

Study Protocol

Naturopathy and yoga based lifestyle intervention for type 2 diabetes mellitus – Study protocol for a randomized parallel group trial

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ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) is one of major life style disorder with multiple systemic complications. Lifestyle modification and management of chronic mental stress plays a major role in treating and preventing T2DM. Naturopathy uses lifestyle modification and natural therapies to cure the diseases. Effectiveness of Yoga practice in stress management is proven through various studies. In this study we evaluate the effect of Naturopathy and Yogic lifestyle intervention on the anthropometric, biochemical, electrophysiological parameters and development of cardiovascular risk among T2DM patients. **Methods:** The study is a prospective randomized parallel group trial. The study is divided into two phases, intensive phase and continuation phase. 252 T2DM patients will be randomized into intervention group and control group after screening. The intervention group will receive intense N&Y intervention with a strict treatment protocol and diet regimen, whereas the control group will not receive any intervention. Data for both groups will be collected on day 1 and day 11, after which participants will be followed prospectively for nine months with intermittent assessments scheduled once in every three months that is, day 1, day 11, day 90, day 180, day 270. As per the protocol we started recruiting the subjects and their data were collected successfully till day 90 and the follow up for the next assessments is being done systematically.

Conclusion: During the intensive phase, patient will be learning a lifestyle regimen which can treat or control T2DM and the prospective follow up will encourage in maintaining it. Hence, we believe that integrated N&Y approach will give more effective and lasting effects in treating and preventing complications of T2DM. The study is potential enough to give scientific evidence on effectiveness of N&Y intervention on T2DM and associated risk factors.

Clinical trial registration number; CTRI/2018/12/016550

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1. Introduction

Type 2 Diabetes Mellitus (T2DM) is a globally prevalent chronic metabolic disorder characterized by chronic hyperglycemia, relative insulin deficiency due to beta cell dysfunction, sub-chronic inflammation and peripheral insulin resistance [1]. India has 10.4% of diabetes population in worldwide [2] and the prevalence is more in urban residents of lower socioeconomic status [3]. One in three or 33% of Indians aged ≥30 years are suffering from one or more lifestyle diseases such as diabetes, elevated cholesterol, hypertension, cancer and thyroid disorders [4]. India is the largest contributor to regional mortality due to diabetes with an estimated one million

deaths. The total health expenditure for diabetes was found to be USD 727 billion in 2017 which may escalate up to USD 776 billion by 2045. There were 38 million T2DM individuals worldwide with disability associated survival of 2.8 million years by 2016 [5].

Complications such as cardiovascular diseases (CVD) majorly coronary artery disease (CAD), heart failure (HF), and stroke are the major causes of death and disability in patients with T2DM [6]. CVD is the predominant cause of death in T2DM population with a reduction in life expectancy of nearly 10 years [2,7]. T2DM is a known cause for the higher incidence of CVDs in Indians [8]. In a study conducted by Van Haterenet al [8], the authors showed a constant increase in the hazard ratio for death due to CVD every year in T2DM patients over 10 years. This suggests that an increasing burden of T2DM will likely be followed by an increasing trend in CVD. Hence the therapeutic goal for the management of diabetes is to delay the onset of T2DM related complications and to reduce their progression, largely by tight glycemic control and attenuation of CVD risk [9,10].

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Urbanization, altered life style, binge eating, low physical activity, exposure to stressors and increasing age are the causes for rise in the prevalence of T2DM and other life threaten diseases [11]. In the management of T2DM, life style modification and non-pharmacological measures do form the cornerstone. Naturopathy is of greatest interest as it is a whole-system of complementary and alternative medicine (CAM) most closely resembling conventional primary care in scope of practice, but with greater delivery of healthy lifestyle counselling. Yoga is an ancient Indian tradition which helps in reducing mental stress and improves the total quality of life. The combination of naturopathy and yoga (N&Y) offer novel approaches to address lifestyle behaviour change for prevention and control of T2DM [12].

By definition, naturopathy is a system of man building in harmony with the constructive principles of nature on physical, mental, moral and spiritual planes of living. It consists of non-invasive treatment modalities such as clay therapy, hydrotherapy, massage therapy, acupressure, acupuncture, chromo therapy, air therapy and magneto therapy. Clay therapy involves direct or indirect application of clay into body surfaces, the application can be to the whole body or to any particular body part depending on the therapeutic need. Hydrotherapy uses water in different temperatures and different modes to get desired effect. As a whole these therapies will be reducing the oxidative stress and general inflammatory status of the body. Further the patients will be motivated to follow a healthy lifestyle [13,14].

The yogic intervention includes Asana, Pranayama, Kriya, Yogic relaxation and Meditation. These will help the patient to manage their chronic mental stress. Reduction in chronic mental stress aids in management of T2DM further it stabilizes the autonomic nervous system with a tendency towards parasympathetic dominance [15]. Previous studies showed that yoga improves the risk factors of diabetic mellitus and reduces further complications through stress reduction there by controlling chronic hyperglycemia [16,17].

The current study is designed to evaluate the effect of integrated naturopathy and yogic lifestyle on the glycemic control and development of cardiovascular risk among type 2 diabetes mellitus individuals. To the best of our knowledge there is no study with 9 month follow up evaluating the effectiveness of integrated N&Y protocol on anthropometric, biochemical, electrophysiological parameters and development of cardiovascular risk among T2DM patients.

2. Materials and methods

2.1. Ethical clearance

The study has got ethical committee clearance and registered prospectively in Clinical Trials Registry- India. Registration number; CTRI/2018/12/016550.

2.1.1. Study design

A prospective randomized parallel group trial. Fig. 1 shows a diagram with the different phases of the study.

2.1.2. Study setting

The study is being conducted in Karnataka state located in the south of India; however people from other south Indian states will be included in the study. Invitation to the study will be made in local language (Kannada) and in English and the same will be given in local news channels, social media and through printed brochures. The respondents will be asked to report for further screening in study center. After screening the eligible subjects will be recruited for study. Female subjects are instructed to come for baseline assessment one day after the completion of their menstrual phase. Accordingly the subjects are being recruited for the study and their

successive follow up till day 90 is completed and successive follow-up is being done for the next assessments.

2.2. Inclusion criteria

- Male and female type 2 diabetes mellitus individuals defined as per the American association of diabetes (ADA) criteria aged between 25 and 65years.
- Those who are on oral antidiabetic therapy.

2.3. Exclusion criteria

- Type 2 diabetes mellitus individuals with established coronary artery disease or any organic vascular disease.
- Type 2 diabetes mellitus individuals who are on insulin therapy.
- Individuals with thyroid disorders and any acute illness.

2.3.1. Duration of the study

For experimental purpose the study will be planned in two phases namely, intensive phase (with in the hospital for ten days) and continuation phase (for nine months) for the domiciliary follow up. The subjects will be asked for 3 follow up visits on 11th, 90th, 180th and 270th days after the base line assessment. (Fig. 2).

2.3.2. Sample size

Sample size is calculated by using G* power 3.1.9 by considering 1:1 allotment ratio with a parallel group design for 90% power and 5% level of significance and an anticipated drop out of 25%. The total sample size was found to be 252 (126 per group).

3. Method of data collection

Before the commencement of study, the subjects will be screened as per the inclusion and exclusion criteria. A duly signed informed consent will be obtained from all the participants after explaining the procedure, study objectives and all the rights of the subject pertaining to the conduction of the study both orally and in writing. The data will be collected at baseline (1st day) and post intervention (11th day) for intervention group and baseline (1st day) and after 10 days (11th day) for control group with no intervention. The participants will be prospectively followed for nine months with intermittent assessments scheduled once in every three months (i.e.90th, 180th and 270th days). The trail is open for subject recruitment.

4. Variables studied

The individual who collect the data will be blinded for which group the subject belongs. In order to avoid diurnal variation data will be collected between 8.30 am and 10.30 am in empty stomach excluding the consumption of water. The initial assessment will be taken after familiarizing about the data collection equipment and atmosphere to the subject to avoid anxiety to the data collecting procedures and environments. Electro physiological data will be collected with empty bowel and bladder in a quiet room with minimal lighting. Before collecting the data, subject will be made to lie down in couch with closed eyes. Standard operating procedure will be followed for anthropometric data collection. Socioeconomic variables given in Table 1 and other individual variable and equipment for measuring it is given in Table 2.

Height: Height is measured using a stadiometer in centimeter round off to the nearest whole digit.

Weight: Weight will be quantified using a Dr. Trust™ digital weighing machine to the nearest 0.5 kg.

Body mass index: From the height and weight BMI will be calculated with the formula weight in kilogram divided by the square of height in meters [18].

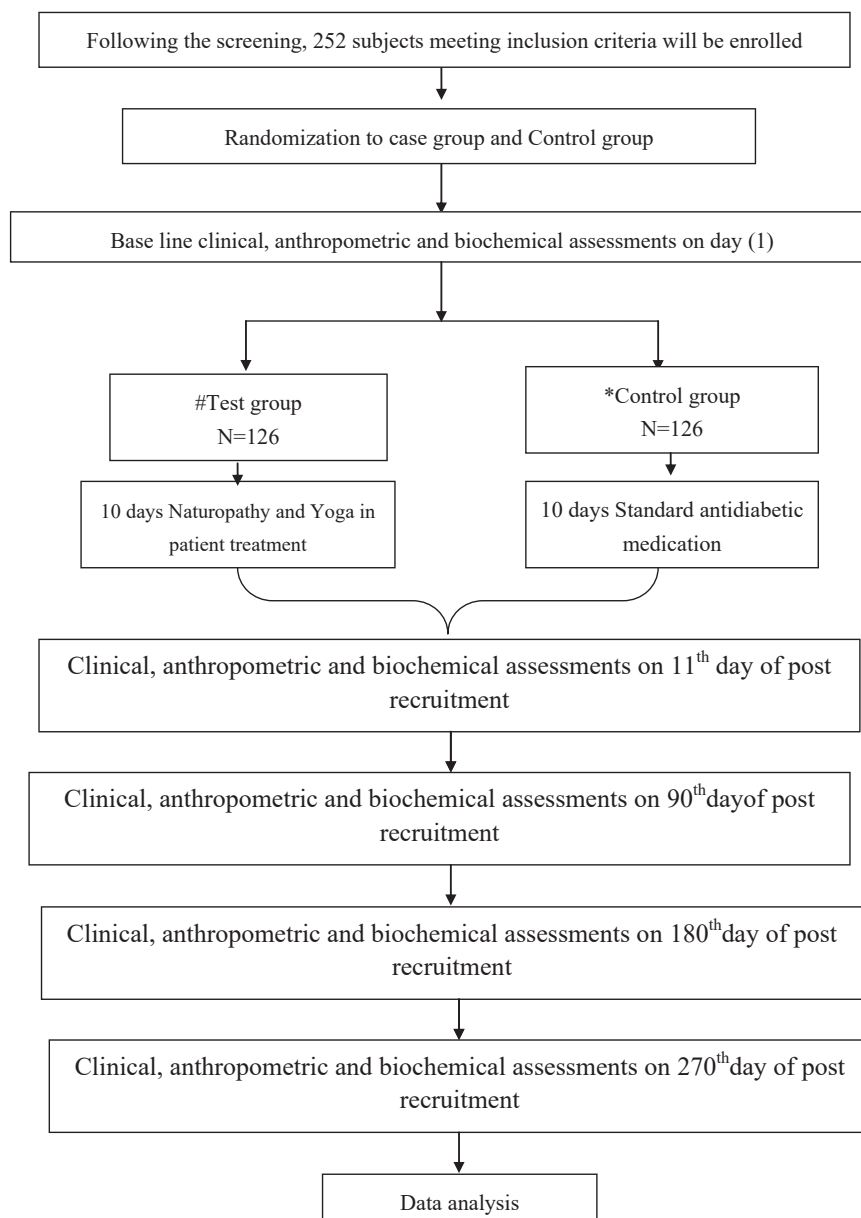


Fig. 1. Consort Diagram: Flow of the participants throughout the study.

Waist-hip ratio: A non-stretchable tape is used in measuring the circumferences. Hip circumference will be measured at the level of greater trochanter and parallel to ground. Waist circumference will be measured at the level of lower margin of last

palpable rib in mid axillary line and parallel to floor. Measurement will be made to the nearest centimeter. Waist to hip ratio will be calculated by dividing the waist by the hip circumference.

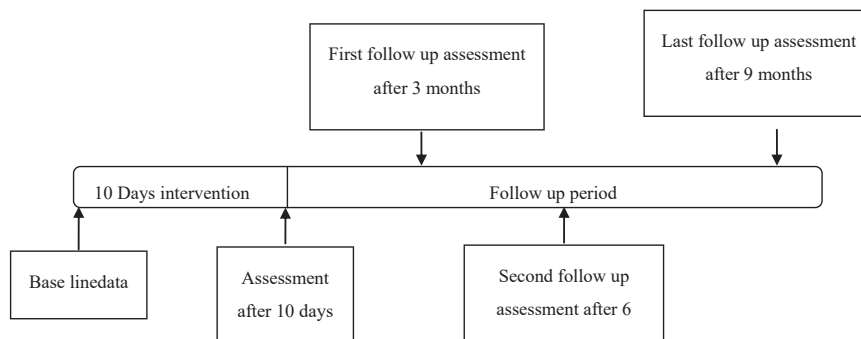


Fig. 2. Data assessment time line.

Table 1
Independent sociodemographic variables.

Variable	Values
Age	In years
Sex	Male / Female
Duration of T2DM	In years
Medication used	Name and dose
Smoking	Yes / No
Tobacco chewing	Yes / No
Alcohol	Yes / No
Physical activity	Cycling/Yoga/Exercise/Gym/Sports
Diet	Vegetarian/ Mixed

Skin fold thickness: Skinfold thickness will be measured with Slim guide caliper. Skinfold thickness is measured in millimeters; it is designed to exert a contact surface pressure of 10 g/mm². Skin fold thickness for males is measured upon triceps, subscapular skinfold thickness (SBS) and chest. Skin fold thickness for females is measured upon triceps, suprailia skinfold (SPS) and abdomen. Two

measurements will be taken at each site at least 15 s apart and the mean of the two readings will be recorded [19].

Body fat analyzer: Body composition will be measured by using Body stat 1500. The electrodes are placed on the foot and hand for recording. Electrodes are placed sideways so that the non-stick electrode connector point is facing the researcher.

- **Foot electrodes:** One electrode is placed centrally, directly where the second and third toe meet the foot. The second electrode is placed at the crease of the ankle (midline to the 'bony' landmarks). Two alligator clips are attached to the electrodes (red nearest the toes, black nearest the ankle).
- **Hand electrodes:** One electrode is placed centrally, directly below the third knuckle of the middle finger. The second electrode is placed on the crease of the wrist (midline to the 'bony' landmarks). Two alligator clips are attached to the electrodes (red nearest the fingers, black nearest the wrist) and reading is taken.

Table 2
Parameters of interest.

Variable group	Individual variable	Unite	Device
Anthropometry	Height	Centimetres	SECA stadiometer
	Total body weight	Kg	DrTrust- digital weighing machine.
	Waist circumference	Centimetres	SECA- non stretchable measuring
	Hip circumference	Centimetres	
	BMI	Kg/M ²	NIH BMI Scale
	Fat percentage	%	BodyStat (Based on bioelectrical impedance principle)
	Fat mass	Kg	
	Lean mass	Kg	
	Dry lean	Kg	
	Total body water	Litre	
	Total Body Water	%	
	Basal Metabolic Rate	Kcal	
	BMR/Weight	Kcal / Kg	
	Diastolic Blood Pressure	mm of Hg	Sphygmomanometer and Schiller Gold standard BP apparatus
Blood flow parameters	Systolic Blood Pressure	mm of Hg	
	Mean Arterial Pressure	Mm of Hg	
	HR	Beats / Min	
Glycaemic profile	Fasting Blood Glucose	mg /dL	Hexokinase method
	Post Prandial Blood Glucose	mg /dL	GODPOD method
	HbA1c	%	HPLC method
	Fasting insulin	μ Unites / mL	ELISA
	Insulin resistance	Glucose in mass units mg/dL	HOMA IR
Extended lipid profile	Total cholesterol	mg /dL	Enzymatic methods
	Triglyceride	mg /dL	
	High Density Lipoprotein	mg /dL	
	Low Density Lipoprotein	mg /dL	
	Total cholesterol / High Density Lipoprotein		Direct Method
	Non High Density Lipoprotein	mg /dL	
	Apolipoprotein A	mg /dL	Immunoturbidimetry
	Apolipoprotein B	mg /dL	
	Apolipoprotein B / Apolipoprotein A		
	Hs CRP	mg /dL	ELISA
Inflammatory profile and complete haemogram	RBC	Million cells / μL	
	Hb	%	
	WBC	10 ⁹ cells / L	
	Eosinophil	%	
	Basophils	%	
	Neutrophil	%	
	Monocytes	%	
	Lymphocytes	%	
	Platelets	10 ⁹ Cells / L	
Antioxidant markers	Protein carbonyls	nmol/mg	ELISA
	Myeloperoxidase	pmol/L	
	Superoxide dismutase	units/mL	
	Advanced Oxidative Protein Products	ng/mL	
Specific Markers	Leptin	ng/mL	ELISA
	Ghrelin	ng/mL	
	Adrenomedullin	fmol/mL	
	Plasma renin (PRE)		
HRV Indices	Four-channel data acquisition system "Power Lab 15 T" by AD instrument, Australia. The recorded data will be analysed by Lab Chart 8, software compatible with AD instruments, to calculate Time domains and frequency domains of HRV.		

Table 3
Naturopathy protocol for type 2 diabetes mellitus - 10 days.

Day	Date	Day to day report	9:30–11:00 AM	2:30–4:00 PM	7:30 PM
1			Steam bath with cold chest pack	Cold hip bath	Cold abdominal pack
2			Enema + Full body massage	Cold hip bath	Cold abdominal pack
3			Enema + Neutral under water massage	Gastro-hepatic pack	Cold abdominal pack
4			Enema + Sauna bath with cold chest pack	Cold immersion bath	Cold abdominal pack
5			Enema + Partial massage to abdomen, back & legs	Gastro-hepatic pack	Cold abdominal pack
6			Enema + Neutral immersion bath	Cold hip bath	Cold abdominal pack
7			Sauna bath with cold chest pack	Cold immersion bath	Cold abdominal pack
8			Full mud bath	Gastro-hepatic pack	Cold abdominal pack
9			Partial massage to abdomen, back & legs	Gastro-hepatic pack	Cold abdominal pack
10			Neutral immersion bath	Cold hip bath	Cold abdominal pack

Blood pressure measurement: Blood pressure will be measured in a quiet and calm environment using digital sphygmomanometer (Schiller) and values such as systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP) and pulse rate (PR) are noted.

Heart rate variability (HRV): The HRV will be recorded for 5 min pre and post intervention (total 5 recordings during the study period). The Electrocardiogram (ECG) will be recorded by using AD instruments 8 channel polygraph. The HRV waveforms will be analyzed by using Labchart Pro software.

4.1. Biochemical parameters

Under aseptic conditions, 4 mL of patient blood sample will be collected 8 h after last meal in a sterile vacutainer by venipuncture. Serum will be obtained after centrifugation at 3000 rpm for 5 min which is stored at -40°C for further analysis.

Fasting blood glucose (Hexokinase method), **HbA1c** (HPLC method), **extended lipid profile** which includes total lipid profile (total cholesterol, High density lipoprotein cholesterol, triglycerides – by enzymatic methods, low density lipoprotein cholesterol – by direct method) ApoA1, ApoB and lipoprotein (a) – by immunoturbidimetry. **Fasting insulin** – by enzyme linked immunosorbent assay (ELISA - DRG- INS kit).

Post prandial blood glucose level: The patient will be made to take 75 gm of oral anhydrous in water or food with equal glucose load. The blood samples will be collected after 2hrs of consumption for serum glucose estimation [1].

Insulin resistance: Insulin resistance is calculated by using Homoeostasis model assessment (HOMA) 2 calculator version 2.2.3 (Diabetes trial unit, Oxford University).

Inflammatory marker: hs-CRP – ELISA technique.

Pro-oxidant and Antioxidant Markers: myeloperoxidase, advanced oxidative protein products, protein carbonyls, superoxide dismutase – ELISA technique.

Quality of life: The quality of life (QOL) of the participants will be assessed at the baseline and at the end of 9th month by using a standard questionnaire specifically designed for diabetes individuals Diabetes quality of life (DQOL) – short version based on Classical Test Theory (CTT).

Cardiovascular risk assessment: The risk of developing cardiovascular disease will be quantified by using Ten-year Framingham coronary risk score.

5. Yoga and naturopathy intervention protocol

A fixed protocol for 10 days is prepared with the previous clinical experiences, though necessary minor day to day changes will be

made by N&Y physician on day to day basis. In case of any adverse event during the intensive phase the subject's data will be excluded from the final analysis. Treatment will be given by trained therapists in the common treatment section and duration of the particular treatment will be individually monitored with wall clocks available in each treatment room. The treatment protocol and diet chart for 10 days is given in Tables 3 and 4 respectively.

Yoga intervention will be given in common yoga class, individual attention will be given to the individual subjects. Daily 60 min Yoga session will be handled by N&Y physician. In the 3rd and 7th day Yogic Kriya will be thought to the subjects under supervision of N&Y Physician (Table 5).

The subjects will be counseled after post data assessment about the importance of following similar diet and yoga practice in home for better results. They will be provided with a diary to write the adherence to the newly developed life style and diet pattern. The diary contains specific pages for marking day to day activities. The diary will be assessed by the data collector after the study period.

6. Control group procedure

The control group's base line data will be collected on day one then they will be counseled for medication adherence and importance of diet and physical activity in treatment of T2DM. Control group subjects will be sensitized about the importance of walking and exercise and encourage to follow the present life style without major lifestyle changes. The participants will be prospectively followed for nine months with intermittent assessments scheduled once in every three months (i.e. 90th, 180th and 270th days). The participants will be provided with a diary to write the day today walking or exercise regimen and day to day diet pattern.

7. Data collection and analysis

The collected data will be recorded in numeric form in Microsoft Excel sheets. This data will be expressed as mean $\pm$ standard deviation or median interquartile range (numerical data) or in proportions (categorical data) after applying appropriate statistical tests (for independent group comparisons unpaired *t*-test or Mann-Whitney *U* test. For pre-post assessments Paired *t*-test or Wilcoxon signed rank test. For categorical data Fischer's exact test by using-statistical package for social sciences (SPSS) software version 20.0. The difference at various time points will be assessed by repeated measures of MANOVA. The level of significance is considered at $p < 0.05$.

Table 4

Diet protocol for type 2 diabetes mellitus - 10 days.

Date		1	2	3	4	5
Day						
7:30 AM		Ash gourd juice 250 mL	Ashgourd juice 250 mL	Bitter gourd juice 250 mL	Ashgourd juice 250 mL	Ashgourd juice 250 mL
9:00 AM		Ragigani 200 mL	Ragigani 200 mL	Ragigani 200 mL	Ragigani 200 mL	Ragigani 200 mL
11:00 AM		2 whole wheat chapathi + 200 gm of boiled vegetables + 100 gm papaya + 200 mL butter milk	200 gm of raw vegetables + 50 gm sprouts + 100 gm papaya + 200 mL butter milk	200 gm of raw vegetables + 50 gm sprouts + 100 gm papaya + 200 mL butter milk	200 gm of raw vegetables + 50 gm sprouts + 100 gm papaya + 200 mL butter milk	200 gm of raw vegetables + 50 gm sprouts + 100 gm papaya + 200 mL butter milk
2:30 PM		Knolkohl juice 250 mL	Pomegranate juice 250 mL	Pomegranate juice 250 mL	Pomegranate juice 250 mL	Pomegranate juice 250 mL
4:00 PM		100 gm Cucumber slices + 50 gm Sprouts	100 gm Cucumber slices + 50 gm Sprouts	100 gm Cucumber slices + 50 gm Sprouts	100 gm Cucumber slices + 50 gm Sprouts	100 gm Cucumber slices + 50 gm Sprouts
6:30 PM		2 whole wheat chapathi + 200 gm of boiled vegetables + 100 gm papaya + 200 mL buttermilk	200 gm of raw vegetables + 100 gm papaya + 200 mL vegetable soup	200 gm of raw vegetables + 100 gm papaya + 200 mL vegetable soup	200 gm of raw vegetables + 100 gm papaya + 200 mL vegetable soup	200 gm of raw vegetables + 100 gm papaya + 200 mL vegetable soup
8:00 PM		Apple 100 gm	Apple 100 gm	Apple 100 gm	Apple 100 gm	Apple 100 gm
DATE						
DAY		7	8	9	10	
7:30 AM		Bitter gourd juice 250 mL	Ash gourd juice 250 mL	Bitter gourd juice 250 mL	Ash gourd juice 250 mL	
9:00 AM		Ragigani 200 mL	Ragigani 200 mL	Ragigani 200 mL	Ragigani 200 mL	
11:00 AM		2 whole wheat chapathi + 200 gm of boiled vegetables + 100 gm papaya + 200 mL butter milk	200 gm of raw vegetables + 50 gm sprouts + 100 gm papaya + 200 mL butter milk	200 gm of raw vegetables + 50 gm sprouts + 100 gm papaya + 200 mL butter milk	200 gm of raw vegetables + 50 gm sprouts + 100 gm papaya + 200 mL butter milk	
2:30 PM		Knolkohl juice 250 mL	Pomegranate juice 250 mL	Pomegranate juice 250 mL	Pomegranate juice 250 mL	
4:00 PM		100 gm Cucumber slices + 50 gm Sprouts	100 gm Cucumber slices + 50 gm Sprouts	100 gm Cucumber slices + 50 gm Sprouts	100 gm Cucumber slices + 50 gm Sprouts	
6:30 PM		2 whole wheat chapathi + 200 gm of boiled vegetables + 100 gm papaya + 200 mL buttermilk	200 gm of raw vegetables + 100 gm papaya + 200 mL vegetable soup	200 gm of raw vegetables + 100 gm papaya + 200 mL vegetable soup	200 gm of raw vegetables + 100 gm papaya + 200 mL vegetable soup	
8:00 PM		Apple 100 gm	Apple 100 gm	Apple 100 gm	Apple 100 gm	

Table 5

Yoga protocol for type 2 diabetes mellitus - 10 days and follow up for 9 months.

SL NO.	Name	Practices	Duration (90 min yoga + 30 min kriya)
1	Prarthana Mantra	Om chanting (3 times) followed by Salutations to MaharshiPathanjali	3 min
2	Kriyas	Jalaneti, Sutra neti, Vamanadhauti	30 min (2 days) - 3rd& 7th day
3	Sithilikaranavyayama	Loosening exercises	7 min
4	Suryanamaskara	Om chanting with mantra followed by practice of 12 suryanamaskara postures 5 rounds	10 min
5	Standing series	Ardhachakrasana, Ardhakatichakrasana, Trikonasana, Parivrittatrikonasana.	10 min
6	Supine series	Pavanamuktasana, Utthanapadasana, Matsyasana, Sarvangasana	10 min
	Quick relaxation		6 min
7	Prone series	Bhujangasana, Shalabhasana, Saraladhanurasana, Naukasana	10 min
8	Sitting series	Vakrasana, Paschimottanasana, Arthamatsyendrasana, Vajrasana	10 min
9	Deep relaxation		6 min
10	Pranayama	Surya anulomaviloma, Bhastrika, Sheetali, Sheetkari, Sadanta, Nadishuddhi, Bhramari	18 min

8. Conclusion

During intensive phase patients will be learning necessary changes in lifestyle for treating and/or controlling T2DM. During routine clinical practice maintenance of changed life style is less seen, hence this study will be helpful to know about the same and it can be implemented to enhance the quality of N&Y lifestyle interventions and follow-ups. Present 9 months prospective follow up will encourage in maintaining the life style changes and effectiveness of the same in day to day life. We believe that integrated N&Y approach will give more effective and lasting effects in treating and preventing complications of T2DM. The study is potential to give scientific evidence on effectiveness of N&Y intervention on T2DM and associated risk factors.

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Conflicts of interest

The authors have no conflicts of interest to declare.

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