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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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STOP practice.mp3





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4 1 **A brief mindfulness-based intervention of “STOP (Stop, Take a Breath,**
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7 2 **Observe, Proceed) touching your face”:** a study protocol of a
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10 3 **randomized controlled trial**
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32 **Abstract**

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

38 **Methods and analysis** This will be a single-blind, randomized, controlled, trial. We will recruit
39 1,000 participants, and will randomize and allocate participants 1:1 to the “STOP touching your
40 face” intervention group (n=500) and the control group (n=500). All participants will be asked to
41 monitor and record their face-touching behavior. The intervention group will receive the brief
42 online mindfulness-based “STOP touching your face” program, and the control group will receive
43 control intervention. Primary outcome will be the efficacy of short-term mindfulness-based
44 “STOP touching your face” intervention for reducing the frequency of face-touching. The
45 secondary outcomes will be the reduction of the duration of face-touching after intervention;
46 the correlation between the psychological traits of mindfulness and face-touching behavior; and
47 the differences of face-touching behavior between left-handers and right-handers. We will
48 recruit 1000 participants from April to June 2020 or until the recruitment process is complete.
49 The follow-up will be completed in June 2020. We expect all trial results to be available by the
50 end of June 2020.

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

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3 54 **Trial registration number** NCT04330352.
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8 56 **Strengths and limitations of this study**
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10 57 • This is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-
11
12 touching behavior.
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15 59 • This is a theoretical framework guided (mindfulness-based cognitive behavior theory) large
16
17 sample size RCT to evaluate the efficacy of “STOP touching your face” during the outbreak of
18 60
19 COVID-19.
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23 62 • “STOP touching your face” program is a free, brief, simple and widely accessible mindfulness-
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25 based behavior change intervention.
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28 64 • There is no digital videotape recording for the behavior of face-touching by researchers.
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30 Alternatively, it will be self-monitored.
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33 66 • This is only a brief intervention by internet. A face to face long-term mindfulness intervention
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35 will help participants gain the maximum benefits of practice.
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69 Introduction

70 Nonverbal behavior plays an important role in interpersonal relations and constitutes a large
71 amount of all communication. But self-touching is usually not used to communicate with others
72 and is often done automatically without thinking about it at all in our daily life¹. It might be one
73 of the so called "autistic" gestures when they have no evident meaning². Spontaneous facial self-
74 touching or face-touching has been defined as *the use of the hand to touch the individual's own*
75 *face* to scratch, rub, groom, or caress it. Research shows that the average face-touching
76 frequency ranges from approximately 16³ to 23⁴ times per hour. Furthermore, research of face-
77 touching across handedness showed that left-handed individuals more frequently touch their
78 face than their counterparts⁵.

79
80 An increase in face-touching frequency may result in increased risk of transmissible infections,
81 defined as self-inoculation or auto-inoculation (a type of contact transmission occurs when a
82 person transfers an infectious disease from one part of the body to another, e.g., when a
83 contaminated hand makes subsequent contact with the nose and introduces contaminated
84 material to those areas)^{3 4}. Of all face-touching behaviors, touching the T-zones will pose a
85 potential risk for transmission and acquisition of a range of infectious diseases. Unfortunately,
86 research found that 42.2%⁶ to 44%⁴ of face-touching involved in contacting with a mucous
87 membrane. Even clinicians touch their T-zones (the mucus membranes of the eyes, nose, and
88 mouth) as frequently as 19 times on average within 2 hours⁷. Many diseases can be spread
89 by self-inoculation in this way, including coronavirus disease 2019 ("COVID-19")^{8 9}. Thus, the

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3 90 Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO)
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6 91 have been telling people to stop touching their faces.
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10 93 However, even we all know that stop touching our faces will minimize spread of coronavirus and
11
12 94 other germs. The question is how to stop this behavior? Although face-touching is often an
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14 95 automatic behavior without conscious thought or decision, research indicates that the frequency
15
16 96 of self-touching and the duration of touch and contact are associated with cognitive and
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18 97 emotional demands^{10 11}. In addition to emotional states, especially negative affect states, self-
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20 98 touching also has been linked to information processing and production¹².
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28 100 Raising self-awareness of face-touching behavior may be effective in reducing or avoiding this
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30 101 behavior. For example, every time when you touch your face, be mindful, notice how you
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32 102 touched your face, check what you are thinking, physical and psychological feeling or your
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34 103 sensation that preceded it. This process or skill is similar to “mindfulness practice” developed by
35
36 104 Jon Kabat Zinn¹³. Mindfulness can be defined as “*Mindful Awareness is the moment-by-moment*
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38 105 *process of actively and openly observing one’s physical, mental and emotional experiences*”
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40 106 (Mindful Awareness Research Center at the University of California at Los Angeles). Mindfulness-
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42 107 based interventions (MBIs) are proven to be clinically efficacious in treatment of behavioral
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44 108 disorders, such as alcohol drinking, smoking, gambling^{14 15}, attention deficit/hyperactivity
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46 109 disorder (ADHD)¹⁶, eating disorders^{17 18}, as well as in enhancing the emotional health of Chinese
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48 110 long-term male prison inmates¹⁹. Increasing peoples' awareness of their habituated face-
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52 111 touching behavior may help individuals to avoid touching their face by contaminated hands, and
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3 112 decrease the risk of spreading infectious diseases. The structured MBIs, such as mindfulness-
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6 113 based stress reduction (MBRS) and mindfulness-based cognitive therapy (MBCT) program, are 8
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8 114 to 10 weeks course²⁰⁻²³, but brief MBIs can also produce numerous health-related outcomes,
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11 115 even only with one session intervention and as brief as 5 minutes^{24 25}. Randomized controlled
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13 116 trials (RCT) of a brief mindfulness-based intervention further suggested the feasibility and
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15 117 effectiveness of short-term, self-guided, internet or smartphone-based interventions^{26 27}.

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20 119 The primary objective of this proposed project is to identify a simple but effective practice to
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23 120 reduce or avoid face-touching to low people's chances of catching infectious diseases like COVID-
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25 121 19. Based on the efficacy of MBIs in treatment of some behavioral disorders and the efficacy of
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28 122 short-term MBIs, we here propose a RCT of an online mindfulness-based brief intervention skill
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30 123 named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face". It is hypothesized
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33 124 that this skill will be an effective, feasible, accessible skill in reducing or avoiding face-touching
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35 125 for people in the general population. To be specific, the primary hypothesis of this brief
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38 126 behavioral intervention is that, compared with a control intervention, the intervention would
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40 127 result in greater reduction of frequency of face-touching. We also hypothesize that the length of
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43 128 face-touching behavior will also be reduced. Based on the theory that both face-touching
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45 129 behavior and mindfulness link to cognitive or emotional process^{10 22}, we hypothesize that people
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48 130 with higher levels of self-reported mindfulness will touch their face less frequently. Given left-
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50 131 handed individuals more frequently touch their face than their counterparts⁵, It is hypothesized
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52 132 that, compared with right-handed participants, left-handed individuals will touch their face more
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55 133 frequently during their self-monitoring of face-touching.

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3 1346 135 **Methods and analysis**9 136 **Patient and public involvement**

11 137 Neither participants nor the public were involved in the design, recruitment or conduct of the
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14 138 study.

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19 140 **Study design and participants**

21 141 In this single-blind, randomized, parallel-group trial, undertaken in China by internet, about 1,000
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23 142 participants willing to participate in “STOP touching your face” training program and provide
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26 143 electronic consent, will be randomly allocated to mindfulness-based “STOP touching your face”
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28 144 intervention group or a control group at a 1:1 ratio. A 2 × 2 (practice group and control
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31 145 group × pre–post measurements) experimental design will be used. All participants
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33 146 who are allocated to the control group will have the opportunity to practice this skill after the
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36 147 end of the study period. An overview of participant eligibility criteria is given in **Table1**.

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41 149 **Sample size and power calculation**

43 150 This study aims to recruit 1000 participants, with 500 in each group. The sample size assessment
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45 151 and power calculations are mainly on the basis of the results of RCTs of different types of
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47
48 152 behavioral intervention--stop smoking behavior²⁸, as well as smartphone-based mindfulness
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51 153 intervention²⁷ and the “Learning Mindfulness Online” intervention²⁶. The RCT of mindfulness
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53 154 training for smoking cessation screened 757 participants, assessed 134 eligible participants,
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55 155 randomized 88 participants with more than 70% participants completed all follow-up interviews.

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3 156 Individuals who received mindfulness intervention showed a trend toward greater 1-week point
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5 prevalence abstinence (stop smoking behavior) at the end of treatment (36% vs. 15%). It is
6 157
7 estimated that, for assessing stop face-touching behavior, a total of 128 participants (64
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9 participants in each group) are required to achieve 80% power (1-beta=0.8), as significant at the
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11 5% level ($\alpha=0.05$), an increase in the primary outcome measure from 15% in the control
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13 group to 36% in the intervention group. However, online interventions often have much higher
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15 dropout rate than face to face intervention. The smartphone-based RCT assessed 537
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17 participants with only 194 participants had been randomized to intervention group (n=97) or
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19 control group(n=97). There were only 13 participants partially completed follow up measures in
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21 the intervention and 11 participants in the control group. The overall loss to follow-up rate was
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23 as high as more than 80% in this RCT. The online program invited 111 participants and
24 166
25 randomized 104 participants (50 participants in the Wait-list control group and 54 participants in
26 167
27 the intervention group). 70% (n=35) from control group and 43%(n=23) from the intervention
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29 group completed post-intervention measures. Considering the high loss to follow-up rate, this
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31 study will have a final target sample size of 1000 participants (500 in each arm), which will have
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33 sufficient power to detect a significant difference.
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173 **Recruitment**

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47 174 As in other similar research, we will advertise this program online using websites, social media
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49 (such as WeChat, QQ). to recruit potential participants. Potential participants will register their
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51 interest by sending messages by social media, email or sending text messages, or making a call
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53 to research assistants (by Dr. Y Wang and Dr. Z Wu). Then, research assistants will contact
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3 178 respondents to assess their eligibility and explain the study to each participant and inform them
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6 179 that they would be allocated to either a control group or to a group that receives the
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8 180 Mindfulness-based “STOP touching your face” program. Before collecting baseline data,
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11 181 electronically informed consent will be obtained from each participant. Participants who enrolled
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13 182 in this study could withdraw at any time. They will also be asked to provide contact information
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15 183 (will not be shared with any third party), in case any problems arise.
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19 20 185 **Baseline data**

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23 186 Prior to randomization, demographic information and self-reported questionnaires will be
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25 187 obtained from all participants at baseline (assessed by Dr. Y Liao, Dr. C Pan and Dr. Q Luo). The
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28 188 demographic information of participants will be gender, age, years of education, marital status,
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30 189 occupation by the International Standard Classification of Occupations (ISCO), living in rural or
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32 190 urban region, smoker types (nonsmoker or current smoker and former smoker). The Five Facets
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35 191 Mindfulness Questionnaire (FFMQ) will be applied to measure the dispositional tendency to
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37 192 be mindful in daily life. The Edinburgh Handedness Inventory (EHI) will be used to assess
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40 193 handedness. Frequency and length of face-touching will be assessed at baseline and after
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42 194 intervention.
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46 47 196 **Randomization and group allocation**

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50 197 Participants will be randomized and assigned (by Dr. Y Liu) to the intervention or control group.
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52 198 Randomization will be run by randomizeR, (<https://CRAN.R-project.org/package=randomizeR>).
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55 199 All Investigators will be masked to participants' treatment assignment until all data have been
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3 200 collected. The investigators (by Dr. J Tang and Dr. Y Liu) who will analyze the data for evaluating
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5 201 outcomes will still be blinded to participants' treatment allocations until the entire analysis has
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8 202 been completed.
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12 13 204 **Development of “STOP touching your face” training program**

14 15 205 ***Theory***

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18 206 Face-touching behavior is often an automatic behavior that could potentially disseminate
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20 207 respiratory infections (eg, influenza, coronavirus), yet can be changed. However, changing the
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22 208 behavior of face-touching is “easier said than done”, as there is only limited evidence for the
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25 209 neuropsychological basis or physiological fundamentals of this behavior. Research shows that
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27 210 the frequency of self-touching increases when attention is distracted¹⁰, as well as under stressful
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29 211 situations or with negative affect¹¹. Cognitive behavioral theory-based mindfulness intervention
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31 212 (mindfulness-based cognitive therapy, MBCT²³) has been used as a psychological intervention for
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33 213 people with mental or behavior problems, targeting both cognitive and behavioral problems.
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35 214 Mindfulness-based interventions (MBIs)¹³ can help people cultivate positive affect, increase self-
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37 215 awareness and concentration that are associated with reducing frequency of face-touching.
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40 41 42 216 ***Practice***

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45 217 STOP²⁹ is an acronym that stands for four action: “Stop”, “Take a breath”, “Observe”, “Proceed”.
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47 218 It is a helpful aid in becoming more mindful of our body, behavior and emotion on a daily basis.
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49 219 The following is the instruction for how to practice STOP:

50 51 52 220 **S = Stop**

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54 221 Remind yourself to STOP. Whatever you are doing in this moment (e.g. touching your mouth,
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3 222 pinching your nose, rubbing your eyes, resting your chin on your hands), pause for a minute.
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6 223 **T = Take**
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8 224 Take a deep breath. This reconnects you with your body. Pay attention to your breathing and
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10 225 just allow yourself to continue to breathe normally and naturally.
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13 226 **O = Observe**
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15 227 OBSERVE what is happening for you in this moment—including thoughts, feelings, and
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17 228 emotions (e.g. feel distracted, anxious or nervous?). What do you notice in your body (e.g. feel
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19 229 itchy or tingling on any part of your face)? You can be aware of anything: posture, sensations,
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21 230 tension in your body, or, once again, your breath. You might notice the sound around you. You
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23 231 might even notice your thoughts or emotions
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27 232 **P = Proceed**
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30 233 Proceed with whatever you were doing before you came to a STOP or something that you want
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32 234 to do in the moment (e.g. proceed with touching your face, or stop face-touching and take an
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34 235 alternative behavior).
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37 236 The STOP Practice is very short, simple, and the acronym (STOP) makes it easy to remember as
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39 237 well. Thus, it has become one of the most popular mindfulness-based practices. The practice of
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41 238 STOP may cultivate a space between stimulus and response, which could help avoid the mostly
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43 239 spontaneous behavior of facial self-touching. The “STOP touching your face” training program in
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45 240 Chinese was already developed by Dr. Y Liao, Dr. Q Luo and Dr. C Pan. Both text and audio
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47 241 description (see Supplementary Material) will be available.
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3 243 **Intervention**

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6 244 ***Intervention group***

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8 245 Eligible participants who are allocated to the intervention group will be required to find a time
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10 246 to monitor and record their behavior of hand-to-face contacts, including the frequency and
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13 247 length (in second) of face-touching in any of the mucosal area (eyes, nose, mouth) and
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15 248 nonmucosal area (ears, cheeks, chin, neck, forehead, hair) during a 60-minute period. Then, they
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18 249 will receive the online mindfulness-based “STOP touching your face” program. Each participant
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20 250 will be required to practice this technique until they feel confident and natural. The systematic
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22
23 251 review showed the efficacy of single session of brief MBIs, the average length of which was
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25 252 15 minutes, ranged from less than 5 to 25 min²⁴. Thus, the requirement practice time will be 15
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28 253 minutes. Later (with a one-hour interval), they will be asked to self-monitor and report their one-
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30 254 hour face-touching behavior again by send them messages via social media app (mainly WeChat).
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32 255 This online mindfulness-based intervention will not have face-to-face interaction between the
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35 256 experimenter and participants throughout the entire study.

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37 257 ***Control group***

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40 258 Participants who allocate to the control group will only receive information to thank them and
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42 259 encourage them to complete the study. They will receive “STOP touching your face” program
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45 260 after the end of this study. The repeat measurement of the face-touching behavior will be done
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47 261 in a one-hour interval.

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49 262 ***Both groups***

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52 263 Participants from both groups will be required to provide information about face-touching
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54 264 behavior before and after intervention. The self-monitoring behavior of face-touching will be
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3 265 asked to be recorded before and after “STOP touching your face” or control intervention. All
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6 266 participants will be encouraged to practice it regularly after the end of the study.
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10 268 **Follow-up**

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13 269 In order to measure the changes of face-touching behavior before and after intervention,
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15 270 frequency and length of face-touching in a 60-minute period will also be self-monitored and
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18 271 reported after intervention for groups with or without “STOP touching your face” practice, with
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20 272 a one-hour interval between the repeated measures. All outcomes will be collected by an online
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23 273 survey through the Chinese professional survey software WenJuanXing (Sojump, Shanghai, China,
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25 274 www.sojump.com). For non-responders, a reminding message will be sent to them by their
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27
28 275 provided contact information for reporting the outcomes.
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32 277 **Outcomes**

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35 278 **Primary outcome:** the efficacy of short-term mindfulness-based “STOP touching your face”
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37 279 intervention for reducing the frequency of face-touching.
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40 280 **Secondary outcomes:** the reduction of the duration of face-touching after intervention; the
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42 281 correlation between the psychological traits of mindfulness and face-touching behavior; the
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45 282 differences of face-touching behavior between left-handers and right-handers.
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49 284 **Measures**

51
52 285 **1. Frequency and length of face-touching:** Self-observation or self-monitoring of face-touching
53
54 286 behavior will be required to report from each participant. A standardized scoring sheet will be
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287 provided to tally the frequency of hand-to-face contacts, the touched area of the face, including
288 the mucosal area (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead,
289 hair) , and the time in seconds of each contact will be recorded in a 60-minute period ⁴.

290 **2. Five Facet Mindfulness Questionnaire (FFMQ)**³⁰⁻³²: this self-report scale is currently the most
291 frequently used mindfulness questionnaire to measure changes in participant's tendency to be
292 mindful in daily life by the following five related facets: observing(noticing, attending to
293 sensations, perceptions, thoughts, feelings; 8 items), describing (labeling feelings, thoughts with
294 words), acting with awareness (automatic pilot, concentration, non-distraction), non-judging
295 internal experience, and non-reactivity to internal experience. Participants will be asked to what
296 extent each of the statements are true of them. Each item is on a 1 to 5 Likert scale, ranging from
297 1 (never or very rarely true) to 5 (very often or always true). The scores represent a spectrum of
298 mindfulness with no cut-off points, higher scores indicate higher levels of mindfulness. The
299 factor structure of the short version (FFMQ-15) will be used in this study, which has been
300 consistent with that of the FFMQ-39³³.

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

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3 309 to, then they will mark this column as “2” and the other column as “0”. If they are really
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6 310 indifferent, they will mark it as “1” in both columns. A laterality quotient ($LQ = R - L/R + L \times 100$)
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8 311 can be calculated, where a score of 100 reflects complete right-handedness, and a score of -100
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10 312 reflects complete left-handedness.

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15 314 **Procedures**

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3 315 After advertising, participants who are interested in this study will be assessed for eligibility by
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6 316 making a call or communicating with social media (mainly WeChat). Then, eligible participants
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8 317 will complete baseline information, and information about frequency and length of face-touching
9
10 318 in a 60-minute period by self-monitoring. Afterwards, one group will receive a brief mindfulness-
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12
13 319 based “STOP touching your face” intervention and other control intervention. With a one-hour
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15 320 interval, a follow-up assessment of face-touching behavior will be taken for both groups. The
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18 321 schedule of enrolment and one follow-up assessment summarizes in **Figure 1**.

322

323 **Withdrawal from the Program**

324 Every participant will feel free to withdraw from the study at any time and without giving any
325 reason. On the basis of the intention-to-treat (ITT) principle³⁶, participants who fail to respond to
326 follow-up assessment will be retained in the analysis and classified as those who continued the
327 same behavior. Only participants who request withdrawal from the study will be excluded from
328 the analysis, and reasons for withdrawal will be noted if they are available.

329

330 **Data collection**

331 Data will be collected on line by WenJuanXing, a Chinese online market research Web site that
332 provides professional online questionnaire survey or data collection for RCTs³⁷. Data will be
333 monitored by data monitoring committee of the hospital. Personal data will be de-identified.

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335 **Data analysis**

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3 336 All data will be automatically collected by internet. A user-specified Excel file will be downloaded
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6 337 from the database. There will be no interim analyses. When all data have been obtained, they
7
8 338 will be analyzed and blinded to intervention assignment by the trial statistician using R software
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10
11 339 (R Foundation for Statistical Computing, Vienna, Austria. <https://www.r-project.org/>) and SPSS
12
13 340 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).
14
15 341 Descriptive statistics will be performed to determine the frequency of touches in a 60-minute
16
17 342 period. In order to determine if the intervention group showed a reduction of face-touching
18
19 343 behavior than the control group, pre- and posttest mean scores by group and “STOP touching
20
21 344 your face” intervention effects will be analyzed with 2 (group) × 2 (time), repeated measures
22
23 345 ANACOVAs (analysis of covariance) (controlling for handedness and prior mindfulness meditation
24
25 346 experience); χ^2 test will be applied to rates of none face-touching behavior between intervention
26
27 347 and control groups, and between left-handers and right-handers; T-test will be applied to assess
28
29 348 the differences of face-touching behavior duration between intervention and control groups, and
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31 349 between left-handers and right-hander; Pearson's correlations will be used to explore the
32
33 350 correlation between the psychological traits of mindfulness and face-touching behavior;
34
35 351 intention-to-treat (ITT) basis will be applied in this study to handle incomplete or missing data.
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37 352 All tests will be 2-tailed. A two-sided $P < 0.05$ will be used to determine statistical significance.
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354 **Safety**

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49 355 Throughout the “STOP touching your face” program, participants will be encouraged to
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51 356 communicate with us if they experience any mindfulness practice relative issues. Adverse events
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53 357 will be monitored during the study. The MBIs are regarded as relatively safe interventions³⁸.
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3 358 Research showed that even highly vulnerable participants (such as patients with major
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6 359 depressive disorder³⁹) can safely practice mindfulness, but if participants experience any health-
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8 360 related issues, they will be encouraged to contact with us or a health care provider.
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12 13 362 **Ethics and dissemination**

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15 363 The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an
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17 364 affiliate of Zhejiang University, Medical College (NO. 20200401-32). All activities associated with
18
19 365 this protocol will be conducted in full compliance with the approved policies and procedures.
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21 366 Electronically Informed consent (this e-consent is a form of written consent) will be
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23 367 communicated and obtained from each participant prior to participation. All participant will be
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25 368 explained about the purpose, procedures and assessments, potential risks and benefits of the
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27 369 trial before recruitment. After fully understanding the study, participants will be informed that
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29 370 their participation in this research study is total voluntary. They can choose to (sign the
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31 371 electronic consent form by selecting “agree to participant”) or not to participate (sign the
32
33 372 electronic consent form by selecting “disagree to participant”). Participation can withdrawal at
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35 373 any time without reasons. Contact information (phone number and social media contact like
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37 374 WeChat contact ID) of the study coordinator for any future questions and concerns will be
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39 375 provided and informed to each participant. We will recruit 1000 participants from April to June
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41 376 2020 or until the recruitment process is complete. The follow-up will be completed in June 2020.
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43 377 We expect all trial results to be available by the end of June 2020. Any results from this trial
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45 378 (publications, conference presentations) will be disseminated via social media and be published
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47 379 in peer-reviewed journals and conference proceedings.
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6 381 **Discussion**

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8 382 This RCT is to investigate the efficacy of brief mindfulness-based intervention of “STOP touching
9 383 your face” for people from general population in China. To our knowledge, this will be the first
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11 384 RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior
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13 385 on the basis of mindfulness and cognitive behavioral principles.
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20 387 The strength of this study is that this is a theoretical framework guided (mindfulness-based
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22 388 cognitive behavior theory) large sample size RCT to evaluate the efficacy of “STOP touching your
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24 389 face” during the outbreak of COVID-19. If “STOP touching your face” program is proved to be
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26 390 effective, it opens up its potential application worldwide at the population level. As “STOP
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28 391 touching your face” program is a free, brief, simple and widely accessible mindfulness-based
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30 392 behavior change intervention, the public health impact of its expansion world-wide could be
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32 393 enormous, helping us to manage any face-touching spread infectious diseases, like COVID-19.
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40 395 There are some limitations in this study. First, there is no digital videotape recording for the
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42 396 behavior of face-touching by researchers. Alternatively, it will be self-monitored. Self-monitoring
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44 397 of physical (such as blood pressure), and mental health (such as anger or frustration that comes
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46 398 from daily life) has been used as a strategy for improving the treatment of a number of chronic
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48 399 conditions or reducing unhealth behaviors including smoking, drinking, gambling and so on⁴⁰.
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50 400 Thus, self-monitoring itself may change participants face-touching behavior by creating a more
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52 401 active role in observing this behavior. Second, this is only an online intervention, participants may
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3 402 be more likely to drop out from the study. Thus, we will encourage participants contact with us
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6 403 if they have any questions or concerns. We will also apply an intention-to-treat principle to
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8 404 prevent potential bias caused by missing data from loss to follow-up. Third, this is only a brief
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10 405 intervention by internet. A face to face long-term mindfulness intervention will help participants
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13 406 gain the maximum benefits of practice. However, neuroimaging study demonstrates that both
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15 407 long and short-term mindfulness practice can improve automatic emotion regulation⁴¹, and RCT
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18 408 shows that brief online mindfulness-based intervention can also increase mindfulness and
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20 409 decrease perceived stress and symptoms of anxiety or depression²⁶.

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25 411 In conclusion, this is the first RCT to evaluate the efficacy of brief mindfulness intervention to
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28 412 reduce face-touching behavior. If “STOP touching your face”, a brief and simple skill, is proven
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30 413 effective, the public health impact of its expansion world-wide could be enormous, its
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33 414 dissemination will help us to manage any face-touching spread infectious diseases, like
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35 415 Coronavirus disease 2019 (COVID-19).

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40 417 **Availability of data and materials**
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42 418 All data in the current study will be available from the corresponding author on reasonable
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45 419 request and with completion of data user agreement.

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50 421 **Authors' Contributions**
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52 422 YLiao and JT developed and designed the study. YLiao took the lead in drafting the manuscript
53
54
55 423 protocol with contributions by JT, LW, WC, CP, QL, JC and XG advised the study design, and

1
2
3 424 coordinated study approval. All authors read and proposed critical comments, as well as
4
5
6 425 approved the manuscript for publication.
7

8 426

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14
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17
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19
20 431 The funders had no role in study design, data collection and analysis, decision to write the report
21
22
23 432 or to submit the paper for publication.
24

25 433

27 434 **Competing interests statement**

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29
30 435 No potential conflicts of interest to declare.
31

32 436

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35
36
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38
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40
41
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43
44
45 441 Mindful Awareness Research Center for providing opportunities to them to learn and practice
46
47 442 mindfulness.
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49 443

51 444 **References**

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3 543 **Figure Legend**

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6 545 **Figure 1** Study Flow Diagram
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3 546 **Table1** study inclusion and exclusion criteria

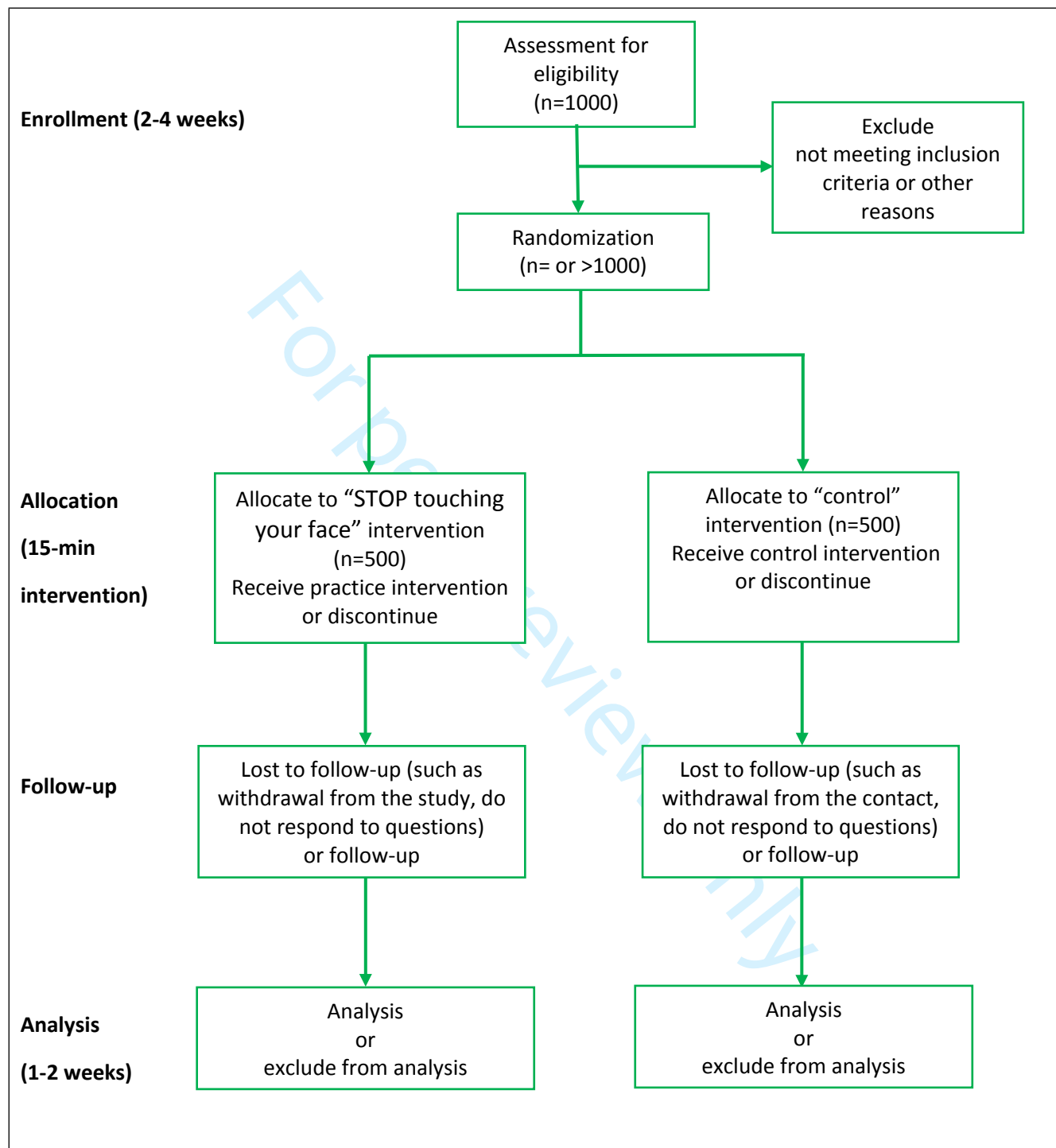
4 Inclusion Criteria:

- 5
6 1. 18 years of age or older
7 2. Being able to access online services
8 3. Being able to read and write in Chinese
9 4. Expressing an interest in participant this study
10 5. Willing to provide informed consent to participate in the study

11 Exclusion Criteria:

- 12
13 1. Under 18 years of age
14 2. Unable to access online services
15 3. Unable to read and write in Chinese
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16 547

548 **Figure 1**

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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
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

1
2 P8, 141-145 Trial 8 Description of trial design including type of trial (eg, parallel group,
3 design crossover, factorial, single group), allocation ratio, and framework (eg,
4 superiority, equivalence, noninferiority, exploratory)
5
6
7

8 **Methods: Participants, interventions, and outcomes**

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10 P8, 141 Study 9 Description of study settings (eg, community clinic, academic hospital)
11 setting and list of countries where data will be collected. Reference to where
12 list of study sites can be obtained
13

14 P8, 147 P26, 546- 10 Inclusion and exclusion criteria for participants. If applicable, eligibility
15 547 Eligibility criteria for study centres and individuals who will perform the
16 criteria interventions (eg, surgeons, psychotherapists)
17
18

19 P13-14, 243-266 11a Interventions for each group with sufficient detail to allow replication,
20 Interventions including how and when they will be administered
21

22 11b Criteria for discontinuing or modifying allocated interventions for a
23 given trial participant (eg, drug dose change in response to harms,
24 participant request, or improving/worsening disease)
25

26 11c Strategies to improve adherence to intervention protocols, and any
27 procedures for monitoring adherence (eg, drug tablet return,
28 laboratory tests)
29

30 11d Relevant concomitant care and interventions that are permitted or
31 prohibited during the trial
32
33

34 P14, 277-282 12 Primary, secondary, and other outcomes, including the specific
35 Outcomes measurement variable (eg, systolic blood pressure), analysis metric
36 (eg, change from baseline, final value, time to event), method of
37 aggregation (eg, median, proportion), and time point for each
38 outcome. Explanation of the clinical relevance of chosen efficacy and
39 harm outcomes is strongly recommended
40
41

42 P19, 375-377; 13 Time schedule of enrolment, interventions (including any run-ins and
43 P16, 314-321 washouts), assessments, and visits for participants. A schematic
44 Participant diagram is highly recommended (see Figure)
45 timeline
46
47

48 P8-9, 149-171 14 Estimated number of participants needed to achieve study objectives
49 Sample size and how it was determined, including clinical and statistical
50 assumptions supporting any sample size calculations
51

52 Recruitment 15 Strategies for achieving adequate participant enrolment to reach
53 target sample size
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55

56 **Methods: Assignment of interventions (for controlled trials)**

57 Allocation:
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2	P10, 197-198	16a	Method of generating the allocation sequence (eg, computer-
3	Sequence		generated random numbers), and list of any factors for stratification.
4	generation		To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions
8			
9			
10	P10-11, 199-	16b	Mechanism of implementing the allocation sequence (eg, central
11	200		telephone; sequentially numbered, opaque, sealed envelopes),
12	Allocation		describing any steps to conceal the sequence until interventions are
13	concealment		assigned
14	mechanism		
15			
16			
17	P10, 197	16c	Who will generate the allocation sequence, who will enrol participants,
18	Implementation		and who will assign participants to interventions
19			
20	P10, 200-202	17a	Who will be blinded after assignment to interventions (eg, trial
21	Blinding		participants, care providers, outcome assessors, data analysts), and
22	(masking)		how
23			
24		17b	If blinded, circumstances under which unblinding is permissible, and
25			procedure for revealing a participant's allocated intervention during
26			the trial
27			
28			
29	Methods: Data collection, management, and analysis		
30			
31	P17, 330-333	18a	Plans for assessment and collection of outcome, baseline, and other
32	Data collection		trial data, including any related processes to promote data quality (eg,
33	methods		duplicate measurements, training of assessors) and a description of
34			study instruments (eg, questionnaires, laboratory tests) along with
35			their reliability and validity, if known. Reference to where data
36			collection forms can be found, if not in the protocol
37			
38			
39		18b	Plans to promote participant retention and complete follow-up,
40			including list of any outcome data to be collected for participants who
41			discontinue or deviate from intervention protocols
42			
43			
44	P17, 335-340	19	Plans for data entry, coding, security, and storage, including any
45	Data		related processes to promote data quality (eg, double data entry;
46	management		range checks for data values). Reference to where details of data
47			management procedures can be found, if not in the protocol
48			
49			
50	P17-18, 341-352	20a	Statistical methods for analysing primary and secondary outcomes.
51	Statistical		Reference to where other details of the statistical analysis plan can be
52	methods		found, if not in the protocol
53			
54		20b	Methods for any additional analyses (eg, subgroup and adjusted
55			analyses)
56			
57		20c	Definition of analysis population relating to protocol non-adherence
58			(eg, as randomised analysis), and any statistical methods to handle
59			missing data (eg, multiple imputation)
60			

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

1 2 3 4 5 6 7 8 9 10 11 12 13	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
14 15 16 17 18 19 20 21 22 23 24 25		31b	Authorship eligibility guidelines and any intended use of professional writers
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

16 17 18 19 20 21 22 23 24 25	In supplementary file, Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" 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

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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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4 1 **A brief mindfulness-based intervention of “STOP (Stop, Take a Breath,**
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7 2 **Observe, Proceed) touching your face”:** a study protocol of a
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10 3 **randomized controlled trial**
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32 **Abstract**

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

38 **Methods and analysis** This will be a single-blind, randomized, controlled, trial. We will recruit
39 1,000 participants, and will randomize and allocate participants 1:1 to the “STOP touching your
40 face” (both 750-word text and 5-min audio description by online) intervention group (n=500) and
41 the wait-list control group (n=500). All participants will be asked to monitor and record their face-
42 touching behavior during a 60-minute period before and after the intervention. Primary outcome
43 will be the efficacy of short-term mindfulness-based “STOP touching your face” intervention for
44 reducing the frequency of face-touching. The secondary outcomes will be the reduction of the
45 duration of face-touching after intervention; the correlation between the psychological traits of
46 mindfulness and face-touching behavior; and the differences of face-touching behavior between
47 left-handers and right-handers. Analysis of covariance, regression analysis, χ^2 test, T-test,
48 Pearson's correlations will be applied in data analysis. We will recruit 1000 participants from April
49 to July 2020 or until the recruitment process is complete. The follow-up will be completed in July
50 2020. We expect all trial results to be available by the end of July 2020.

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

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3 54 **Trial registration number** NCT04330352.
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8 56 **Strengths and limitations of this study**
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10 57 • This is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-
11
12 touching behavior.
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15 59 • This is a theoretical framework guided (mindfulness-based cognitive behavior theory) large
16
17 sample size RCT to evaluate the efficacy of “STOP touching your face” during the outbreak of
18 60
19 COVID-19.
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23 62 • “STOP touching your face” program is a free, brief, simple and widely accessible mindfulness-
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25 based behavior change intervention.
26 63

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28 64 • There is no digital videotape recording for the behavior of face-touching by researchers.
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30 Alternatively, it will be self-monitored.
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33 66 • This is only a brief intervention by internet. A face to face long-term mindfulness intervention
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35 will help participants gain the maximum benefits of practice.
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69 Introduction

70 Nonverbal behavior plays an important role in interpersonal relations and constitutes a large
71 amount of all communication. But self-touching is usually not used to communicate with others
72 and is often done automatically without thinking about it at all in our daily life¹. It might be one
73 of the so called "autistic" gestures when they have no evident meaning². Spontaneous facial self-
74 touching or face-touching has been defined as *the use of the hand to touch the individual's own*
75 *face* to scratch, rub, groom, or caress it. Research shows that the average face-touching
76 frequency ranges from approximately 16³ to 23⁴ times per hour. Furthermore, research of face-
77 touching across handedness showed that left-handed individuals more frequently touch their
78 face than their counterparts⁵.

79
80 An increase in face-touching frequency may result in increased risk of transmissible infections,
81 defined as self-inoculation or auto-inoculation (a type of contact transmission occurs when a
82 person transfers an infectious disease from one part of the body to another, e.g., when a
83 contaminated hand makes subsequent contact with the nose and introduces contaminated
84 material to those areas)^{3 4}. Of all face-touching behaviors, touching the T-zones will pose a
85 potential risk for transmission and acquisition of a range of infectious diseases. Unfortunately,
86 research found that 42.2%⁶ to 44%⁴ of face-touching involved in contacting with a mucous
87 membrane. Even clinicians touch their T-zones (the mucus membranes of the eyes, nose, and
88 mouth) as frequently as 19 times on average within 2 hours⁷. Many diseases can be spread
89 by self-inoculation in this way, including coronavirus disease 2019 ("COVID-19")^{8 9}. Thus, the

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3 90 Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO)
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6 91 have been telling people to stop touching their faces.
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10 93 However, even we all know that stop touching our faces will minimize spread of coronavirus and
11
12 94 other germs. The question is how to stop this behavior? Although face-touching is often an
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14 95 automatic behavior without conscious thought or decision, research indicates that the frequency
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16 96 of self-touching and the duration of touch and contact are associated with cognitive and
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18 97 emotional demands^{10 11}. In addition to emotional states, especially negative affect states, self-
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20 98 touching also has been linked to information processing and production¹².
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27 100 Raising self-awareness of face-touching behavior may be effective in reducing or avoiding this
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29 101 behavior. For example, every time when you touch your face, be mindful, notice how you
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31 102 touched your face, check what you are thinking, physical and psychological feeling or your
32
33 103 sensation that preceded it. This process or skill is similar to “mindfulness practice” developed by
34
35 104 Jon Kabat Zinn¹³. Mindfulness can be defined as “*Mindful Awareness is the moment-by-moment*
36
37 105 *process of actively and openly observing one’s physical, mental and emotional experiences*”
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39 106 (Mindful Awareness Research Center at the University of California at Los Angeles). Mindfulness-
40
41 107 based interventions (MBIs) are proven to be clinically efficacious in treatment of behavioral
42
43 108 disorders, such as alcohol drinking, smoking, gambling¹⁴⁻¹⁶, attention deficit/hyperactivity
44
45 109 disorder (ADHD)¹⁷, eating disorders^{18 19}, as well as in enhancing the emotional health of Chinese
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47 110 long-term male prison inmates²⁰. Increasing peoples' awareness of their habituated face-
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49 111 touching behavior may help individuals to avoid touching their face by contaminated hands, and
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3 112 decrease the risk of spreading infectious diseases. The structured MBIs, such as mindfulness-
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6 113 based stress reduction (MBRS) and mindfulness-based cognitive therapy (MBCT) program, are 8
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8 114 to 10 weeks course²¹⁻²⁴, but brief MBIs can also produce numerous health-related outcomes,
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11 115 even only with one session intervention and as brief as 5 minutes^{25 26}. Randomized controlled
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13 116 trials (RCT) of a brief mindfulness-based intervention further suggested the feasibility and
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15 117 effectiveness of short-term, self-guided, internet or smartphone-based interventions^{27 28}.
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20 119 The primary objective of this proposed project is to identify a simple but effective practice to
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23 120 reduce or avoid face-touching to low people's chances of catching infectious diseases like COVID-
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25 121 19. Based on the efficacy of MBIs in treatment of some behavioral disorders and the efficacy of
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28 122 short-term MBIs, we here propose a RCT of an online mindfulness-based brief intervention skill
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30 123 named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face". It is hypothesized
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33 124 that this skill will be an effective, feasible, accessible skill in reducing or avoiding face-touching
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35 125 for people in the general population. To be specific, the primary hypothesis of this brief
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38 126 behavioral intervention is that, compared with a control intervention, the intervention would
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40 127 result in greater reduction of face-touching behavior. We also hypothesize that the frequency of
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43 128 face-touching behavior will also be reduced. Based on the theory that both face-touching
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45 129 behavior and mindfulness link to cognitive or emotional process^{10 23}, we hypothesize that people
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48 130 with higher levels of self-reported mindfulness will touch their face less frequently. Given left-
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50 131 handed individuals more frequently touch their face than their counterparts⁵, It is hypothesized
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52 132 that, compared with right-handed participants, left-handed individuals will touch their face more
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55 133 frequently during their self-monitoring of face-touching.
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134

135 **Methods and analysis**

136 **Patient and public involvement**

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

139

140 **Study design and participants**

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

148

149 **Sample size and power calculation**

150 This study aims to recruit 1000 participants, with 500 in each group. The sample size assessment
151 and power calculations are mainly on the basis of the results of RCTs of different types of online
152 short-term mindfulness intervention for behavioral changes, such as for alcohol consumption¹⁶
153 and stopping smoking or decreasing smoking craving²⁹, or for positive psychological changes,
154 such as enhancing wellbeing²⁸ and reducing perceived stress and anxiety/depression symptoms²⁷.
155 A single brief session of mindfulness of 11-minutes (n=34) detected a significant reduction in

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3 156 alcohol consumption compared with a relaxation control intervention (n=34)¹⁶. It is estimated
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6 157 that, for assessing stop face-touching behavior, individuals who received mindfulness
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8 158 intervention will at least twice likely to reduce the chance of touching T-Zone than the control
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11 159 group (5 to 10% vs. 2 to 4%). Thus, a total of 562 participants (281 participants in each group) are
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13 160 required to achieve 80% power (1-beta=0.8), as significant at the 5% level (alpha=0.05), an
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15 161 increase in the primary outcome measure from 4% in the control group to 10% in the intervention
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17 162 group. However, online interventions often have much higher dropout rate than face to face
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19
20 163 intervention. A web-based guided self-help intervention for preventing depression reported
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22 164 about 20% dropout rate at 6-month follow-up³⁰, but a brief online mindfulness-based
23
24 165 intervention for reducing stress, anxiety and depression reported 30% dropout rate in the
25
26 166 intervention group and more than a half in the waiting list control group²⁷ Considering the high
27
28 167 loss to follow-up rate, this study will have a final target sample size of 1000 participants (500 in
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30 168 each arm), which will have sufficient power to detect a significant difference.
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170 **Recruitment**

40 171 As in other similar research, we will advertise this program online using social media (such as
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42 172 WeChat and QQ) to recruit potential participants. Potential participants will register their interest
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45 173 by sending messages by social media, email or sending text messages, or making a call to research
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47 174 assistants (by Dr. Y Wang and Dr. Z Wu). Then, research assistants will contact respondents to
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50 175 assess their eligibility and explain the study to each participant and inform them that they would
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52 176 be allocated to either a control group or to a group that receives the Mindfulness-based “STOP
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54 177 touching your face” program. Before collecting baseline data, electronically informed consent
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3 178 will be obtained from each participant. Participants who enrolled in this study could withdraw at
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6 179 any time. They will also be asked to provide contact information (will not be shared with any third
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8 180 party), in case any problems arise.
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13 182 **Baseline data**

15 183 Prior to randomization, demographic information and self-reported questionnaires will be
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18 184 obtained from all participants at baseline (assessed by Dr. Y Liao, Dr. C Pan and Dr. Q Luo). The
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20 185 demographic information of participants will be gender, age, years of education, marital status,
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23 186 occupation by the International Standard Classification of Occupations (ISCO), living in rural or
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25 187 urban region, smoker types (nonsmoker or current smoker and former smoker). The Five Facets
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28 188 Mindfulness Questionnaire (FFMQ) will be applied to measure the dispositional tendency to
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30 189 be mindful in daily life. The Edinburgh Handedness Inventory (EHI) will be used to assess
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32
33 190 handedness. Frequency of face-touching will be assessed at baseline and after intervention.
34

35 191

37 192 **Randomization and group allocation**

40 193 After reporting the first 60-min self-monitoring face-touching behavior, participants will be
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42 194 randomized and assigned (by Dr. Y Liu) to either start the intervention immediately (intervention
43
44
45 195 condition) or to a wait-list control condition (who will be offered the intervention immediately
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47 196 after reporting the second 60-min self-monitoring face-touching behavior). Randomization will
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50 197 be run by randomizeR, (<https://CRAN.R-project.org/package=randomizeR>). All participants will
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52 198 report the first self-monitoring by the same link (the same Excel file will be downloaded), and the
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55 199 second will be reported by two different links (two separated Excel files will be downloaded) to
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3 200 detect group allocation. Group allocation will not be concealed to investigators who will provide
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6 201 interventions. But the investigators (by Dr. J Tang and Dr. Y Liu) who will analyze the data for
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8 202 evaluating outcomes will be blinded to participants' treatment allocations until the entire
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11 203 analysis has been completed.

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15 205 **Development of “STOP touching your face” training program**

17 206 ***Theory***

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20 207 Face-touching behavior is often an automatic behavior that could potentially disseminate
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23 208 respiratory infections (eg, influenza, coronavirus), yet can be changed. However, changing the
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26 209 behavior of face-touching is “easier said than done”, as there is only limited evidence for the
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29 210 neuropsychological basis or physiological fundamentals of this behavior. Research shows that
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32 211 the frequency of self-touching increases when attention is distracted¹⁰, as well as under stressful
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35 212 situations or with negative affect¹¹. Cognitive behavioral theory-based mindfulness intervention
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38 213 (mindfulness-based cognitive therapy, MBCT²⁴) has been used as a psychological intervention for
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41 214 people with mental or behavior problems, targeting both cognitive and behavioral problems.
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43
44 215 Mindfulness-based interventions (MBIs)¹³ can help people cultivate positive affect, increase self-
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46
47 216 awareness and concentration that are associated with reducing frequency of face-touching.

48 217 ***Practice***

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50 218 STOP³¹ is an acronym that stands for four action: “Stop”, “Take a breath”, “Observe”, “Proceed”.
51
52 219 It is a helpful aid in becoming more mindful of our body, behavior and emotion on a daily basis.
53
54
55 220 The following is the instruction for how to practice STOP:

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2
3 221 **S = Stop**
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5
6 222 Remind yourself to STOP. Whatever you are doing in this moment (e.g. touching your mouth,
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8 223 pinching your nose, rubbing your eyes, resting your chin on your hands), pause for a minute.
9

10
11 224 **T = Take**
12

13 225 Take a deep breath. This reconnects you with your body. Pay attention to your breathing and
14
15 226 just allow yourself to continue to breathe normally and naturally.
16

17
18 227 **O = Observe**
19

20 228 OBSERVE what is happening for you in this moment—including thoughts, feelings, and
21
22 229 emotions (e.g. feel distracted, anxious or nervous?). What do you notice in your body (e.g. feel
23
24 230 itchy or tingling on any part of your face)? You can be aware of anything: posture, sensations,
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26 231 tension in your body, or, once again, your breath. You might notice the sound around you. You
27
28 232 might even notice your thoughts or emotions
29
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31
32 233 **P = Proceed**
33
34

35 234 Proceed with whatever you were doing before you came to a STOP or something that you want
36
37 235 to do in the moment (e.g. proceed with touching your face, or stop face-touching and take an
38
39 236 alternative behavior).
40

41
42 237 The STOP Practice is very short, simple, and the acronym (STOP) makes it easy to remember as
43
44 238 well. Thus, it has become one of the most popular mindfulness-based practices. The practice of
45
46 239 STOP may cultivate a space between stimulus and response, which could help avoid the mostly
47
48 240 spontaneous behavior of facial self-touching. The “STOP touching your face” training program in
49
50 241 Chinese was already developed by Dr. Y Liao, Dr. Q Luo and Dr. C Pan. Both 750-word text and 5-
51
52 242 min audio description (see **Supplementary file 1**) will be available by online.
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243 **Procedures**

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

252

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

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

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2
3 264 Instruction: *"1. Please find a convenient time, no need to deliberately change your routine life*
4
5
6 265 *(such as working or studying at the desk, watching TV), observe and record how many times you*
7
8 266 *touched your hair, forehead, eyes, nose, mouth, ears, cheeks , Chin and neck in one-hour period*
9
10 267 *(if you touched your mouth and nose at one time, you should count one time for mouth-touching*
11
12
13 268 *and one time for nose-touching). If there is any information that you cannot understand, please*
14
15 269 *contact with me at any time; 2. fill in the following content immediately after completion of self-*
16
17
18 270 *monitoring (with a link to "hand-to-face contacts" behavior monitoring record 1); 3. please*
19
20 271 *contact with me to send the information about intervention to you when you completed the link.*
21
22
23 272 *4. You will repeat another one-hour period self-monitoring after your receiving another*
24
25 273 *information (either "STOP touching your face" program or just thanks words)."*
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29

30 275 **Step 2. Intervention**

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32 276 **The intervention group:** Participants from the intervention group will receive the online
33
34
35 277 mindfulness-based "STOP touching your face" program (both 750-word text and 5-min audio
36
37 278 description). Each participant will be required to read the text of the program first and then listen
38
39
40 279 to the audio. They will be encouraged to practice this technique until they feel confident and
41
42 280 natural. The systematic review showed the efficacy of single session of brief MBIs, the average
43
44
45 281 length of which was 15 minutes, ranged from less than 5 to 25 min²⁵. Thus, the requirement
46
47 282 practice time will be at least 15 minutes (excluding the time of reading the text and the first time
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49
50 283 of listening to the audio). This online mindfulness-based intervention will not have face-to-face
51
52 284 interaction between the experimenter and participants throughout the entire study.

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54 285 **The control group:** Participants who allocate to the control group will only receive information
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3 286 to thank them and encourage them to complete the study. They will be reminded to receive
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6 287 “STOP touching your face” program after the end of this study.
7

8 288 **Both groups:** Participants from both groups will be reminded to contact with us to provide the
9
10 289 instruction of another self-monitoring behavior of face-touching.
11
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13 290

14
15 291 ***Step 3. The second self-monitoring of face-touching behavior (after intervention)***
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17
18 292 After intervention, all participants will be required to monitor their face-touching behavior during
19
20 293 a 60-minute period again. When participants tell us “*I am ready to do another self-monitoring*”,
21
22 294 they will receive instruction of how to complete the second self-monitoring of face-touching
23
24
25 295 behavior during a 60-minute period. The repeat measurement of the face-touching behavior will
26
27
28 296 be done at least 1 hour apart from the first self-monitoring. All participants will be encouraged
29
30 297 to monitor their face-touching behavior in two similar situations.
31

32 298 Instruction: “*1. Again, please find a convenient time, no need to deliberately change your routine*
33
34 299 *life (such as working or studying at the desk, watching TV), observe and record how many times*
35
36 300 *you touched your hair, forehead, eyes, nose, mouth, ears, cheeks , Chin and neck in one-hour*
37
38 301 *period (if you touched your mouth and nose at one time, you should count one time for mouth-*
39
40 302 *touching and one time for nose-touching). It is better to find a similar situation (the similar time*
41
42 303 *if not in the same day, same place, and when you are doing the same thing). You need to do it at*
43
44 304 *least 1 hour apart from the last observation. If there is any information that you cannot*
45
46 305 *understand, please contact with me at any time; 2. fill in the following content immediately after*
47
48 306 *completing self-monitoring (with a link to "hand-to-face contacts" behavior monitoring record 2,*
49
50 307 *the two groups will receive different links); 3. please let me known when you completed the link*
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3 308 *(the intervention group); please contact with me to send the program to you when you completed*
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6 309 *the link (the control group)."*
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8 310
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10 311 All participants will be thanked and encouraged to practice "STOP touching your face" regularly
11
12 312 after the end of the study. All outcomes will be collected by an online survey through the Chinese
13
14 313 professional survey software WenJuanXing (Sojump, Shanghai, China, www.sojump.com). For
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16 314 non-responders, a reminding message will be sent to them by their provided contact information
17
18 315 for reporting the outcomes.
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24 25 317 **Outcomes**

26
27 318 **Primary outcome:** the efficacy of short-term mindfulness-based "STOP touching your face"
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29 319 intervention (≥ 15 min) for reducing face-touching behavior, measuring by reduction of
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31 320 percentage of the T-Zone touching during a 60-minute period by intervention.
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33

34
35 321 **Secondary outcomes:** the reduction of the frequency of face-touching after intervention; the
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37 322 factors (demographic characteristics, psychological traits of mindfulness) that would be
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39 323 associated with reduction of frequency of face-touching; the differences of face-touching
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41 324 behavior between left-handers and right-handers.
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45 325

46 47 326 **Measures**

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49 327 **1. Frequency of face-touching:** Self-observation or self-monitoring of face-touching behavior will
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51 328 be required to report from each participant. A standardized scoring sheet will be provided to tally
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53 329 the frequency of hand-to-face contacts, the touched area of the face, including the mucosal area
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330 (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) , and the
331 time in seconds of each contact will be recorded in a 60-minute period ⁴.

332 **2. Reduction of frequency of face-touching behavior:** this will be calculated as the total times of
333 face-touching (including the eyes, nose, mouth, ears, cheeks, chin, neck, forehead, hair) during a
334 60-minute period before the intervention minus the total times of face-touching after the
335 intervention.

336 **3. Five Facet Mindfulness Questionnaire (FFMQ)**³²⁻³⁴: this self-report scale is currently the most
337 frequently used mindfulness questionnaire to measure changes in participant's tendency to be
338 mindful in daily life by the following five related facets: observing(noticing, attending to
339 sensations, perceptions, thoughts, feelings; 8 items), describing (labeling feelings, thoughts with
340 words), acting with awareness (automatic pilot, concentration, non-distraction), non-judging
341 internal experience, and non-reactivity to internal experience. Participants will be asked to what
342 extent each of the statements are true of them. Each item is on a 1 to 5 Likert scale, ranging from
343 1 (never or very rarely true) to 5 (very often or always true). The scores represent a spectrum of
344 mindfulness with no cut-off points, higher scores indicate higher levels of mindfulness. The
345 factor structure of the short version (FFMQ-15) will be used in this study, which has been
346 consistent with that of the FFMQ-39³⁵.

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

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3 352 under “left (L)” or “right (R)” columns, indicating strength of preference for each activity.
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6 353 Participants will be asked write “2”, “1” or “0” in the appropriate corresponding column. If the
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8 354 preference is very strong that they would never try to use the other hand unless absolutely forced
9
10 355 to, then they will mark this column as “2” and the other column as “0”. If they are really
11
12 356 indifferent, they will mark it as “1” in both columns. A laterality quotient ($LQ = R - L / R + L \times 100$)
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14 357 can be calculated, where a score of 100 reflects complete right-handedness, and a score of -100
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16 358 reflects complete left-handedness.
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22 360 **Withdrawal from the Program**

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25 361 Every participant will feel free to withdraw from the study at any time and without giving any
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27 362 reason. On the basis of the intention-to-treat (ITT) principle³⁸, participants who fail to respond to
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29 363 follow-up assessment will be retained in the analysis and classified as those who continued the
30
31 364 same behavior. Only participants who request withdrawal from the study will be excluded from
32
33 365 the analysis, and reasons for withdrawal will be noted if they are available. However, self-
34
35 366 monitoring itself may increase the awareness of face-touching behavior, then consequently
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37 367 increase or decrease the frequency of face-touching behavior in the second time of observation.
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39 368 Alternatively, a complete case analysis will also be performed in which any participant withdrew
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41 369 from the study in the second observation will be excluded.
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49 371 **Data collection**

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52 372 Data will be collected on line by WenJuanXing, a Chinese online market research Web site that
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54 373 provides professional online questionnaire survey or data collection for RCTs³⁹. Data will be
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3 374 monitored by data monitoring committee of the hospital. Personal data will be de-identified.
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8 376 **Data analysis**
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10 377 All data will be automatically collected by internet. A user-specified Excel file will be downloaded
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12
13 378 from the database. There will be no interim analyses. When all data have been obtained, they
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15 379 will be analyzed and blinded to intervention assignment by the trial statistician using R software
16

17
18 380 (R Foundation for Statistical Computing, Vienna, Austria. <https://www.r-project.org/>) and SPSS
19

20 381 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).
21

22
23 382 Descriptive statistics will be applied for demographic and face-touching-related characteristics at
24

25 383 baseline; two sample T-test or Mann-Whitney U test (for continuous variables) and χ^2 test (for
26

27
28 384 categorical variables) will be applied to compare the demographic information and face-touching
29

30 385 behavior at baseline between the STOP intervention group and control group. Percentage of
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32 386 touching the T-Zone participants between pre- and post- intervention in the STOP group and the
33

34
35 387 control group will be compared by χ^2 test. In order to determine if the "STOP touching your face"
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37 388 intervention group showed a reduction of face-touching behavior than the control group, two
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40 389 sample T-test or Mann-Whitney U test will first be applied to compared group differences in
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42 390 reduction of the frequency of face-touching. Then, analysis of covariance (ANCOVA) will be
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45 391 applied with controlling for demographic information (such age, handedness and prior
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47 392 mindfulness meditation experience). In ANCOVA model, the dependent variable will be the
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49
50 393 reduction of face-touching behavior. The pre-intervention measure of the total times of face-
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52 394 touching will be controlled as a covariate, and intervention will be a fix factor. This model will
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54
55 395 assess the differences in the post-intervention means after accounting for pre-intervention
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3 396 values; Pearson's correlations or regression analysis (linear and binary regression model) will be
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5
6 397 used to explore the any factor that associated with face-touching behavior at baseline and
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8 398 reduction of face-touching behavior in the intervention group and in the control group. Intention-
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10 399 to-treat (ITT) basis will be applied in this study to handle incomplete or missing data (assuming
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12
13 400 for no reduction of the frequency of face-touching). In addition, a complete case analysis will be
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15 401 performed in which any participant with missing information on the follow-up will be
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17
18 402 excluded. All tests will be 2-tailed. A two-sided $P < 0.05$ will be used to determine statistical
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20 403 significance.
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23 404

24 25 405 **Safety**

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27 406 Throughout the “STOP touching your face” program, participants will be encouraged to
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29
30 407 communicate with us if they experience any mindfulness practice relative issues. Adverse events
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32
33 408 will be monitored during the study. The MBIs are regarded as relatively safe interventions⁴⁰.
34
35 409 Research showed that even highly vulnerable participants (such as patients with major
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37 410 depressive disorder⁴¹) can safely practice mindfulness, but if participants experience any health-
38
39
40 411 related issues, they will be encouraged to contact with us, or we will refer a health care provider.
41
42 412 This study is not clinical-facilitated and may have very low risk of any safety issue. We will send a
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44
45 413 message to each participant to check whether they have any safety issues after providing them
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47 414 with intervention instruction.
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51 52 416 **Ethics and dissemination**

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3 417 The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an
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6 418 affiliate of Zhejiang University, Medical College (NO. 20200401-32). All activities associated with
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8 419 this protocol will be conducted in full compliance with the approved policies and procedures.
9
10 420 Electronically Informed consent (this e-consent is a form of written consent) will be
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12 421 communicated and obtained from each participant prior to participation. All participant will be
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15 422 explained about the purpose, procedures and assessments, potential risks and benefits of the
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17 423 trial before recruitment. After fully understanding the study, participants will be informed that
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19 424 their participation in this research study is total voluntary. They can choose to (sign the
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21 425 electronic consent form by selecting “agree to participant”) or not to participate (sign the
22
23 426 electronic consent form by selecting “disagree to participant”). Participation can withdrawal at
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27 427 any time without reasons. Contact information (phone number and social media contact like
28
29 428 WeChat contact ID) of the study coordinator for any future questions and concerns will be
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32 429 provided and informed to each participant. We will recruit 1000 participants from April to July
33
34 430 2020 or until the recruitment process is complete. The follow-up will be completed in July 2020.
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36
37 431 We expect all trial results to be available by the end of July 2020. Any results from this trial
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39 432 (publications, conference presentations) will be disseminated via social media and be published
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41 433 in peer-reviewed journals and conference proceedings.
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47 435 **Discussion**

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50 436 This RCT is to investigate the efficacy of brief mindfulness-based intervention of “STOP touching
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52 437 your face” for people from general population in China. To our knowledge, this will be the first
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3 438 RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior
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6 439 on the basis of mindfulness and cognitive behavioral principles.
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10 441 The strength of this study is that this is a theoretical framework guided (mindfulness-based
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12 442 cognitive behavior theory) large sample size RCT to evaluate the efficacy of “STOP touching your
13
14 443 face” during the outbreak of COVID-19. If “STOP touching your face” program is proved to be
15
16 444 effective, it opens up its potential application worldwide at the population level. As “STOP
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18 445 touching your face” program is a free, brief, simple and widely accessible mindfulness-based
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20 446 behavior change intervention, the public health impact of its expansion world-wide could be
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22 447 enormous, helping us to manage any face-touching spread infectious diseases, like COVID-19.
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30 449 There are some limitations in this study. First, there is no digital videotape recording for the
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32 450 behavior of face-touching by researchers. Alternatively, it will be self-monitored. Self-monitoring
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34 451 of physical (such as blood pressure), and mental health (such as anger or frustration that comes
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36 452 from daily life) has been used as a strategy for improving the treatment of a number of chronic
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38 453 conditions or reducing unhealth behaviors including smoking, drinking, gambling and so on⁴².
39
40 454 Thus, self-monitoring itself may change participants face-touching behavior by creating a more
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42 455 active role in observing this behavior. Also, self-reported results of self-monitored times of face
43
44 456 touching may be overestimated or underestimated. The results will be more accurate under lab
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46 457 conditions. In order to reduce the bias, we will invite a sub-group of participants with video
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48 458 record by another person to confirm the consistency of these results. Second, this is only an
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50 459 online intervention, participants may be more likely to drop out from the study. Thus, we will
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3 460 encourage participants contact with us if they have any questions or concerns. We will also apply
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6 461 an intention-to-treat principle to prevent potential bias caused by missing data from loss to
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8 462 follow-up, as well as a complete case analysis. Third, this is only a brief intervention by internet.
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10 463 A face to face long-term mindfulness intervention will help participants gain the maximum
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13 464 benefits of practice. However, neuroimaging study demonstrates that both long and short-term
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15 465 mindfulness practice can improve automatic emotion regulation⁴³, and RCT shows that brief
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18 466 online mindfulness-based intervention can also increase mindfulness and decrease perceived
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20 467 stress and symptoms of anxiety or depression²⁷. Last, this is a mindfulness-based intervention,
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22
23 468 and mindfulness could make participants better at catching themselves touching their faces, so
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25 469 participants from the intervention group may report higher frequency than the control group in
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28 470 the second self-monitoring of face-touching behavior.

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30 471
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32 472 In conclusion, this is the first RCT to evaluate the efficacy of brief mindfulness intervention to
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35 473 reduce face-touching behavior. If “STOP touching your face”, a brief and simple skill, is proven
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38 474 effective, the public health impact of its expansion world-wide could be enormous, its
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40 475 dissemination will help us to manage any face-touching spread infectious diseases, like
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42 476 Coronavirus disease 2019 (COVID-19).
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47 478 **Availability of data and materials**

49 479 All data in the current study will be available from the corresponding author on reasonable
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51
52 480 request and with completion of data user agreement.
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482 **Authors' Contributions**

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

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497 **Competing interests statement**

498 No potential conflicts of interest to declare.

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3 504 Mindful Awareness Research Center for providing opportunities to them to learn and practice
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5
6 505 mindfulness.

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11 507 **References**

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3 613 **Figure Legend**

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6 615 **Figure 1** Study Flow Diagram

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16 620 **Note:** Participants from the “control” intervention will receive “STOP touching your face”
17 621 intervention (both text and audio description) immediately after completing the second self-
18 622 monitoring face-touching behavior. But they will not be required to practice it or to practice it
19 623 at least 15 minutes.
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3 **625 Table1** study inclusion and exclusion criteria

4 Inclusion Criteria:

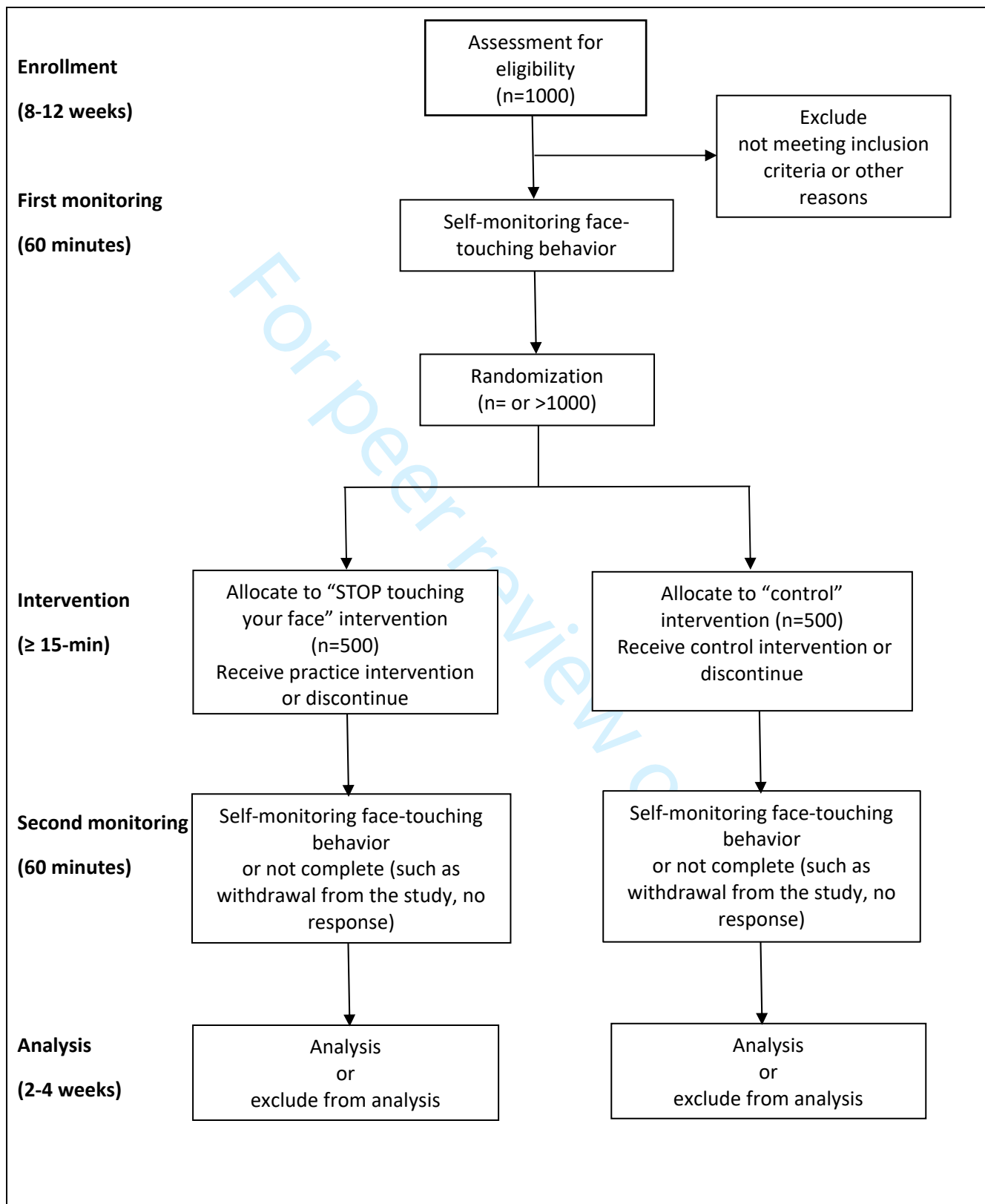
- 5
6 1. 18 years of age or older
7 2. Being able to access online services
8 3. Being able to read and write in Chinese
9 4. Expressing an interest in participant this study
10 5. Willing to provide informed consent to participate in the study

11 Exclusion Criteria:

- 12
13 1. Under 18 years of age
14 2. Unable to access online services
15 3. Unable to read and write in Chinese
16 4. Already received “not to touch your face” training
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18 **626**

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

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3 personal information about you will be disclosed.
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6 **9. What if an adverse event occurs?**

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

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



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

1
2 P8, 140-147 Trial 8 Description of trial design including type of trial (eg, parallel group,
3 design crossover, factorial, single group), allocation ratio, and framework (eg,
4 superiority, equivalence, noninferiority, exploratory)
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6
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8 **Methods: Participants, interventions, and outcomes**

9
10 P8, 141 Study 9 Description of study settings (eg, community clinic, academic hospital)
11 setting and list of countries where data will be collected. Reference to where
12 list of study sites can be obtained
13

14 P8, 147 P26, 546- 10 Inclusion and exclusion criteria for participants. If applicable, eligibility
15 547 Eligibility criteria for study centres and individuals who will perform the
16 criteria interventions (eg, surgeons, psychotherapists)
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19 P14-15, 275-289 11a Interventions for each group with sufficient detail to allow replication,
20 Interventions including how and when they will be administered
21

22 11b Criteria for discontinuing or modifying allocated interventions for a
23 given trial participant (eg, drug dose change in response to harms,
24 participant request, or improving/worsening disease)
25

26 11c Strategies to improve adherence to intervention protocols, and any
27 procedures for monitoring adherence (eg, drug tablet return,
28 laboratory tests)
29

30 11d Relevant concomitant care and interventions that are permitted or
31 prohibited during the trial
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34 P16, 317-324 12 Primary, secondary, and other outcomes, including the specific
35 Outcomes measurement variable (eg, systolic blood pressure), analysis metric
36 (eg, change from baseline, final value, time to event), method of
37 aggregation (eg, median, proportion), and time point for each
38 outcome. Explanation of the clinical relevance of chosen efficacy and
39 harm outcomes is strongly recommended
40
41

42 P21, 429-431 13 Time schedule of enrolment, interventions (including any run-ins and
43 Participant washouts), assessments, and visits for participants. A schematic
44 timeline diagram is highly recommended (see Figure)
45
46

47 P8-9, 149-168 14 Estimated number of participants needed to achieve study objectives
48 Sample size and how it was determined, including clinical and statistical
49 assumptions supporting any sample size calculations
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51 Recruitment 15 Strategies for achieving adequate participant enrolment to reach
52 target sample size
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54 **Methods: Assignment of interventions (for controlled trials)**

55 Allocation:
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2	P10-11, 197-	16a	Method of generating the allocation sequence (eg, computer-
3	201 Sequence		generated random numbers), and list of any factors for stratification.
4	generation		To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions
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9			
10	P10-11, 199-	16b	Mechanism of implementing the allocation sequence (eg, central
11	200		telephone; sequentially numbered, opaque, sealed envelopes),
12	Allocation		describing any steps to conceal the sequence until interventions are
13	concealment		assigned
14	mechanism		
15			
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17	P10, 196-203	16c	Who will generate the allocation sequence, who will enrol participants,
18	Implementation		and who will assign participants to interventions
19			
20	P10, 200-203	17a	Who will be blinded after assignment to interventions (eg, trial
21	Blinding		participants, care providers, outcome assessors, data analysts), and
22	(masking)		how
23			
24		17b	If blinded, circumstances under which unblinding is permissible, and
25			procedure for revealing a participant's allocated intervention during
26			the trial
27			
28			
29	Methods: Data collection, management, and analysis		
30			
31	P17, 330-333	18a	Plans for assessment and collection of outcome, baseline, and other
32	Data collection		trial data, including any related processes to promote data quality (eg,
33	methods		duplicate measurements, training of assessors) and a description of
34			study instruments (eg, questionnaires, laboratory tests) along with
35			their reliability and validity, if known. Reference to where data
36			collection forms can be found, if not in the protocol
37			
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39		18b	Plans to promote participant retention and complete follow-up,
40			including list of any outcome data to be collected for participants who
41			discontinue or deviate from intervention protocols
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44	P18-19, 371-374	19	Plans for data entry, coding, security, and storage, including any
45	Data		related processes to promote data quality (eg, double data entry;
46	management		range checks for data values). Reference to where details of data
47			management procedures can be found, if not in the protocol
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50	P19-20, 376-403	20a	Statistical methods for analysing primary and secondary outcomes.
51	Statistical		Reference to where other details of the statistical analysis plan can be
52	methods		found, if not in the protocol
53			
54		20b	Methods for any additional analyses (eg, subgroup and adjusted
55			analyses)
56			
57		20c	Definition of analysis population relating to protocol non-adherence
58			(eg, as randomised analysis), and any statistical methods to handle
59			missing data (eg, multiple imputation)
60			

Methods: Monitoring

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	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

26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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

1			
2	P21, 431-433	31a	Plans for investigators and sponsor to communicate trial results to
3	Dissemination		participants, healthcare professionals, the public, and other relevant
4	policy		groups (eg, via publication, reporting in results databases, or other
5			data sharing arrangements), including any publication restrictions
6			
7		31b	Authorship eligibility guidelines and any intended use of professional
8			writers
9			
10		31c	Plans, if any, for granting public access to the full protocol, participant-
11			level dataset, and statistical code
12			
13			

Appendices

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16	In supplementary	32	Model consent form and other related documentation given to
17	file,		participants and authorised surrogates
18	Informed consent		
19	materials		
20			
21			
22	Not applicable,	33	Plans for collection, laboratory evaluation, and storage of biological
23	Biological		specimens for genetic or molecular analysis in the current trial and for
24	specimens		future use in ancillary studies, if applicable
25			

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-041364.R2
Article Type:	Protocol
Date Submitted by the Author:	28-Sep-2020
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Primary Subject Heading:	Public health

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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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4 1 **A brief mindfulness-based intervention of “STOP (Stop, Take a Breath,**
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10 3 **randomized controlled trial**
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15 5 Yanhui Liao^{1,2,3*}; Ling Wang⁴; Tao Luo^{5,6}; Shiyu Wu⁷; Zhenzhen Wu^{8,9}; Jianhua Chen¹⁰; Chen
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32 **Abstract**

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

38 **Methods and analysis** This will be an online-based, randomized, controlled, trial. We will recruit
39 1,000 participants, and will randomize and allocate participants 1:1 to the “STOP touching your
40 face” (both 750-word text and 5-min audio description by online) intervention group (n=500) and
41 the wait-list control group (n=500). All participants will be asked to monitor and record their face-
42 touching behavior during a 60-minute period before and after the intervention. Primary outcome
43 will be the efficacy of short-term mindfulness-based “STOP touching your face” intervention for
44 reducing the frequency of face-touching. The secondary outcomes will be percentage of
45 participants touching their faces; the correlation between the psychological traits of mindfulness
46 and face-touching behavior; and the differences of face-touching behavior between left-handers
47 and right-handers. Analysis of covariance, regression analysis, χ^2 test, T-test, Pearson's
48 correlations will be applied in data analysis. We will recruit 1000 participants from April to July
49 2020 or until the recruitment process is complete. The follow-up will be completed in July 2020.
50 We expect all trial results to be available by the end of July 2020.

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

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3 54 **Trial registration number** NCT04330352.
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8 56 **Strengths and limitations of this study**
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10 57 • This is the first RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-
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12 touching behavior.
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15 59 • This is a theoretical framework guided (mindfulness-based cognitive behavior theory) large
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17 sample size RCT to evaluate the efficacy of “STOP touching your face” during the outbreak of
18 60
19 COVID-19.
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23 62 • “STOP touching your face” program is a free, brief, simple and widely accessible mindfulness-
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25 based behavior change intervention.
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28 64 • There is no digital videotape recording for the behavior of face-touching by researchers.
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30 Alternatively, it will be self-monitored.
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33 66 • This is only a brief intervention by internet. A face to face long-term mindfulness intervention
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35 will help participants gain the maximum benefits of practice.
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69 Introduction

70 Nonverbal behavior plays an important role in interpersonal relations and constitutes a large
71 amount of all communication. But self-touching is usually not used to communicate with others
72 and is often done automatically without thinking about it at all in our daily life¹. It might be one
73 of the so called "autistic" gestures when they have no evident meaning². Spontaneous facial self-
74 touching or face-touching has been defined as *the use of the hand to touch the individual's own*
75 *face* to scratch, rub, groom, or caress it. Research shows that the average face-touching
76 frequency ranges from approximately 16³ to 23⁴ times per hour. Furthermore, research of face-
77 touching across handedness showed that left-handed individuals more frequently touch their
78 face than their counterparts⁵.

79
80 An increase in face-touching frequency may result in increased risk of transmissible infections,
81 defined as self-inoculation or auto-inoculation (a type of contact transmission occurs when a
82 person transfers an infectious disease from one part of the body to another, e.g., when a
83 contaminated hand makes subsequent contact with the nose and introduces contaminated
84 material to those areas)^{3 4}. Of all face-touching behaviors, touching the T-zones will pose a
85 potential risk for transmission and acquisition of a range of infectious diseases. Unfortunately,
86 research found that 42.2%⁶ to 44%⁴ of face-touching involved in contacting with a mucous
87 membrane. Even clinicians touch their T-zones (the mucus membranes of the eyes, nose, and
88 mouth) as frequently as 19 times on average within 2 hours⁷. Many diseases can be spread
89 by self-inoculation in this way, including coronavirus disease 2019 ("COVID-19")^{8 9}. Thus, the

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3 90 Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO)
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6 91 have been telling people to stop touching their faces.
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10 93 However, even we all know that stop touching our faces will minimize spread of coronavirus and
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12 94 other germs. The question is how to stop this behavior? Although face-touching is often an
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14 95 automatic behavior without conscious thought or decision, research indicates that the frequency
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16 96 of self-touching and the duration of touch and contact are associated with cognitive and
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18 97 emotional demands^{10 11}. In addition to emotional states, especially negative affect states, self-
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20 98 touching also has been linked to information processing and production¹².
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27 100 Raising self-awareness of face-touching behavior may be effective in reducing or avoiding this
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29 101 behavior. For example, every time when you touch your face, be mindful, notice how you
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31 102 touched your face, check what you are thinking, physical and psychological feeling or your
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33 103 sensation that preceded it. This process or skill is similar to “mindfulness practice” developed by
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35 104 Jon Kabat Zinn¹³. Mindfulness can be defined as “*Mindful Awareness is the moment-by-moment*
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37 105 *process of actively and openly observing one’s physical, mental and emotional experiences*”
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39 106 (Mindful Awareness Research Center at the University of California at Los Angeles). Mindfulness-
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41 107 based interventions (MBIs) are proven to be clinically efficacious in treatment of behavioral
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43 108 disorders, such as alcohol drinking, smoking, gambling¹⁴⁻¹⁶, attention deficit/hyperactivity
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45 109 disorder (ADHD)¹⁷, eating disorders^{18 19}, as well as in enhancing the emotional health of Chinese
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47 110 long-term male prison inmates²⁰. Increasing peoples' awareness of their habituated face-
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49 111 touching behavior may help individuals to avoid touching their face by contaminated hands, and
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3 112 decrease the risk of spreading infectious diseases. The structured MBIs, such as mindfulness-
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5 113 based stress reduction (MBRS) and mindfulness-based cognitive therapy (MBCT) program, are 8
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8 114 to 10 weeks course²¹⁻²⁴, but brief MBIs can also produce numerous health-related outcomes,
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10 115 even only with one session intervention and as brief as 5 minutes^{25 26}. Randomized controlled
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12 116 trials (RCT) of a brief mindfulness-based intervention further suggested the feasibility and
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14 117 effectiveness of short-term, self-guided, internet or smartphone-based interventions^{27 28}.
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20 119 The primary objective of this proposed project is to identify a simple but effective practice to
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22 120 reduce or avoid face-touching to low people's chances of catching infectious diseases like COVID-
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24 121 19. Based on the efficacy of MBIs in treatment of some behavioral disorders and the efficacy of
25
26 122 short-term MBIs, we here propose a RCT of an online mindfulness-based brief intervention skill
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28 123 named "STOP (Stop, Take a Breath, Observe, Proceed) touching your face". It is hypothesized
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30 124 that this skill will be an effective, feasible, accessible skill in reducing or avoiding face-touching
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32 125 for people in the general population. To be specific, the primary hypothesis of this brief
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34 126 behavioral intervention is that, compared with a control intervention, the intervention would
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36 127 result in greater reduction of face-touching behavior. We also hypothesize that the frequency of
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38 128 face-touching behavior will also be reduced. Based on the theory that both face-touching
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40 129 behavior and mindfulness link to cognitive or emotional process^{10 23}, we hypothesize that people
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42 130 with higher levels of self-reported mindfulness will touch their face less frequently. Given left-
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44 131 handed individuals more frequently touch their face than their counterparts⁵, It is hypothesized
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46 132 that, compared with right-handed participants, left-handed individuals will touch their face more
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48 133 frequently during their 60-minute self-monitoring of face-touching.
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135 **Methods and analysis**

136 **Patient and public involvement**

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

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140 **Study design and participants**

141 In this online-based, randomized, parallel-group trial, undertaken in China by internet, about
142 1,000 participants willing to participate in “STOP touching your face” training program and
143 provide electronic consent (e-consent), will be randomly allocated to mindfulness-based “STOP
144 touching your face” intervention group or a control group at a 1:1 ratio. A 2 × 2 (practice group
145 and control group × pre–post measurements) experimental design will be used. Since
146 participants will be told that they will either receive “STOP touching your face” training program
147 before (intervention group) or after (control group) the second 60-minute self-monitoring face-
148 touching behavior, blinding of participants will not be possible. Blinding of the investigators
149 (mainly Dr. Y Liao and Dr. L Wang) who are directly involved in interventions will also not be
150 possible because of the nature differences of these two interventions (“STOP touching your face”
151 training program intervention and control intervention). The investigators (Dr. J Tang and Dr. Y
152 Liu) who will assess the outcomes will be blinded to participants’ allocated groups until all data
153 have been analyzed. All participants who are allocated to the control group will have the
154 opportunity to practice this skill after the end of the study period. An overview of participant
155 eligibility criteria is given in **Table1**.

156

157 Sample size and power calculation

158 This study aims to recruit 1000 participants, with 500 in each group. The sample size assessment
159 and power calculations are mainly on the basis of the results of RCTs of different types of online
160 short-term mindfulness intervention for behavioral changes, such as for alcohol consumption¹⁶
161 and stopping smoking or decreasing smoking craving²⁹, or for positive psychological changes,
162 such as enhancing wellbeing²⁸ and reducing perceived stress and anxiety/depression symptoms²⁷.
163 A single brief session of mindfulness of 11-minutes (n=34) detected a significant reduction in
164 alcohol consumption compared with a relaxation control intervention (n=34)¹⁶. It is estimated
165 that, for assessing stop face-touching behavior, individuals who received mindfulness
166 intervention will at least twice likely to reduce the chance of touching T-Zone than the control
167 group (5 to 10% vs. 2 to 4%). Thus, a total of 562 participants (281 participants in each group) are
168 required to achieve 80% power (1-beta=0.8), as significant at the 5% level (alpha=0.05), an
169 increase in the outcome measure from 4% in the control group to 10% in the intervention group.
170 However, online interventions often have much higher dropout rate than face to face
171 intervention. A web-based guided self-help intervention for preventing depression reported
172 about 20% dropout rate at 6-month follow-up³⁰, but a brief online mindfulness-based
173 intervention for reducing stress, anxiety and depression reported 30% dropout rate in the
174 intervention group and more than a half in the waiting list control group²⁷ Considering the high
175 loss to follow-up rate, this study will have a final target sample size of 1000 participants (500 in
176 each arm), which will have sufficient power to detect a significant difference for the outcomes.

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3 **178 Recruitment**
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6 179 As in other similar research, we will advertise this program online using social media (such as
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8 180 WeChat and QQ) to recruit potential participants. Potential participants will register their interest
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10 181 by sending messages by social media, email or sending text messages, or making a call to research
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12 182 assistants (by Dr. Y Wang and Dr. Z Wu). Then, research assistants will contact respondents to
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14 183 assess their eligibility and explain the study to each participant and inform them that they would
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16 184 be allocated to either a control group or to a group that receives the Mindfulness-based “STOP
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18 185 touching your face” program. Before collecting baseline data, electronically informed consent
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20 186 will be obtained from each participant. Participants who enrolled in this study could withdraw at
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22 187 any time. They will also be asked to provide contact information (will not be shared with any third
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24 188 party), in case any problems arise.
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32 **190 Baseline data**
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35 191 Prior to randomization, demographic information and self-reported questionnaires will be
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37 192 obtained from all participants at baseline (assessed by Dr. Y Liao, Dr. C Pan and Dr. Q Luo). The
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39 193 demographic information of participants will be gender, age, years of education, marital status,
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41 194 occupation by the International Standard Classification of Occupations (ISCO), living in rural or
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43 195 urban region, smoker types (nonsmoker or current smoker and former smoker). The Five Facets
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45 196 Mindfulness Questionnaire (FFMQ) will be applied to measure the dispositional tendency to
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47 197 be mindful in daily life. The Edinburgh Handedness Inventory (EHI) will be used to assess
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49 198 handedness. Frequency of face-touching will be assessed at baseline and after intervention.
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200 **Randomization and group allocation**

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

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213 **Development of "STOP touching your face" training program**

214 ***Theory***

215 Face-touching behavior is often an automatic behavior that could potentially disseminate
216 respiratory infections (eg, influenza, coronavirus), yet can be changed. However, changing the
217 behavior of face-touching is "easier said than done", as there is only limited evidence for the
218 neuropsychological basis or physiological fundamentals of this behavior. Research shows that
219 the frequency of self-touching increases when attention is distracted¹⁰, as well as under stressful
220 situations or with negative affect¹¹. Cognitive behavioral theory-based mindfulness intervention
221 (mindfulness-based cognitive therapy, MBCT²⁴) has been used as a psychological intervention for

222 people with mental or behavior problems, targeting both cognitive and behavioral problems.

223 Mindfulness-based interventions (MBIs)¹³ can help people cultivate positive affect, increase self-

224 awareness and concentration that are associated with reducing frequency of face-touching.

225 ***Practice***

226 STOP³¹ is an acronym that stands for four action: “Stop”, “Take a breath”, “Observe”, “Proceed”.

227 It is a helpful aid in becoming more mindful of our body, behavior and emotion on a daily basis.

228 The following is the instruction for how to practice STOP:

229 **S = Stop**

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

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

232 **T = Take**

233 Take a deep breath. This reconnects you with your body. Pay attention to your breathing and

234 just allow yourself to continue to breathe normally and naturally.

235 **O = Observe**

236 OBSERVE what is happening for you in this moment—including thoughts, feelings, and

237 emotions (e.g. feel distracted, anxious or nervous?). What do you notice in your body (e.g. feel

238 itchy or tingling on any part of your face)? You can be aware of anything: posture, sensations,

239 tension in your body, or, once again, your breath. You might notice the sound around you. You

240 might even notice your thoughts or emotions

241 **P = Proceed**

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

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

245 The STOP Practice is very short, simple, and the acronym (STOP) makes it easy to remember as
246 well. Thus, it has become one of the most popular mindfulness-based practices. The practice of
247 STOP may cultivate a space between stimulus and response, which could help avoid the mostly
248 spontaneous behavior of facial self-touching. The STOP Practice in Chinese was already
249 developed by Dr. Y Liao, Dr. Q Luo and Dr. C Pan. Dr. Y Liao developed the “STOP touching your
250 face” training program. Both 750-word text and 5-min audio description (see **Supplementary file**
251 **1**) will be available by online.

252 **Procedures**

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

261

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

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

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3 265 reported the frequency of face-touching in any of the mucosal area (eyes, nose, mouth) and
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6 266 nonmucosal area (ears, cheeks, chin, neck, forehead, hair) during a 60-minute period. All
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8 267 participants will be required to monitor their face-touching behavior during a 60-minute period,
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10 268 and be encouraged to do it in a manageable situation. Wearing facial mask will not be permitted
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13 269 during the time of self-monitoring face-touching. All participants will be provided with the same
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15 270 link to complete their baseline information and the first 60-minute self-monitoring of face-
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17 271 touching behavior, and be encouraged to complete this questionnaire immediately after
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20 272 completion of self-monitoring.

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23 273 Instruction: *"1. Please find a convenient time, no need to deliberately change your routine life
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25 274 (such as working or studying at the desk, watching TV), observe and record how many times you
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27 275 touched your hair, forehead, eyes, nose, mouth, ears, cheeks, Chin and neck in one-hour period
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29 276 (if you touched your mouth and nose at one time, you should count one time for mouth-touching
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31 277 and one time for nose-touching). If there is any information that you cannot understand, please
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33 278 contact with me at any time; 2. fill in the following content immediately after completion of self-
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35 279 monitoring (with a link to "hand-to-face contacts" behavior monitoring record 1); 3. please
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37 280 contact with me to send the information about intervention to you when you completed the link.
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40 281 4. You will repeat another one-hour period self-monitoring after your receiving another
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42 282 information (either "STOP touching your face" program or just thanks words)."*

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48 49 284 **Step 2. Intervention**

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52 285 **The intervention group:** Participants from the intervention group will receive the online
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54 286 mindfulness-based "STOP touching your face" program (both 750-word text and 5-min audio
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3 287 description). Each participant will be required to read the text of the program first and then listen
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6 288 to the audio. They will be encouraged to practice this technique until they feel confident and
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8 289 natural. The systematic review showed the efficacy of single session of brief MBIs, the average
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10 290 length of which was 15 minutes, ranged from less than 5 to 25 min²⁵. Thus, the requirement
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13 291 practice time will be at least 15 minutes (excluding the time of reading the text and the first time
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15 292 of listening to the audio). This online mindfulness-based intervention will not have face-to-face
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18 293 interaction between the experimenter and participants throughout the entire study.

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20 294 **The control group:** Participants who allocate to the control group will only receive information
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22 295 to thank them and encourage them to complete the study. They will be reminded to receive
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25 296 “STOP touching your face” program after the end of this study.

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28 297 **Both groups:** Participants from both groups will be reminded to contact with us to provide the
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30 298 instruction of another self-monitoring behavior of face-touching.

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35 300 **Step 3. The second 60-minute self-monitoring of face-touching behavior (after intervention)**

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37 301 After intervention, all participants will be required to monitor their face-touching behavior during
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39 302 a 60-minute period again. When participants tell us “*I am ready to do another self-monitoring*”,
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42 303 they will receive instruction of how to complete the second 60-minute self-monitoring of face-
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45 304 touching behavior during a 60-minute period. The repeat measurement of the face-touching
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47 305 behavior will be done at least 1 hour apart from the first self-monitoring. All participants will be
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49 306 encouraged to monitor their face-touching behavior in two similar situations.

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52 307 Instruction: “*1. Again, please find a convenient time, no need to deliberately change your routine*
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54 308 *life (such as working or studying at the desk, watching TV), observe and record how many times*

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3 309 *you touched your hair, forehead, eyes, nose, mouth, ears, cheeks , Chin and neck in one-hour*
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6 310 *period (if you touched your mouth and nose at one time, you should count one time for month-*
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8 311 *touching and one time for nose-touching). It is better to find a similar situation (the similar time*
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10 312 *if not in the same day, same place, and when you are doing the same thing). You need to do it at*
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12 313 *least 1 hour apart from the last observation. If there is any information that you cannot*
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14 314 *understand, please contact with me at any time; 2. fill in the following content immediately after*
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16 315 *completing self-monitoring (with a link to "hand-to-face contacts" behavior monitoring record 2,*
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18 316 *the two groups will receive different links); 3. please let me known when you completed the link*
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20 317 *(the intervention group); please contact with me to send the program to you when you completed*
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22 318 *the link (the control group)."*
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30 320 All participants will be thanked and encouraged to practice "STOP touching your face" regularly
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32 321 after the end of the study. All outcomes will be collected by an online survey through the Chinese
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34 322 professional survey software WenJuanXing (Sojump, Shanghai, China, www.sojump.com). For
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36 323 non-responders, a reminding message will be sent to them by their provided contact information
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38 324 for reporting the outcomes.
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45 326 **Outcomes**

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47 327 **Primary outcome:** the efficacy of short-term mindfulness-based "STOP touching your face"
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49 328 intervention (≥ 15 min) for reducing face-touching behavior, measuring by reduction of frequency
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51 329 of face touching behavior (this will be calculated as the total times of face-touching (including
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3 330 the eyes, nose, mouth, ears, cheeks, chin, neck, forehead, hair) during a 60-minute period before
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6 331 the intervention minus the total times of face-touching after the intervention).

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8 332 **Secondary outcomes:** the reduction of percentage of participants touching their faces (this will
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10 333 be calculated as the percentage of participants touching their faces (including any of the
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13 334 following areas: the eyes, nose, mouth, ears, cheeks, chin, neck, forehead, hair) during a 60-
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15 335 minute period before the intervention - the percentage of participants touching their faces after
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17 336 the intervention) after intervention; the factors (demographic characteristics, psychological traits
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19 337 of mindfulness) that would be associated with reduction of frequency of face-touching; the
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21 338 differences of face-touching behavior between left-handers and right-handers.
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26 27 340 **Measures**

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30 341 **1. Frequency of face-touching:** Self-observation or self-monitoring of face-touching behavior will
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32 342 be required to report from each participant. A standardized scoring sheet will be provided to tally
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34 343 the frequency of hand-to-face contacts, the touched area of the face, including the mucosal area
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36 344 (eyes, nose, mouth) and nonmucosal area (ears, cheeks, chin, neck, forehead, hair) , and the
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38 345 time in seconds of each contact will be recorded in a 60-minute period ⁴.

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42 346 **2. Percentage of participants touching their faces:** this will be the number of participants who
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44 347 touched any of the following areas: the eyes, nose, mouth, ears, cheeks, chin, neck, forehead,
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46 348 hair, during their 60-minute self-monitoring of face-touching / the total number of participants
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48 349 in the intervention group or the control group.

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51 350 **3. Five Facet Mindfulness Questionnaire (FFMQ)**³²⁻³⁴: this self-report scale is currently the most
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53 351 frequently used mindfulness questionnaire to measure changes in participant's tendency to be
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3 352 mindful in daily life by the following five related facets: observing(noticing, attending to
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6 353 sensations, perceptions, thoughts, feelings; 8 items), describing (labeling feelings, thoughts with
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8 354 words), acting with awareness (automatic pilot, concentration, non-distraction), non-judging
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10 355 internal experience, and non-reactivity to internal experience. Participants will be asked to what
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13 356 extent each of the statements are true of them. Each item is on a 1 to 5 Likert scale, ranging from
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15 357 1 (never or very rarely true) to 5 (very often or always true). The scores represent a spectrum of
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18 358 mindfulness with no cut-off points, higher scores indicate higher levels of mindfulness. The
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20 359 factor structure of the short version (FFMQ-15) will be used in this study, which has been
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22
23 360 consistent with that of the FFMQ-39³⁵.

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25 361 **4. The Edinburgh Handedness Inventory (EHI)** ^{36 37}: EHI is the most widely used 10-item self-
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27 362 report inventory to assess handedness. It is comprised of the following 10 activities: (1) writing,
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30 363 (2) drawing, (3) throwing, (4) using scissors, (5) a toothbrush (6) knife (without fork), (7) spoon,
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32 364 and such activities involving both hands as (8) using a broom (upper hand), (9) striking a match,
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35 365 and (10) unscrewing the lid of a bottle. To complete the EHI, one or two check marks are placed
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37 366 under “left (L)” or “right (R)” columns, indicating strength of preference for each activity.
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40 367 Participants will be asked write “2”, “1” or “0” in the appropriate corresponding column. If the
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42 368 preference is very strong that they would never try to use the other hand unless absolutely forced
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45 369 to, then they will mark this column as “2” and the other column as “0”. If they are really
46
47 370 indifferent, they will mark it as “1” in both columns. A laterality quotient ($LQ = R - L/R + L \times 100$)
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49 371 can be calculated, where a score of 100 reflects complete right-handedness, and a score of -100
50
51 372 reflects complete left-handedness.

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374 **Withdrawal from the Program**

375 Every participant will feel free to withdraw from the study at any time and without giving any
376 reason. On the basis of the intention-to-treat (ITT) principle³⁸, participants who fail to respond to
377 the second assessment will be retained in the analysis according to the arm they were
378 randomized to, irrespective of whether they did the intervention or not. Only participants who
379 request withdrawal from the study will be excluded from the analysis, and reasons for withdrawal
380 will be noted if they are available. However, self-monitoring itself may increase the awareness of
381 face-touching behavior, then consequently increase or decrease the frequency of face-touching
382 behavior in the second time of observation. Alternatively, a complete case analysis will also be
383 performed in which any participant withdrew from the study in the second observation will be
384 excluded.

386 **Data collection**

387 Data will be collected on line by WenJuanXing, a Chinese online market research Web site that
388 provides professional online questionnaire survey or data collection for RCTs³⁹. Data will be
389 monitored by data monitoring committee of the hospital. Personal data will be de-identified.

391 **Data analysis**

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

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3 396 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).
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6 397 Descriptive statistics will be applied for demographic and face-touching-related characteristics at
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8 398 baseline; two sample T-test or Mann-Whitney U test (for continuous variables) and χ^2 test (for
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10 399 categorical variables) will be applied to compare the demographic information and face-touching
11
12 400 behavior at baseline between the STOP intervention group and control group. Percentage of
13
14 401 touching the T-Zone participants between pre- and post- intervention in the STOP group and the
15
16 402 control group will be compared by χ^2 test. For assessing the primary outcome, determining if the
17
18 403 “STOP touching your face” intervention group showed a reduction of face-touching behavior than
19
20 404 the control group, two sample T-test or Mann-Whitney U test will first be applied to compared
21
22 405 group differences in reduction of the frequency of face-touching. Then, analysis of covariance
23
24 406 (ANCOVA) will be applied with controlling for demographic information (such age, handedness
25
26 407 and prior mindfulness meditation experience). In ANCOVA model, the dependent variable will be
27
28 408 the reduction of face-touching behavior. The pre-intervention measure of the total times of face-
29
30 409 touching will be controlled as a covariate, and intervention will be a fix factor. This model will
31
32 410 assess the differences in the post-intervention means after accounting for pre-intervention
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34 411 values. Pearson's correlations or regression analysis (linear and binary regression model) will be
35
36 412 used to explore the any factor that associated with face-touching behavior at baseline and
37
38 413 reduction of face-touching behavior in the intervention group and in the control group. Intention-
39
40 414 to-treat (ITT) basis will be applied in this study, all participants who complete the first 60-minute
41
42 415 self-monitoring face-touching behavior will be retained in the analysis. The last-observation-
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44 416 carried-forward (LOCF) method will be applied to handle incomplete or missing data (assuming
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46 417 for no reduction of the frequency of face-touching). In addition, a complete case analysis will be
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3 418 performed in which any participant with missing information on the follow-up will be
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6 419 excluded. All tests will be 2-tailed. A two-sided $P < 0.05$ will be used to determine statistical
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8 420 significance.

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12 422 **Safety**

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15 423 Throughout the “STOP touching your face” program, participants will be encouraged to
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17 424 communicate with us if they experience any mindfulness practice relative issues. Adverse events
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19 425 will be monitored during the study. The MBIs are regarded as relatively safe interventions⁴⁰.
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21 426 Research showed that even highly vulnerable participants (such as patients with major
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23 427 depressive disorder⁴¹) can safely practice mindfulness, but if participants experience any health-
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25 428 related issues, they will be encouraged to contact with us, or we will refer a health care provider.
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27 429 This study is not clinical-facilitated and may have very low risk of any safety issue. We will send a
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29 430 message to each participant to check whether they have any safety issues after providing them
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31 431 with intervention instruction.
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40 433 **Ethics and dissemination**

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42 434 The study protocol has been approved by The Ethics Committee of Sir Run Run Shaw hospital, an
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44 435 affiliate of Zhejiang University, Medical College (NO. 20200401-32). All activities associated with
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46 436 this protocol will be conducted in full compliance with the approved policies and procedures.
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48 437 Electronically Informed consent (this e-consent is a form of written consent) will be
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50 438 communicated and obtained from each participant prior to participation. All participant will be
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52 439 explained about the purpose, procedures and assessments, potential risks and benefits of the
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3 440 trial before recruitment. After fully understanding the study, participants will be informed that
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6 441 their participation in this research study is total voluntary. They can choose to (sign the
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8 442 electronic consent form by selecting “agree to participant”) or not to participate (sign the
9
10 443 electronic consent form by selecting “disagree to participant”). Participation can withdrawal at
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12
13 444 any time without reasons. Contact information (phone number and social media contact like
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15 445 WeChat contact ID) of the study coordinator for any future questions and concerns will be
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18 446 provided and informed to each participant. We will recruit 1000 participants from April to July
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20 447 2020 or until the recruitment process is complete. The follow-up will be completed in July 2020.
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23 448 We expect all trial results to be available by the end of July 2020. Any results from this trial
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25 449 (publications, conference presentations) will be disseminated via social media and be published
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27
28 450 in peer-reviewed journals and conference proceedings.

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31 32 452 **Discussion**

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35 453 This RCT is to investigate the efficacy of brief mindfulness-based intervention of “STOP touching
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38 454 your face” for people from general population in China. To our knowledge, this will be the first
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40 455 RCT to evaluate the efficacy of brief mindfulness intervention to reduce face-touching behavior
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43 456 on the basis of mindfulness and cognitive behavioral principles.

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48 458 The strength of this study is that this is a theoretical framework guided (mindfulness-based
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50 459 cognitive behavior theory) large sample size RCT to evaluate the efficacy of “STOP touching your
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53 460 face” during the outbreak of COVID-19. If “STOP touching your face” program is proved to be
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55 461 effective, it opens up its potential application worldwide at the population level. As “STOP

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3 462 touching your face” program is a free, brief, simple and widely accessible mindfulness-based
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6 463 behavior change intervention, the public health impact of its expansion world-wide could be
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8 464 enormous, helping us to manage any face-touching spread infectious diseases, like COVID-19.
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13 466 There are some limitations in this study. First, there is no digital videotape recording for the
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15 467 behavior of face-touching by researchers. Alternatively, it will be self-monitored. Self-monitoring
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18 468 of physical (such as blood pressure), and mental health (such as anger or frustration that comes
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20 469 from daily life) has been used as a strategy for improving the treatment of a number of chronic
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23 470 conditions or reducing unhealth behaviors including smoking, drinking, gambling and so on⁴².

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25 471 Thus, self-monitoring itself may change participants face-touching behavior by creating a more
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28 472 active role in observing this behavior. Also, self-reported results of self-monitored times of face
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30 473 touching may be overestimated or underestimated. Furthermore, self-monitoring itself may
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33 474 increase the awareness of face-touching behavior, then consequently increase or decrease the
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35 475 frequency of face-touching behavior in the second time of observation. The results will be more
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38 476 accurate under lab conditions. In order to reduce the bias, we will invite a sub-group of
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40 477 participants with video record by another person to confirm the consistency of these results.

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42 478 Second, this is only an online intervention, participants may be more likely to drop out from the
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45 479 study. Thus, we will encourage participants contact with us if they have any questions or concerns.

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47 480 We will also apply an intention-to-treat principle to prevent potential bias caused by missing data
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50 481 from loss to follow-up, as well as a complete case analysis. Third, this is only a brief intervention
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52 482 by internet. A face to face long-term mindfulness intervention will help participants gain the
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55 483 maximum benefits of practice. However, neuroimaging study demonstrates that both long and

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3 484 short-term mindfulness practice can improve automatic emotion regulation⁴³, and RCT shows
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6 485 that brief online mindfulness-based intervention can also increase mindfulness and decrease
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8 486 perceived stress and symptoms of anxiety or depression²⁷. Fourth, this is a mindfulness-based
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11 487 intervention, and mindfulness could make participants better at catching themselves touching
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13 488 their faces, so participants from the intervention group may report higher frequency than the
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16 489 control group in the second 60-minute self-monitoring of face-touching behavior. Last, we
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18 490 submitted this protocol to the journal during the time of recruiting.
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22
23 492 In conclusion, this is the first RCT to evaluate the efficacy of brief mindfulness intervention to
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25 493 reduce face-touching behavior. If “STOP touching your face”, a brief and simple skill, is proven
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28 494 effective, the public health impact of its expansion world-wide could be enormous, its
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30 495 dissemination will help us to manage any face-touching spread infectious diseases, like
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32 496 Coronavirus disease 2019 (COVID-19).
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37 498 **Availability of data and materials**
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40 499 All data in the current study will be available from the corresponding author on reasonable
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42 500 request and with completion of data user agreement.
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47 502 **Authors' Contributions**
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50 503 YLiao and JT developed and designed the study. YLiao, CP and QL developed STOP Practice, YLiao
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52 504 developed the “STOP touching your face” training program. Yliao discussed with LW and WC on
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54 505 the planning and conduct of the study, and discussed with YLiu and JT on the acquisition of data
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3 506 and the planning of data analysis. YLiao, LW, TL, SW, ZW, JC, CP, YW, LX and JZ conducted the
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5 507 interventions. JT and YLiu conducted data analysis. YLiao took the lead in drafting the manuscript
6
7 508 protocol with contributions by JT and JC. LQ, XG and WC advised the study design, and
8
9
10 509 coordinated study approval. All authors read and proposed critical comments, as well as
11
12
13 510 approved the manuscript for publication.
14

15 511

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19
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21
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23
24 515 University, and the K.C. Wong Postdoctoral Fellowship to study at King's College London (KCL).
25
26
27 516 The funders had no role in study design, data collection and analysis, decision to write the report
28
29
30 517 or to submit the paper for publication.
31

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35 519 **Competing interests statement**

36
37 520 Dr. Y Liao developed the “STOP touching your face” training program. No other potential conflicts
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40 521 of interest to declare.
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42 522

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46
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48
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51
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3 527 Mindful Awareness Research Center for providing opportunities to them to learn and practice
4
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6 528 mindfulness.

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636 **Figure Legend**

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638 **Figure 1** Study Flow Diagram

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

For peer review only

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2
3 **648 Table1** study inclusion and exclusion criteria

4 Inclusion Criteria:

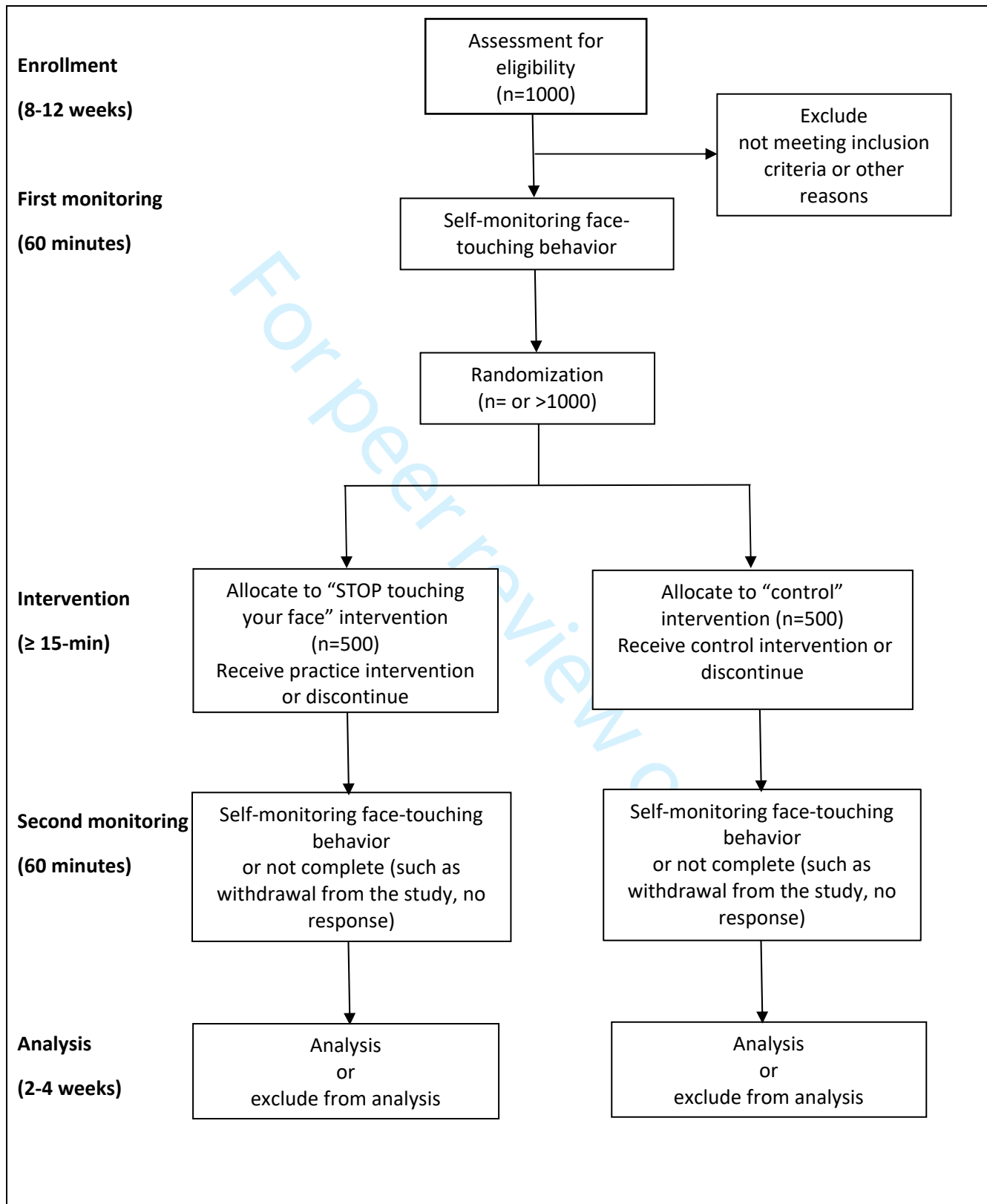
- 5
6 1. 18 years of age or older
7 2. Being able to access online services
8 3. Being able to read and write in Chinese
9 4. Expressing an interest in participant this study
10 5. Willing to provide informed consent to participate in the study

11 Exclusion Criteria:

- 12
13 1. Under 18 years of age
14 2. Unable to access online services
15 3. Unable to read and write in Chinese
16 4. Already received “not to touch your face” training
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18 **649**

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

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3 personal information about you will be disclosed.
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6 **9. What if an adverse event occurs?**

7 If you are harmed by participating in this study: In the event of damages related to this
8 clinical study, our medical team will help you to get timely treatment, and adverse events
9 will be handled as routine medical events in the hospital. You can choose not to participate
10 in this research, or notify the researcher to withdraw from the research at any time, your
11 data will not be included in the research results, and any of your medical treatment and
12 rights will not be affected. If you need other treatments, or if you do not follow the study
13 plan, or have a study-related injury or for any other reason, the study physician can
14 terminate your continued participation in this study.
15

16
17
18 **10. How to contact the researcher?**

19 You can keep abreast of the information and research progress related to this research. If
20 you have any questions related to this research, or if you have any discomfort or injury
21 during the research, or have questions about the rights of participants in this research You
22 can contact the researchers at any time (18890098852), 11th Floor, Inpatient Department,
23 Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, No. 368, Xiasha Road,
24 Economic and Technological Development Zone, Hangzhou, Zhejiang). If you have any
25 questions about your rights as a patient participating in the study, please contact The
26 Medical Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of
27 Medicine, 0571-86006811.
28
29

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



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

1
2 P8, 140-154 Trial 8 Description of trial design including type of trial (eg, parallel group,
3 design crossover, factorial, single group), allocation ratio, and framework (eg,
4 superiority, equivalence, noninferiority, exploratory)
5
6
7

8 **Methods: Participants, interventions, and outcomes**
9

10 P8, 141 Study 9 Description of study settings (eg, community clinic, academic hospital)
11 setting and list of countries where data will be collected. Reference to where
12 list of study sites can be obtained
13

14 P8,154-155, P30, 10 Inclusion and exclusion criteria for participants. If applicable, eligibility
15 647-648 Eligibility criteria for study centres and individuals who will perform the
16 criteria interventions (eg, surgeons, psychotherapists)
17
18

19 P14-15, 284-289 11a Interventions for each group with sufficient detail to allow replication,
20 Interventions including how and when they will be administered
21

22 11b Criteria for discontinuing or modifying allocated interventions for a
23 given trial participant (eg, drug dose change in response to harms,
24 participant request, or improving/worsening disease)
25

26 11c Strategies to improve adherence to intervention protocols, and any
27 procedures for monitoring adherence (eg, drug tablet return,
28 laboratory tests)
29
30

31 11d Relevant concomitant care and interventions that are permitted or
32 prohibited during the trial
33

34 P16, 326-338 12 Primary, secondary, and other outcomes, including the specific
35 Outcomes measurement variable (eg, systolic blood pressure), analysis metric
36 (eg, change from baseline, final value, time to event), method of
37 aggregation (eg, median, proportion), and time point for each
38 outcome. Explanation of the clinical relevance of chosen efficacy and
39 harm outcomes is strongly recommended
40
41

42 P22, 446-448 13 Time schedule of enrolment, interventions (including any run-ins and
43 Participant washouts), assessments, and visits for participants. A schematic
44 timeline diagram is highly recommended (see Figure)
45
46

47 P9, 157-176 14 Estimated number of participants needed to achieve study objectives
48 Sample size and how it was determined, including clinical and statistical
49 assumptions supporting any sample size calculations
50

51 P10, 178-188 15 Strategies for achieving adequate participant enrolment to reach
52 Recruitment target sample size
53
54

55 **Methods: Assignment of interventions (for controlled trials)**
56

57 Allocation:
58
59
60

1			
2	P11, 204-208	16a	Method of generating the allocation sequence (eg, computer-
3	Sequence		generated random numbers), and list of any factors for stratification.
4	generation		To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions
8			
9			
10	P11, 208-209	16b	Mechanism of implementing the allocation sequence (eg, central
11	Allocation		telephone; sequentially numbered, opaque, sealed envelopes),
12	concealment		describing any steps to conceal the sequence until interventions are
13	mechanism		assigned
14			
15	P11, 201-208	16c	Who will generate the allocation sequence, who will enrol participants,
16	Implementation		and who will assign participants to interventions
17			
18			
19	P11, 209-211	17a	Who will be blinded after assignment to interventions (eg, trial
20	Blinding		participants, care providers, outcome assessors, data analysts), and
21	(masking)		how
22			
23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial
26			
27			

Methods: Data collection, management, and analysis

28			
29			
30	P19, 386-389	18a	Plans for assessment and collection of outcome, baseline, and other
31	Data collection		trial data, including any related processes to promote data quality (eg,
32	methods		duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol
36			
37			
38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols
41			
42	P19, 388-389	19	Plans for data entry, coding, security, and storage, including any
43	Data		related processes to promote data quality (eg, double data entry;
44	management		range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol
46			
47			
48	P19-21, 391-420	20a	Statistical methods for analysing primary and secondary outcomes.
49	Statistical		Reference to where other details of the statistical analysis plan can be
50	methods		found, if not in the protocol
51			
52		20b	Methods for any additional analyses (eg, subgroup and adjusted
53			analyses)
54			
55		20c	Definition of analysis population relating to protocol non-adherence
56			(eg, as randomised analysis), and any statistical methods to handle
57			missing data (eg, multiple imputation)
58			
59			
60			

Methods: Monitoring

1			
2			
3			
4	P19, 388-389	21a	Composition of data monitoring committee (DMC); summary of its role
5	Data monitoring		and reporting structure; statement of whether it is independent from
6			the sponsor and competing interests; and reference to where further
7			details about its charter can be found, if not in the protocol.
8			Alternatively, an explanation of why a DMC is not needed
9			
10		21b	Description of any interim analyses and stopping guidelines, including
11			who will have access to these interim results and make the final
12			decision to terminate the trial
13			
14			
15	P21, 422-431	22	Plans for collecting, assessing, reporting, and managing solicited and
16	Harms		spontaneously reported adverse events and other unintended effects
17			of trial interventions or trial conduct
18			
19	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and
20			whether the process will be independent from investigators and the
21			sponsor
22			
23			

Ethics and dissemination

24			
25			
26	P21, 434-435	24	Plans for seeking research ethics committee/institutional review board
27	Research ethics		(REC/IRB) approval
28	approval		
29			
30	Protocol	25	Plans for communicating important protocol modifications (eg,
31	amendments		changes to eligibility criteria, outcomes, analyses) to relevant parties
32			(eg, investigators, REC/IRBs, trial participants, trial registries, journals,
33			regulators)
34			
35			
36	P21-22, 437-443	26a	Who will obtain informed consent or assent from potential trial
37	Consent or assent		participants or authorised surrogates, and how (see Item 32)
38			
39		26b	Additional consent provisions for collection and use of participant data
40			and biological specimens in ancillary studies, if applicable
41			
42			
43	P19, 389	27	How personal information about potential and enrolled participants will
44	Confidentiality		be collected, shared, and maintained in order to protect confidentiality
45			before, during, and after the trial
46			
47	P25, 519-521	28	Financial and other competing interests for principal investigators for
48	Declaration of		the overall trial and each study site
49	interests		
50			
51			
52	P11, 209-2011	29	Statement of who will have access to the final trial dataset, and
53	Access to data		disclosure of contractual agreements that limit such access for
54			investigators
55			
56	P8, 153-154	30	Provisions, if any, for ancillary and post-trial care, and for
57	Ancillary and		compensation to those who suffer harm from trial participation
58	post-trial care		
59			
60			

1 2 3 4 5 6 7 8 9 10 11 12 13	P22, 448-450 Dissemination policy	31a 31b 31c	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 Authorship eligibility guidelines and any intended use of professional writers Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
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Appendices

14 15 16 17 18 19 20 21 22 23 24 25	In supplementary file, Informed consent materials Not applicable, Biological specimens	32 33	Model consent form and other related documentation given to participants and authorised surrogates 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
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*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.