HIC#: 2000020105

COMPOUND AUTHORIZATION & CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL, UNIVERSITY OF PUERTO RICO, UNIVERSITY OF THE VIRGIN ISLANDS, UNIVERSITY OF THE WEST INDIES
(Baseline and Follow-up Surveys/Clinical Assessments)

Study Title: Diabetes Prevention through Lifestyle Intervention with Metformin Escalation (LIME)
Principal Investigator:
Marcella Nunez-Smith, MD, MHS
Funding Source: National Institutes on Minority Health and Disparities

Invitation to Participate and Description of Project

You are invited to participate in a research study. This study is designed to prevent diabetes among individuals at high risk for developing the disease – those who have blood sugar levels that are higher than normal but not high enough to have diabetes (we call this pre-diabetes). We are recruiting participants from New York, Trinidad and Tobago, Barbados, US Virgin Islands and Puerto Rico. You have been asked to participate because you live in the USA or in the Eastern Caribbean and are a resident of one of these islands.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, you will first have a finger stick blood test that will check your hemoglobin A1c (HbA1c). This tells us your average blood sugar over the last 3 months. If your level is in the high (between 6 and 6.4%) it means you are at risk for developing diabetes and can participate in the study. If not, your level is less than 6% or greater than 6.4%, you will be referred to your primary care doctor for further care. Other reasons you will not be able to take part of the study are: if you have a history of kidney problems or if you are pregnant (women <50years will have a urine pregnancy test done). If you enroll in the study, you will undergo a brief physical exam, blood collection and complete a survey. In the survey, we will be asking about your medical and family history, and health behaviors. You will take the survey on a computer in the clinic site. If you would prefer not to use a computer, a paper version of the survey will be provided to you. The survey is available in both English and Spanish. Blood samples will be collected from you at the clinic by a nurse. 15ml (or 3 teaspoons) of blood will be collected. Some of your blood will be tested, soon after the samples are collected. The tests will measure the creatinine and cholesterol levels in your blood. Creatinine is a measure of how well your kidneys are working (to make sure it is safe for you to take part in the study). Cholesterol is measured because high levels of bad cholesterol in your blood put you at risk for heart disease (we would like to see how the level of cholesterol changes during the study).
After you complete the baseline survey, physical exam and blood tests, you will be asked to attend six workshops that inform and educate you on lifestyle practices that will help you prevent diabetes. In the workshops, you will learn about the causes of diabetes, and ways to prevent diabetes through healthy eating, stress management and physical activity. Each workshop is 2.5 hours long and will take place weekly, for six weeks. We will contact you 6 months after we enroll you in the study to come in for a follow-up visit. At this visit, you will complete a follow-up survey, brief physical exam and we will carry

out another test to see if your HbA1c level has come down. If your HbA1c is reduced, then we will encourage you to continue your lifestyle changes and bring you in for follow up again every 6 months; you will not be prescribed the medication Metformin. If your HbA1c level remains unchanged or has increased, we will refer you to your primary care physician to prescribe you a medication called Metformin. You will continue this medication for the remaining period of the study (30 months total). Metformin pills help reduce your blood sugar and therefore your HbA1c level. Metformin is safe to use in people with pre-diabetes and has been shown to help prevent diabetes.

We will contact you again at 12months from the start of the study to complete a follow up survey, undergo a physical exam and blood testing for HbA1c. Your cholesterol will also be measured at 12. If you do not come to the office to complete the follow-up survey, tests and physical exam, we will make at least three additional attempts to contact you to complete them. During your first visit we will ask you for the names and contact information of family members or friends that we can contact if we cannot reach you.

Results from the blood tests that are collected and tested immediately can be made available to your doctor. Study staff will contact you if anything abnormal is found in your results.

No identifying information will be included on the survey, the information from the physical exam or the samples we collect from you. We will collect your name and contact information so that we can contact you for follow-up. This contact information will be kept separate from your test results and the information you provide on the survey. If any identifying information is accidentally obtained, it will be deleted at the time of review. All written information will be identified by a number so they will not be traceable to you as an individual. Only aggregated data will be presented in any publicly disseminated materials. All data will be kept securely. The Yale University Human Investigation Committee (the Committee that reviews, approves, and monitors human subject research) may review study records for auditing purposes. However, these individuals are required to keep all information confidential. Risks and Inconveniences

You have the choice to withdraw from participation in the study at anytime. You may be contacted after your withdrawal to ask if you would be interested in answering additional questions to help us understand the reason for your withdrawal.

You may also be contacted after completion of the study to understand reasons for completion or not of the study.

As part of the LIME lifestyle workshops you will be asked to join a WhatsApp group to facilitate discussion between members of your group. You are free to choose to join or not join the WhatsApp Group. You are free to leave the group at anytime. If you decide to join the group, please note that the leaders of the workshop will also be part of the group to help facilitate discussion and answer any questions. These workshop leaders are also part of the study team. As part of the WhatsApp group you will be asked if you approve of the chat text to be used for research purposes. You will have the option to decline use of your posts or any WhatsApp data for research purposes. No monitoring or collection of WhatsApp data will occur before you provide your additional approval. This approval request will be sent to you via the WhatsApp group and will provide you with a secure link to accept or decline.

We will keep your information confidential. We ask that all group members not repeat any information shared during the group to others. However, we have no control over what happens outside of the group. Therefore, please, be aware of what you share in the group.

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.

Risks and Inconveniences

Risks that we foresee include lost work time, inconvenience and potential discomfort with some of the questions on survey, the physical exam and sample collection. Drawing blood may cause minor pain, bruising, lightheadedness and on rare occasions, infection. You may choose to withdraw from the study at any time prior to completion of this study. You do not have to answer any question you do not want to although completed surveys are more helpful than incomplete surveys. When you are in the workshops, you will know the identities of other participants and they will know yours, thus your identity and those of your group members will not be confidential in this setting. However, participants will be told that participation in the trial is confidential and asked not to share the identities of other participants with others in their community.

Additional risks are associated with Metformin therapy if you are prescribed this drug. Metformin is a safe drug that is approved for and often given to patients with diabetes and pre-diabetes. However, like all medications, it has possible side effects. The most common side effect is diarrhea. This is reduced by starting with a small dose and slowly increasing the dose which we will be sure to do. Rare side effects that we do not anticipate you getting but you should know about include headache, dizziness, chest discomfort, fast heart rate and rash. Additionally, Metformin can cause low levels of a vitamin called vitamin B12; your doctor can test for this if he/she thinks you have signs of low levels of this vitamin (tingling in your feet, feeling tired). Very rare side effects that we don't anticipate you having is an acid health problem in the blood called lactic acidosis. This is more common in people who have kidney problems which is why you are not able to be part of this study if you have kidney problems.

Benefits

It is expected that you will gain significant benefits from the lifestyle and educational sessions, both through joining a supportive community of other individuals working to control their pre-diabetes, and through information sharing, tools provided for weight loss and lowering your risks for diabetes. It is expected that these benefits will outweigh the inconvenience of attending educational sessions. There is no financial incentive to attending the lifestyle and educational sessions.

It is expected that the social benefits you will gain from participating in a supportive group that works toward the common goal of reducing diabetes incidence will outweigh the risk of losing anonymity through participation.

Economic Considerations

You will receive also a $20 incentive at each survey and clinical assessment visit you make.
In addition, when you complete an end of workshop survey you will be entered you into a sweepstake for a $400 prize. *For participants in Puerto Rico, you will receive in addition, either a $5 parking card or $10 to cover your commute to the study visit.*

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Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, address, telephone number, email address, social security number or country ID, and dates related to you, such as date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator (PI) will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. Any research materials will be stored in locked cabinets. All data stored on the computer will be password-protected. Any samples collected from you will be stored in locked rooms inside of locked freezers that only research staff can access. The link to your personal information will be kept indefinitely.

If you decide to take part in this research study, you will be required to give us information about your health. In spite of our obligation to protect your identity and information, we would voluntarily report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.

The information about your health that will be collected in this study includes:
Research study records, medical and laboratory records of only those services provided in connection with this Study, the entire research record and any medical information obtained through your participation in this study (including the survey and tested samples), records about phone calls made as part of this research, records about your study visits. Information obtained during this research regarding: your health from physical exams, laboratory and other test results, and survey responses.

Information about you and your health which might identify you may be reviewed by the Study Principal Investigator, the National Institutes of Health (study finding source), and the Human Investigations Committee (Yale University) or the Institutional Review Boards at the institutions, overseeing the studies in your country (the committees that review, approve and monitors research on human subjects), and the U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about metformin involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies. By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

In Case of Injury

The Yale School of Medicine do 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 by your primary care provider. You or your insurance carrier will be expected to pay the costs of 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.

Voluntary Participation and Withdrawal

You are free to choose not to take part in this study. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not agree to participate. However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you do become a subject, you are free to stop and withdraw from this study at any time during its course.

If you sign this authorization, allowing the researchers to use your study information, and you change your mind, please understand that the researchers may continue to use information from your participation that has already been collected. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments. If you do not want the researchers to continue to use the information they have already collected, you must also follow up your phone call by sending a written notice to revoke this authorization to the principal investigator (Marcella Nunez-Smith, ECHORN/Yale University School of Medicine; Ste200A, 100 Church St South, New Haven, CT. 06519).

This authorization to use and disclose your health information will never expire unless and until you change your mind and revoke it.

The researchers may withdraw you from participating in the research if necessary. Reasons for this include the following: you develop any of the conditions that make you ineligible for participation (e.g. pregnancy, kidney problems); you develop diabetes, you repeatedly exhibit inappropriate behavior towards study staff.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

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Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Marcella Nunez-Smith, at 203.785.6454. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.
Barbados: Dr. Joseph Herbert -- (246) 426-5051/5053
Trinidad: Dr. Kavita Dharamraj -- (868) 225-4325 Ext. 3361
USVI: Ms. Lyna Fredericks -- (340) 774-7477
Puerto Rico: Dr. Elsie Cruz – (787) 701-1121