CONSENT TO TAKE PART IN RESEARCH

Dartmouth College
Meditative Movement (Qigong) for COPD Symptoms in Non-Smoking Flight Attendants
Phase 1
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You are being asked to take part in a research study. Taking part in research is voluntary. Taking part in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information to help patients in the future.

Your decision whether or not to take part will not influence your future medical care, job status, academic standing, or eligibility for insurance. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The purpose of the study is to learn if doing gentle Meditative Movement (MM) type exercise that includes stretching and breathing exercises, that are specific to the needs of individuals with COPD (Chronic Obstructive Pulmonary Disease) and related respiratory disorders, can have a beneficial impact on health for former or current flight attendants with respiratory symptoms.

Will you benefit from taking part in this study?

You might not personally benefit from being in this research study. We hope to gather information that may help people in the future.

What does this study involve?

We will ask you to take part in a screening process to determine your eligibility and to record your baseline health status.

-- Half of the study participants will be randomly assigned to attend group training in MM for approximately 18 hours over a 12 week period.
--Half of the study participants will receive standard of care without MM training. Study participants assigned to standard of care would be eligible to participate in Phase 2 of this study in which all participants will take part in MM training.

Screening Tests:

You will need to have the following tests and to fill out questionnaires to find out if you can be in the study and to record your baseline health data.

- Flight Attendant health and work history questionnaire found on the web at www.FAHealth.org/dart
- Your heart rate will be monitored with a portable monitor on two or more occasions during the study.
- You will be asked to do a 6 minute walk test and your blood pressure and heart rate will be taken before and after this test
- Questions about your breathing (COPD symptom assessment test questionnaire)
- Breathing test (spirometry)
- You will be asked to complete questionnaires about anxiety, depression, and your health
- Blood sampling by finger prick to measure C-Reactive Protein and HbA1c (inflammatory biomarkers).
- Your will be asked for urine samples at the beginning and end of the study to determine stress hormone and melatonin levels.
- Answer questions about how much you notice and resound to sensations within your own body.

If the tests show that you can be in the study and you choose to take part, then you will enter the study. All volunteers will participate in Visit 1 and Visit 8 activities (baseline and end of study measurements). Standard of care volunteers will not participate in Visits 2-7.

Visit 1: May be a separate visit or may happen on the same day as visit two.

- Review and sign consent form. Consent may also be obtained by phone.
- You will be asked to do a 6 minute walk test and your blood pressure and heart rate will be taken before and after this test
- Questions about your breathing (COPD symptom assessment test questionnaire)
- Breathing test (spirometry)
- You will be asked to complete questionnaires about anxiety, depression and your health
- Blood sampling by finger prick to measure C-Reactive Protein, HbA1c and Melatonin (inflammatory biomarkers).
- You will be asked questions about how much you notice and resound to sensations within your own body.

Visit 2-7: about 3 hours each visit

MM training will be provided in a group setting involving other study participants. Feedback from participants will be sought by the research team, regarding suitability and effectiveness of various exercises. The gentle exercises that will be used do require attention but little exertion. You will be asked to keep a daily log of your health and the exercises and techniques that you practice.

Visit 8: about 90 minutes

- You will be asked to do a 6 minute walk test and your blood pressure and heart rate will be taken before and after this test
- Questions about your breathing (COPD symptom assessment test questionnaire)
- Breathing test (spirometry)
- You will be asked to complete questionnaires about anxiety, depression and your health
- Blood sampling by finger prick to measure C-Reactive Protein, HbA1c and Melatonin (inflammatory biomarkers).
- You will be asked questions about how much you notice and resound to sensations within your own body.

What are the options if you do not want to take part in this study?

You are not required to take part in this study. You can read this information and decide not to take part. You may ask questions about the study.

If you take part in this study, what activities will be done only for research purposes?

All the procedures, tests, and activities described in this consent form are being done only for research purposes.

What are the risks involved with taking part in this study?

This study was designed to have minimal risks. You may experience some discomfort from the finger prick used to collect a small blood sample. You may find some of the questionnaires to be boring. The meditative movement activities are gentle and are not normally associated with discomfort or physical problems. However, there may be a remote risk of discomfort or dizziness or other changes that could occur. You should immediately stop any activity that makes you uncomfortable and notify a member of the research team.

If you are assigned to the standard of care group, your health would be expected to progress, as before the study. You would not be expected to receive any benefit, other than information, from the tests that you will take. Participants assigned to standard of care would be eligible to participate in Phase 2 of this study.

Leaving the study:

You may choose to stop taking part in this study at any time for any reason.

New Information: New information related to this research will be made known to you when it becomes available. This may affect your decision to stay in this study.

Funding: The Flight Attendant Medical Research Institute (FAMRI) and ZRT Laboratory are funding this study.

Number of people in this study: We expect 50 people to enroll in Phase 1 of this study.

How will your privacy be protected?

Each participant will be assigned a code number. All data collected will be recorded as related to that code number. The file connecting that code to a specific participant will be kept in a locked filing cabinet.

We will only collect data that comes from the answers you give on questionnaires, and that we determine from biometric, pulmonary function, endurance and from blood, urine and saliva samples.

We are careful to protect the identities of the people in this study; we will keep the identities of participants secure and confidential.

We plan to maintain the data files for the purpose of recruiting participants into subsequent studies related to respiratory health of flight attendants. We also hope to be able to follow the health and progression of disease in participants in the future.

The information collected for this study will be used only for the purposes of research as stated earlier in this form.

Who may use or see your health information?

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Committee for the Protection of Human Subjects (CPHS) at Dartmouth College

During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study. If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information

collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call about this study?

If you have questions about this study or need to report a study related injury, you can call your doctor or the research director for this study: Dr. Mardi Crane at (603 653-9970) or Ingrid Svensborn, RN at (603-653-9128) during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-6482 during normal business hours.

What about the costs of this study?

There will be no charges to you nor to your insurance company to participate in this study.

Will you be paid to take part in this study?

No, however, participants may request to be reimbursed for reasonable local travel expenses as agreed upon by the institution and the study sponsor. If you wish to request reimbursement for mileage, your name, address, and social security number will be given to an office at DHMC that arranges for payments and reports payments to the IRS. If you do not provide a social security number, no payment can be made. This DHMC office sometimes checks to make sure that social security numbers and names match.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

CONSENT

I have read the above information about Meditative Movement (Qigong) for COPD Symptoms in Non-Smoking Flight Attendants, Phase 1 and have been given time to ask questions. I agree to take part in this study and I will be given a copy of this signed consent form.

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Participant's Signature and Date PRINTED NAME

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Researcher or Designee Signature and Date PRINTED NAME