

## APPENDICES

### APPENDIX 1: INTERVENTION

*Table 30: Details of 1 year Yoga Based Lifestyle programme for yoga group*

SN	Practices	No of Rounds	Time in Minutes
1	<b>Starting Prayer</b> ( <i>Asatoma Sat Gamaya....</i> )		1 minutes
2	<b>SukshmaVyayama &amp; Shithilikarana</b> (Preparatory Practices)		6 minutes
	I. Urdhvahastashvasan (Hand Stretch Breathing)		
	<i>a) Hand Stretch Breathing at 90°</i>	<i>3 rounds</i>	
	<i>b) Hand Stretch Breathing at 135°</i>	<i>3 rounds</i>	
	<i>c) Hand Stretch Breathing at 180°</i>	<i>3 rounds</i>	
	II. Kati Sakti Vikasaka		
	<i>a) Forward and Backward Bending</i>	<i>3 rounds</i>	
	<i>b) Twisting</i>	<i>3 rounds</i>	
	III. Sarvangapusthi (clockwise & anti-clockwise)	3 rounds each	
3	<b>Surya Namaskara</b>		9 minutes
	I. 10-step fast Suryanamaskara	6 rounds	
	II. 12-step slow Suryanamaskara	1 round	

4	<b>Asanas</b>		15 minutes
	<b>I. Standing</b>		
	<i>a) Trikonasana</i>	<i>1 round each side</i>	<i>1 minute</i>
	<i>b) ParivrittaTrikonasana</i>	<i>1 round each side</i>	<i>1 minute</i>
	<i>c) PrasaritaPadhastasana</i>	<i>2 rounds</i>	<i>1 minute</i>
	<b>II. Supine</b>		
	<i>a) JatarParivartanasana</i>	<i>1 round each side</i>	<i>1 minute</i>
	<i>b) Pavanamuktasana</i>	<i>2 rounds</i>	<i>1 minute</i>
	<i>c) Viparatikarani</i>	<i>2 rounds</i>	<i>1 minute</i>
	<b>III. Prone</b>		
	<i>a) Bhujangasana</i>	<i>2 rounds</i>	<i>1 minute</i>
	<i>b) Dhanurasana followed by Pavanmuktasana</i>	<i>1 round</i>	<i>2 minutes</i>
	<b>IV. Sitting</b>		
	<i>a) Mandukasana</i>	<i>2 rounds</i>	<i>1 minute</i>
	<i>b) Vakrasana</i>	<i>1 round each side</i>	<i>1 minute</i>
	<i>c) Paschimatanasana</i>	<i>2 rounds</i>	<i>1 minute</i>
	<i>d) Ardha Ustrasana</i>	<i>2 rounds</i>	<i>1 minute</i>
	<i>e) Relaxation with abdominal breathing in supine position</i>		<i>2 minutes</i>
5	<b>Kriyas</b>		3 minutes
	<b>I. Agnisara</b>		1 minute
	<b>II. Kapalabhati (1 minute practice and 1 minute rest)</b>		2 minutes

6	<b>Pranayama</b>		9 minutes
	I. Nadishuddhi		6 minutes
	II. Bhramari		3 minutes
7	<b>Deep Relaxation Technique (DRT)</b>		15 minutes
8	<b>Resolve</b>		1 minute
9	<b>Closing Prayer</b> ( <i>Sarvebhavantu Sukhinaha....</i> )		1 minute
<p><b>Counselling on yoga-based lifestyle:</b> Disease according to yoga, yogic concepts of healthy life style, yogic management of stress and diabetes, role of mind in disease aggravation, how to cultivate stability of mind in stressful situations, yoga based personality types <i>Sattva</i>, <i>rajas</i> and <i>Tamas</i>, lifestyle for individual personality types based on yogic literature, concept of <i>Sattvic</i> diet, importance of continued practice, importance of mediation and mantra chanting.</p>			

**Table 31: Details of the 1 year Physical Exercise and Health Education programme for physical exercise group**

SN	Practices	No of Rounds	Time in Minutes
1	Drill walk		3 minutes
2	Jogging		5 minutes
3	Sit up	20 rounds	2 minutes
4	Forward-backward bending	20 rounds	1 minute
5	Side bending	20 rounds	1 minute
6	Twisting	20 rounds	1 minute

7	Neck movements (forward-backward, side, twisting)	10 rounds each	1 minute
8	Shoulder rotation (clockwise and anticlockwise)	10 rounds each	1 minute
9	Full arm rotation (clockwise and anticlockwise)	10 rounds each	1 minute
10	Hip rotation (clockwise and anticlockwise)	10 rounds each	1 minute
11	Knee movement (right and left)	10 rounds each	1 minute
12	Knee rotation (right and left; clockwise and anticlockwise)	10 each	2 minutes
13	Knee cap tightening	100 rounds	2 minutes
14	Straight leg rising (right and left)	10 rounds each	2 minutes
15	Side leg rising (right and left)	10 rounds each	2 minutes
16	Cycling (supine; clockwise and anticlockwise)	10 rounds each	2 minutes
17	Rocking and rolling	10 rounds each	2 minutes
18	Brisk Walk		15 minutes
19	Supine rest		15 minutes
<b>Health education:</b> Causes and management of diabetes, modern concept of healthy lifestyle, modern management of stress and diabetes			

## APPENDIX 2: INFORM CONSENT FORM

### **INFORMED CONSENT FORM FOR SUBJECTS SUFFERING FROM TYPE 2 DIABETES**

*Title of the Study;*

**“Yoga Based Lifestyle Intervention for Type 2 Diabetes: A Randomized Controlled Study with One Year Follow up using Thermal Imaging and Electro-photonic Imaging”**

#### *Participant Information Sheet (Patients)*

I, Mr Suman Bista, working as PhD Scholar at S-VYASA University, am conducting yoga research in Type 2 Diabetes Mellitus (T2DM).

#### **‘What is the purpose of this study?’**

T2DM is a common metabolic disorder. This project is planned with two major objectives: 1) To test the potential of thermal imaging and electro-photonic parameters in diagnosing as well as predicting type 2 diabetes and its complications compared with biochemical assay of HbA1c as standard, and 2) to test the efficacy of Yoga in T2DM as an add-on to medications. Along with medication, yoga has also been found to be useful in treating T2DM. Through this research project, we would like to study whether we can monitor progress of T2DM using thermal imaging and electro-photonic imaging techniques, and whether there is any correlation between those images and your blood sugar levels (HbA1C). The effect of an add-on yoga-based programme, in terms of improvement in certain blood investigation, thermal imaging parameters and electro-photonic parameters will also be studied.

We would also like to compare the results of patients with T2DM who are a part of 1 year add-on yoga programme and those not undergoing any yoga programme (but are undergoing simple aerobic exercises and walking) for T2DM.

**‘Why have I been invited to participate in this study?’**

As you are already receiving drug treatment and/or other treatment(s) for T2DM, we invite you to take part in our research project. Your participation will help us understand better, the usefulness of practising yoga in terms of symptom improvement and change in biological, thermal imaging and electro-photonic parameters.

**‘What if I don’t want to participate in this study, or I want to withdraw later?’**

Your participation in this study is entirely voluntary. You can choose to withdraw from the study at any point of time, even after initial acceptance to participate in the research. Refusing to participate in the research will not affect your treatment in anyway, offered at this hospital.

**‘What will happen to me if I take part in this study?’**

If you agree to join the study, we shall conduct blood investigation by drawing 6 ml of blood from you and take images of your face, hand and feet using non-invasive thermal imaging technique. We also take the images of electrical glow from your 10 finger tips to understand your energy levels using non-invasive electro-photonic imaging technique. Same tests including blood tests, thermal imaging and electro-photonic parameters will be repeated every 6 months till next 1 year (i.e. total 3 times in 1 year).

Through a randomisation process you shall be allocated to either Yoga or control group. If you come under Yoga group, you shall undergo Yoga therapy program for T2DM. If you come under control group then you shall undergo aerobic exercise and walking program for in the same way as the yoga group. You may or may not undergo Yoga intervention. You will be taught either aerobic exercises or Yoga. Irrespective of you being in a yoga group or No Yoga group, you will be seen by a diabetologist at the beginning, and then every 6 months for 1 year. If you are in non-yoga (exercise or control group), then you will be requested to avoid any yoga practice for the duration of the study. If you are not given Yoga, and you wish to practice Yoga,

you will be offered yoga therapy at the end of study period i.e. after 1 year, free of cost. But if you are not willing to wait that long, then you will not be included in the research study anymore but this won't affect your treatment, you will be offered free of cost yoga service for T2DM at NIMHANS Yoga centre. Whether you belong to yoga/no yoga group, it will not affect your treatment, you shall receive same lifestyle advices by your diabetologist. At your visits, an interviewer will ask you and your care-giver a few questions about your mental state and symptoms.

You are free to avoid any yoga practices which you feel are inconvenient and culturally unacceptable and can also seek our help at any time with the contact details provided to you along with this consent form. At the beginning and end of study, you will undergo all the other investigations as well. You will be taught a validated (safe and feasible) yoga or exercise program for diabetes by a trained therapist.

**‘What investigations will be conducted in this study?’**

Present study involves using thermal camera related imaging and blood investigations to be done once in every 6 months for 1 year.

1. Thermal camera to obtain images of your different body parts for assessing temperature of those body parts (face, legs and hands). It will be like taking any routine photograph and will take 5-10 minutes.
2. Electro-photonic imaging: Second assessment involves assessing your subtle energy levels (aura) using electro-photonic imaging technique based on Kirlian photography technique. It involves putting your fingers one by one on a glass plate in a device called gas discharge visualisation device (GDV) and the CCD camera will capture electrical discharges from your finger, you won't feel any sensation (It is like a biometric tool

which is commonly used for marking attendance using fingers). This assessment will also take 5-10 minutes.

3. Blood Investigation: Thirdly, 6 ml of blood will be drawn from your veins to assess your fasting sugar and HbA1C levels at first in the beginning of the study and then every six months once for 1 year. These are routine tests done in diabetics and will take only a few minutes. Though strict aseptic precautions will be taken, but possibility of developing an infection while or after drawing blood cannot be denied. If you have any such difficulty or any other problem during this study, you may contact the investigators, their numbers are given below. Immediate actions will be taken. If required, necessary medical services will be provided in case of any emergency due to project related procedures, free of cost. The procedures involved in the study have no major risk to your health. If we find any abnormality during your investigations, we shall inform you and guide you to take necessary precautions and actions. You are free to withdraw from this study anytime you desire. Your withdrawal from the study will not affect your treatment at all. The information obtained during this study shall remain completely confidential and shall not be used for any other purpose except this study.
4. Height, weight, waist circumference, hip circumference, and blood pressure will be measured by using standard methods. Depression, Anxiety Stress Scale – 42 (DASS-42) will be used to measure the status of depression, anxiety and stress.

All the above mentioned investigations (thermography imaging, electro-photonic imaging and blood investigations) will be performed once in 6 months for a period of 1 year i.e. total of 3 times in 1 year. All due precautions will be taken during the procedures, these procedures are conducted by qualified and competent experts. After understanding the nature of the assessments, if you choose not to undergo the tests, your decision will be respected by us.



**‘Will I benefit from this study?’**

As incentive, we shall provide you all the travel expenses related to current study. However it may help us widen the knowledge and usefulness of yoga in T2DM in a better way. Taking part in this study does not involve any risks to your health, as we would be following internationally accepted safety measures while administering all investigations.

**‘How will my confidentiality be protected?’**

We will keep the information you provide with utmost confidentiality. It will be used only for the research purpose. It will not be revealed to anybody other than the research team, unless it is directly related to your health. You will be assigned a unique number and your name or contact details or any other such details will not be revealed to anybody.

**‘What happens with the results?’**

The results may be published in medical journals for knowledge dissemination and for use in other patients in the society. Your identity will not be revealed in any publication. Results of the study will be provided to you, if you wish.

**‘What should I do if I want to discuss this study further before I decide?’**

You need not accept to participate in the research immediately. You can take your time to decide for participating in the study. You may clarify with us or with any other competent researcher regarding the research or your participation, if you wish.

**‘Who is organising and funding the study?’**

This study is organised by the National institute of Mental Health and Neuro-sciences and funded by the Department of Science and Technology, Ministry of Health.

### **‘Who has reviewed the study?’**

This study was initially reviewed by the Medical Ethics & Scientific Committee of the hospital (NIMHANS), S-VYASA Yoga University as well as the research review committee of Department of Science and Technology. We may publish the results of this study in scientific journals for dissemination of knowledge. You will be assigned a unique number, your identity will not be revealed.

Thank you for taking time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

### **Undertaking by the investigator:**

Your consent to participate in the above study is sought. You have the right to refuse consent or withdraw the same during any part of the study without giving any reason. In such an event, you will still receive best possible treatment, without any prejudice. We undertake to maintain complete confidentiality regarding the information obtained from the subject/patient during the course of the study. If you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact any of the investigators for clarification if you so desire. The list of investigators and their phone numbers is given below:

<b>SN</b>	<b>Investigator</b>	<b>Phone</b>
1	Mr Suman Bista	00919901053538
2	Dr Hemant Bhargav	00918762019348
3	Dr Prahlada Ramarao	00917760785666

**Consent**

I have been informed about the procedures of the study. The possible risks too have been explained to me/us as stated in the information. I have understood that I/We have the right to refuse my consent or withdraw it any time during the study without adversely affecting my treatment. I am aware that by subjecting to this investigation, I will have to give more time for assessments by the research team and that these assessments do not interfere with the benefits.

I, ....., the undersigned, give my consent to be a participant of this study.

Signature of the patient (Name and address)

I, ....., the undersigned, give my consent for my relative to be contacted to be a participant of this study.

Signature of the relative (Name and address)

Signature of the witness (Name and address)

Signature of the Doctor/investigator:

Date:

Place:

## APPENDIX 3: INSTITUTIONAL ETHICS COMMITTEE LETTER



# स्वामी विवेकानन्द योग अनुसंधान संस्थान Swami Vivekananda Yoga Anusandhāna Samsthāna

(Declared as Deemed-to-be University under Section 3 of the UGC Act, 1956)

Eknath Bhavan, # 19, Gavipuram Circle, Kempegowda Nagar, Bangalore - 560 019

Ph: 080 - 2661 2669, Telefax: 080 - 2660 8645

E-mail: svyasa@svyasa.org Website: www.svyasa.org

RES/IEC-SVYASA/129/2018

21 Aug 2018

To,  
Mr. Suman Bista,  
PhD Scholar,  
S-VYASA University,  
Bengaluru.

Reference:

"Yoga Based Lifestyle Intervention for Type 2 Diabetes: A Randomized Controlled Study with One Year Follow up using Thermal Imaging and Electro-photonic Imaging", - Committee Approval of the above mentioned study.

**Dear Mr. Suman Bista,**

We have received from you the following study related documents vide your letter dated 24 June 2018.

1	Project Proposal
2	Informed consent form

Ethics committee meeting was held on **30 June 2018** between 2:00 PM and 5:00 PM at Eknath Bhavan, Bengaluru. Above documents were examined and discussed in the meeting. After due consideration, the committee has decided to approve conducting the aforementioned study.





# स्वामी विवेकानन्द योग अनुसंधान संस्थान

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E-mail: [svyasa@svyasa.org](mailto:svyasa@svyasa.org) Website: [www.svyasa.org](http://www.svyasa.org)

This is to confirm that neither Mr. Suman Bista nor any staff participating in this study were involved in the voting procedures and decision making.

The Institutional Review Board / Institutional Ethics Committee (IEC) are expected to be informed about the progress of the study / any changes in the protocol and patient information / informed consent. The investigators are also expected to submit a copy of the final report to IEC for records.

This approval is valid up to the completion of the study at the site.

Please submit to the IEC, the status report of the study as per the SOPs.

The IEC is organized & operates according to the requirements of ICH-GCP, Indian Council of Medical Research Guidelines & Schedule Y.

Best Wishes,

Dr. Sanjib Kumar Patra,  
Member Secretary,  
Institutional Ethics Committee,  
S-VYASA, Bengaluru.

## APPENDIX 4: QUESTIONNAIRES

### DEPRESSION ANXIETY STRESS SCALE – 42 (DASS-42)

<h1>DASS</h1>		<i>Name:</i>	<i>Date:</i>
<p>Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you <i>over the past week</i>. There are no right or wrong answers. Do not spend too much time on any statement.</p> <p><i>The rating scale is as follows:</i></p> <p>0 Did not apply to me at all            1 Applied to me to some degree, or some of the time            2 Applied to me to a considerable degree, or a good part of time            3 Applied to me very much, or most of the time</p>			
1	I found myself getting upset by quite trivial things	0	1 2 3
2	I was aware of dryness of my mouth	0	1 2 3
3	I couldn't seem to experience any positive feeling at all	0	1 2 3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1 2 3
5	I just couldn't seem to get going	0	1 2 3
6	I tended to over-react to situations	0	1 2 3
7	I had a feeling of shakiness (eg, legs going to give way)	0	1 2 3
8	I found it difficult to relax	0	1 2 3
9	I found myself in situations that made me so anxious I was most relieved when they ended	0	1 2 3
10	I felt that I had nothing to look forward to	0	1 2 3
11	I found myself getting upset rather easily	0	1 2 3
12	I felt that I was using a lot of nervous energy	0	1 2 3
13	I felt sad and depressed	0	1 2 3
14	I found myself getting impatient when I was delayed in any way (eg, lifts, traffic lights, being kept waiting)	0	1 2 3
15	I had a feeling of faintness	0	1 2 3
16	I felt that I had lost interest in just about everything	0	1 2 3
17	I felt I wasn't worth much as a person	0	1 2 3
18	I felt that I was rather touchy	0	1 2 3
19	I perspired noticeably (eg, hands sweaty) in the absence of high temperatures or physical exertion	0	1 2 3
20	I felt scared without any good reason	0	1 2 3
21	I felt that life wasn't worthwhile	0	1 2 3

*Please turn the page* ↗

*Reminder of rating scale:*

0 Did not apply to me at all

1 Applied to me to some degree, or some of the time

2 Applied to me to a considerable degree, or a good part of time

3 Applied to me very much, or most of the time

22	I found it hard to wind down	0	1	2	3
23	I had difficulty in swallowing	0	1	2	3
24	I couldn't seem to get any enjoyment out of the things I did	0	1	2	3
25	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
26	I felt down-hearted and blue	0	1	2	3
27	I found that I was very irritable	0	1	2	3
28	I felt I was close to panic	0	1	2	3
29	I found it hard to calm down after something upset me	0	1	2	3
30	I feared that I would be "thrown" by some trivial but unfamiliar task	0	1	2	3
31	I was unable to become enthusiastic about anything	0	1	2	3
32	I found it difficult to tolerate interruptions to what I was doing	0	1	2	3
33	I was in a state of nervous tension	0	1	2	3
34	I felt I was pretty worthless	0	1	2	3
35	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
36	I felt terrified	0	1	2	3
37	I could see nothing in the future to be hopeful about	0	1	2	3
38	I felt that life was meaningless	0	1	2	3
39	I found myself getting agitated	0	1	2	3
40	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
41	I experienced trembling (eg, in the hands)	0	1	2	3
42	I found it difficult to work up the initiative to do things	0	1	2	3

## DASS 42 SCORE SHEET

Enter each score from the questionnaire into the first two columns.  
 Add up each row and enter the score into the available box (D, A or S)  
 Add up the each of the D, A and S columns.  
 The total for each column is the score for that trait:  
     D = Depression  
     A = Anxiety  
     S = Stress  
 Use the ratings table below to assess the meaning of each score.

### Score Calculation:

Q	Score	Q	Score	All D scores	All A scores	All S scores
1		22				
2		23				
3		24				
4		25				
5		26				
6		27				
7		28				
8		29				
9		30				
10		31				
11		32				
12		33				
13		34				
14		35				
15		36				
16		37				
17		38				
18		39				
19		40				
20		41				
21		42				
				Total for D	Total for A	Total for S

### Score Interpretation:

	Depression (D)	Anxiety (A)	Stress (S)
<b>Normal</b>	0 – 9	0 – 7	0 – 14
<b>Mild</b>	10 – 13	8 – 9	15 – 18
<b>Moderate</b>	14 – 20	10 – 14	19 – 25
<b>Severe</b>	21 – 27	15 – 19	26 – 33
<b>Extremely Severe</b>	28+	20+	34 +

*Lovibond, S.H. & Lovibond, P.F. (1995). Manual for the Depression Anxiety Stress Scales (2nd. Ed.). Sydney: Psychology Foundation.*