The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**A Tai Chi intervention to promote smoking cessation among cancer survivors**
Principal Investigator:	**Ce Shang**
Sponsor:	**The Ohio State University**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether to be a part of this study. More detailed information is listed later in this form.

Tai Chi is a practice that involves a series of slow gentle movements and physical postures, a meditative state of mind, and controlled breathing. Tai chi originated as an ancient martial art in China. Over the years, it has become more focused on health promotion and rehabilitation.

The aim of our project is to find out if an online Tai Chi program can help cancer survivors who smoke quit smoking. Participants will be randomly assigned to an intervention group or control group. The study will last for 8 months for both groups. During the 8 months, intervention group participants will complete an 8-week online

instructor-led Tai Chi program and four surveys. The control group will complete 4 surveys during the 8 months. The control group will receive a free 8-week online Tai Chi program after the last survey if they complete at least two out of the three follow-up surveys.

Participants in both groups will also use a device that measures carbon monoxide (CO) levels. The carbon monoxide device is easy to use and is not invasive. The participant will need to blow air into this device.

Tai Chi is a gentle form of exercise that can be done while sitting or standing and does not involve any medications or medical procedures. This study is low-risk, and we believe it could be beneficial for cancer survivors who want to quit smoking.

Intervention Group: Tai Chi (WaQi Program):
The 8-week online Tai Chi program will start in February or March 2025. There will be live online classes with an instructor and self-administered sessions. There will also be surveys and CO measures to complete.

1. 60-minute live online classes with an instructor
    - 2 classes per week for 8-weeks.
    - Classes are offered live via password-protected Zoom.
    - Classes are led by a Tai Chi instructor certified in WaQi teaching.
    - Each session will include a warmup, agility training, meditation, slow movement, and meditation for cooling down.
    - Participants are encouraged to leave their camera on during class so the instructor can give feedback. This is only a recommendation and not required.
    - Participating live during class is ideal, but class recordings will also be available.
    - Participants will have access to class recordings for 6 months after the Tai Chi 8-week session ends.

Exercise	**Average Length**
Energy cultivation or core strength/form routine to warm up and boost energy	10 minutes
Standing meditation to build stamina, improve posture and enhance sleep	10 minutes
Basic agility/form routine to boost endurance, balance, strength, and cognition	10 minutes
Lying down meditation to enhance sleep and relieve pan	10 minutes
Spiral flexibility/form routine to improve flexibility and posture	10 minutes
Sitting meditation for the tranquility and resilience of the mind	10 minutes
Total	**60 minutes**

2. 10-minute self-administered daily sessions
    - 5 days per week for 8-weeks.
    - Sessions are recorded and can be streamed via WaQi's official webpage with a free subscription for each participant.
    - The participant can decide when and where to complete the session each day.
    - Each session involves meditation, slow movement, and agility training.

Exercise	**Average Length**
Stillness: sitting, standing, and lying down meditation to improve awareness, posture, strength, and relaxation	3 minutes
Slow to moderate qigong and tai chi movements: energy cultivation for pain prevention, spiral flexibility, and core strength training.	3 minutes
Agility exercises: enhance muscle strength, balance, and cardio capacity	4 minutes
Total	**10 minutes**

Twenty-minute surveys will be at study enrollment and 1 week, 3 months and 6 months after the 8-week Tai Chi program. There will also be 5-minute, weekly check-ins during the 8-week program. Carbon monoxide measurements will be taken at each follow-up survey time-point and at week 4 of the Tai Chi program.

Participants who miss more than two consecutive weeks of the Tai Chi classes, and do not try to make up those classes, will be withdrawn from the study.

Control Group
The control group is not participating in the intervention (Tai Chi program) but will be on the same study timeline as the intervention group. Twenty-minute surveys, along with the carbon monoxide measures, will be at study enrollment and at 1 week, 3 months and 6 months after the intervention. A carbon monoxide measure will also be completed at week 4 of the intervention.

After the last follow-up survey the control group will receive a free 8-week online Tai Chi self-administered program, if the control group participant completed at least two of the three follow-up surveys. Control group participants will have access to the online Tai Chi program for 8 months.

1. Why is this study being done?

As a mind-body exercise, Tai Chi has shown its health benefits in all stages of cancer care, including treatment, coping, pain management, recovery, and health promotion. It is

a low-cost exercise that doesn't require any equipment and can be done at a light-to-moderate intensity.

There haven't been many studies on whether mind-body exercises like Tai Chi can help cancer survivors quit smoking. This project aims to fill that gap by conducting a randomized controlled trial to see if a Tai Chi program, combined with information about standard smoking cessation treatments, can help cancer survivors aged 21 and over reduce their dependence on cigarettes and quit smoking.

2. How many people will take part in this study?

We are aiming to recruit 200 participants in this study, with 100 in the control group and 100 in the intervention group.

3. What will happen if I take part in this study?

If you join our study, you will be randomly assigned to either the intervention group or the control group. Both groups will receive an email that contains National Cancer Institutes' resource page for quitting smoking (standard smoking cessation treatment). The intervention group will also learn Tai Chi by participating in the Tai Chi WaQi program for 8 weeks. After the last survey, the control group will receive a free 8-week online Tai Chi self-administered program. Both groups will complete surveys.

If you take part in this study, you are required to have an electronic device such as a smartphone, laptop, or tablet (ex. iPad, Amazon Fire) that can connect to the Internet. For this study, you will need to be able to access Zoom (a free online communication platform). You will also need to download a free app to an iOS or Android device for the carbon monoxide measurement.

We will mail a carbon monoxide device called Bedfont's iCOquit after enrolling in the study and scheduling the orientation. The participant will use Bedfont's iCOquit to measure the amount of carbon monoxide (CO) in a breath using the portable monitor, which will be synced to the participants' smartphones or tablet (iOS or Android supported device). Participants will need to download the free iCOquit app. With each CO measure, participants will be asked to complete a brief smoking habit survey. These questions will take 1-2 minutes to complete. The participant will need to share their CO result with the study team immediately after measuring, which will help us check if the participant has stopped smoking. In the orientation session, the study team will explain and teach the participant how to use the iCOquit device. Device instructions and a short video will be sent to the participant as well.

Participants randomized to the intervention group will need to create an account with the Center of Taiji and Qigong Studies, the online Tai Chi program for this study. This website hosts research studies involving Tai Chi, and although account creation will

require demographic identifiers, this website will not ask about personal health information. Account creation includes a sign-in name, a password and other additional information that will assist the Tai Chi program in authenticating identity when logging in. Participants will also need to accept the program's Terms of Use and Privacy Policy.

Intervention Group study schedule:

Study Schedule	**Average Length**	**When**
Orientation	20 minutes	After enrolling in the study
Baseline survey, CO measure	20 minutes	Shortly after orientation; before the first Tai Chi session
Tai Chi program	8 weeks	60-minute class 2x a week; 10-minute self-guided Tai Chi session 5x week; 5-minute weekly check-ins
Carbon monoxide measurements	25 minutes total (5 minutes/time 5 times total)	One time during the 8-week Tai Chi program (during week 4); measurements at baseline, 1 week, 3 months, and 6 months after completion of Tai Chi program.
1st follow-up survey, CO	20 minutes	1 week after completing the Tai Chi Program
2nd follow-up survey, CO measure	20 minutes	3 months after completing the Tai Chi Program
3rd follow-up survey, CO measure	20 minutes	6 months after completing the Tai Chi Program

Control Group study schedule:

Study Schedule	**Average Length**	**When**
Orientation	20 minutes	After enrolling in the study
Baseline survey, CO measure	20 minutes	Shortly after orientation
CO measure	5 mins	4 weeks after the start of the intervention
1st follow-up survey, CO measure	20 minutes	1 week after the intervention
2nd follow-up survey, CO measure	20 minutes	3 months after the intervention
3rd follow-up survey, CO measure	20 minutes	6 months after the intervention
Tai Chi program		Control group participants will receive access to a free 8-week online self-guided Tai Chi program

4. How long will I be in the study?

Each study participant will be expected to commit for 8 months.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

This study involves minimal risks and discomforts. The Tai Chi program is designed for cancer survivors. The program requires light to moderate exercise and can be performed by sitting or standing. Depending on your health condition and fitness level, you may feel slight discomfort when performing the Tai Chi program. The CO measurement is non-invasive. For the CO measurement, the participant will need to blow air into the device.

This study involves minimal risk in data confidentiality and safety. Any information collected will be in a secure database accessible only to registered key study personnel. All efforts are made to safeguard participants' data, confidentiality, and privacy.

It is also possible that some participants may feel uncomfortable answering certain survey questions. Participants can skip any questions that they do not feel comfortable answering.

7. What benefits can I expect from being in the study?

You will be connected with a Tai Chi program. Tai Chi has shown health benefits in all stages of cancer care, including treatment, coping, pain management, recovery, and health promotion. You may experience smoking cessation benefits. There may be no additional benefit to you from participating in this research. The information that you provide through the surveys and carbon monoxide measures can improve our understanding and our ability to help cancer survivors who want to quit smoking.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

It is free to participate in this study.

10. Will I be paid for taking part in this study?

By law, payments to participants are considered taxable income.
Our study offers compensation for the appreciation of participants' time in our study. Electronic gift cards will be sent in an email as participants complete each study item based on the schedule below.

Intervention Group: Timeline	**Compensation (e-gift cards)**
Orientation	$10
Baseline survey, with CO	$10
16 live Tai Chi classes ($5 each)	$80
Short weekly check-ins, 8 weeks ($5 each); CO measurement with week 4	$40
First follow-up survey, with CO	$10
Second follow-up survey, with CO	$20
Third follow-up survey, with CO	$20
Total	**$180**

Control Group: Timeline	**Compensation (e-gift cards)**
Orientation	$10
Baseline survey, with CO	$10
CO, 4 weeks after intervention starts	$5
First follow-up survey, with CO	$10
Second follow-up survey, with CO	$20
Third follow-up survey, with CO	$20
Total	**$65**

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

The Center for Taiji and Qigong Studies, the organization conducting the Tai Chi program, adheres to industry standards for encryption, secure data transmission, and restricted access to ensure data privacy and compliance with all applicable regulations. All collected data will be managed exclusively for the purposes outlined in the project, with no sharing of personal information beyond authorized personnel and approved uses.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Tobacco use
  Questionnaires
- Records about any study drug you received;
- Records about the study device; and

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or

- owned by the sponsor.

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient at The Ohio State University Wexner Medical Center, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact ***Ce Shang at ce.shang@osumc.edu OR call at 917-868-8682***.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact ***The Ohio State University Comprehensive Cancer Center – Office of Compliance and Integrity; phone: 614-293-4477, email: privacyoffice@osumc.edu or fax: 614-685-3765.***

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***Ce Shang at ce.shang@osumc.edu OR call at 917-868-8682***.

Providing Consent

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

If I agree to participate, I will be emailed a copy of this combined consent and HIPAA research authorization form. To print or save a copy of this page, select the print button on your web browser.

If you agree to participate, please click here.

If you do not agree to participate, please click here to answer one question that may help us improve the study. You may then close your browser window. If you do not wish to answer the question, you may close your browser window now.