

Participant Information Sheet

Title of the study:

Effect of Yoga intervention on Skeletal Muscle linked Glucose Homeostasis in Pre-diabetic individuals.

Dear Sir / Madam,

You are being requested to volunteer in the above research study. Dr. Supriya Bhalerao is the Principal investigator for the study. This document will provide you with the information needed to help you decide whether you wish to take part in this study. You may read the text before you consent to participate in the study.

Information and importance of the study:

Prevalence of Diabetes is increasing globally. India has highest number of diabetic patients and is called diabetes capital of the world. Pre-diabetes (Stage before diabetes) is a condition in which blood sugar levels appear higher than normal but not high enough as in diabetes. It can develop into diabetes in due course of time. Around 90% of pre-diabetic people are unaware that they have it. There are no symptoms present or treatment options available for pre-diabetes. Hence, Lifestyle intervention in such pre-diabetic people can help revert back pre-diabetic stage and delay or even reverse the onset of full-blown diabetes.

Doctors in diabetic patients often recommend yoga and exercise. Yoga includes breathing exercises, asanas and meditation techniques while exercise comprises of brisk walking, jogging and many other forms of physical activity. Both yoga and exercise have been known to have beneficial effects on regulating blood sugar levels in diabetics. Interestingly, both of them are known to cause toning of muscles. Muscles play an important role in this function, especially skeletal muscles. Hence maintaining proper strength and health of muscles is important to delay onset of diabetes. Exercise facilitate glucose uptake through muscles is well reported but there is no such studies available on Yoga.

In this pilot study we will identify pre-diabetic individuals and assign them to either yoga or exercise groups to test their effects on muscles and eventually blood sugar levels.

Objective of the study:

- To evaluate the effect of yoga interventions on muscle mass, strength, endurance and flexibility which are direct or indirect indicators of fat deposition in skeletal muscles.

- To study the association between changes in muscle quality/ functionality and glycaemic control.

How will this study be done?

Ethics Committee of Bharati Vidyapeeth Deemed University will review and approve the study. The study co-ordinator will explain you all the procedures involved in the study. A physician will assess your fitness to carry out Yoga or exercise clinically. Once your eligibility to participate in the study is confirmed, you will be called to the study site in a fasting state and asked to sign on a form to indicate your consent for the initial stage. Blood will be drawn (4ml approx.) and blood tests (blood glucose, glycosylated haemoglobin and TSH) will be done. If the results of blood glucose or glycosylated haemoglobin tests are higher than normal values, a confirmatory blood test (Oral glucose tolerance test; OGTT) will be done, the next day. This test procedure will take at least 2.5-3 hours to complete. You will be called in a fasting state and glucose will be measured. After this, you will be given a glucose solution to drink, followed by repeated blood collection for glucose measurement, at 30 minutes interval up to 2 hours (2ml each time). For this test, a cannula (needle) will be placed in your antecubital vein to prevent recurrent pricking. If you are found to be pre-diabetic in this test, your stress ECG will be done to check your physical fitness. If there are no ischemic changes in the ECG, then you will be considered eligible to participate in further study. At this time point, you will be assigned either exercise or yoga group as per method followed for the group allocation. You will undergo a training period of one month.

Yoga and exercise (as given in Table 1) will be performed under supervision of trained instructor.

Table 1: Details of yoga asanas and exercises:

Yoga protocol	Exercise protocol
Breathing practices- 6 min	Warm up- 5 min
Loosening exercises- 10 min	Tread mill- 15 min
Yogasana-32 min	Cycling- 15 min
Deep Relaxation Technique- 6 min	Cross trainer exercise- 15 min
Pranayama- 6 min	Abdominal exercise- 10 min

In training period, you will be assessed for proper execution of exercise or yoga along with your punctuality and interest levels. The assessment of your muscles will be done before and after the training period. Similarly, your Samhanan (body tone and flaccidity), dietary pattern and psychological stress levels will be recorded before and then at the end of the training period. In addition, ayurvedic assessments like Prakriti (body constitution), Sara (tissue quality) and signs & symptoms indicating proneness to diabetes will be evaluated only pre-training.

After successful completion of training period, few blood tests (by taking 10ml blood approx) will be also done. You need to then follow the yoga or exercise regimen for 3 months. There will be 6 sessions of one hour each of yoga/exercise per week and thus 24 sessions per month. You can attend these sessions either in morning batch (6am to 8am) or evening batch (6pm to 8pm) as per your convenience. An attendance of minimum 18 sessions per month is compulsory. You will be withdrawn from the study if your attendance is less than 18 sessions per month or you remain absent for more than 4 consecutive days. At the end of the study, blood tests and muscle assessment tests will be repeated. Blood glucose, Samhanan (body tone and flaccidity), dietary pattern and psychological stress levels will be assessed every month during the study period.

No compensation will be given to you for participation in the study.

Advantage of this study

If you participate in the study and follow the exercise/yoga regime properly, your muscle function may improve and you may revert from pre-diabetic stage. Practicing the same further will delay the onset of diabetes or may even prevent it.

What happens if you refuse to take part in the study or change your mind after you agree?

Participation in study is voluntary and you have right to withdraw your participation from the study anytime.

Participant's responsibilities in this study

Following the instructions of yoga/gym instructor will be basic responsibility of the participant. Further, you are requested to comply with the other requisites of the study.

Possible risk, if any

Blood examination may cause nil/ minimal discomfort at the site of needle pricks. There is chance that slight muscle sprain or pain may occur initially during practicing yoga /exercise which the physician, if needed will treat properly. Apart from this, no other potential risk is involved.

Confidentiality of study and medical records

Your confidentiality would be protected as required by law. All the records will be kept confidential and used for scientific purposes only. Only study personnel will be allowed to see these records. These records will not be available to the public or any other person not connected with the project. Only the Institutional Ethics Committee and other regulatory bodies under Government of India law would have access to these records. If you have any doubts or questions, the investigator/s will give you required answers or clarifications.

Result of the study may be presented at meetings or may be published?

The results of the study may be published for scientific purpose, however identity of the participants will not be revealed.

Who to contact for the study related queries and rights of the subjects

If you have any questions about your rights as a research volunteer, you may contact the Institutional Ethics Committee (IEC), BVDU

Name of IEC Member Secretary: Dr Prasad Pore

Contact Number: 9921073540

If you have, any query related to the study and information of the study will be acquired from the study investigators mentioned below.

Dr. Supriya Bhalerao

Principal Investigator

Phone: 9527589516

Dr. Pranita Ashok

Co-Investigator 1

Phone: 9850062612

Mrs. Anita Patil

Co-Investigator 2

Phone: 9881064610

Informed Consent Form

I, _____ age _____ yrs., exercising my free power of choice, hereby give my consent to be screened for eligibility and to be included as a participant in the clinical study entitled **“Effect of Yoga intervention on Skeletal Muscle linked Glucose Homeostasis in Pre-diabetic individuals”**

Patient Name : _____

Patient Initials : _____

Date of Birth : _____

Age : __ years __ months

(Please tick in the adjoining box if you agree to the following)	
I confirm that I have read/have been read and understood the information sheet dated..... for the above study and have had the opportunity to ask questions	[]
I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[]
I understand that the sponsor of the study, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to his access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[]
I agree not to restrict the use of any data or results that arise from this study provided such a use only for scientific purpose(s)	[]
I understand that no compensation will be given to me for participation in the study	[]
I agree to take part in the above study	[]

Name of the Participant

Signature (Thumb impression)

Date

Name of the Investigator

Signature

Date

Name of an Impartial witness

Signature (Thumb impression)

Date