

A Pilot Study to Assess the Effectiveness of Diabetic Risk Reduction Package on Knowledge, Lifestyle and Biophysiological Measures among Prediabetic Employees in Selected Institutions, Thiruvallur District

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ABSTRACT

Background: Diabetes is considered as a multi system disorder, whose prevalence is globally increasing and is considered as a global health change of 21st century. World Health Organization (WHO) estimates the adults having diabetes in 2014 was 422 million with obesity considered as a major contributing factor. Prediabetes is defined as impaired fasting Glucose or impaired glucose tolerance with fasting blood glucose 100-125mg/dl. Prediabetes is considered as a distinct entity under the classification of ICD-10 with diagnostic code R73-09. It's a reversible condition projecting the last window opportunity against impending diabetes. Diabetes can be considerably overcome through simple and safe measures to promote health and prevent development of Diabetes from Prediabetes.

Aim: The pilot study aimed at assessing the reliability and feasibility of the data collection and intervention tool and its effectiveness in Preventing or delaying diabetes.

Methods: Quantitative research approach with quasi experimental design was used. A total of 32 prediabetic employees aged between 30-60 years, who could understand English and were teaching in the selected schools formed the samples, with 16 prediabetic employees each group from four selected schools of Thiruvallur District, formed the experimental and control group. Enumerative sampling technique was used to select the samples. Data was collected using the Questionnaire prepared by the investigator.

Results: Both the data collection tools were found to be highly reliable. Statistical analysis of the background variables revealed homogeneity between the experimental and control group in the pre-test. With regard to knowledge in post test the experimental group showed statistical significance at $p < 0.001$. Selected lifestyle variables namely consumption of red meat, junk foods, fruits, skipping of meals and skipping of meals showed statistical significance. Since there was minimal difference in biophysiological variables there was statistical significance seen only in BMI at $p < 0.05$. Mild positive correlation was identified between the knowledge and life style and negative fair correlation between life style and biophysiological measures.

Conclusion: The results indicated that assessment tools used, namely the questionnaire and the intervention tool are highly reliable and appropriate for assessing the effectiveness of DRRP. It was found to be simple and practicable for maintain the healthy life and preventing the progression to diabetes.

Recommendation: The components of prediabetic screening like BMI, WC, IDRS and FBS need to be an integral part of health assessment in all the primary, secondary and tertiary level of health care settings.

Key words: Assess, Prediabetes, diabetic risk reduction package, IDRS

INTRODUCTION

Health is the central happiness to every human being. Good health results in overall performance and efficiency. Over past few years our life style has been changed and we have become the prey for various lifestyle diseases including Diabetes, hypertension and cancer. Diabetes is considered as a multi system disorder, whose prevalence is globally increasing. The diabetes impose burden on individuals, family and nation economy. ^[1]

Life Style Changes in human behaviour over the last century have resulted in a dramatic increase in the incidence of worldwide Diabetes. The epidemic is mainly associated with the condition known 'metabolic syndrome'. In concurrence with genetic susceptibility, particularly in certain ethnic groups, type 2 diabetes is brought on by environmental and behavioural factors such as a sedentary lifestyle, over nutrition and obesity. ^[2]

Diabetes is preceded by a condition known as Pre diabetes. Pre-diabetes (impaired glucose tolerance) usually has no symptoms. It's known only when blood with drawn for some or the other reason. As Prediabetes is often asymptomatic but there is presence of Prediabetes before onset of diabetes. World health organization criteria is FPG 110 -125mg/dl and ADA on other hand says IFG 100-125mg/dl as Prediabetes. ^[3] Prediabetes has a higher conversion rate to diabetes. There is a decrease prevalence of IGT in urban population; this may be due to rapid progression from normal state to diabetes as termed as diabetic epidemic. Modernisation accompanied with high fatty foods, less physical activity and sedentary occupation has doubled the prevalence of obesity and type 2 diabetes in younger generation.

Mohan V, Sandeep S, Deepa R, Shah B, Varghese C stated that India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed the "Diabetes capital of the world". According to the Diabetes Atlas 2006 published by the International

Diabetes Federation, the number of people with diabetes in India currently around 40.9 million is expected to rise to 69.9 million by 2025. The so called "Asian Indian Phenotype" refers to certain unique clinical and biochemical abnormalities in Indians which include increased insulin resistance, greater abdominal adiposity *i.e.*, higher waist circumference despite lower body mass index, lower adiponectin and higher high sensitive C-reactive protein levels. This phenotype makes Asian Indians more prone to diabetes and premature coronary artery disease. ^[4]

The ICMR-INDIAB national survey stated that in 2011, 62.4 million people had diabetes and 77 million had Prediabetes and it's predicted by 2035, 109 million people in India will develop diabetes making India the diabetic capital of the world. WHO stated that sedentary lifestyle are the leading causes of death and disability. These deaths are mainly from CVS diseases in which people with type 2 diabetes and Prediabetes are at much higher risk than others. Approximately one in three people with pre-diabetes will develop diabetes without lifestyle changes, including healthy eating, exercise and losing weight. Adaptation of increasing awareness on disease, behavioural changes and encouraging healthy life style can blunt this galloping trend. ^[5]

The effectiveness of lifestyle changes in preventing the progression to diabetes has been proven in large studies: The Finnish Diabetes Prevention Study (2003) Da Qing (chinese) 1997 and the Diabetes Prevention Program (2007). The long term effect on risk of diabetes, its micro vascular and macro vascular complications and mortality was assessed among 577 adults with Prediabetes selected from 33 clinics in china during 1986. The adults were randomly assigned to 3 groups which included diet alone, exercise alone and last group with both diet and activity. Active intervention at the end of 6 years revealed that 51% had lower incidence of diabetes and a follow up after 20 years

revealed 43% had lower incidence of diabetes. The average annual incidence of diabetes was 7% in intervention group and 11% in control group, the 20 year cumulative incidence of diabetes was 80% in intervention group and 93% in control group. The study concluded that group based life style intervention can delay or prevent diabetes for about 14 years. [6]

Need for the study

World Health Day 2016 calls for global action to halt the raise of diabetes and improve care for people living with diabetes. Non-communicable diseases kill 40 million people each year, equivalent to 70% of all deaths globally. Each year, 17 million people die from NCDs before the age of 70, 87% of these "premature" deaths occur in low and middle-income countries. [7]

India is one of the 6 countries in International Diabetes Federation (IDF). South East Asian (SEA) region states that 415 million people have diabetes in the World. [8]

The raise of halting can be achieved by being physically active, eating healthy and avoiding excessive weight gain. This pilot study was taken up as a test run to evaluate the reliability and appropriateness of the tools (Diabetic Risk Reduction Package) and teaching strategies selected to delay or prevent diabetes among prediabetic employees.

Aim

The study was done as a pilot test, aimed at testing the reliability and feasibility of the data collection and intervention tools to assess the effectiveness of Diabetic Risk Reduction Package on knowledge, life style and bio physiological measures among prediabetic employees, in selected institutions, Thiruvallur District.

Objectives

1. To assess and evaluate the effectiveness of diabetic risk reduction package on knowledge, life style and bio physiological measures among prediabetic employees in experimental and control group.

2. To correlate the mean differed score of knowledge, life style and biophysiological measures among prediabetic employees in experimental and control group.
3. To associate the pretest and post test mean difference level of knowledge, life style and biophysiological measures with selected demographic variables of experimental and control group.

Assumptions

1. Awareness of risk factors for developing diabetes mellitus will help the employees to improve quality of life and will avert complication
2. Diabetic risk reduction package on prediabetic employees can modify life style of the individuals; thereby can prevent the development of diabetes and its associated complications.

MATERIALS AND METHODS

Research Design: Quasi experimental design was used.

Setting of the study: The study was conducted at selected schools of Thiruvallur District.

Population: The study population consisted of prediabetic employees aged between 30-60 years, who could understand English and were working as employees (school teachers) in the selected schools.

Sample: consisted of a total of 32 employees with 16 from two schools in the experimental and 16 from two schools in control group.

Sampling technique: Enumerative sampling technique was selected

Description of the tools

Section 1- Data Collection Tool

The tool used for the data collection was structured questionnaire categorized into two parts a **PART I:** IDRS screening tool which was used to identify the prediabetic employees from the teaching faculty consisted of measurement of age, abdominal obesity, physical activity and family history. The total score was 100 and teachers who scored greater than 30 were

considered as the risk group for Diabetes. Screening of FBS was done and the value for falling in the category of Prediabetes was determined as 100-125mg/dl were considered as prediabetic employees those who had a score of 30 and above with IDRS and FBS 100-125mg/dl were considered as prediabetic employees.

PART II: It comprises of 4 sections and presented as follows.

Section A: Includes demographic variables

(a) General Demographic Variables:

This includes sex, religion, marital status, type of family, educational status, family income, total no of family members, Family history of diabetes mellitus, History of thyroid disorders, Number of teaching Hrs/Week and Type of institution, **Gender specific disorder-female:** Attained menopause, History of polycystic ovary diseases (PCODS), History of GDM.

Section B: Assessment of knowledge on various aspects of Prediabetes

Structured Questionnaire was used to assess the knowledge on meaning and basic concepts (9), risk factors (5), dietary factors (7) and physical activity and others (4). Totally there were 25 questions on various aspects of prediabetes.

Section C: Life style factor variables

This include

a. Food Frequency Questionnaire -Type of diet, use of roots and tubers, refined cereals, fish varieties, red meat, sweet and sweetener, junk foods, coffee and tea beverages, cool drinks and beverages, vegetables, fruits, skipping of meals, use of deep fried items, use of millets, quantity of water consumed per day.

b. Activity Questionnaire - smoking habit, second hand smoking, consumption of alcohol, physical activity.

Section D: Assessment of bio physiological measurements

Bio-Physiological Variables included in this study were height, weight, BMI, waist circumference and FBS

Section II: Intervention Tool

The instrument was developed and compiled by the investigator with the guidance of experts and review of literature.

The Diabetic risk reduction package which includes:

Knowledge

The IEC package on significance of prediabetes and its risk reducing behaviors in preventing diabetes mellitus. Life style changes like nutrition, exercise, monitoring for complication and its prevention in development of diabetes mellitus is delivered through computer assisted teaching.

Life style

a. Dietary modifications- Computer assisted teaching focusing on the diets to be included and excluded, importance of fibre and magnesium foods. Role of glycemic index foods

b. Activity- Demonstration of exercises

c. providing Food and Activity tracker to monitor the achievement of goal.

Plan for data analysis Statistical methods - Descriptive statistics and inferential statistics was used data analysis and interpretation

RESULTS AND DISCUSSION

Section 1: Description of Background Variables.

Section 1.1: Distribution of demographic variables of the experimental and control group.

Most of the prediabetic employees in both the groups were aged between 30-60 years and majority was females. Majority was Christian and married living in a Nuclear family. Maximum teachers in the both groups had Post Graduate Degree and were working for >18 hours of teaching/week in private institution. Monthly family income range in experimental group was Rs. 20001 – 30000 and 10001– 20000 in control group.

Both groups had family members 4 – 6 and in both groups only 25 -30% attained menopause. None of the women had a history of PCOD and majority didn't have a history of GDM. All the above variables,

when compared between the two groups using chi square test, showed no statistical significance, thus indicating homogeneity between groups.

Section 1.2: Distribution of pre-test and post-test lifestyle variables of the experimental and control group.

In pre test most of teachers in both groups were non veg, consumed roots and tubers, refined cereals, fish varieties, red meat, sweet and sweetner, Junk foods, fruits and vegetables, deep fried items, millets 1-2 days / week. Similarly many teachers in both groups had vegetables and coffee all days. All teachers in both groups consumed 7-8 glass of water /day and were non smokers and non alcoholic. None of the variables showed statistical significance when computed using Chi square test.

Section 2: Assessment of Effectiveness Diabetic Risk Reduction Package on Knowledge, Lifestyle and Biophysiological Measures among Predibatic Employees.

Section 2.1.1 Assessment of pretest and post test level of knowledge in experimental and control group.

Table 1 revealed that in the pre-test there was no statistically significant difference in the knowledge of prediabetic employees between the experimental and control group indicating that both groups were homogenous, whereas, in the post-test, a statistically very high level of significance was identified using chi square test at p <0.01. This shows that the knowledge had increased in the experimental group but showed very minimal variation in the control group.

Table 1: Frequency and percentage distribution of Pre test and post test level of knowledge score in the groups (N=32)

KNOWLEDGE SCORE		Group				Chisquare test
		Experiment(n=16)		Control(n=16)		
		n	%	n	%	
pretest	Inadequate	11	68.8%	10	62.5%	$\chi^2=0.13$ p=0.71
	Moderate	5	31.3%	6	37.5%	
posttest	Inadequate	0	0.0%	9	56.3%	$\chi^2=19.01$ p=0.01**
	Moderate	6	37.5%	7	43.8%	
	Adequate	10	62.5%	0	0.0%	

Not significant P >0.05 * significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001

Section 2.1.2: Comparison of pre-test and post-test level of knowledge of prediabetes in the experimental and control group.

Table 2 showed the comparison of pre test and post test level of knowledge in both the groups. In the experimental group, the mean knowledge score was 11.75 in pre-test, and 19.06 in post test. So the mean difference score is 7.31. This difference showed very high statistical significance using Wilcoxon signed Rank test at p<0.001.

In the control group, the mean knowledge score was 11.25 in the pre-test, and 11.81 in the post-test. So the mean difference score is 0.56. This difference did not show any statistical significance .This indicates that the diabetic risk reduction package administered to the employees in the experimental group had a significant effect in increasing the knowledge score in comparison to the control group who did not receive the intervention.

Table - 2: Comparison of pre-test and post-test level of knowledge score of prediabetic employees in the experimental and control group (N=32).

Group	Pretest		Posttest		Mean difference	Wilcoxon signed-rank test
	Mean	SD	Mean	SD		
Experiment	11.75	3.04	19.06	1.57	7.31	Z=3.52P=0.001*** significant
Control	11.25	2.98	11.81	3.29	0.56	z=1.79 P=0.08 not significant

Not significant P >0.05 * significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001

The figure 1 showed that the post-test knowledge score of the experimental

group was significantly higher than that of the pre-test, whereas the pre-test and post-test scores of the control group are almost

similar, indicating that the administration of Diabetic risk reduction package to the experimental group had a significant effect in improving the knowledge.

Section 2.2.1 Assessment of pretest and post life style variable score in experimental and control group.

Table 3 revealed that in the pre-test there was no statistically significant difference in the life style variable score of prediabetic employees between the experimental and control group indicating that both groups were homogenous, whereas, in the post-test, a statistically very high level of significance was identified using chi square test at $p < 0.01$. This shows that the life style had taken place in the experimental group but showed very minimal variation in the control group.

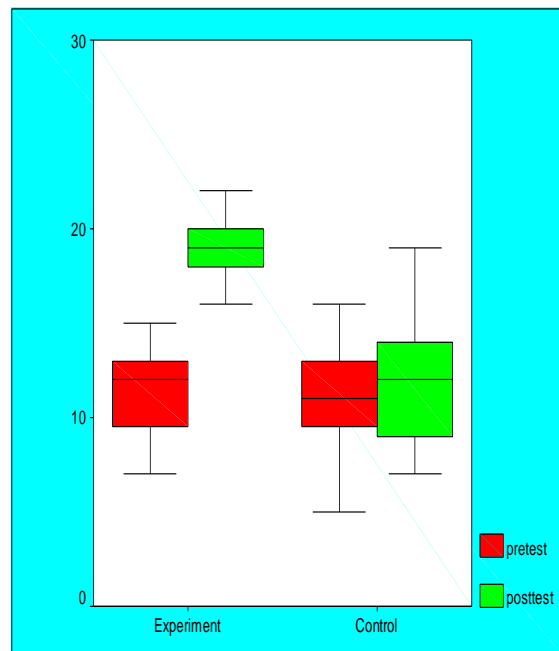


Figure- 1: Box-plot comparing pre-test and post-test level of knowledge score of prediabetic employees in the experimental and control group

Table 3 : Frequency and percentage distribution of Pre test and post test life style variable score in the groups (N=32)

		Experiment(n=16)		Control(n=16)		Chisquare test
		n	%	n	%	
Pretest	Poor	11	68.8%	10	62.5%	$\chi^2=0.13$ $p=0.71$ not significant
	moderate	5	31.3%	6	37.5%	
	Good	0	0.0%	0	0.0%	
Posttest	Poor	2	12.5%	9	56.3%	$\chi^2=9.70$ $p=0.01$ significant
	moderate	9	56.3%	7	43.8%	
	Good	5	31.3%	0	0.0%	

Not significant $P > 0.05$ * significant at $P \leq 0.05$ ** highly significant at $P \leq 0.01$ *** very high significant at $P \leq 0.001$

Section 2.2.2: Comparison of pre-test and post-test life style variable score of prediabetic employees in the experimental and control group.

Table 4 showed the comparison of pre test and post test level of life style variable score in both the groups. In the experimental group, the mean life style variable score was 48.25 in pre-test, and 66.19 in posttest. So the mean difference score is 17.94. This difference showed very high statistical significance using Wilcoxon signed Rank test at < 0.001 .

In the control group, the mean life style variable score was 49.69 in the pre-test, and 51.56 in the post-test. So the mean difference score is 1.89. This difference did not show any statistical significance. This indicates that the diabetic risk reduction package administered to the employees in the experimental group had a significant effect in increasing the life style in comparison to the control group who did not receive the intervention.

Table 4: Comparison of pre-test and post-test life style variable score of prediabetic employees in the experimental and control group (N=32).

	Pre test		Post test		Mean difference	Wilcoxon signed-rank test
	Mean	SD	Mean	SD		
Experiment	48.25	4.02	66.19	6.13	17.94	$Z=3.59$ $P=0.001$ *** significant
Control	49.69	3.50	51.56	4.81	1.89	$z=1.83$ $P=0.07$ not significant

Not significant $P > 0.05$ * significant at $P \leq 0.05$ ** highly significant at $P \leq 0.01$ *** very high significant at $P \leq 0.001$

The figure 2 showed that the post-test life style variable score of the experimental group was significantly higher than that of the pre-test, whereas the pre-test and post-test scores of the control group are almost similar, indicating that the administration of Diabetic risk reduction package to the experimental group had a significant effect in improving the life style score.

Section 2.3.1: Comparison of pretest and post test biophysiological measures of prediabetic employees in the experimental group.

Table 5 showed the comparison of pre test and post test level of in experimental group. In the experimental group, the mean BMI score was 28.95 in pre-test, and 28.48 in posttest. So the mean difference score is 0.47. This difference showed statistical significance using Wilcoxon signed Rank test at <0.05. The other variables waist circumference and weight did not show much difference .This indicates that the diabetic risk reduction package administered to the employees in

the experimental group had a significant effect in the reduction of the BMI in comparison to the control group who did not receive the intervention.

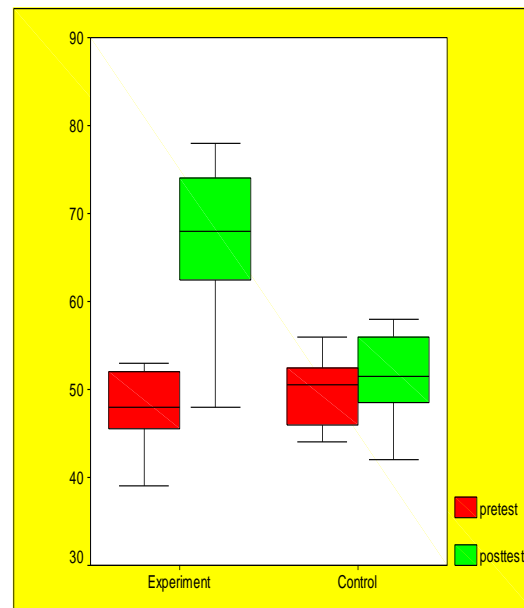


Figure- 2: Box-plot comparing pre-test and post-test life style variable score of prediabetic employees in the experimental and control group.

Table 5: Comparison of pre-test and post-test Biophysiological variables of prediabetic employees in the experimental group (N=16).

	Group				Mean Difference	Wilcoxon signed-rank test
	pretest		posttest			
	Mean	SD	Mean	SD		
Weight	66.87	12.63	65.81	10.97	0.94	Z=0.67P=0.50
BMI	28.95	4.85	28.48	4.90	0.47	Z=2.03P=0.05*
Waist Circumference	94.88	6.73	94.41	6.78	0.47	Z=1.58P=0.11
FBS	102.00	1.79				
HbA1c	5.84	.19				

Not significant P >0.05 * significant at P ≤ 0.05 ** highly significant at P ≤ 0.01 *** very high significant at P ≤ 0.001

Section 3: Correlation of Mean Difference Level of Knowledge, Life Style and Biophysiological Variable in the Experimental and Control Group.

Among the experimental group there was a significant, mild positive correlation between knowledge and lifestyle, where as there was negative fair correlation between knowledge and biophysiological variables (weight and BMI). There also existed negative fair correlation between life style and biophysiological variables. It means that when knowledge score increases life style modifications occur and this in turn leads to REducation of Biophysiological measures within normal limits. Among the

control group there is an insignificant, poor correlation between knowledge, life style and biophysiological measures.

DISCUSSION

The main focus of this study was to test the reliability and feasibility of the data collection tools and intervention tool and its acceptability and effectiveness in enhancing the understanding of the prediabetic employees regarding Prediabetes and encouraging them to incorporate the specified, simple, non-pharmacological measures to prevent or delay diabetes and there by improve living. The results

indicated that assessment tools used are highly reliable.

The above findings were consistent with the study M. Y. Bertram, S.S. Lim, J. J. Barendregt, T. Vos, et al (2010) [9] evaluated the cost effectiveness of a screening program for Prediabetes which was followed by a pharmacological intervention (or) life style interventions in order to prevent the onset of diabetes. The effect of lifestyle changes will decline by 10% per year, while the effect of pharmacological intervention remains constant. The dieticians and exercise physiologist need to deliver lifestyle change intervention to support pharmacological intervention.

The pilot study also showed that the enumerative sampling technique based on the set inclusion and exclusion criteria was appropriate for sample selection. The method of administering the Diabetic risk reduction package teaching methods selected and the proposed analytical measures were suitable for the study.

The importance of detecting prediabetic status was emphasized by the study done by Narayanappa D, Rajani HS, Mahendrappa KB, Prabhakar AK on 726 children aged 5-10 years were screened for Prediabetes from three schools in Mysore by analysis of fasting blood glucose and the prevalence was only 3.7%. Recognition of asymptomatic prediabetic stage is needed to prevent the development of diabetes. [9]

The comparison within and between the groups in this pilot study showed that there was a statistical significance indicating that the diabetic risk reduction package and the overall plan was effective feasible and practicable to be applied in the main study.

LIMITATIONS

- It was not possible to do FBS after one month.
- Some of the questions were not clear so they will be reframed for the main study.

CONCLUSION

- The pilot study on effectiveness of diabetic risk reduction package on knowledge, lifestyle and biophysiological measures among prediabetic employees in the selected schools Thiruvallur District revealed that the data collection tools used was reliable, feasible and appropriate to be applied to the samples in the main study
- The Diabetic risk reduction package was effective in significantly improving the knowledge of employees and helps them in preventing or delaying diabetes. Hence the same plan of research could be applied in the main study.

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