

Informed consent

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

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

Primary Investigator: Liao, Yanhui

1. Invitation to participate in this research:

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

2. What kind of research is this?

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

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

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

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

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

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

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

3. What does the participant need to do?

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

4. What risks and discomforts will it bring?

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

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

5. What are the benefits?

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

6. Do I need to pay related fees?

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

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

Participating in this research will not receive financial compensation.

8. Who will see my information?

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

personal information about you will be disclosed.

9. What if an adverse event occurs?

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

10. How to contact the researcher?

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

Informed consent Signed page

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

Subject's electronic signature: _____

Date: _____ year _____ month _____ day