Title: A Pilot Study of a Lifestyle Intervention on the Metabolic Syndrome

NCT02233088

Date: 8/12/2014

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Title of Study: **3ELM: A pilot study of a lifestyle intervention on the metabolic syndrome**

Sponsor: **National Heart, Lung and Blood Institute**

RUSH

Subject Information Sheet and Consent Document

Introduction

This form provides you with information so you can understand the possible risks and benefits of participating in this study; so that you can decide whether or not you want to be a part of this research study. Before deciding whether to participate in this study, you should read the information provided on this document and ask questions regarding this study. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate.

Why are you invited to participate in this study?

You are being asked to take part in this study because you are between 21-72 years old. You are healthy with no history, symptoms, or signs suggestive of cardiovascular disease or heart failure. You also have had laboratory testing which suggests that you have metabolic syndrome. Metabolic syndrome includes at least of the following: elevated blood glucose (sugar) levels, elevated blood pressure, obesity (extra inches around your waist), low HDL ("healthy" cholesterol) levels and elevated levels of triglycerides (a type of fat in the blood). It increases your risk of developing diabetes and heart failure. You have been asked to participate because you are highly motivated to improve your health and you are willing to participate in testing a lifestyle program that may reverse metabolic syndrome.

Research studies can only include people who choose to take part. People who agree to be a part of a research study are called "participants" instead of "patients." Please take your time to make your decision and discuss it with your family, friends, and/or doctor. Remember that your participation is completely voluntary. There is no penalty if you decide not to take part in this study or decide that later you want to stop participating in this research study. Your care at Rush University Medical Center will not be affected if you decide not to participate.

What is the purpose of this study?

The purpose of this study is to find out whether ELM Classes, ELM Groups, or ELM Individual are the same, or better for your health and for treating your metabolic syndrome. The purpose of all three different types of treatment are to help you treat your metabolic syndrome by changing your health behaviors, including what you eat, how much you engage in physical activity, and how you handle stress. By participating in one of these groups, and learning to change your health behaviors, you might be able to lower your blood pressure and blood sugar levels, triglycerides, increase your HDL (good cholesterol in your blood) and decrease your waist size (or reduce the fat around your waist).

How many people are expected to take part in the study?

There will be 48 participants total in this study. The participants will be recruited and assigned to one of the three ELM groups (Groups, Classes, Individual).

What will you be asked to do?

After you have decided to participate in the study, you will first be asked to participate in an individual assessment (evaluation) of your current diet, stress, and physical activity level. This assessment will be broken down into two appointments that will both take place at the Triangle Office Building at Rush University Medical Center. The first session will include a diet assessment recalling all the food and beverages over the past day. You will also be asked to answer questions about your health and lifestyle, and will have blood sampling from a vein (approximately 2 tablespoons in volume). These blood samples will be tested for blood glucose levels, hemoglobin A_{1C} (a test of long-term blood sugar control), inflammation (C - reactive protein, uric acid) and lipid levels (cholesterol, triglycerides, and the lipid particle numbers and sizes). We will also take measurements such as your weight, height and waist circumference (measurement around) and blood pressure. Finally, we will ask you to wear a physical activity monitoring device called an Accelerometer. This accelerometer is attached to a belt that you wear just above your right hip, and is worn under clothing. The meter takes less than 1 minute to put on and take off each day. We ask you to wear this meter because it measures the energy spent during moderate activity and your daily step count. It does not measure type of activity, location, or anything else.

After you finish your first appointment, we will ask you to come back seven days later for your second appointment. You will wear the accelerometer during the time. During this second appointment, you will drop off your accelerometer, and will finish any of the surveys you might have not had a chance to finish. We will also answer any questions you might have at that time. These first two appointments should take a total of two hours to complete.

Next, you will be assigned, by chance to one of the three different groups: ELM Classes, ELM Groups, or ELM Individual. You cannot pick which group that you are assigned to, so you must be willing to participate in any of these groups in order to participate in the study. You will be asked to attend regular meetings over the course of 6 months. The frequency of these meetings will depend whether the computer assigns you to ELM Groups, ELM Classes, or ELM Individual.

If you are in ELM Classes, you will be asked to come for a class every week on Tuesdays for the first 3 months, and then a class on Tuesday's every other week for the last three months with 20-100 other people. The classes will talk about how to live healthy and prevent heart disease. We will be inviting guest speakers to talk in these classes at Rush University Medical Center.

If you are in ELM Groups, you will be asked to attend 16 2-hour meetings, taking place on Tuesday evenings with 7 other participants. Initially meeting will take place every week (for the first three months), then every 2 weeks for another three months. You will be asked to participate in 30-minutes of moderate physical activity on exercise equipment each session. You will be asked to participate in a program related grocery shopping activity at a local food store. You will be asked to prepare a shopping list with a nutritionist and lead a healthy cooking demonstration at least once during the course of the intervention. The meetings will include a 60-minute conversation over dinner about stress, diet, and physical activity, and setting diet and exercise goals. You will be receiving phone calls between meetings from your group coach to check how

you are doing. The phone calls and group sessions may be recorded to assure quality. The group sessions may be up to two hours long, and will be held at the Triangle Office Building at Rush University Medical Center (1700 W Van Buren).

If you are in the ELM Individual group, you will be asked to follow a lifestyle change manual published by government agencies that provide health care advice to patients. This program is meant to be an individualized, self-administered program that may help you adopt a healthier lifestyle.

Then, regardless of which group you have been assigned, we will ask you to come back again to the Rush Triangle Center three months after you started your group activities (Group, Classes or Individual). This appointment will take approximately one hour, and will consist of surveys very similar to your first group of surveys, a blood sample from your vein, and the same physical measurements as the first appointment including your weight, waist circumference (measurement around) and blood pressure.

Finally, you will be asked to come back to the Center for one final appointment six months after you started your group activities (Groups, Classes, or Individual). This last assessment will be identical to you first assessment, and woo will go through the exact same surveys and physical measures as in the first two appointments. You will also be asked to wear the accelerometer for 7 days in a row. This final assessment will take two hours and will be spread over two days, seven days apart.

We also ask you to allow the research team to contact your physician to access your medical record, if needed, to monitor your mental and physical health changes and safety over the period of 6 months in the study. You will be presented with a separate waiver that allows your medical doctor to access your medical records and/or contact your primary care doctor if you any of your tests or surveys lead us to believe that you might have an urgent medical or mental health problem. However, you can choose not to sign this waiver.

How long will you be in the study?

The total length of your participation in the study is six months.

You may be removed from this study without your consent for any of the following reasons: the study doctor decides that you continued participation in the study will be harmful to your disease becomes worse, you are unable to take the treatment as indicated, or the study is canceled.

What are the possible risks of the study?

The risks associated with participation in this study are relatively minimal. You may feel like Attending the group sessions or answering the questionnaires is an inconvenience, or you may feel uncomfortable. We will make every effort to accommodate your schedule for these meetings.

You may experience pain or discomfort, and/or bleeding, and bruising at the site the needle enters the body, and in rare cases, fainting or infection as a result of blood collection. Blood will be collected by a trained professional who has many years of experience drawing blood and will do everything to minimize any discomfort you may feel.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.** However, the study may have potential health benefits such as weight loss, increased fitness, as well as increased knowledge in areas of diet, physical activity, and stress reduction – which may benefit you and your overall health, and also may reverse aspects of metabolic syndrome.

What other options are there?

Alternative options may be to enroll in a commercial weight loss or physical activity program. You may choose to individually increase your physical activity, improve eating, and stress in consultation with your health care providers.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. The records will not be given to anyone who is not helping on this study, unless you agree to have the records given out by signing the accompanying waiver. All information you provide will be identified by an identification number, not by name. Specific study related information may be available to the National Heart, Lung, and Blood Institute.

Your identity will not be revealed on any report, publication, or in presentations at scientific meetings.

In order to conduct this study, the study doctor, Dr. Kazlauskaite will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam, and laboratory results. The study doctor will use this information to complete the research. In addition, we also ask that you sign an additional Waiver that will allow the study doctor to quickly discuss any potentially harmful medical or mental health issues that are revealed during your assessment visits with your treating physician. This waiver will allow your study doctor to quickly get you the help you may need. However, you do not have to sign this waiver, and you do not need to sign this waiver in order to participate in the study.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research to check that the rules and regulations are followed.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as blood work will be free of charge and paid for by the study. There are no charges to you or your insurance company for participating in this trial. Your parking at Rush for these visits will be paid. The study procedures are being paid by the National Heart, Lung and Blood Institute to conduct this research, and the study doctors volunteer their time to oversee this study and analyze the data. A portion of the money will go to Rush University Medical Center to compensate for other institutional research related costs.

Will you be compensated or paid?

You will not be paid for your participation; however, you will be compensated for your time. You will receive $40 for your first assessment (divided into two payments of $20 at each appointment), $20 for the second shorter assessment at three months, and then $40 for the final

assessment at six months. We will also pay for your parking for any study related appointments or group activities.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. You insurance company may not pay.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study. The National Heart, Lung and Blood Institute has no program for financial compensation for injuries, which you may incur as a result of participation in this study.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Rasa Kazlauskaite, MD, at (312) 942-3133 or the Project Manager, Lisa Walt, PhD at (773) 454-1072. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given, or someone has read it to you. You have had the opportunity to ask questions.

SIGNATURE BY THE SUBJECT OR THE SUBJECT'S LEGAL REPRESENTATIVE:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE WITNESS:
I observed the verbal consent to this study.

Signature of Witness	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature
Signature of the Principal Investigator	Date of Signature