Symptom Perception, Behavior, and Outcomes in Older Asthmatics
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TITLE OF RESEARCH STUDY:

Title: Symptom perception, behavior, and outcomes in older asthmatics

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to evaluate the role of symptom perception as a key determinant of poorer outcomes and lower adherence to asthma self-management behaviors among older asthmatics.

You may qualify to take part in this research study because you are 60 years old or older, speak English or Spanish, and have been diagnosed with asthma by a healthcare provider.

Funds for conducting this research are provided by the National Heart, Lung, and Blood Institute.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last up to 15 months.

The number of people expected to take part in this research study at this site is 200. The total number of people expected to take part in this research study is 400.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

This study involves completing three in-person or remote interviews at baseline (starting point), 6-month and 12-months. After a remote visit, you may be asked to complete an additional in-person visit to complete asthma testing. In the interviews, we will ask you about your asthma history, severity, medication regimen, disease and medication beliefs, self-management behaviors, asthma control, quality of life, pulmonary function tests and depression symptoms. The baseline interview takes approximately 60 minutes to complete. The follow up interviews take between 20 and 40 minutes to complete.

All interviews will take place in-person in a private room in the clinical offices of Mount Sinai Hospital or remotely via telephone or HIPAA complaint Zoom platform.

After you have read this consent and agreed to participate in this study, you will be asked by the study doctor or someone from his research team to have asthma testing. These tests will be done in the clinical offices of the Primary Care of Mount Sinai Hospital. The tests will involve the following:

(1) To assess your asthma, you will have a peak expiratory flow (PEF) and pulmonary function testing. For PEF measurement, you will be asked to blow as hard as you can for one second into a PEF instrument. You may be asked to do this as many as three times in a row. For pulmonary function testing, you will be asked to blow as hard as you can into a machine for six seconds. This may also be repeated three times.

(2) You will also be asked questions about depression at the baseline and 12 month interviews. If you present with suicidal ideation during the interview, you may be referred for further care at the Mount Sinai Hospital. In addition, if your test reveals that you may be depressed, we will ask for your permission to reach out to your primary care provider about these findings.

You will also receive an electronic device so that we can measure your asthma medication use for one month after the baseline, 6 and 12 month interviews. You will be asked to bring in your new inhaler or diskus that you have received from your regular doctor before your next visit. You will also receive a device to measure your peak flow (PEF) at home for six weeks after each of your interviews. This device does not replace the peak flow meter that you may currently be using to track your PEF. It should be used in addition to your current peak flow meter. Also, you will not be able to see the information recorded by the PEF device.

The interviews and other data collection in this study are for research purposes only. All of this information will be kept confidential and only the investigators will have access to it.

You may also be chosen to participate in a pilot study program as part of your participation. This participation will be assigned randomly. The pilot will include three additional interviews at 12.5, 13 and 14 months. You will be asked questions about your medication regimen, beliefs about your asthma and medications, self-management behaviors, treatment credibility, ED visits and asthma-related hospitalizations. You will also be asked to use the PEF measurement device and a medication measurement device just like those used earlier in the study. Each of these interviews will take place either at your home or at our research offices or remotely via phone or HIPAA complaint Zoom platform.

If you participate in the pilot study, we may audio record your 12.5-month interview with the research team for quality assurance purposes. The research staff will inform you before beginning the interview if we intend to record and will ask for your permission before recording. If you do not wish to be recorded, you still may participate in the pilot study and your interview will not be recorded. If you do agree to be recorded, the audio file will be accessible only to the research team and will be stored on our secure drive. Your name and any identifying information will be erased from the file before storing.

We will also review your medical record to look at all comorbidities and diagnoses as part of the study.

Future Research Opportunities:

The researchers would like to ask your permission to keep your contact information to contact you for future research studies.

(1) Do you give permission to have your contact information given to other researchers at Mount Sinai or other institutions for use in research **that is related to the purpose of this study**? Please initial your choice:

Yes…….. No…….

(2) Do you give permission to have your contact information given to other researchers at Mount Sinai or other institutions for use in research **that is not related to the purpose of this study**? Please initial your choice:

Yes……No…….

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: to respond to the questions asked in the interview, perform the spirometry test, and to return any electronic monitoring device we give to you. Please note that you will not be held responsible for broken, lost or stolen devices.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you for your time and effort after each interview. Study participants may receive up to $310 for participating in the study, if they complete both this study and the Pilot Study that follows it. If study participants complete only this study, they may receive up to $190. Study participants will receive a total of up to $70 for completing all parts of the baseline interview. Study participants will receive $50 in cash/money order after the completion of the baseline interview. In addition, $20 will be given to the participants after they return all electronic monitoring devices for their medication(s) and the electronic peak flow meter. If devices are returned in person, the participant will be paid in cash at the time of return. If devices are mailed back to Mount Sinai, the participant will be paid in cash at the next in-person interview. If the participant has no upcoming in-person interviews and is unable to drop off devices in person, the participant will mail in devices and a money order will be mailed back to the participant. Participants will receive a total of up to $60 for each of the follow-up interviews upon completing all parts of the follow-up interview. Participants will receive $40 in cash after the completion of each follow-up interview (6 months and 12 months). An additional $20 will be given to the participants after they return all electronic monitoring devices for their medication(s) and the electronic peak flow meter after each follow up interview.

If you choose to participate in the pilot study, you will receive a total of up to $120 for completing all arts of the pilot study. For the initial pilot interview (12.5 months) you will receive $20 in cash/money rder upon completion of the session. For each of the pilot follow-up interviews (14 months and 15 onths), you will receive another $30 in cash/money order. An additional $20 will be given to the

participants after they return all electronic monitoring devices for their medication(s) and the electronic peak flow meter after each pilot interview. Payment for each interview and device return is not contingent upon the completion of the entire study. Study participants will be paid in cash/money order for returning their devices at the next visit unless otherwise requested. If subjects receive a device at the 15-month pilot visit and return it (or any other visit if they choose to withdraw before completing the study), they will be paid by money order for returning that device.

Explanation of Payment Chart

Interview Period	Payment Amount	Medication and PEF Device Return Payment	Possible Total Payment
Baseline	$50	$20	$70
6-month Interview	$40	$20	$60
12-month Interview	$40	$20	$60
PILOT (some participants)			
12.5-month Interview	$20	$0	$20
13-month Interview	$30	$20	$50
14-month Interview	$30	$20	$50

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits to others include asthma patients that may experience benefits due to future findings.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The questionnaire is about your asthma and should not cause any distress in answering them.

The spirometry (breathing test) will take approximately 5 minutes, will consist of blowing air into a tube that is connected to a computer, and you will have enough time to do this test without any discomfort.

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. You may stop participation at any time or skip any question if you feel uncomfortable.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number 212-824-7567. *If you experience an emergency during your participation in this research, contact the Principal Investigator at 212-824-7567.*

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, date of birth and medical record number.

The researchers will also get information from your medical record at Mount Sinai Hospital.

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent
- Reviewing mental health records for presence or absence of treatment

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Jacobi Medical Center/Montefiore Medical Center
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Heart, Lung, and Blood Institute
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by Name, Address, Telephone number, date of birth and Medical record number unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted o do so under federal or state law. You also have a right to request a list of people who may receive or

use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject	Date
Printed name of subject	Time

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	Time