STRIDE
Strengthening Translational Research In Diverse Enrollment

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

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: A Study to Determine the Potential Benefits of an Exercise Program Using Yoga for Patients with Type 2 Diabetes

Sponsor:

Investigator: Dr. _____

Full address

Daytime Phone Number: 774-200-XXXX

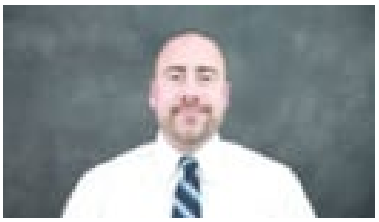
24-Hour Phone Number: 774-200-XXXX

Consent Version: STRIDE 001 7.17.2018

You are being invited to take part in a research study. Someone will explain this research to you.

I would like to view stories about research participation





Watch Angela's Story Watch Darryl's Story Watch Daniel's Story

KEY INFORMATION

You are being invited to participate in a research study because you are 18 years old, or older, and have Type 2 Diabetes.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is if a daily yoga practice will help improve overall health for patients with diabetes.

If you join this research, you will be randomly assigned (like pulling a name out of a hat) to receive either:

- Group A: No Yoga Intervention OR
- Group B: Yoga Intervention
- As part of the study, you will need to return for follow up for a physical exam at 30 days. You will have follow up monitoring at 1, 6, 9, and 12 months. We will also call you at 12 and 18 months to see how you are doing. We will continue to collect information from your medical record for as long as 5 years.

You may not want to be in this study if you are uncomfortable with:

- The fact that neither you nor your doctor will get to pick which group you are in
- Sharing your private information with researchers

Risks:

We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. There may also be risks that we do not know yet.

Benefits:

We cannot promise any benefits if you take part in this research. Patients in Group B: Yoga Intervention may experience health improvements such as greater flexibility, stamina, and reduced stress. Your participation will help us to gain knowledge that may help Type 2 Diabetes in the future.

Alternatives: Patients with Type 2 diabetes do not have to participate in a study to receive the standard of care (blood sugar monitoring and/or insulin treatment).

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

Why is this research being done?

The purpose of this study is to see if participation in a daily yoga practice can help patients with Type 2 Diabetes improve overall health (reduce stress, reduce the need for medication, lower blood sugar, lower blood pressure, and/or achieve weight loss, gain flexibility, improve circulation).

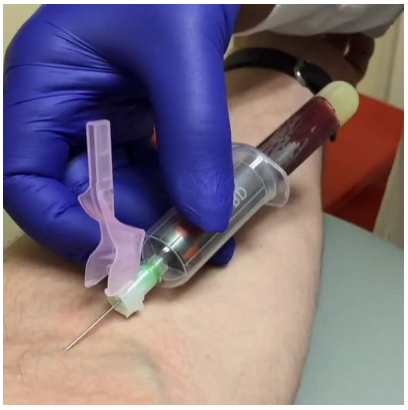
How many people will take part in this research?

About 25 people will take part at UMass Medical School. About 200 people will participate nationwide.

How long will I be in this research?

The table below outlines the timing and study events that will occur as part of the study.

Timing	Study Event
Day 1	Sample collection: blood, saliva, urine
Weeks 1-12	Sample collection: urine
Weeks 3, 9	Sample collection: blood, saliva, urine
1 Month	Physical exam
12 Weeks	Focus group
6 Months	Follow up monitoring Sample collection: blood, saliva, urine
9 Months	Follow up monitoring Sample collection: blood, saliva, urine
12 Months	Sample collection: blood, saliva, urine Follow up monitoring and physical exam End of patient participation.
5 Years	End of possible span of time researchers monitor your medical record.



Blood Sample Collection Video

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

If you participate in the study you will exercise (walk, or yoga) every day, and give periodic samples, including saliva, blood, and urine. You will be part of a focus group, to share your feedback with researchers about participation, barriers, and facilitators. You will also give periodic samples (saliva, blood, urine) and/or have physical exam follow ups.

- Study activities will take place at the UMass Memorial Center for Diabetes and at the hospital fitness center.
- You will be put into a study group by chance (like pulling names out of a hat). About 12 people will be in Group A and 12 people will be in Group B. You cannot choose your study group.

Will you be collecting any specimens from me?

You will be asked to give blood, saliva, and urine samples, according to the Timing/Study Events table above.

- Specimens collected for this study will be used for this study only, and maintained up to 3 years for secondary investigation (same study goal, exploring the question with a slight change to the question).
- Specimens will not be used for non-secondary research.
- Genome sequencing will not be conducted.

Could being in this research hurt me?

The risks of this study are minimal, and may include:

Physical risk is minimal, and may include exercise-induced muscle soreness: minor soreness following exercise, which should resolve on its own and occur less frequently as the 12 weeks proceed. Blood sample collection: slight pain when the needle is inserted, harmless black and blue mark, arm soreness. Infection, light-headedness, and fainting are also possible, but unlikely.

Psychological risks are minimal and may include embarrassment if participating in an unfamiliar exercise program in a group setting.

Privacy risks are minimal, but there is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small, but we cannot guarantee they will not occur.

Will being in this research help me in any way?

We cannot promise any benefits if you take part in this research. However, you may experience reduced stress from exercise, increased flexibility, strength, and stamina. You may also experience reduced blood sugar, need for medication. After the study, you may experience the desire to continue exercise, which may bring additional benefits.

Your participation will help us to gain knowledge that may help treat other patients with Type 2 Diabetes in the future.

Will it cost me any money to take part in this research?

Taking part in this research may lead to minor added costs to you, such as loose-fitting clothing for yoga, or appropriate shoes for walking.

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

You will not be paid for taking part in this research.

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

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

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Follow exercise protocols to include the frequency, intensity, and duration of exercise
- Alert research staff immediately if you experience lightheadedness, difficulty breathing, excessive sweating, or chest and/or arm pain during exercise
- Follow the directions of the study doctor and research staff.
- Tell your study doctor and staff about all prescriptions, over the counter medications, and vitamins or herbal supplements you are taking, and about your health issues.
- Tell your other health care providers that you are in a research study.

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

If you decide to leave this research, contact the research team so that the investigator can remove you from the active roster. If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

Data that we have already used will stay in the study database and cannot be removed. It must remain to maintain the integrity of the research.

You may ask us to destroy your specimens at any time. However, we will not be able to destroy any research data that has already been created. We also will not be able to destroy specimens that have already been shared outside of UMMS.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant

- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

How will my information and specimens be stored and when will it/they be destroyed?

We will remove your name and any other information that could directly identify you from your data and specimens. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data and specimens.

We will keep specimens and paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data and specimens. We will destroy the master list of identifiers at the conclusion of the study.

We will not use or share your data and specimens for any future research unrelated to this study, even if identifiers are removed.

It is possible that we might use the research data and specimens in other future research. We may also share data and specimens with researchers and companies that are not part of UMMS. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results
- All tests and procedures that will be done in the study

In the event you die while enrolled in the study, all medical records related to your treatment and death at any healthcare facility will be released to Dr. Naomi Kendall and research staff.

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsor
- People who work with the research sponsor
- Federal and state government agencies, such as state auditors
- The Institutional Review Board (IRB) that reviewed this research

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

We are legally required to disclose information about child abuse, abuse of the elderly or disabled, you potentially harming yourself or others, and certain reportable diseases. If you test positive for HIV, Hepatitis B, or Hepatitis C, these tests results will be reported to the local Board of Health and Massachusetts Department of Public Health.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

You may not be allowed to review some of the research-related information in your medical record until after the study is completed. When the study is over, you will have the right to access the information again.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We will not collect any new information and may only use the information already collected for this research study. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

We can share your individual results with you if you ask. However, because these are research tests, they are for your interest only. They cannot tell you about your health or diagnose any condition.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. 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 participant.

You want to get information or provide input about this research.

Signature Block for Capable Adults

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

_____

Signature of adult research participant / date

_____

Printed name of adult research participant / date

_____

Signature of person obtaining consent / date