Official Title: Asthma and Mindfulness-Based Stress Reduction (MBSR)

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UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of research study: Living Healthy with Asthma

Investigators: Lori Pbert Ph.D., James Carmody Ph.D.

Sponsor: National Institutes of Health

Why are you being invited to take part in a research study?

You are being asked to participate because you have asthma.

What should you know about a research study?

- Your participation is entirely voluntary.
- You do not have to be in this research study. If you join the study, you can stop or leave at any time with no changes in the quality of the health care you receive.
- You will be told about any new information or changes in the study that could affect you.
- You can ask all the questions you want before deciding if you want to be in this study.

Why are we doing this research?

Many people with asthma have tried a number of approaches in addition to medication to help manage their asthma symptoms, including adopting a healthier lifestyle and learning to cope with stress. Such behavioral approaches have the potential for producing improvements in the control of asthma.

The goal of this research is to test the possible effects of two interventions on helping people improve their asthma control. The interventions are an 8-session stress reduction program and an 8-session healthy living course.

How long will the research last?

We expect that you will be in this study for eighteen months.

How many people will be studied?

We expect about 170 people will be in this study at UMass Memorial Health Care out of 254 people in the entire study nationally.

Will I definitely receive the experimental program?

Since no one knows yet whether taking a stress reduction course or a healthy living course will be effective in helping improve asthma symptoms, not everyone in the research study will be taking the same course. The decision as to which course you will be assigned to will be made by chance, like the flip of a coin, not by your doctor or based on your medical condition. You have a 50% chance of getting assigned to the stress reduction program and a 50% chance of getting assigned to the healthy living course.

What happens if I say yes, I want to be in this research?

If you agree to be in the study you will be asked to complete questionnaires and a spirometry procedure at four time points, attend eight weekly classes, and keep track of your asthma symptoms each day for two weeks at each time point. The time points are an initial visit and 6, 12, and 18 months later.

The questionnaires ask a number of questions about your health, medical history and your asthma symptoms.

The spirometry will be in the UMass Medical School Pulmonary Diagnostic Laboratory to assess the level of your air flow limitation. First, you will take in the deepest breath you can and blow as hard as you are able through a tube connected to a machine. During the test, soft nose clips may be used to prevent air escaping through the nose. This procedure will be repeated at least three times to be sure we get a good reading. We will ask you not to take a bronchodilator at least 4 hours prior to your spirometry.

You will also be asked to breathe into a tube and tell us how much air resistance you felt while breathing out.

You will then be given a form to track any asthma medications you take over the next two weeks. You also will be asked to measure and document your peak flows over a two week period first thing in the morning and last thing at night. We will provide you with a peak flow meter (PFM) and instruct you on its use. A PFM is a small hand-held instrument used to measure how fast air can travel through the large airways of your lungs. You will hold the PFM to your mouth and after a slow deep breath you will blow into the mouthpiece.

It will take approximately one hour to complete all the assessments at each clinic visit. The questionnaire takes an additional one half hour and can be completed during the clinic visit or at home.

At the initial visit you will be randomly assigned to either the stress reduction program or the healthy living course. If you are assigned to the stress reduction program you will receive guided instruction in mindfulness practices and the integration of mindfulness into everyday life. If you are assigned to the healthy living course you will receive instruction in adopting a healthy lifestyle, including nutrition, physical fitness, coping with stress, and balancing work with life. Each course involves attending eight weekly 2 ½ hour classes and one all-day class on a weekend day and doing and recording daily homework. The classes will be at UMass Medical School and will have approximately 20 to 25 participants, not all of whom will be in this study.

Two days prior to your initial MBSR and HLC classes, the Research Coordinator will call you to remind you that your program is starting, He will remind you that you are required to attend the intervention sessions, and problem solve any challenges you might have about intervention class attendance. If you have missed a class, the Research Coordinator will follow-up with a call to identify barriers to participation and brainstorm strategies for you to attend future classes.

What are the risks of being in this study?

The study classes are educational in nature and there is minimal risk. It is a possibility that discussions in class might result in some psychological or social stress, but the instructors of these classes have received excellent training on how to help individuals presenting such issues.

Another risk of being in this study is that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected.

There is a remote risk of a collapsed lung during the forced exhalations of the spirometric maneuvers. Risk is minimized by having experienced pulmonary function technicians conduct the tests and by testing according to criteria of the American Thoracic Society.

Will being in this study help me in any way?

It is possible that your personal health may improve, but we cannot guarantee this. In addition, your participation may help others with this condition in the future as a result of knowledge gained from the research.

Will being in this study cost me any money?

No, there will be no additional cost to you from being in this research study. The classes and spirometry that are done for research purposes will be provided at no cost to you.

What happens to information about me?

We will try to limit access to your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. NIH and the UMMS Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) and other representatives of UMMS may need to review your records. As a result, they may see your name, but they are required not to reveal your identity to others. Your identity will remain confidential in any study results that are made public.

If we learn that you plan to hurt yourself or others, we will break confidentiality to help you.

If we learn of any child or elder abuse, we are required to break confidentiality and report this to state authorities.

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

What happens if I am injured because I took part in this research?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Will I be given any money or other compensation for being in this study?

You will be paid $50 for the initial visit and again at 6 months, and $75 at the 12 and 18 month visits to reimburse you for your time, travel and other expenses associated with this research study.

What are my other options?

You do not have to be in this study. If you decide not to be in the research now or later, it will not affect your usual care and it won't be held against you. You can sign up for the classes without being in the research study.

What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research. However, you can ask us to destroy any information that identifies you so that no one can tell the data belonged to you. Our contact information is below.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can take you out of the study even if you do not want to leave. This may happen if:

1. The investigator decides that continuing in the study would be harmful to you.
2. You fail to keep your appointments.
3. The study is canceled by the University of Massachusetts Medical School Institutional Review Board or the National Institutes of Health.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at 508 856-5529.

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	TIME SIGNED _____ AM PM
Signature of person obtaining consent	Date
Printed name of person obtaining consent	