
7. Elder NC, Sawyer W, Pallerla H, et al. Hand hygiene and face touching in family medicine offices: a Cincinnati Area Research and Improvement Group (CARInG) network study. *The Journal of the American Board of Family Medicine* 2014;27(3):339-46.
8. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *The Lancet* 2020;395(10223):497-506.
9. Ong SWX, Tan YK, Chia PY, et al. Air, surface environmental, and personal protective equipment contamination by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from a symptomatic patient. *Jama* 2020
10. Mueller SM, Martin S, Grunwald M. Self-touch: Contact durations and point of touch of spontaneous facial self-touches differ depending on cognitive and emotional load. *PloS one* 2019;14(3)
11. Grunwald M, Weiss T, Mueller S, et al. EEG changes caused by spontaneous facial self-touch may represent emotion regulating processes and working memory maintenance. *brain research* 2014;1557:111-26.
12. Harrigan JA. Self-touching as an indicator of underlying affect and language processes. *Social science & medicine* 1985;20(11):1161-68.
13. Kabat-Zinn J. Mindfulness-based interventions in context: past, present, and future. *Clinical psychology: Science and practice* 2003;10(2):144-56.
14. Cavicchioli M, Movalli M, Maffei C. The Clinical Efficacy of Mindfulness-Based Treatments for Alcohol and Drugs Use Disorders: A Meta-Analytic Review of Randomized and Nonrandomized Controlled Trials. *European addiction research* 2018;24(3):137-62. doi: 10.1159/000490762 [published Online First: 2018/07/18]
15. Sancho M, De Gracia M, Rodríguez RC, et al. Mindfulness-based interventions for the treatment of substance and behavioral addictions: a systematic review. *Frontiers in psychiatry* 2018;9:95.
16. Kamboj SK, Irez D, Serfaty S, et al. Ultra-Brief Mindfulness Training Reduces Alcohol Consumption in At-Risk Drinkers: A Randomized Double-Blind Active-Controlled Experiment. *International Journal of Neuropsychopharmacology* 2017;20(11):936-47. doi: 10.1093/ijnp/pyx064

17. Haydicky J, Wiener J, Badali P, et al. Evaluation of a mindfulness-based intervention for adolescents with learning disabilities and co-occurring ADHD and anxiety. *Mindfulness* 2012;3(2):151-64.
18. Kristeller JL, Wolever RQ. Mindfulness-based eating awareness training for treating binge eating disorder: the conceptual foundation. *Eating disorders* 2010;19(1):49-61.
19. Wanden-Berghe RG, Sanz-Valero J, Wanden-Berghe C. The application of mindfulness to eating disorders treatment: a systematic review. *Eating disorders* 2010;19(1):34-48.
20. Xu W, Jia K, Liu X, et al. The effects of mindfulness training on emotional health in Chinese long-term male prison inmates. *Mindfulness* 2016;7(5):1044-51.
21. Shonin E, Van Gordon W, Griffiths M. Mindfulness-based interventions: Towards mindful clinical integration. *Frontiers in Psychology* 2013;4:194.
22. Carmody J, Baer RA. Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of behavioral medicine* 2008;31(1):23-33.
23. Grossman P, Niemann L, Schmidt S, et al. Mindfulness-based stress reduction and health benefits: A meta-analysis. *Journal of psychosomatic research* 2004;57(1):35-43.
24. Segal ZV, Teasdale J. Mindfulness-based cognitive therapy for depression: Guilford Publications 2018.
25. Howarth A, Smith JG, Perkins-Porras L, et al. Effects of Brief Mindfulness-Based Interventions on Health-Related Outcomes: a Systematic Review. *Mindfulness* 2019:1-12.
26. Chen Y, Yang X, Wang L, et al. A randomized controlled trial of the effects of brief mindfulness meditation on anxiety symptoms and systolic blood pressure in Chinese nursing students. *Nurse education today* 2013;33(10):1166-72.
27. Cavanagh K, Strauss C, Cicconi F, et al. A randomised controlled trial of a brief online mindfulness-based intervention. *Behaviour research and therapy* 2013;51(9):573-78.
28. Howells A, Ivtzan I, Eiroa-Orosa FJ. Putting the 'app'in happiness: a randomised controlled trial of a smartphone-based mindfulness intervention to enhance wellbeing. *Journal of Happiness Studies* 2016;17(1):163-85.
29. Garrison KA, Pal P, O'Malley SS, et al. Craving to quit: a randomized controlled trial of smartphone app–based mindfulness training for smoking cessation. *Nicotine and Tobacco Research* 2020;22(3):324-31.
30. Buntrock C, Ebert DD, Lehr D, et al. Effect of a web-based guided self-help intervention for prevention of major depression in adults with subthreshold depression: a randomized clinical trial. *Jama* 2016;315(17):1854-63.
31. Smalley SL, Winston D. Fully present: The science, art, and practice of mindfulness: Da Capo Lifelong Books 2010.
32. Deng Y-Q, Liu X-H, Rodriguez MA, et al. The five facet mindfulness questionnaire: psychometric properties of the Chinese version. *Mindfulness* 2011;2(2):123-28.
33. de Bruin EI, Topper M, Muskens JG, et al. Psychometric properties of the Five Facets Mindfulness Questionnaire (FFMQ) in a meditating and a non-meditating sample. *Assessment* 2012;19(2):187-97.
34. Baer RA, Smith GT, Hopkins J, et al. Using self-report assessment methods to explore facets of mindfulness. *Assessment* 2006;13(1):27-45.
35. Gu J, Strauss C, Crane C, et al. Examining the factor structure of the 39-item and 15-item versions of the Five Facet Mindfulness Questionnaire before and after mindfulness-based cognitive therapy for people with recurrent depression. *Psychological assessment* 2016;28(7):791.
36. Yang N, Waddington G, Adams R, et al. Translation, cultural adaption, and test–retest reliability of Chinese versions of the Edinburgh Handedness Inventory and Waterloo Footedness Questionnaire. *Laterality: Asymmetries of Body, Brain and Cognition* 2018;23(3):255-73.

37. Oldfield RC. The assessment and analysis of handedness: the Edinburgh inventory. *Neuropsychologia* 1971;9(1):97-113.
38. Montori VM, Guyatt GH. Intention-to-treat principle. *Cmaj* 2001;165(10):1339-41.
39. Fitzpatrick T, Zhou K, Cheng Y, et al. A crowdsourced intervention to promote hepatitis B and C testing among men who have sex with men in China: study protocol for a nationwide online randomized controlled trial. *BMC infectious diseases* 2018;18(1):489.
40. Wong SY, Chan JY, Zhang D, et al. The safety of mindfulness-based interventions: a systematic review of randomized controlled trials. *Mindfulness* 2018;9(5):1344-57.
41. Piet J, Hougaard E. The effect of mindfulness-based cognitive therapy for prevention of relapse in recurrent major depressive disorder: a systematic review and meta-analysis. *Clinical psychology review* 2011;31(6):1032-40.
42. Kim JY, Wineinger NE, Steinhubl SR. The influence of wireless self-monitoring program on the relationship between patient activation and health behaviors, medication adherence, and blood pressure levels in hypertensive patients: a substudy of a randomized controlled trial. *Journal of medical Internet research* 2016;18(6):e116.
43. Kral TR, Schuyler BS, Mumford JA, et al. Impact of short-and long-term mindfulness meditation training on amygdala reactivity to emotional stimuli. *Neuroimage* 2018;181:301-13.

Figure Legend

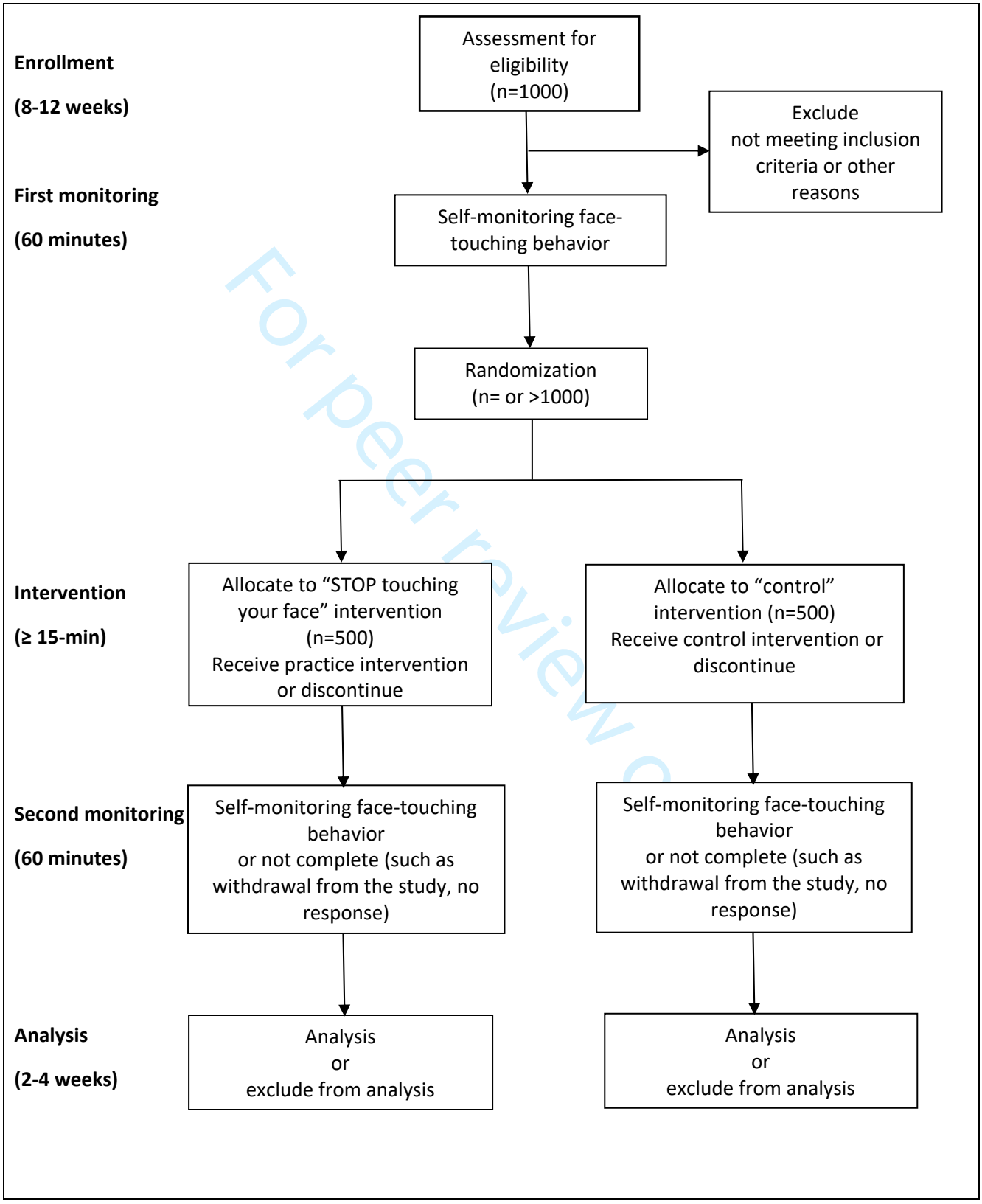
Figure 1 Study Flow Diagram

Note: Participants from the "control" intervention will receive "STOP touching your face" intervention (both text and audio description) immediately after completing the second self-monitoring face-touching behavior. But they will not be required to practice it or to practice it at least 15 minutes.

Table1 study inclusion and exclusion criteria

Inclusion Criteria:
1. 18 years of age or older
2. Being able to access online services
3. Being able to read and write in Chinese
4. Expressing an interest in participant this study
5. Willing to provide informed consent to participate in the study
Exclusion Criteria:
1. Under 18 years of age
2. Unable to access online services
3. Unable to read and write in Chinese
4. Already received “not to touch your face” training

Figure 1



Informed consent

Program name: A brief mindfulness-based intervention of "STOP (Stop, Take a Breath, Observe, Proceed) touching your face": a randomized controlled trial
Informed Consent Version Number: 1.0, Date: March 23, 2020
Primary Investigator: Liao, Yanhui

1. Invitation to participate in this research:
You will be invited to participate in a clinical study. This informed consent form provides you with some information to help you decide whether to participate in this clinical study or not. Please read it carefully. If you have any questions, please ask the researcher who is in charge of the study. Your participation in this study is totally voluntary. This study has been reviewed and approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32).

2. What kind of research is this?
Research purpose: Behaviour changes are very important for disease prevention, such as changing smoking behaviour to non-smoking behaviour, and using a pen tip to touch elevator buttons during the new coronavirus epidemic. However, many people touch their faces unconsciously. Avoiding this behaviour is an important way to prevent new coronavirus infections, especially for people in areas where there is a lack of masks (masks can also help people reduce touching their mouth and nose). The STOP technique of mindfulness intervention was originally a simple and effective way to relieve stress and anxiety. By practicing the simple technique of STOP, it may help us avoid touching our faces.
The main purpose of this study is to evaluate an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face" in reducing face-touching behaviour.
Research process and duration: The research process lasts at least more than 2 hours.
Research method and content: This randomized controlled trial (RCT) will enroll 1,000 healthy volunteers, and randomly assign subjects to a brief mindfulness intervention or control group at a ratio of 1:1. You need to find a convenient time, no need to deliberately change your life and work plan, you still can work and study. Prepare a paper and pen, or a recorder, then observe and record the number of times you touch your hair, forehead, eyes, nose, mouth, ears, cheeks, chin, and neck within 1 hour, and the time (seconds) of each touch. The intervention group will receive mindfulness-based STOP technology, and observe and record face touching again after practice it. The control group received control information of reminding them to observe and record face touching again. As part of the research, your interview information will be stored in Sir Run Run Shaw hospital of Zhejiang University School of Medicine for analysis or shared with other qualified researchers for research purposes. During the research process, we will use a unified standardized code to encode your private personal information, etc., and we will protect your information in accordance with relevant laws and regulations. If you are assigned to the control group, we will send you the STOP technique that received by the intervention group for free after the study.
Funding sources and possible conflicts of interest for the trial: The research plan was

designed by Dr, Yanhui Liao from Department of Psychiatry, Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, supported by Zhejiang University special scientific research fund for COVID-19 prevention and control (2020XGZX046).

Alternative therapies outside of this trial: Participation in this research is completely voluntary. You can refuse to participate in the research or opt out of the research at any time during the research process without any reason. This decision will not affect you in any way. If you decide to withdraw from this study, please notify your investigator in advance.

3. What does the participant need to do?

In the process of participating, you need to cooperate with a brief mindfulness intervention training, and give feedback on touching your face as required.

4. What risks and discomforts will it bring?

This study is a brief behavioural intervention, generally without adverse reactions; in terms of privacy protection, your personal information may be identified due to information leakage during information storage and sharing. The probability of the above risks is extremely small.

In addition to the existing risks, unknown risks may also occur during the research process.

5. What are the benefits?

You will not receive any compensation for participating in this study. Participating in this study can participate in brief mindfulness training, which may reduce the probability of unconsciously touching your face, which can reduce the chance of infection of infectious diseases such as the new coronavirus.

6. Do I need to pay related fees?

To participate in this research project, you do not need to pay related fees.

7. Compensation for participating in research, including compensation for injury.

Participating in this research will not receive financial compensation.

8. Who will see my information?

If you decide to participate in this study, your participation in the trial and your personal information in the trial are confidential. Your behaviour monitoring records and other information will be identified by the research number instead of your name. Information that can identify you will not be disclosed to members other than the research team unless with your permission. All research members and research sponsors are required to keep your identity confidential. Your files will be kept in a locked filing cabinet, which is only accessible to researchers. To ensure that the research is conducted in accordance with the regulations, when necessary, members of the government management department or the ethics review committee can access your personal data in the research unit according to the regulations. When the results of this research are published, no

personal information about you will be disclosed.

9. What if an adverse event occurs?

If you are harmed by participating in this study: In the event of damages related to this clinical study, our medical team will help you to get timely treatment, and adverse events will be handled as routine medical events in the hospital. You can choose not to participate in this research, or notify the researcher to withdraw from the research at any time, your data will not be included in the research results, and any of your medical treatment and rights will not be affected. If you need other treatments, or if you do not follow the study plan, or have a study-related injury or for any other reason, the study physician can terminate your continued participation in this study.

10. How to contact the researcher?

You can keep abreast of the information and research progress related to this research. If you have any questions related to this research, or if you have any discomfort or injury during the research, or have questions about the rights of participants in this research You can contact the researchers at any time (18890098852), 11th Floor, Inpatient Department, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, No. 368, Xiasha Road, Economic and Technological Development Zone, Hangzhou, Zhejiang). If you have any questions about your rights as a patient participating in the study, please contact The Medical Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, 0571-86006811.

Informed consent Signed page

- I have read this informed consent form.
- I have the opportunity to ask questions and all questions have been answered.
- I understand that participation in this study is voluntary.
- I can choose not to participate in this research, or I will withdraw after notifying the researcher at any time without being discriminated against or retaliated. Any of my medical treatment and rights will not be affected.
- If I need other treatment, or if I do not follow the research plan, or there is a research-related injury or for any other reason, the research physician can terminate my continued participation in this research.

Subject's electronic signature: _____

Date: _____ year_____month_____day

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
P1,1-3 Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
P4, 54 Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Not applicable, Protocol version	3	Date and version identifier
P24,488-493 Funding	4	Sources and types of financial, material, and other support
P1-2, 5-31; P24, 482-486 Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
P5-7, 69-117 Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
P7 119-133 Objectives	7	Specific objectives or hypotheses

P8, 140-147 Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
P8, 141 Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
P8, 147 P26, 546-547 Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
P14-15, 275-289 Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
P16, 317-324 Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
P21, 429-431 Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
P8-9, 149-168 Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

P10-11, 197-201 Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
P10-11, 199-200 Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
P10, 196-203 Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
P10, 200-203 Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
P17, 330-333 Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
P18-19, 371-374 Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
P19-20, 376-403 Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods: Monitoring

P18-19, 373-374 Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
P20, 405-414 Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

P20-21, 416-418 Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
P21, 420-429 Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
P19, 374 Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
P24, 495-496 Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
P11, 201-203 Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
P8, 145-147 Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

P21, 431-433 Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
In supplementary file, Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Not applicable, Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A brief mindfulness-based intervention of "STOP (Stop, Take a Breath, Observe, Proceed) touching your face": a study protocol of a randomized controlled trial

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Primary Subject Heading:	Public health

Secondary Subject Heading:	Mental health, Infectious diseases
Keywords:	EDUCATION & TRAINING (see Medical Education & Training), MENTAL HEALTH, PUBLIC HEALTH, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT
Note: The following files were submitted by the author for peer review, but cannot be converted to PDF. You must view these files (e.g. movies) online.	
Supplementary file 1_STOP_practice.mp3	

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A brief mindfulness-based intervention of "STOP (Stop, Take a Breath, Observe, Proceed) touching your face": a study protocol of a randomized controlled trial

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Abstract

Introduction Face-touching behavior often happens frequently and automatically, and poses potential risk for spreading infectious disease. Mindfulness-based interventions (MBIs) have shown its efficacy in the treatment of behavior disorders. This study aims to evaluate an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face" in reducing face-touching behavior.

Methods and analysis This will be an online-based, randomized, controlled, trial. We will recruit 1,000 participants, and will randomize and allocate participants 1:1 to the "STOP touching your face" (both 750-word text and 5-min audio description by online) intervention group (n=500) and the wait-list control group (n=500). All participants will be asked to monitor and record their face-touching behavior during a 60-minute period before and after the intervention. Primary outcome will be the efficacy of short-term mindfulness-based "STOP touching your face" intervention for reducing the frequency of face-touching. The secondary outcomes will be percentage of participants touching their faces; the correlation between the psychological traits of mindfulness and face-touching behavior; and the differences of face-touching behavior between left-handers and right-handers. Analysis of covariance, regression analysis, χ^2 test, T-test, Pearson's correlations will be applied in data analysis. We will recruit 1000 participants from April to July 2020 or until the recruitment process is complete. The follow-up will be completed in July 2020. We expect all trial results to be available by the end of July 2020.

Ethics and dissemination The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32). Study results will be disseminated via social media and peer-reviewed publications.

Trial registration number NCT04330352.

Strengths and limitations of this study

- This is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior.
- This is a theoretical framework guided (mindfulness-based cognitive behavior theory) large sample size RCT to evaluate the efficacy of "STOP touching your face" during the outbreak of COVID-19.
- "STOP touching your face" program is a free, brief, simple and widely accessible mindfulness-based behavior change intervention.
- There is no digital videotape recording for the behavior of face-touching by researchers. Alternatively, it will be self-monitored.
- This is only a brief intervention by internet. A face to face long-term mindfulness intervention will help participants gain the maximum benefits of practice.

Introduction

Nonverbal behavior plays an important role in interpersonal relations and constitutes a large amount of all communication. But self-touching is usually not used to communicate with others and is often done automatically without thinking about it at all in our daily life[1]. It might be one of the so called "autistic" gestures when they have no evident meaning[2]. Spontaneous facial self-touching or face-touching has been defined as *the use of the hand to touch the individual's own face* to scratch, rub, groom, or caress it. Research shows that the average face-touching frequency ranges from approximately 16[3] to 23[4] times per hour. Furthermore, research of face-touching across handedness showed that left-handed individuals more frequently touch their face than their counterparts[5].

An increase in face-touching frequency may result in increased risk of transmissible infections, defined as self-inoculation or auto-inoculation (a type of contact transmission occurs when a person transfers an infectious disease from one part of the body to another, e.g., when a contaminated hand makes subsequent contact with the nose and introduces contaminated material to those areas)[3 4]. Of all face-touching behaviors, touching the T-zones will pose a potential risk for transmission and acquisition of a range of infectious diseases. Unfortunately, research found that 42.2%[6] to 44%[4] of face-touching involved in contacting with a mucous membrane. Even clinicians touch their T-zones (the mucus membranes of the eyes, nose, and mouth) as frequently as 19 times on average within 2 hours[7]. Many diseases can be spread by self-inoculation in this way, including coronavirus disease 2019 ("COVID-19") [8 9]. Thus, the

Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have been telling people to stop touching their faces.

However, even we all know that stop touching our faces will minimize spread of coronavirus and other germs. The question is how to stop this behavior? Although face-touching is often an automatic behavior without conscious thought or decision, research indicates that the frequency of self-touching and the duration of touch and contact are associated with cognitive and emotional demands[10 11]. In addition to emotional states, especially negative affect states, self-touching also has been linked to information processing and production[12].

Raising self-awareness of face-touching behavior may be effective in reducing or avoiding this behavior. For example, every time when you touch your face, be mindful, notice how you touched your face, check what you are thinking, physical and psychological feeling or your sensation that preceded it. This process or skill is similar to "mindfulness practice" developed by Jon Kabat Zinn[13]. Mindfulness can be defined as *"Mindful Awareness is the moment-by-moment process of actively and openly observing one's physical, mental and emotional experiences"* (Mindful Awareness Research Center at the University of California at Los Angeles). Mindfulness-based interventions (MBIs) are proven to be clinically efficacious in treatment of behavioral disorders, such as alcohol drinking, smoking, gambling[14-16], attention deficit/hyperactivity disorder (ADHD)[17], eating disorders[18 19], as well as in enhancing the emotional health of Chinese long-term male prison inmates[20]. Increasing peoples' awareness of their habituated face-touching behavior may help individuals to avoid touching their face by contaminated hands, and

decrease the risk of spreading infectious diseases. The structured MBIs, such as mindfulness-based stress reduction (MBRS) and mindfulness-based cognitive therapy (MBCT) program, are 8 to 10 weeks course[21-24], but brief MBIs can also produce numerous health-related outcomes, even only with one session intervention and as brief as 5 minutes[25 26]. Randomized controlled trials (RCT) of a brief mindfulness-based intervention further suggested the feasibility and effectiveness of short- term, self-guided, internet or smartphone-based interventions[27 28].

The primary objective of this proposed project is to identify a simple but effective practice to reduce or avoid face-touching to low people's chances of catching infectious diseases like COVID-19. Based on the efficacy of MBIs in treatment of some behavioral disorders and the efficacy of short-term MBIs, we here propose a RCT of an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face". It is hypothesized that this skill will be an effective, feasible, accessible skill in reducing or avoiding face-touching for people in the general population. To be specific, the primary hypothesis of this brief behavioral intervention is that, compared with a control intervention, the intervention would result in greater reduction of face-touching behavior. We also hypothesize that the frequency of face-touching behavior will also be reduced. Based on the theory that both face-touching behavior and mindfulness link to cognitive or emotional process[10 23], we hypothesize that people with higher levels of self-reported mindfulness will touch their face less frequently. Given left-handed individuals more frequently touch their face than their counterparts[5], It is hypothesized that, compared with right-handed participants, left-handed individuals will touch their face more frequently during their 60-minute self-monitoring of face-touching.

Methods and analysis

Patient and public involvement

Neither participants nor the public were involved in the design, recruitment or conduct of the study.

Study design and participants

In this online-based, randomized, parallel-group trial, undertaken in China by internet, about 1,000 participants willing to participate in "STOP touching your face" training program and provide electronic consent (e-consent), will be randomly allocated to mindfulness-based "STOP touching your face" intervention group or a control group at a 1:1 ratio. A 2 × 2 (practice group and control group × pre–post measurements) experimental design will be used. Since participants will be told that they will either receive "STOP touching your face" training program before (intervention group) or after (control group) the second 60-minute self-monitoring face-touching behavior, blinding of participants will not be possible. Blinding of the investigators (mainly Dr. Y Liao and Dr. L Wang) who are directly involved in interventions will also not be possible because of the nature differences of these two interventions ("STOP touching your face" training program intervention and control intervention). The investigators (Dr. J Tang and Dr. Y Liu) who will assess the outcomes will be blinded to participants' allocated groups until all data have been analyzed. All participants who are allocated to the control group will have the opportunity to practice this skill after the end of the study period. An overview of participant eligibility criteria is given in **Table1.**

Sample size and power calculation

This study aims to recruit 1000 participants, with 500 in each group. The sample size assessment and power calculations are mainly on the basis of the results of RCTs of different types of online short-term mindfulness intervention for behavioral changes, such as for alcohol consumption[16] and stopping smoking or decreasing smoking craving[29], or for positive psychological changes, such as enhancing wellbeing[28] and reducing perceived stress and anxiety/depression symptoms[27]. A single brief session of mindfulness of 11-minutes (n=34) detected a significant reduction in alcohol consumption compared with a relaxation control intervention (n=34)[16]. It is estimated that, for assessing stop face-touching behavior, individuals who received mindfulness intervention will at least twice likely to reduce the chance of touching T-Zone than the control group (5 to 10% vs. 2 to 4%). Thus, a total of 562 participants (281 participants in each group) are required to achieve 80% power (1-beta=0.8), as significant at the 5% level (alpha=0.05), an increase in the outcome measure from 4% in the control group to 10% in the intervention group. However, online interventions often have much higher dropout rate than face to face intervention. A web-based guided self-help intervention for preventing depression reported about 20% dropout rate at 6-month follow-up[30], but a brief online mindfulness-based intervention for reducing stress, anxiety and depression reported 30% dropout rate in the intervention group and more than a half in the waiting list control group[27] Considering the high loss to follow-up rate, this study will have a final target sample size of 1000 participants (500 in each arm), which will have sufficient power to detect a significant difference for the outcomes.

Recruitment

As in other similar research, we will advertise this program online using social media (such as WeChat and QQ) to recruit potential participants. Potential participants will register their interest by sending messages by social media, email or sending text messages, or making a call to research assistants (by Dr. Y Wang and Dr. Z Wu). Then, research assistants will contact respondents to assess their eligibility and explain the study to each participant and inform them that they would be allocated to either a control group or to a group that receives the Mindfulness-based "STOP touching your face" program. Before collecting baseline data, electronically informed consent will be obtained from each participant. Participants who enrolled in this study could withdraw at any time. They will also be asked to provide contact information (will not be shared with any third party), in case any problems arise.

Baseline data

Prior to randomization, demographic information and self-reported questionnaires will be obtained from all participants at baseline (assessed by Dr. Y Liao, Dr. C Pan and Dr. Q Luo). The demographic information of participants will be gender, age, years of education, marital status, occupation by the International Standard Classification of Occupations (ISCO), living in rural or urban region, smoker types (nonsmoker or current smoker and former smoker). The Five Facets Mindfulness Questionnaire (FFMQ) will be applied to measure the dispositional tendency to be mindful in daily life. The Edinburgh Handedness Inventory (EHI) will be used to assess handedness. Frequency of face-touching will be assessed at baseline and after intervention.

Randomization and group allocation

After reporting the first 60-minute self-monitoring face-touching behavior, participants will be randomized and assigned (by Dr. Y Liu) to either start the intervention immediately (intervention condition) or to a wait-list control condition (who will be offered the intervention immediately after reporting the second 60-minute self-monitoring face-touching behavior). Randomization will be run by randomizeR, (https://CRAN.R-project.org/package=randomizeR). All participants will report the first self-monitoring by the same link (the same Excel file will be downloaded), and the second will be reported by two different links (two separated Excel files will be downloaded) to detect group allocation. Group allocation will not be concealed to investigators who will provide interventions. But the investigators (by Dr. J Tang and Dr. Y Liu) who will analyze the data for evaluating outcomes will be blinded to participants' treatment allocations until the entire analysis has been completed.

Development of "STOP touching your face" training program

Theory

Face-touching behavior is often an automatic behavior that could potentially disseminate respiratory infections (eg, influenza, coronavirus), yet can be changed. However, changing the behavior of face-touching is "easier said than done", as there is only limited evidence for the neuropsychological basis or physiological fundamentals of this behavior. Research shows that the frequency of self-touching increases when attention is distracted[10], as well as under stressful situations or with negative affect[11]. Cognitive behavioral theory-based mindfulness intervention (mindfulness-based cognitive therapy, MBCT[24]) has been used as a psychological intervention for

people with mental or behavior problems, targeting both cognitive and behavioral problems. Mindfulness-based interventions (MBIs)[13] can help people cultivate positive affect, increase self-awareness and concentration that are associated with reducing frequency of face-touching.

Practice

STOP[31] is an acronym that stands for four action: "Stop", "Take a breath", "Observe", "Proceed". It is a helpful aid in becoming more mindful of our body, behavior and emotion on a daily basis. The following is the instruction for how to practice STOP:

S = Stop

Remind yourself to STOP. Whatever you are doing in this moment (e.g. touching your month, pinching your nose, rubbing your eyes, resting your chin on your hands), pause for a minute.

T = Take

Take a deep breath. This reconnects you with your body. Pay attention to your breathing and just allow yourself to continue to breathe normally and naturally.

O = Observe

OBSERVE what is happening for you in this moment—including thoughts, feelings, and emotions (e.g. feel distracted, anxious or nervous?). What do you notice in your body (e.g. feel itchy or tingling on any part of your face)? You can be aware of anything: posture, sensations, tension in your body, or, once again, your breath. You might notice the sound around you. You might even notice your thoughts or emotions

P = Proceed

Proceed with whatever you were doing before you came to a STOP or something that you want

to do in the moment (e.g. proceed with touching your face, or stop face-touching and take an alternative behavior).

The STOP Practice is very short, simple, and the acronym (STOP) makes it easy to remember as well. Thus, it has become one of the most popular mindfulness-based practices. The practice of STOP may cultivate a space between stimulus and response, which could help avoid the mostly spontaneous behavior of facial self-touching. The STOP Practice in Chinese was already developed by Dr. Y Liao, Dr. Q Luo and Dr. C Pan. Dr. Y Liao developed the "STOP touching your face" training program. Both 750-word text and 5-min audio description (see **Supplementary file 1**) will be available by online.

Procedures

After advertising, participants who are interested in this study will be assessed for eligibility by making a call or communicating with social media (mainly WeChat). Then, eligible participants will sign a e-consent form (**Supplementary file 2**), and complete baseline information and the first self-monitoring of frequency of face-touching in a 60-minute period by online. Afterwards, participants will receive a brief mindfulness-based "STOP touching your face" intervention or control intervention. For both groups, the second self-monitoring of frequency of face-touching behavior will be taken at least 1 hour apart from the first one. The schedule of study procedures summarizes in **Figure 1.** The details of the procedure will include the following 3 steps:

Step 1. The first 60-minute self-monitoring of face-touching behavior (before intervention)

In order to measure the changes of face-touching behavior before and after intervention, all eligible participants will receive the instruction (in Chinese) of how to self-monitored and

reported the frequency of face-touching in any of the mucosal area (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) during a 60-minute period. All participants will be required to monitor their face-touching behavior during a 60-minute period, and be encouraged to do it in a manageable situation. Wearing facial mask will not be permitted during the time of self-monitoring face-touching. All participants will be provided with the same link to complete their baseline information and the first 60-minute self-monitoring of face-touching behavior, and be encouraged to complete this questionnaire immediately after completion of self-monitoring.

Instruction: *"1. Please find a convenient time, no need to deliberately change your routine life (such as working or studying at the desk, watching TV), observe and record how many times you touched your hair, forehead, eyes, nose, mouth, ears, cheeks , Chin and neck in one-hour period (if you touched your mouth and nose at one time, you should count one time for month-touching and one time for nose-touching). If there is any information that you cannot understand, please contact with me at any time; 2. fill in the following content immediately after completion of self-monitoring (with a link to "hand-to-face contacts" behavior monitoring record 1); 3. please contact with me to send the information about intervention to you when you completed the link. 4. You will repeat another one-hour period self-monitoring after your receiving another information (either "STOP touching your face" program or just thanks words)."*

Step 2. Intervention

The intervention group: Participants from the intervention group will receive the online mindfulness-based "STOP touching your face" program (both 750-word text and 5-min audio

description). Each participant will be required to read the text of the program first and then listen to the audio. They will be encouraged to practice this technique until they feel confident and natural. The systematic review showed the efficacy of single session of brief MBIs, the average length of which was 15 minutes, ranged from less than 5 to 25 min[25]. Thus, the requirement practice time will be at least 15 minutes (excluding the time of reading the text and the first time of listening to the audio). This online mindfulness-based intervention will not have face-to-face interaction between the experimenter and participants throughout the entire study.

The control group: Participants who allocate to the control group will only receive information to thank them and encourage them to complete the study. They will be reminded to receive "STOP touching your face" program after the end of this study.

Both groups: Participants from both groups will be reminded to contact with us to provide the instruction of another self-monitoring behavior of face-touching.

Step 3. The second 60-minute self-monitoring of face-touching behavior (after intervention)

After intervention, all participants will be required to monitor their face-touching behavior during a 60-minute period again. When participants tell us *"I am ready to do another self-monitoring"*, they will receive instruction of how to complete the second 60-minute self-monitoring of face-touching behavior during a 60-minute period. The repeat measurement of the face-touching behavior will be done at least 1 hour apart from the first self-monitoring. All participants will be encouraged to monitor their face-touching behavior in two similar situations.

Instruction: *"1. Again, please find a convenient time, no need to deliberately change your routine life (such as working or studying at the desk, watching TV), observe and record how many times*

you touched your hair, forehead, eyes, nose, mouth, ears, cheeks , Chin and neck in one-hour period (if you touched your mouth and nose at one time, you should count one time for month-touching and one time for nose-touching). It is better to find a similar situation (the similar time if not in the same day, same place, and when you are doing the same thing). You need to do it at least 1 hour apart from the last observation. If there is any information that you cannot understand, please contact with me at any time; 2. fill in the following content immediately after completing self-monitoring (with a link to "hand-to-face contacts" behavior monitoring record 2, the two groups will receive different links); 3. please let me known when you completed the link (the intervention group); please contact with me to send the program to you when you completed the link (the control group)."

All participants will be thanked and encouraged to practice "STOP touching your face" regularly after the end of the study. All outcomes will be collected by an online survey through the Chinese professional survey software WenJuanXing (Sojump, Shanghai, China, www.sojump.com). For non-responders, a reminding message will be sent to them by their provided contact information for reporting the outcomes.

Outcomes

Primary outcome: the efficacy of short-term mindfulness-based "STOP touching your face" intervention (≥15min) for reducing face-touching behavior, measuring by reduction of frequency of face touching behavior (this will be calculated as the total times of face-touching (including

the eyes, nose, mouth, ears, cheeks, chin, neck, forehead, hair) during a 60-minute period before the intervention minus the total times of face-touching after the intervention).

Secondary outcomes: the reduction of percentage of participants touching their faces (this will be calculated as the percentage of participants touching their faces (including any of the following areas: the eyes, nose, mouth, ears, cheeks, chin, neck, forehead, hair) during a 60-minute period before the intervention - the percentage of participants touching their faces after the intervention) after intervention; the factors (demographic characteristics, psychological traits of mindfulness) that would be associated with reduction of frequency of face-touching; the differences of face-touching behavior between left-handers and right-handers.

Measures

1. Frequency of face-touching: Self-observation or self-monitoring of face-touching behavior will be required to report from each participant. A standardized scoring sheet will be provided to tally the frequency of hand-to-face contacts, the touched area of the face, including the mucosal area (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) , and the time in seconds of each contact will be recorded in a 60-minute period [4].

2. Percentage of participants touching their faces: this will be the number of participants who touched any of the following areas: the eyes, nose, mouth, ears, cheeks, chin, neck, forehead, hair, during their 60-minute self-monitoring of face-touching / the total number of participants in the intervention group or the control group.

3. Five Facet Mindfulness Questionnaire (FFMQ)[32-34]: this self-report scale is currently the most frequently used mindfulness questionnaire to measure changes in participant's tendency to be

mindful in daily life by the following five related facets: observing(noticing, attending to sensations, perceptions, thoughts, feelings; 8 items), describing (labeling feelings, thoughts with words), acting with awareness (automatic pilot, concentration, non-distraction), non-judging internal experience, and non-reactivity to internal experience. Participants will be asked to what extent each of the statements are true of them. Each item is on a 1 to 5 Likert scale, ranging from 1 (never or very rarely true) to 5 (very often or always true). The scores represent a spectrum of mindfulness with no cut-off points, higher scores indicate higher levels of mindfulness. The factor structure of the short version (FFMQ-15) will be used in this study, which has been consistent with that of the FFMQ-39[35].

4. The Edinburgh Handedness Inventory (EHI) [36 37]: EHI is the most widely used 10-item self-report inventory to assess handedness. It is comprised of the following 10 activities: (1) writing, (2) drawing, (3) throwing, (4) using scissors, (5) a toothbrush (6) knife (without fork), (7) spoon, and such activities involving both hands as (8) using a broom (upper hand), (9) striking a match, and (10) unscrewing the lid of a bottle. To complete the EHI, one or two check marks are placed under “left (L)” or “right (R)” columns, indicating strength of preference for each activity. Participants will be asked write “2”, ”1” or ”0” in the appropriate corresponding column. If the preference is very strong that they would never try to use the other hand unless absolutely forced to, then they will mark this column as “2” and the other column as “0”. If they are really indifferent, they will mark it as “1” in both columns. A laterality quotient ($LQ = R - L/R + L \times 100$) can be calculated, where a score of 100 reflects complete right-handedness, and a score of −100 reflects complete left-handedness.

Withdrawal from the Program

Every participant will feel free to withdraw from the study at any time and without giving any reason. On the basis of the intention-to-treat (ITT) principle[38], participants who fail to respond to the second assessment will be retained in the analysis according to the arm they were randomized to, irrespective of whether they did the intervention or not. Only participants who request withdrawal from the study will be excluded from the analysis, and reasons for withdrawal will be noted if they are available. However, self-monitoring itself may increase the awareness of face-touching behavior, then consequently increase or decrease the frequency of face-touching behavior in the second time of observation. Alternatively, a complete case analysis will also be performed in which any participant withdrew from the study in the second observation will be excluded.

Data collection

Data will be collected on line by WenJuanXing, a Chinese online market research Web site that provides professional online questionnaire survey or data collection for RCTs[39]. Data will be monitored by data monitoring committee of the hospital. Personal data will be de-identified.

Data analysis

All data will be automatically collected by internet. A user-specified Excel file will be downloaded from the database. There will be no interim analyses. When all data have been obtained, they will be analyzed and blinded to intervention assignment by the trial statistician using R software (R Foundation for Statistical Computing, Vienna, Austria. https://www.r-project.org/) and SPSS

(IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Descriptive statistics will be applied for demographic and face-touching-related characteristics at baseline; two sample T-test or Mann-Whitney U test (for continuous variables) and χ2 test (for categorical variables) will be applied to compare the demographic information and face-touching behavior at baseline between the STOP intervention group and control group. Percentage of touching the T-Zone participants between pre- and post- intervention in the STOP group and the control group will be compared by χ^2 test. For assessing the primary outcome, determining if the "STOP touching your face" intervention group showed a reduction of face-touching behavior than the control group, two sample T-test or Mann-Whitney U test will first be applied to compared group differences in reduction of the frequency of face-touching. Then, analysis of covariance (ANCOVA) will be applied with controlling for demographic information (such age, handedness and prior mindfulness meditation experience). In ANCOVA model, the dependent variable will be the reduction of face-touching behavior. The pre-intervention measure of the total times of face-touching will be controlled as a covariate, and intervention will be a fix factor. This model will assess the differences in the post-intervention means after accounting for pre-intervention values. Pearson's correlations or regression analysis (linear and binary regression model) will be used to explore the any factor that associated with face-touching behavior at baseline and reduction of face-touching behavior in the intervention group and in the control group. Intention-to-treat (ITT) basis will be applied in this study, all participants who complete the first 60-minute self-monitoring face-touching behavior will be retained in the analysis. The last-observation-carried-forward (LOCF) method will be applied to handle incomplete or missing data (assuming for no reduction of the frequency of face-touching). In addition, a complete case analysis will be

performed in which any participant with missing information on the follow-up will be excluded. All tests will be 2-tailed. A two-sided P<0.05 will be used to determine statistical significance.

Safety

Throughout the "STOP touching your face" program, participants will be encouraged to communicate with us if they experience any mindfulness practice relative issues. Adverse events will be monitored during the study. The MBIs are regarded as relatively safe interventions[40]. Research showed that even highly vulnerable participants (such as patients with major depressive disorder[41]) can safely practice mindfulness, but if participants experience any health-related issues, they will be encouraged to contact with us, or we will refer a health care provider. This study is not clinical-facilitated and may have very low risk of any safety issue. We will send a message to each participant to check whether they have any safety issues after providing them with intervention instruction.

Ethics and dissemination

The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32). All activities associated with this protocol will be conducted in full compliance with the approved policies and procedures. Electronically Informed consent (this e-consent is a form of written consent) will be communicated and obtained from each participant prior to participation. All participant will be explained about the purpose, procedures and assessments, potential risks and benefits of the

trial before recruitment. After fully understanding the study, participants will be informed that their participation in this research study is total voluntary. They can choose to (sign the electronic consent form by selecting "agree to participant") or not to participate (sign the electronic consent form by selecting "disagree to participant"). Participation can withdrawal at any time without reasons. Contact information (phone number and social media contact like WeChat contact ID) of the study coordinator for any future questions and concerns will be provided and informed to each participant. We will recruit 1000 participants from April to July 2020 or until the recruitment process is complete. The follow-up will be completed in July 2020. We expect all trial results to be available by the end of July 2020. Any results from this trial (publications, conference presentations) will be disseminated via social media and be published in peer-reviewed journals and conference proceedings.

Discussion

This RCT is to investigate the efficacy of brief mindfulness-based intervention of "STOP touching your face" for people from general population in China. To our knowledge, this will be the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior on the basis of mindfulness and cognitive behavioral principles.

The strength of this study is that this is a theoretical framework guided (mindfulness-based cognitive behavior theory) large sample size RCT to evaluate the efficacy of "STOP touching your face" during the outbreak of COVID-19. If "STOP touching your face" program is proved to be effective, it opens up its potential application worldwide at the population level. As "STOP

touching your face" program is a free, brief, simple and widely accessible mindfulness-based behavior change intervention, the public health impact of its expansion world-wide could be enormous, helping us to manage any face-touching spread infectious diseases, like COVID-19.

There are some limitations in this study. First, there is no digital videotape recording for the behavior of face-touching by researchers. Alternatively, it will be self-monitored. Self-monitoring of physical (such as blood pressure), and mental health (such as anger or frustration that comes from daily life) has been used as a strategy for improving the treatment of a number of chronic conditions or reducing unhealth behaviors including smoking, drinking, gambling and so on[42]. Thus, self-monitoring itself may change participants face-touching behavior by creating a more active role in observing this behavior. Also, self-reported results of self-monitored times of face touching may be overestimated or underestimated. Furthermore, self-monitoring itself may increase the awareness of face-touching behavior, then consequently increase or decrease the frequency of face-touching behavior in the second time of observation. The results will be more accurate under lab conditions. In order to reduce the bias, we will invite a sub-group of participants with video record by another person to confirm the consistency of these results. Second, this is only an online intervention, participants may be more likely to drop out from the study. Thus, we will encourage participants contact with us if they have any questions or concerns. We will also apply an intention-to-treat principle to prevent potential bias caused by missing data from loss to follow-up, as well as a complete case analysis. Third, this is only a brief intervention by internet. A face to face long-term mindfulness intervention will help participants gain the maximum benefits of practice. However, neuroimaging study demonstrates that both long and

short-term mindfulness practice can improve automatic emotion regulation[43], and RCT shows that brief online mindfulness-based intervention can also increase mindfulness and decrease perceived stress and symptoms of anxiety or depression[27]. Fourth, this is a mindfulness-based intervention, and mindfulness could make participants better at catching themselves touching their faces, so participants from the intervention group may report higher frequency than the control group in the second 60-minute self-monitoring of face-touching behavior. Last, we submitted this protocol to the journal during the time of recruiting.

In conclusion, this is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior. If "STOP touching your face", a brief and simple skill, is proven effective, the public health impact of its expansion world-wide could be enormous, its dissemination will help us to manage any face-touching spread infectious diseases, like Coronavirus disease 2019 (COVID-19).

Availability of data and materials

All data in the current study will be available from the corresponding author on reasonable request and with completion of data user agreement.

Authors' Contributions

YLiao and JT developed and designed the study. YLiao, CP and QL developed STOP Practice, YLiao developed the "STOP touching your face" training program. Yliao discussed with LW and WC on the planning and conduct of the study, and discussed with YLiu and JT on the acquisition of data

and the planning of data analysis. YLiao, LW, TL, SW, ZW, JC, CP, YW, LX and JZ conducted the interventions. JT and YLiu conducted data analysis. YLiao took the lead in drafting the manuscript protocol with contributions by JT and JC. LQ, XG and WC advised the study design, and coordinated study approval. All authors read and proposed critical comments, as well as approved the manuscript for publication.

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Competing interests statement

Dr. Y Liao developed the "STOP touching your face" training program. No other potential conflicts of interest to declare.

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References

1. Harrigan JA, Kues JR, Weber JG. Impressions of hand movements: Self-touching and gestures. *Perceptual and motor skills* 1986;63(2):503-16.
2. Krout MH. Autistic gestures: An experimental study in symbolic movement. *Psychological Monographs* 1935;46(4):i.
3. Nicas M, Best D. A study quantifying the hand-to-face contact rate and its potential application to predicting respiratory tract infection. *Journal of occupational and environmental hygiene* 2008;5(6):347-52.
4. Kwok YLA, Gralton J, McLaws M-L. Face touching: A frequent habit that has implications for hand hygiene. *American journal of infection control* 2015;43(2):112-14.
5. Dimond S, Harries R. Face touching in monkeys, apes and man: Evolutionary origins and cerebral asymmetry. *Neuropsychologia* 1984;22(2):227-33.
6. Measurement of Face-touching Frequency in a Simulated Train. E3S Web of Conferences; 2019. EDP Sciences.
7. Elder NC, Sawyer W, Pallerla H, et al. Hand hygiene and face touching in family medicine offices: a Cincinnati Area Research and Improvement Group (CARInG) network study. *The Journal of the American Board of Family Medicine* 2014;27(3):339-46.
8. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *The Lancet* 2020;395(10223):497-506.
9. Ong SWX, Tan YK, Chia PY, et al. Air, surface environmental, and personal protective equipment contamination by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from a symptomatic patient. *Jama* 2020
10. Mueller SM, Martin S, Grunwald M. Self-touch: Contact durations and point of touch of spontaneous facial self-touches differ depending on cognitive and emotional load. *PloS one* 2019;14(3)
11. Grunwald M, Weiss T, Mueller S, et al. EEG changes caused by spontaneous facial self-touch may represent emotion regulating processes and working memory maintenance. *brain research* 2014;1557:111-26.
12. Harrigan JA. Self-touching as an indicator of underlying affect and language processes. *Social science & medicine* 1985;20(11):1161-68.
13. Kabat-Zinn J. Mindfulness-based interventions in context: past, present, and future. *Clinical psychology: Science and practice* 2003;10(2):144-56.
14. Cavicchioli M, Movalli M, Maffei C. The Clinical Efficacy of Mindfulness-Based Treatments for Alcohol and Drugs Use Disorders: A Meta-Analytic Review of Randomized and Nonrandomized Controlled Trials. *European addiction research* 2018;24(3):137-62. doi: 10.1159/000490762 [published Online First: 2018/07/18]
15. Sancho M, De Gracia M, Rodríguez RC, et al. Mindfulness-based interventions for the treatment of substance and behavioral addictions: a systematic review. *Frontiers in psychiatry* 2018;9:95.
16. Kamboj SK, Irez D, Serfaty S, et al. Ultra-Brief Mindfulness Training Reduces Alcohol Consumption in At-Risk Drinkers: A Randomized Double-Blind Active-Controlled Experiment. *International Journal of Neuropsychopharmacology* 2017;20(11):936-47. doi: 10.1093/ijnp/pyx064

17. Haydicky J, Wiener J, Badali P, et al. Evaluation of a mindfulness-based intervention for adolescents with learning disabilities and co-occurring ADHD and anxiety. *Mindfulness* 2012;3(2):151-64.
18. Kristeller JL, Wolever RQ. Mindfulness-based eating awareness training for treating binge eating disorder: the conceptual foundation. *Eating disorders* 2010;19(1):49-61.
19. Wanden-Berghe RG, Sanz-Valero J, Wanden-Berghe C. The application of mindfulness to eating disorders treatment: a systematic review. *Eating disorders* 2010;19(1):34-48.
20. Xu W, Jia K, Liu X, et al. The effects of mindfulness training on emotional health in Chinese long-term male prison inmates. *Mindfulness* 2016;7(5):1044-51.
21. Shonin E, Van Gordon W, Griffiths M. Mindfulness-based interventions: Towards mindful clinical integration. *Frontiers in Psychology* 2013;4:194.
22. Carmody J, Baer RA. Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of behavioral medicine* 2008;31(1):23-33.
23. Grossman P, Niemann L, Schmidt S, et al. Mindfulness-based stress reduction and health benefits: A meta-analysis. *Journal of psychosomatic research* 2004;57(1):35-43.
24. Segal ZV, Teasdale J. Mindfulness-based cognitive therapy for depression: Guilford Publications 2018.
25. Howarth A, Smith JG, Perkins-Porras L, et al. Effects of Brief Mindfulness-Based Interventions on Health-Related Outcomes: a Systematic Review. *Mindfulness* 2019:1-12.
26. Chen Y, Yang X, Wang L, et al. A randomized controlled trial of the effects of brief mindfulness meditation on anxiety symptoms and systolic blood pressure in Chinese nursing students. *Nurse education today* 2013;33(10):1166-72.
27. Cavanagh K, Strauss C, Cicconi F, et al. A randomised controlled trial of a brief online mindfulness-based intervention. *Behaviour research and therapy* 2013;51(9):573-78.
28. Howells A, Ivtzan I, Eiroa-Orosa FJ. Putting the 'app'in happiness: a randomised controlled trial of a smartphone-based mindfulness intervention to enhance wellbeing. *Journal of Happiness Studies* 2016;17(1):163-85.
29. Garrison KA, Pal P, O'Malley SS, et al. Craving to quit: a randomized controlled trial of smartphone app–based mindfulness training for smoking cessation. *Nicotine and Tobacco Research* 2020;22(3):324-31.
30. Buntrock C, Ebert DD, Lehr D, et al. Effect of a web-based guided self-help intervention for prevention of major depression in adults with subthreshold depression: a randomized clinical trial. *Jama* 2016;315(17):1854-63.
31. Smalley SL, Winston D. Fully present: The science, art, and practice of mindfulness: Da Capo Lifelong Books 2010.
32. Deng Y-Q, Liu X-H, Rodriguez MA, et al. The five facet mindfulness questionnaire: psychometric properties of the Chinese version. *Mindfulness* 2011;2(2):123-28.
33. de Bruin EI, Topper M, Muskens JG, et al. Psychometric properties of the Five Facets Mindfulness Questionnaire (FFMQ) in a meditating and a non-meditating sample. *Assessment* 2012;19(2):187-97.
34. Baer RA, Smith GT, Hopkins J, et al. Using self-report assessment methods to explore facets of mindfulness. *Assessment* 2006;13(1):27-45.
35. Gu J, Strauss C, Crane C, et al. Examining the factor structure of the 39-item and 15-item versions of the Five Facet Mindfulness Questionnaire before and after mindfulness-based cognitive therapy for people with recurrent depression. *Psychological assessment* 2016;28(7):791.
36. Yang N, Waddington G, Adams R, et al. Translation, cultural adaption, and test–retest reliability of Chinese versions of the Edinburgh Handedness Inventory and Waterloo Footedness Questionnaire. *Laterality: Asymmetries of Body, Brain and Cognition* 2018;23(3):255-73.

37. Oldfield RC. The assessment and analysis of handedness: the Edinburgh inventory. *Neuropsychologia* 1971;9(1):97-113.
38. Montori VM, Guyatt GH. Intention-to-treat principle. *Cmaj* 2001;165(10):1339-41.
39. Fitzpatrick T, Zhou K, Cheng Y, et al. A crowdsourced intervention to promote hepatitis B and C testing among men who have sex with men in China: study protocol for a nationwide online randomized controlled trial. *BMC infectious diseases* 2018;18(1):489.
40. Wong SY, Chan JY, Zhang D, et al. The safety of mindfulness-based interventions: a systematic review of randomized controlled trials. *Mindfulness* 2018;9(5):1344-57.
41. Piet J, Hougaard E. The effect of mindfulness-based cognitive therapy for prevention of relapse in recurrent major depressive disorder: a systematic review and meta-analysis. *Clinical psychology review* 2011;31(6):1032-40.
42. Kim JY, Wineinger NE, Steinhubl SR. The influence of wireless self-monitoring program on the relationship between patient activation and health behaviors, medication adherence, and blood pressure levels in hypertensive patients: a substudy of a randomized controlled trial. *Journal of medical Internet research* 2016;18(6):e116.
43. Kral TR, Schuyler BS, Mumford JA, et al. Impact of short-and long-term mindfulness meditation training on amygdala reactivity to emotional stimuli. *Neuroimage* 2018;181:301-13.

Figure Legend

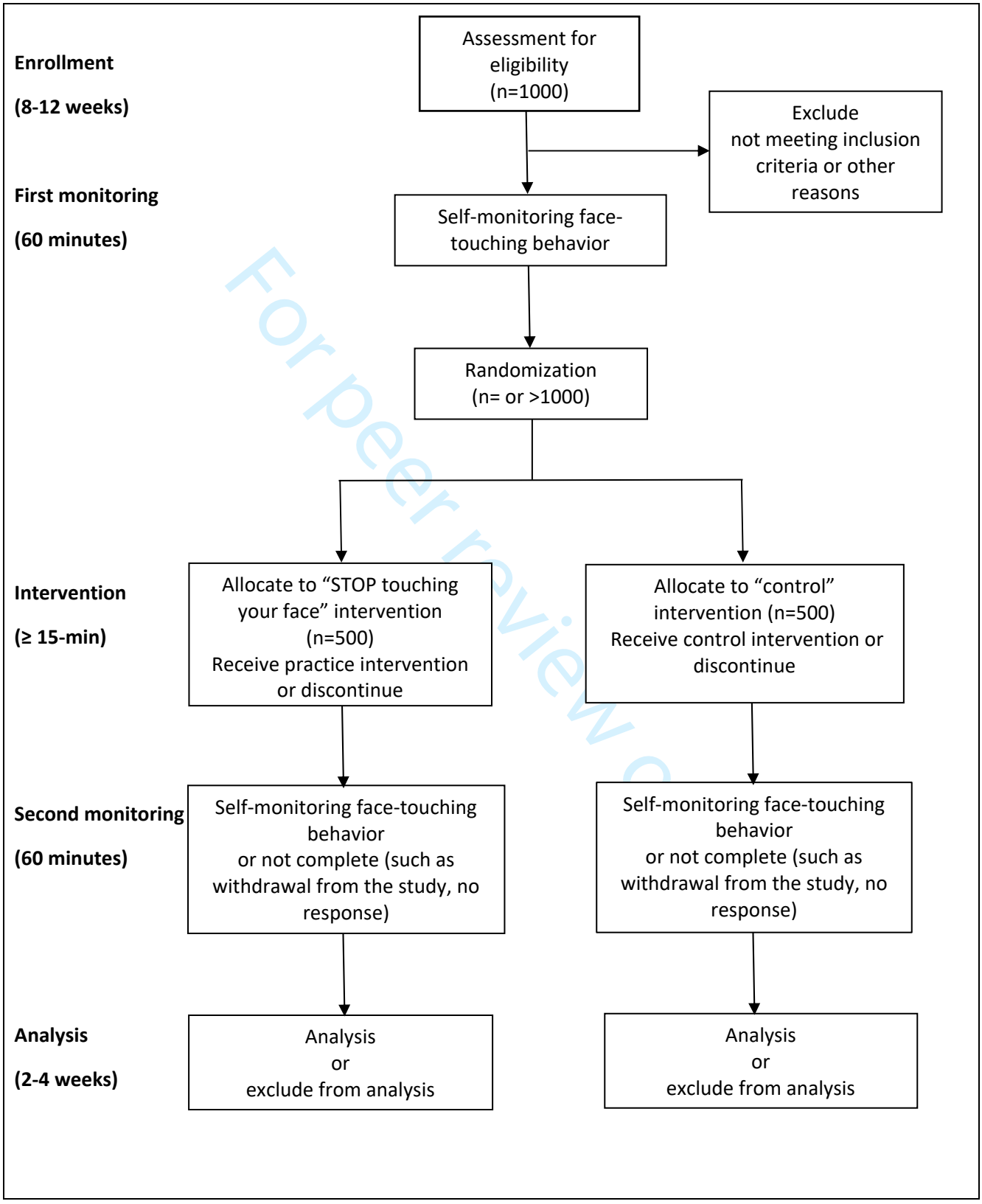
Figure 1 Study Flow Diagram

Note: Participants from the "control" intervention will receive "STOP touching your face" intervention (both text and audio description) immediately after completing the second self-monitoring face-touching behavior. But they will not be required to practice it or to practice it at least 15 minutes.

Table1 study inclusion and exclusion criteria

Inclusion Criteria:
1. 18 years of age or older
2. Being able to access online services
3. Being able to read and write in Chinese
4. Expressing an interest in participant this study
5. Willing to provide informed consent to participate in the study
Exclusion Criteria:
1. Under 18 years of age
2. Unable to access online services
3. Unable to read and write in Chinese
4. Already received “not to touch your face” training

Figure 1



Informed consent

Program name: A brief mindfulness-based intervention of "STOP (Stop, Take a Breath, Observe, Proceed) touching your face": a randomized controlled trial

Informed Consent Version Number: 1.0, Date: March 23, 2020

Primary Investigator: Liao, Yanhui

1. Invitation to participate in this research:

You will be invited to participate in a clinical study. This informed consent form provides you with some information to help you decide whether to participate in this clinical study or not. Please read it carefully. If you have any questions, please ask the researcher who is in charge of the study. Your participation in this study is totally voluntary. This study has been reviewed and approved by The Ethics Committee of Sir Run Run Shaw hospital, an affiliate of Zhejiang University, Medical College (NO. 20200401-32).

2. What kind of research is this?

Research purpose: Behaviour changes are very important for disease prevention, such as changing smoking behaviour to non-smoking behaviour, and using a pen tip to touch elevator buttons during the new coronavirus epidemic. However, many people touch their faces unconsciously. Avoiding this behaviour is an important way to prevent new coronavirus infections, especially for people in areas where there is a lack of masks (masks can also help people reduce touching their mouth and nose). The STOP technique of mindfulness intervention was originally a simple and effective way to relieve stress and anxiety. By practicing the simple technique of STOP, it may help us avoid touching our faces.

The main purpose of this study is to evaluate an online mindfulness-based brief intervention skill named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face" in reducing face-touching behaviour.

Research process and duration: The research process lasts at least more than 2 hours.

Research method and content: This randomized controlled trial (RCT) will enroll 1,000 healthy volunteers, and randomly assign subjects to a brief mindfulness intervention or control group at a ratio of 1:1. You need to find a convenient time, no need to deliberately change your life and work plan, you still can work and study. Prepare a paper and pen, or a recorder, then observe and record the number of times you touch your hair, forehead, eyes, nose, mouth, ears, cheeks, chin, and neck within 1 hour, and the time (seconds) of each touch. The intervention group will receive mindfulness-based STOP technology, and observe and record face touching again after practice it. The control group received control information of reminding them to observe and record face touching again. As part of the research, your interview information will be stored in Sir Run Run Shaw hospital of Zhejiang University School of Medicine for analysis or shared with other qualified researchers for research purposes. During the research process, we will use a unified standardized code to encode your private personal information, etc., and we will protect your information in accordance with relevant laws and regulations. If you are assigned to the control group, we will send you the STOP technique that received by the intervention group for free after the study.

Funding sources and possible conflicts of interest for the trial: The research plan was

designed by Dr, Yanhui Liao from Department of Psychiatry, Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, supported by Zhejiang University special scientific research fund for COVID-19 prevention and control (2020XGZX046).
Alternative therapies outside of this trial: Participation in this research is completely voluntary. You can refuse to participate in the research or opt out of the research at any time during the research process without any reason. This decision will not affect you in any way. If you decide to withdraw from this study, please notify your investigator in advance.

3. What does the participant need to do?
In the process of participating, you need to cooperate with a brief mindfulness intervention training, and give feedback on touching your face as required.

4. What risks and discomforts will it bring?
This study is a brief behavioural intervention, generally without adverse reactions; in terms of privacy protection, your personal information may be identified due to information leakage during information storage and sharing. The probability of the above risks is extremely small.
In addition to the existing risks, unknown risks may also occur during the research process.

5. What are the benefits?
You will not receive any compensation for participating in this study. Participating in this study can participate in brief mindfulness training, which may reduce the probability of unconsciously touching your face, which can reduce the chance of infection of infectious diseases such as the new coronavirus.

6. Do I need to pay related fees?
To participate in this research project, you do not need to pay related fees.

7. Compensation for participating in research, including compensation for injury.
Participating in this research will not receive financial compensation.

8. Who will see my information?
If you decide to participate in this study, your participation in the trial and your personal information in the trial are confidential. Your behaviour monitoring records and other information will be identified by the research number instead of your name. Information that can identify you will not be disclosed to members other than the research team unless with your permission. All research members and research sponsors are required to keep your identity confidential. Your files will be kept in a locked filing cabinet, which is only accessible to researchers. To ensure that the research is conducted in accordance with the regulations, when necessary, members of the government management department or the ethics review committee can access your personal data in the research unit according to the regulations. When the results of this research are published, no

personal information about you will be disclosed.

9. What if an adverse event occurs?

If you are harmed by participating in this study: In the event of damages related to this clinical study, our medical team will help you to get timely treatment, and adverse events will be handled as routine medical events in the hospital. You can choose not to participate in this research, or notify the researcher to withdraw from the research at any time, your data will not be included in the research results, and any of your medical treatment and rights will not be affected. If you need other treatments, or if you do not follow the study plan, or have a study-related injury or for any other reason, the study physician can terminate your continued participation in this study.

10. How to contact the researcher?

You can keep abreast of the information and research progress related to this research. If you have any questions related to this research, or if you have any discomfort or injury during the research, or have questions about the rights of participants in this research You can contact the researchers at any time (18890098852), 11th Floor, Inpatient Department, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, No. 368, Xiasha Road, Economic and Technological Development Zone, Hangzhou, Zhejiang). If you have any questions about your rights as a patient participating in the study, please contact The Medical Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, 0571-86006811.

Informed consent Signed page

- I have read this informed consent form.
- I have the opportunity to ask questions and all questions have been answered.
- I understand that participation in this study is voluntary.
- I can choose not to participate in this research, or I will withdraw after notifying the researcher at any time without being discriminated against or retaliated. Any of my medical treatment and rights will not be affected.
- If I need other treatment, or if I do not follow the research plan, or there is a research-related injury or for any other reason, the research physician can terminate my continued participation in this research.

Subject's electronic signature: _____

Date: _____ year_____month_____day

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
P1,1-3 Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
P4, 54 Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Not applicable, Protocol version	3	Date and version identifier
P25,512-517 Funding	4	Sources and types of financial, material, and other support
P1-2, 5-31; P24-25, 502-510 Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
P5-7, 69-117 Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
P7 119-133 Objectives	7	Specific objectives or hypotheses

P8, 140-154 Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
P8, 141 Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
P8,154-155, P30, 647-648 Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
P14-15, 284-289 Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
P16, 326-338 Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
P22, 446-448 Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
P9, 157-176 Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
P10, 178-188 Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

P11, 204-208 Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
P11, 208-209 Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
P11, 201-208 Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
P11, 209-211 Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

Methods: Data collection, management, and analysis

P19, 386-389 Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
P19, 388-389 Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
P19-21, 391-420 Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods: Monitoring

P19, 388-389 Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
P21, 422-431 Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

P21, 434-435 Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
P21-22, 437-443 Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
P19, 389 Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
P25, 519-521 Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
P11, 209-2011 Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
P8, 153-154 Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

P22, 448-450 Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
In supplementary file, Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Not applicable, Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.