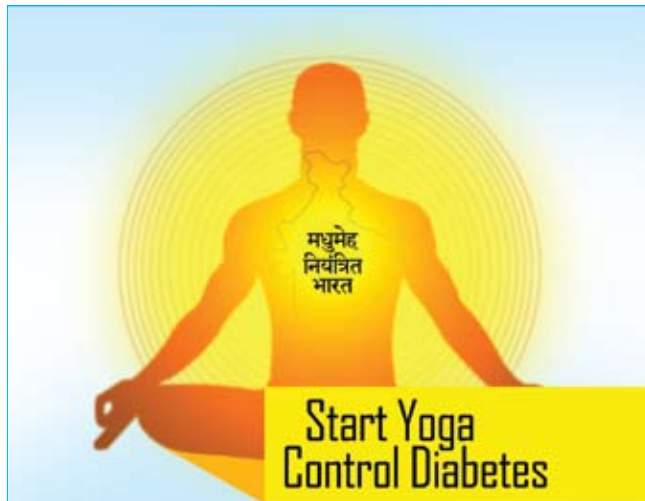


Madhumeka Niyantrita Bharat (MNB) Abhiyaan Multi Centric Matched Control Trial



Aim

1. To make SDM an acceptable national health program for 2017-18
2. To provide feasibility data before June 2017, the next international day of yoga.

Objectives

1. To conduct multi centric research to provide scientifically acceptable feasibility data from all sections of society.
2. To develop evidence for the effect of yoga in primary prevention (prevent conversion of pre dm to dm).
3. To observe the acceptability, benefits and feasibility of implementing yoga based life style change for management of DM2
4. Conduct camps with 3 months follow up in all districts - To provide evidence for feasibility of using voluntary and govt. network.

Methodology

Sample Size

Based on the available data of conversion of pre-diabetes to diabetes in one year, and six months, the statistical experts from NIMHANS have arrived at a number of 24,000 prediabetics as the required sample size for this study. We need

24,000 prediabetics from all parts of the country to show any significant reduction in conversion of pre-diabetes to diabetes within 3 months. In order to get this 24,000, we have to screen 2.4 lakh household population above the age of 20 years round the country.

Randomization and Selection of Places

We have identified 30 states combining some small states and UTs together. Selection of the number of districts to be covered was based on the population size reported in the 2011 census data (<http://censusindia.gov.in/>). A list of 30 states along with number of districts in each of this state has been provided in annexure 1. If the size of the state/ UT was small (less than ten districts) then it was clubbed with neighboring state.

Districts in each state were randomly selected based on the ratio of 1:10, i.e., one district would be selected from a state for ten available districts. Thus 60 districts were selected to get the adequate sample size. We need to screen 4000 persons (20-60 years of age) per district throughout India. The total number of persons to be screened is $60 \times 4000 = 2.4$ lakhs. Hence 2000 persons in urban and rural areas need to be screened in each district.

In each district as the expected prevalence of pre-diabetes and diabetes is about 10% each, we expect to have 24,000 diabetics and 24,000 prediabetics. Number of subjects for yoga and control groups per district = 200 T2DM, 200 pre-DM.

Selection of Rural Population

Door to door survey will be performed to screen 2,40,000 population in 60 districts selected randomly in all states. From each of these districts, rural (villages) and urban (towns & cities) areas have to be randomly selected. We prepared a list of villages of around 150 to 175 households in each districts (population

Message from
Hon'ble Prime Minister Shri Narendra Modi Ji



“Yoga is an invaluable gift of our ancient tradition. It embodies unity of mind and body; thought and action; restraint and fulfillment; harmony between man and nature; a holistic approach to health and well being. Yoga is not about exercise but to discover the sense of oneness with ourselves, the world and the nature. By changing our lifestyle and creating consciousness, it can help us deal with climate change.

Let us work towards adopting an International Yoga Day.”

*Speech of Hon'ble Prime Minister of India
at 69th United Nations General Assembly on September 27, 2014*

In the second International Day of Yoga (IDY) on June 21st, 2016, in his speech, in Chandigarh the Hon'ble Prime Minister gave a call to all yoga institutions to work synergistically to Control Diabetes in India

ranging from 500 to 1000) to get about 20 T2DM and 20 pre-DM. To get 24,000 prediabetics and 24,000 diabetics we have randomly selected four villages in each district. Two villages for yoga (neighboring villages) and two villages for control separated by 25 km distance were selected.

Selection in Urban

Select any town in the state and cover 4000 population 2000 in one end of the town/ city and 2000 in another end of city/ town in the randomly selected district. One group will be for yoga and one group of 2000 will be control.

Design

- Two groups pre-post matched controlled multi-centric design
- Two assessment points: baseline and after 3 months
- Two groups: Yoga and wait-list Control

Inclusion Criteria for Diabetes Patients

- Gender: Both male and female
- Age range: 20-60 years
 - Diagnosis of T2DM or Pre-DM as per American Diabetic Association guidelines
 - Both Gender
 - With or without Hypertension
 - With or without obesity
 - Those on oral hypo-glycemic agents
 - Those on insulin
 - Fit subjects who can follow the yoga protocol

Exclusion Criteria for diabetes patients

- Those who are not able to follow the yoga protocol
- H/o of Cardiac illness or any other major complication of diabetes which disables the person
- H/o Major surgery in the past

List of Experts

SNo	Name	Designation and Place
1	Dr. Nagendra HR	Chancellor, S-VYASA, Bengaluru (Chairman)
2	Dr. Manoj Nesari	Adviser (Ay.), Ministry of AYUSH, New Delhi
3	Dr. Subodh Tiwari	Director, Kaivalyadhama, Lonavala
4	Dr. I N Acharya	Director, CCRYN, New Delhi
5	Dr. Ranjani Harish	Senior Scientist, Dr. Mohan's Diabetes Specialties Centre and Madras Diabetes Research Foundation Mohan's Diabetes Foundation, Chennai
6	Dr. Sulochana Bhat	In-charge, Regional Ayurveda Research Institute for Metabolic Disorders (RARIMD), CCRAS, Ministry of AYUSH, Bengaluru
7	Shri Srinivasan	Krishnamachari Yoga Mandiram, Chennai
8	Dr. Razvi	RIMYI, Iyengar Yoga, Pune
9	Dr. Nikhil Tandon	Dept. of Endocrinology and Metabolism All India Institute of Medical Sciences, New Delhi
10	Dr. R Nagarathna	Medical Director, VYASA, Bangalore
11	Dr. Ishwar Basavareddy	Director, MDNIY, New Delhi
12	Acharya Pratishtha	Mokshayatan Yog Sansthan, Yamuna Vihar, Delhi
13	Dr. V Mohan	Dr. Mohan's Diabetes Specialties Centre & Madras Diabetes Research Foundation, Chennai
14	Dr. Shirley Telles	Director of Research, Patanjali Research Foundation, Haridwar
15	Dr Shashidhar Doddamani	RO (S-2),RARIMD, Bengaluru
16	Dr. Ananda Balyogi Bhavanani	Yoganjali Natyalayam, Iyyanar Nagar, Pondicherry
17	Dr. Nisha Manikantan	Founder Director, Sri Sri Ayurveda, Bengaluru

- H/o Tuberculosis

- H/o Head injury, neurological or psychiatric disorder in the past

Inclusion criteria for pre diabetes

- Adults between 20-60 years
- Both genders
- Those who score >50 on IDRS
- Those with HbA1c between 5.7 and 6.4%
- Those who consent for the study

Exclusion criteria for pre diabetes

- Severe obesity
- Associated cardiac and other major illnesses
- Those who cannot do yoga

Intervention

- T2DM and Pre-DM subjects as per the initial survey.
- Yoga: protocol developed by national committee will be taught by trained teachers in 9 days yoga camp followed by weekly classes for next 81 days (total 90 days intervention) ; conducted by a motivated local trainer who will be trained in imparting the yoga protocol.
- He/she will be paid for this.
- Control: Conventional lifestyle advices. The group will be visited by the teachers once a week to document life style habits of the subjects as a group.

Project Summary

Phase 1 - Training and Screening Phase 2 - Running Camps Phase 3 - Follow-up - 3 months - 12 weeks Phase 4 - Report Writing	
a.	The sample survey numbers in each region: Total Subjects above the age of 20 years for screening: 240,000 persons We have clubbed small States into one so that we will have about 35 states Total Districts in all states: 65; we need about 4000 to be screened / district
b.	Out of the sample survey, the number of pre-diabetics / diabetics to be selected: 24000 DM and 24000 Pre-DMs
c.	Out of the selected pre-diabetics/ diabetics, how many people will be in each group: 12000, 12000 in control and Yoga in DM and PreDM
d.	Number of days of supervised training to the Yoga group: 9 days camps 2 Persons will conduct 2 camps in the month of December
e.	Number of days of follow-up training to the Yoga group and Targets: Weekly follow up for three months from January Control group also weekly follow up
f.	Manpower Requirement: Total 1200 YIDM; about 60 Districts in 30 States 20 YIDM / District; total SRFs 35; No of RA 2
g.	Time Line: Nov, 2016 - Training of YIDMs Dec, 2016 - mid Jan, 2017 - Screening Jan, 2017 - Apr, 2017: Completion of the 3 months Follow-up Apr, 30, 2017 - All Data to come May 30, 2017 - Analysis of Data, Report Writing June 10, 2017 - Presentation of Data

Assessments

- Waist Circumference
- Hip Circumference
- BMI • IDRS

Blood Tests

- FBS – for about 60,000 population
- PPBS for 50,000
- HbA1C for 50,000
- Hb%- for 60.000

Man Power and Duties

- Local trainer – YIDM trained teachers (2 per 20 Dm + 20 pre dm): 2 / ward = 1200
- Senior Research Fellow (1 per 40 teachers): 35
- Research associate: 2
- Duration: 6 months

Training for YIDM (Yoga Instructors for DM) – 5 days

- Total YIDM persons needed: 1200
- First Training Camp in Art of Living, Bengaluru, from Nov 16-20
- Second Training Camp in Brahmakumaris Retreat Center, Manesar, from Nov 21-25
- Similarly the Training Camps will take place in different parts of the Country

Duties of YIDM

One yoga teacher for 400 - 500 population – screening , teaching, and reporting to SRF or coordinators

1. Screening of persons

Total persons to be screened Per District:
4000

Rural 500 in each Village and Urban 4000 in 2

Flow Chart of the Project

Screening 2.4 lakh adults in 30 states 4000 adult population / distric	
Design in Rural Sector In each village there are two YIDM instructors who have to take care of 100 persons (50 diabetics and 50 pre-diabetics)	
Step 1	Names of the villages in your district with about 500 population (about 160-170 households) is provided by research team (house hold defined as one family that uses one kitchen) population select 4 such villages 2 neighboring villages for yoga and 2 neighboring villages for control separated by about 25 kms.
Step 2	Door to door survey to be done for all houses in the village Instructors will fill up the screening form for all adults above 20-60 yrs of age will take BP and waist circumference
Step 3	From the screening form - make a list of all diabetics in the village calculate number of persons with high score of IDRS >50 by totaling the answers to five questions. Out of about 500 such persons screened in entire village, we may get about 60 with high score and 40-50 known diabetics taking medicines.
Step 4	Arrange blood tests by calling local SRL persons after you have gathered about 100 persons. Blood test has to be done within one week after getting the selected group after screening. Mark exactly the number of subjects eligible to enter the study in yoga camps or control villages.
Design in Urban Sector In each ward (1000 adult population) there are two YIDM instructors who have to take care of 200 persons (100 diabetics and 100 pre-diabetics)	
Step 1	Name of one town or city selected by random numbers is provided Select two wards of 1000 population -one in north or west for yoga and one in south or east for control.
Step 2	Do survey of entire ward. Fill up screening forms. BP and waist circumference
Step 3	Select the high risk persons on IDRS, also select all known diabetics from entire ward we may get about 60 with high score and 40-50 known diabetics who are taking medicines
Step 4	Arrange blood test for all persons having high risk or known diabetes Blood tests should be done within one week after completing the screening of the ward. you should not leave any house in that ward
Step 5	Send the list immediately to central office and SRF who will tell you exactly who should be attending our camps and be followed up based on the inclusion criteria. <small>Screening and selection of subjects should be completed by the end of December in both rural and urban sector V important - fix the coding of the participants and use the same in all records and references very carefully as it has to be exactly the same for SRL blood tests</small>
Step 6	Arrange venue for camps for 20 yoga group Conduct 9 days camps 2 hrs / day Theory and practice
Step 7	Follow up classes once a week for yoga group Follow up documents to be filled at each weekly interaction
Step 8	Arrange one 2 hour class at 3 months Collect follow up data Arrange blood test next week
Step 9	Send all data to SRF and central office Introduce yoga in control village and ward

Wards of selected Towns or cities (500 in each Village or Ward); 1000 per Ward - 1 Ward for Control and 1 Ward for Yoga

Four YIDM has to screen 400 persons; Total $400 \times 1200 / 2 = 240,000$

One day two persons can take data on 20 persons. Then it needs 20 days! Say one month; whole December. By the end of December we should have all pre-data on 240,000 persons. RAs will start analyzing the data.

2. Teaching - you have to motivate all Pre-diabetics and Diabetics in your area and see that they participate. Conduct camps or daily classes to cover the whole area in yoga village or yoga ward.
For one year with initial phase of 3 months. Arrange blood tests, check all parameters, document and send
3. Keep the center informed of the progress on weekly basis. Your contact for any problems and reporting will be your local

co coordinator, SRF and our central team at sdm@svyasa.org

SRF

One SRF for each state - VYASA trained faculty with PGDYT or above-plan, arrange, co-ordinate and monitor camps and follow up for 3 months. Conduct daily meetings on phone and weekly meetings physically. Report to the center on daily basis.

Duties of SRFs

- 1 SRF per state will look after 40 YIDM, give guidance, necessary support, answer all their queries, solve their problems, monitor the practices, data taking, progress of Camps, follow up etc. Put all data into computer from hard copies into Excel, Check for correctness and send to RA for analysis
- Each SRF will handle 1600 DM and Pre DM persons
- Districts in each State: 1-7

National Diabetes Control Program (Madhumeha Niyantrita Bharat Abhiyaan) Ministry of AYUSH, Govt of India, New Delhi

Name and Contact Details of SRFs in various States of India

SNo	States	Name of SRF's	Cell
1	Andhra Telangana	Mr. Krishna Manasa	91605 77793
2	Assam	Ms. Dheepa Chandarkar	80110 90045 94357 08835
3	Gujarat	Mr. Viral Raval	94096 24572
4	Jammu & Kashmir	Dr. Guruprasad	70066 34633
5	Karnataka	Mr. Sanjay	89516 38709
6	Maharashtra	Dr. Amit Mishra	98204 87697
7	Manipur / Seven Sisters	Mr. Ganga	97740 77155
8	Madhya Pradesh & Chattisgarh	Dr. Lata R S Dr. Bhupen Saxena Dr. Purnima Datey	94251 26644
9	Punjab / Chandigarh	Dr. Purnemdu Sharma	96724 22869
10	Rajasthan	Ms. Lara Sharma	94144 99727
11	Uttaranchal	Mr. Sanjay	--
12	Uttar Pradesh	Mr. Upadhyay	70546 32242
13	West Bengal	Ms. Priti Nandi	94749 14522
Remaining SRFs List will follow			

- SRF will be trained in the training camps for 5 days on practices, theory etc on one hand and other aspects for data collections
- Will ensure that the Camps will start soon after screening without waiting for completion of all Screening.
- Get the full screening data by Mid January, or latest by end Jan, 2017
- SRFs will go to each camp - one or two in a day - total 40 Camps to be covered in one month
- SRF will visit each Village (4-6) and each Ward (4-6) in their state during this month and check
- One day one or two - total 11-12 days
- Communicate with each of the 40 YIDM (phone, SMS and or email) every day and guide them
- Get the data by email or SMS; check for correctness and give comments
- Communicate with each YIDM with CC to their AYUSH email on a daily basis
- By end December each SRF should have all pre-data of their state, check and send to RA. One RA will be in charge of 15 SRFs
- SRFs will have their offices in Directorate of AYUSH
- Essentially one SRF has to take care of 40 YIDM persons
- Director (Member Secretary of the State DMCOP Committee) and in-charge RA in Prashanti Kutiram by
- Meeting at the end of Camps in State HQ of AYUSH to be organized
- Director should be present; SRF will report
- Preferably all members of State Level Committee should be present
- Discussions and plan for the future 3 months follow up

Duties of RA

- Participate in Planning and Design
- 2 RAs for the whole project in central office.
- Keep in touch with committee members organize meeting of state level when possible attend state meetings
- Communication with state level SRFs on daily basis

- Planning the whole process with Dr. Nagarathna and Dr. Nagendra
- One RA will take care of 15 SRFs
- Office in Prashanti Kutiram campus
- Organize Meetings at National Level for this Project in Prashanti or Delhi
- Keep all records fully in Computer and use all Security Measures for safe data storage
- Analyze the data on a regular basis and report to Dr. Nagarathna and Dr. Nagendra
- Write progress reports every week and communicate to the State Level Committees and National Level Committee and at the end of Phases 1,2, 3 and 4
- Final Consolidated Project Report
- Write Research Papers for Publications

State Level Committee

- Meeting before start of Camps in State HQ of AYUSH
- Director should be present; SRF will report
- Preferably all members of the State Level Committee should be present
- Discussions and Plan for the future 1 month for camps

Methods

Camps

- Total Number of Yoga camps per District: 200 urban, 200 rural / 20 = 20 Camps
- Total number of YIDM in each district: 20
- Each camp will be run by 2 YIDM - 9 days
- 4 camps to be completed in one Month - Mid December to mid January
- Either in the morning or in the evening
- We will start the Camps soon after screening without waiting for completion of all Screening.
- We will have the full camp data by Mid January or latest by end Jan, 2017
- Essentially one YIDM person has to take care of 20 persons with yoga and 20 persons with no yoga.

Population for Intervention CONTROL (800) + YOGA (800) Groups / District								
Sector	400 pre DM			400 DM2			Yoga Camps / district (9 days)	No. of pts / camp DM & pre DM
Region	Total	Yoga	Control	Total	Yoga	Control		
Rural	200	100	100	200	100	100	10	20
Urban	200	100	100	200	100	100	10	20

Follow - up

- Weekly once they have to meet for 2 hours
- Rest of the days during the week, they have to talk to them and inspire them to do the practices.
- Check their practices; Collect the data needed
- Total three months: 12 weeks
- Feb, March and April; collect at the end of 3 months
- We should have all data by end April
- SRFs will compile all data and give the same to RA for Analysis, etc

From May up to June 21st

- YIDM will teach yoga module to Control - 9 days camp as done for Yoga group?
- They will continue to make Yoga group to practice
- And allow them to teach others who have DM, etc
- Weekly meetings will continue and data will be recorded
- Prepare both Yoga and Control groups for the demonstration on June 21st in their own Villages / Wards - organize the same wherever possible in a big way
- Each DM and pre-DM person should teach at least 10 persons - total number of persons for demonstration will be $10 \times 400 \times 60 = 2.4$ lakh population
- Collect the data of number of persons demonstrated on June 21st, 2017 and send to SRFs
- They can even have normal persons to

practice - that can increase the number

Time Lines

- **Nov, 2016** - Training of YIDMs
- **Dec, 2016** - mid Jan, 2017 - Screening
- **Jan, 2017 - Apr, 2017** - Completion of the 3 months Follow-up
- **Apr, 30, 2017** - All Data to come
- **May 30, 2017** - Analysis of Data, Report Writing
- **June 10, 2017** - Presentation of Data

Expected outcome

1. Screening data on 2.4 Lakhs population, prevalence of DM and pre-diabetics from randomly selected population from all states in the country and the related details of DM and pre-diabetic persons
2. Large scale awareness about DM and its prevention by Yoga for creating Madhumeha Niyantrita Bharata
3. Prevention of many other NCDs
4. Percent Conversion of pre-diabetics to Diabetics in yoga versus control groups in 3 months which is most needed to establish primary prevention
5. Comparison of changes in HbA1c levels in about 10,000 Diabetics between Yoga and control groups followed up for 3 months
6. About 4 publications in high impact journals
7. Improved Quality of life, reduction of complications of DM and
8. Based on the evidence based results from this

mission, paving way for nation-wide DM control modality through Yoga

Responsibilities of the Institutes Participating in the Research Work

- SVYASA - Technical Support, Documentation, Analysis of Data and Publications
- Other major Yoga Institutions - Recruitment of Yoga Instructors, Membership of State Committees, Participation in National Committee of IYA

Monitoring Mechanism

- The SRFs will monitor the YIDM persons in each state
- The RAs will monitor the SRFs

- The State level committees will monitor the progress, give adequate support for the successful implementation of the program; the technical committee will monitor the SRFs through regular reporting
- The national level committee of IYA) will support all State level committees and the main technical committee will monitor the research outcome

Final Output

Announcement of the results in 3rd IDY by the PM on June 21st, 2017 about the achievements of DM Control Program conducted throughout the country giving new direction about the usefulness of Yoga based life style protocol developed by the National Committee of AYUSH