Title:Dance as an Intervention to Improve Diabetes and Prediabetes Self-Management
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Wake Forest School of Medicine

WAKE FOREST School of Medicine
Informed Consent

Department/ Section of Family and Community

Dance as an Intervention to Improve Diabetes and Prediabetes Self-Management (Dance for Diabetes)

Informed Consent Form to Participate in Research
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SUMMARY

The Dance for Diabetes program was designed as a community service project for the North Carolina Albert Schweitzer Fellowship. The purpose of this research is to evaluate the effectiveness of the project and its impact on participants. This study will assess whether a group dance workshop along with diabetes education can help people with diabetes and prediabetes. This is a pilot study, which means we are testing whether or not a group dance workshop is useful and effective. If it is, we plan to refine our workshop model and do additional dance classes in the future. You are invited to be in the study because you showed interest in the Dance for Diabetes program, and you fit the criteria for participating.

Your participation in this research will involve attending a live dance workshop once a week for 2 months using an online, video-conferencing computer application. You will also receive information about exercise and how to manage your diabetes. You will receive a phone call every two weeks during the 2 months to assess your experience. You will be asked to complete surveys at the beginning and end of the 2-month session, as well as 1 month and 2 months after the classes end. (*Note: there is only a live view of this participation and no recording will be stored.) If you need additional instruction or miss a workshop, added information will be given.

All research studies involve some risks. A risk to this study that you should be aware of is moving in a way that causes you any harm. We will be very careful with instructions for movement that is slow and reduces the risk of causing your body any harm. There is the possibility that you may benefit from participation in this study with the added activity you would get from dancing.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to, but you cannot participate in "Dance for Diabetes" unless you are enrolled in this research study. There may be other choices available to you. Some other choices may include other forms of activity such as walking. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study

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is *Dr. Julienne Kirk*. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her phone number is [redacted]. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted]

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have prediabetes or diabetes. Your participation is voluntary. Take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to assess the use of dance and education intervention for patients with diabetes to improve the physical activity levels and self-management of diabetes.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 60 people will take part in this study. There will be 4 groups of sessions offered over a one-year period.

WHAT IS INVOLVED IN THE STUDY?

This study will ask participants to attend a once a week live dance workshop for 2 months. During each session, the instructors will guide participants through a light-to-moderate intensity dance class that is 60 minutes long with planned rest breaks. This will be followed by a 15-minute session on diabetes education and a 15-minute discussion session. These will be held in a group setting through videoconferencing, where each participant can see each other and know the other participants' identities.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 2 months. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to performing slow dance movements may include muscle soreness or discomfort.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be improvement in blood sugar and/or physical fitness.

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WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you could pick another form of activity.

WHAT ARE THE COSTS?

There is no charge for the dance classes. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Family and Community Medicine, Wake Forest School of Medicine.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

If you are injured, the sponsor may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the sponsor is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, [redacted]

You do not give up any legal rights as a research participant by signing this consent form. For

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more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Julienne Kirk at [redacted] or [redacted]

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: your age, health conditions and any glucose (blood sugar) related information.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the

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research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will be destroyed or de-identified.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time. Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

You can tell Julienne Kirk that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Julienne Kirk
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or

loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because an injury is preventing you from dancing. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that could affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Julienne Kirk at [redacted] or [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted]

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature:_____Date:_____Time:_____am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____Date:_____Time:_____am pm