Primary Prevention of Type 2 Diabetes Mellitus: Multiple Health Care Strategies

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Abstract

Kerala being the diabetic capital of India, need to evolve a less expensive method to reduce the tangible and intangible cost of type 2 diabetes mellitus(T2DM). Hospital based single blinded randomised controlled trial was undertaken at Indian Institute of diabetes, Kerala, India with an aim to assess the effect of multilateral health care strategies on metabolic profile. Pre-diabetic individuals were screened using American Diabetic Association criteria and randomly allocated to experimental and control group. Experimental group received 3 weeks training in yoga, exercise and healthy diet preparation. Control group received only heath counselling alone on diabetes prevention. Subjects were followed up for one year. The multiple health strategies were planned based on evidences and successfully implemented to curtail the menace of DM in India. The present paper details the multiple health care strategies and methodology addressing the primary prevention of primary prevention of T2DM.

Key words: *pre-diabetes, metabolic profile, life style modification, yoga*

Introduction

Diabetes is a metabolic disease demonstrated by hyper glycaemia resulting from defective insulin secretion, insulin action, or both. This hyper glycaemia is often associated with long-term complications of vital organs like eyes, kidneys, nerves, heart, and blood vessels.[1] The World Health Organization and International Diabetes Federation estimated that 246 million people in 2007 had diabetes, with numbers increasing to 380 million by 2025. [(2, 3)] 79% of adults with diabetes are living in low- and middle-income countries. [(4)]

India has 69.1 million people with DM and is estimated to have the second highest number of cases of DM in the world.[(5)] The diabetic capital of India is Kerala. Overall prevalence of type 2 diabetes in an urban district of Kerala was 16.3%. In the 30-64 age group, age standardised prevalence was 13.7%. [(6, 7)] Delaying the onset of the disease in high-risk individuals is urgently needed. [(8)] Large randomised controlled trials (RCTs) from the USA, [(9)] China, [(10)] Finland, [(11)], India [(12)] and Japan [(13)] have now demonstrated that lifestyle interventions can prevent T2DM by up to 60% among individuals with pre-diabetes. The present study utilised multiple health care strategies to combat this disease which has multiple aetiologies.

The present paper mainly illustrates the multiple health care strategies and methodology used in the study which aimed to assess the effect of these strategies to prevent the incidence of type 2 diabetes mellitus.

Methodology

Study Setting

The setting was, Indian Institute of diabetes (IID), Pulayanarkotta, Thiruvananthapuram, Kerala.

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Study design

A hospital based cross sectional survey was conducted tor detecting pre diabetics in phase 1. Phase 2 of the study was single blinded randomised controlled clinical trial (RCT) among in subjects who were diagnosed as pre-diabetes according to the American Diabetes Association (ADA) criteria i.e. Fasting blood glucose (FBS) 100 mg/dl to 125 mg/dl and or Oral glucose tolerance test (OGTT) 140 mg/dl to 199 mg/dl.: Group 1(control group) subjects were given standard health care counselling on diabetes prevention, Group 2 (experimental group) subjects followed multilateral health care strategies which included yoga, exercises and dietary modifications based on 3 weeks training given from the Institute. The sample size was 130 in each group after accounting for a type 1 error of 5%, 80% power, and allowing a dropout rate of 10%. Using block randomisation, a total of 65 blocks were created using a 1:1 allocation ratio.

Data collection

Following human ethical clearance, the subjects were invited for the screening for pre diabetes. The subjects were informed about the study and base line information was collected from those who consented for the study subjects were randomised into the experimental group and control group randomly using block randomisation.. Subjects in experimental group received the group-based training for 3 weeks on multi-lateral health care strategies for the prevention of diabetes mellitus and the control group received only the routine counselling . Both groups were followed up for one year. Every 6 months, subjects in both groups were called for (metabolic profile, anthropometric, knowledge, psychological stress and quality of life assessment. The internal safety committee monitored the quality of the study monthly.

Result

8610 subjects attended the screening. Pre-diabetes was detected among 677 subjects (7.86 %). The socio demographic characteristics of pre diabetics are outlined in Table 1. 32.3% and 35.4% of pre-diabetics belonged to the age group of 45 -49 years in the experimental and the control group respectively, 66.2% of the experimental and 69.2% of the control group were females (Table 1).

Prevalence of diabetes and pre-diabetes

Pre-diabetes was detected among 677 subjects (7.86 %).There were 1740 (20.20 %) old diabetic patients and 185(2.14%) were newly detected diabetics.

1.Multilateral health care strategies

Refers to the training on yoga, exercises, and healthy dietary preparation given to the pre diabetic individuals

Yoga training

They were taught a sequence of asanas and pranayamas for stress reduction which is selected from Patanjali Yoga sutras for 5 days. The asanas and pranayamas taught were depicted in Table 2

Exercise training

Training based on WHO recommendation which was 150 minutes of moderate-intensity aerobic physical activity throughout the week or 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate - and vigorous-intensity activity. All subjects underwent a 12 lead ECG and blood pressure was recorded to exclude any cardiac abnormalities prior to the training.

Menu preparation

Menu preparation based on recommended daily allowances for Indians (National Institute of Nutrition, India). Table 3 describes the daily caloric requirement of Indian adults .

2. Effect

Refers to the outcome of multilateral health care strategies on metabolic profile among pre diabetics

3. Pre diabetics

Refers to subjects with fasting blood sugar level 100 – 125 mg/ dl (5.6 to 7.0 mmol/L) or 2 hour OGTT value of 140- 199 mg/ dl (7.8 to11.1mmol / L)

4. Metabolic profile

Refers to the biochemical parameters like fasting blood sugar, oral glucose tolerance, Hb A1C, serum total cholesterol, high density lipoprotein, low density lipoprotein and very low density lipoprotein .

Fasting capillary blood glucose (CBG) was determined using a One Touch Ultra glucose meter (Johnson & Johnson, Milpitas, CA, USA). Oral glucose test was done after the administration of 75 g of anhydrous glucose and a 2 h post load blood glucose assessment .The centre had fully equipped ISO and NABH certified laboratory where the equipment's are calibrated on a regular basis.

5. Anthropometric measurements

Measurement included in the study were body mass index (BMI) and waist hip ratio (WHR)

Body mass index (BMI).

By following WHO standard protocol,(14) height was measured in meter (using SECA 213 standalone stadiometer), weight in kilogram (using SECA 813 Electronic flat weighing scale) .

Waist-to-Hip Ratio (WHR)

Waist circumference was measured using a SECA constant tension tape to the nearest 0.1 cm. Anthropometric measures were defined as per Asian Indian cut offs (15)

Data collection instrument

Tool I: Interview schedule

The interview schedule consist of 2 sections

Section 1 – Socio demographic data

Section 2 – Clinical data

Tool II : Questionnaire to assess the knowledge in relation to the prevention of type 2 DM

Tool III : General physical activity questionnaire (WHO)

Tool IV : General stress index scale

Tool V : Quality of life scale (WHO QOL BREF-26)

Tool VI : Glucometer, auto analyser for biochemical assay, weighing machine, inch tape

for anthropometric assessment

Description of adapted tools

1.Translated version of General physical activity questionnaire (WHO)

GPAQ which comprised 19 questions about physical activity performed in a typical or usual week. [16]The GPAQ measure asked about the frequency (days) and time (minutes/hours) spent doing moderate- and vigorous-intensity physical activity in three domains: (i) work related physical activity (paid and unpaid including household chores), (ii) active commuting (walking and cycling), and (iii) discretionary leisure-time (recreation) physical activity.

2. General stress index scale

General Stress Index (GSI) was designed to measure the general stress of the patients as well as normal. [17] The test consists of 10 items aimed to measure the general stress.

3.Translated version of WHOQOL-BREF- 26

WHOQOL-BREF - 26 was translated to the local language, Malayalam in a cross sectional study in Kerala. [18]

Table 1: Socio demographic characteristics of pre diabetics

Socio personal data	Experimental Group (N=130)		Control Group (N =130)		p-value
	N	%	N.	%	
Age					
35 - 39	26	20	21	16.2	
40 - 44	27	20.8	22	16.9	0.637
45 -49	42	32.3	46	35.4	
50 - 55	35	26.9	41	31.5	
Gender					
Male	44	33.8	40	30.8	0.596
Female	86	66.2	90	69.2	
Religion					
Hindu	82	63.1	87	66.9	0.542
Christian	20	15.4	14	10.8	
Muslim	28	21.5	29	22.3	

2 Details of yoga training

Pranayamas		Duration
1.	Anulom vilom	5 min
2.	Bhramari pranayama	5 min
3.	Pranav Pranayama	5 min
Asanas		
1.	Kaya Kriya	6- 10 min
2.	Uttana Shishosana	5 min
3.	Shavasana	10 min

Table 3: Details of the daily caloric requirement of Indian adults

Man		**Energy requirement (k cal/ day)**
1.	Sedentary work	2320
2.	Moderate work	2730
3.	Heavy work	3490
Woman		
1.	Sedentary work	1900
2.	Moderate work	2230
3.	Heavy work	2850

Discussion

Prediabetes is not only a clinical entity but also increases the risk for diabetes and cardiovascular disease (CVD). [19]

The primary outcome in this study was to assess the development of diabetes, diagnosed using ADA criteria. [20].

Numerous clinical studies has provided evidence that a substantial number of individuals with prediabetes will develop into diabetes later accounting to an average annual risk approximating, 5–10% compare to below 1 % in normo glycaemic subjects. [21-23]

This was a hospital-based cross sectional study done as phase 1 of an RCT (phase 2) which could provide a reasonably precise and reliable estimate of the prevalence of pre diabetes and newly diagnosed diabetes among persons who reported for screening in the centre.

Ours was the ever first study in Kerala that estimated the prevalence of pre-diabetes and newly detected diabetes in a hospital setting.

In the present study, we evolved, a methodology that curtail the multiple modifiable aetiologies to prevent the conversion of pre-diabetes to diabetes. Many prospective randomised controlled studies such as the Diabetes Prevention Program (DPP) in the USA (10), the Finnish Diabetes Prevention Study [12] (DPS), the Da Qing IGT and Diabetes Study in China. [11] have shown that lifestyle modification involving diet and enhanced physical activity helps to delay or prevent the progression of prediabetes to diabetes. Primary prevention is desirable in India which is facing an enormous burden from a high diabetic prevalence. [23]

The Indian Diabetes Prevention (IDPP) study was an RCT over 3 years with 4 groups mainly control with standard advice, life style modification (LSM), metformin and with LSM and metformin. It was shown that the relative risk was 29 % with LSM, 20 % with metformin and 20 % with LSM and metformin. [12]

Chennai Urban Population Study used individual and population based intervention for increasing physical activity and the result revealed that proportion exercise in the residents increased from [14]% to 59 %.[23]

We used yoga as an intervention to reduce the psychological stress. Psychological stress mobilizes biological responses implicated in type 2 diabetes mellitus (T2DM), including the release of glucose and lipids into the circulation, inflammatory cytokine expression and increased blood pressure [24]. Yoga mediate parasympathetic system to reduce the stress response thereby brings glycaemic control. [25,26].Yoga decreases the need for oral hypo glycaemia medications, decreasing low density lipoproteins (LDL) and increasing HDL[26]

Regular practice of yoga has been shown to be beneficial in reducing depression and anxiety and therefore may affect diabetes control. [27]

This was an ever first RCT in Kerala state incorporating multiple strategies to prevent type 2 diabetes mellitus. We sort a low-cost strategies after identifying at-risk individuals, followed by the implementation of group-based, inexpensive lifestyle interventions along with yoga.

The strength of our study was we could identify at risk population of diabetes that is pre-diabetes. Its inferred that, diabetes prevention programme should target and counsel those at high risk of diabetes development regarding reduction of stress, health diet and exercise.

Conclusion

The methodology adopted in the study was designed based on scientific evidences from previous epidemiological and clinical trials. The present study successfully combined modern medicine with yogic science for better prevention of type 2 DM.

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Awards

· **Selected and nominated for the best paper award in 30 th Kerala Science Congress**

· Got best paper award at the 15th International conference on publishing with impact at Sree Ramachandra Medical University, Chennai, India.

Conflict of Interest: None

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