

## RESULTS AND DISCUSSION

The results of the present the study entitled “**Hypoglycemic Effect of Bitter Gourd (*Momordica charantia L.*) on Prediabetics and Type II Diabetics**” is presented under the following headings:

### PHASE I

#### **A. Background information of the selected Type II diabetics**

- a. Socio-economic status
- b. Dietary pattern
- c. Family and personal history of disease condition
- d. Life style pattern

#### **B. Nutritional assessment of the selected Type II diabetics**

- a. Anthropometric measurements
- b. Biochemical estimations

#### **C. Bitter gourd consumption pattern among Type II diabetics**

- a. Purchase of bitter gourd
- b. Frequency and quantity of bitter gourd consumption
- c. Form of bitter gourd consumption
- d. Health benefits of bitter gourd

### PHASE II

#### **D. Development and standardisation of bitter gourd recipes**

- a. Analysis of anti oxidant activity of bitter gourd recipes
- b. Analysis of crude residue percentage
- c. Organoleptic evaluation of bitter gourd recipes

### PHASE III

#### **E. Identification and screening of prediabetics by IDRS**

- a. Age and sex wise distribution of the selected participants
- b. Anthropometric measurements of the selected participants
- c. Physical activity of the selected participants
- d. Family history of the selected participants

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**F. Preface data of the selected prediabetics**

- a. Socio economic status
- b. Dietary pattern
- c. Family history
- d. Life style pattern

**PHASE IV****G. Impact of intervention with bitter gourd juice on prediabetics**

- a. Anthropometric measurements of prediabetics
- b. Mean food and nutrient intake of prediabetics
- c. Measurement of blood pressure level and body fat percentage
- d. Biochemical profile of the prediabetics

**PHASE V****H. Effect of supplementation of bitter gourd on Type II diabetics**

- a. Anthropometric measurements before and after the supplementation
- b. Dietary survey of Type II diabetics
- c. Biochemical profile of the diabetics before and after the supplementation

**PHASE I****A. Background information of the selected Type II diabetics****a. Socio-economic status**

The type of ailment, its degree of severity and access of health services influenced by the demographic profile of the persons and area involved. The demographic profile like age, gender, educational level, occupation, activity pattern, family system and income level of all the 332 Type II diabetics were collected and discussed in the following pages.

**Demographic profile of the selected Type II diabetics**

Demographic profile of the selected 332 Type II diabetics is furnished in Table VII and Figure 3.

**TABLE VII**  
**DEMOGRAPHIC PROFILE OF THE SELECTED TYPE II DIABETICS**

Details	Male		Female		Total	
	Number	Per cent	Number	Per cent	Number	Per cent
<b>Age (years)</b>						
<b>&lt;30</b>	6	3.5	3	1.9	9	2.7
<b>31-40</b>	46	26.6	37	23.3	83	25.0
<b>41-50</b>	59	34.1	55	34.6	114	34.3
<b>51-60</b>	45	26.0	34	21.4	79	23.8
<b>&gt;60</b>	17	9.8	30	18.9	47	14.2
<b>Total</b>	173	100.0	159	100.0	332	100.0
<b>Educational qualification</b>						
<b>Illiterates</b>	15	8.7	29	18.2	44.0	13.3
<b>Primary</b>	28	16.2	37	23.3	65.0	19.6
<b>High school</b>	53	30.6	41	25.8	94.0	28.3
<b>Degree</b>	51	29.5	34	21.4	85.0	25.6
<b>Professional</b>	26	15.0	18	11.3	44.0	13.3
<b>Total</b>	173	100.0	159	100.0	332	100.0
<b>Occupation</b>						
<b>Doctor</b>	1	0.6	-	0.0	1	0.3
<b>Engineer</b>	9	5.2	5	3.1	14	4.2
<b>Government</b>	35	20.2	21	13.2	56	16.9
<b>Private</b>	26	15.0	24	15.1	50	15.1
<b>Farmer</b>	63	36.4	22	13.8	85	25.6
<b>Business</b>	18	10.4	5	3.1	23	6.9
<b>House wife</b>	-	0.0	75	47.2	75	22.6
<b>Retired</b>	21	12.1	7	4.4	28	8.4
<b>Total</b>	173	100.0	159	100.0	332	100.0
<b>Activity</b>						
<b>Sedentary</b>	129	74.6	89	56.0	218	65.7
<b>Moderate</b>	35	20.2	67	42.1	102	30.7
<b>Heavy</b>	9	5.2	3	1.9	12	3.6
<b>Total</b>	173	100.0	159	100.0	332	100.0

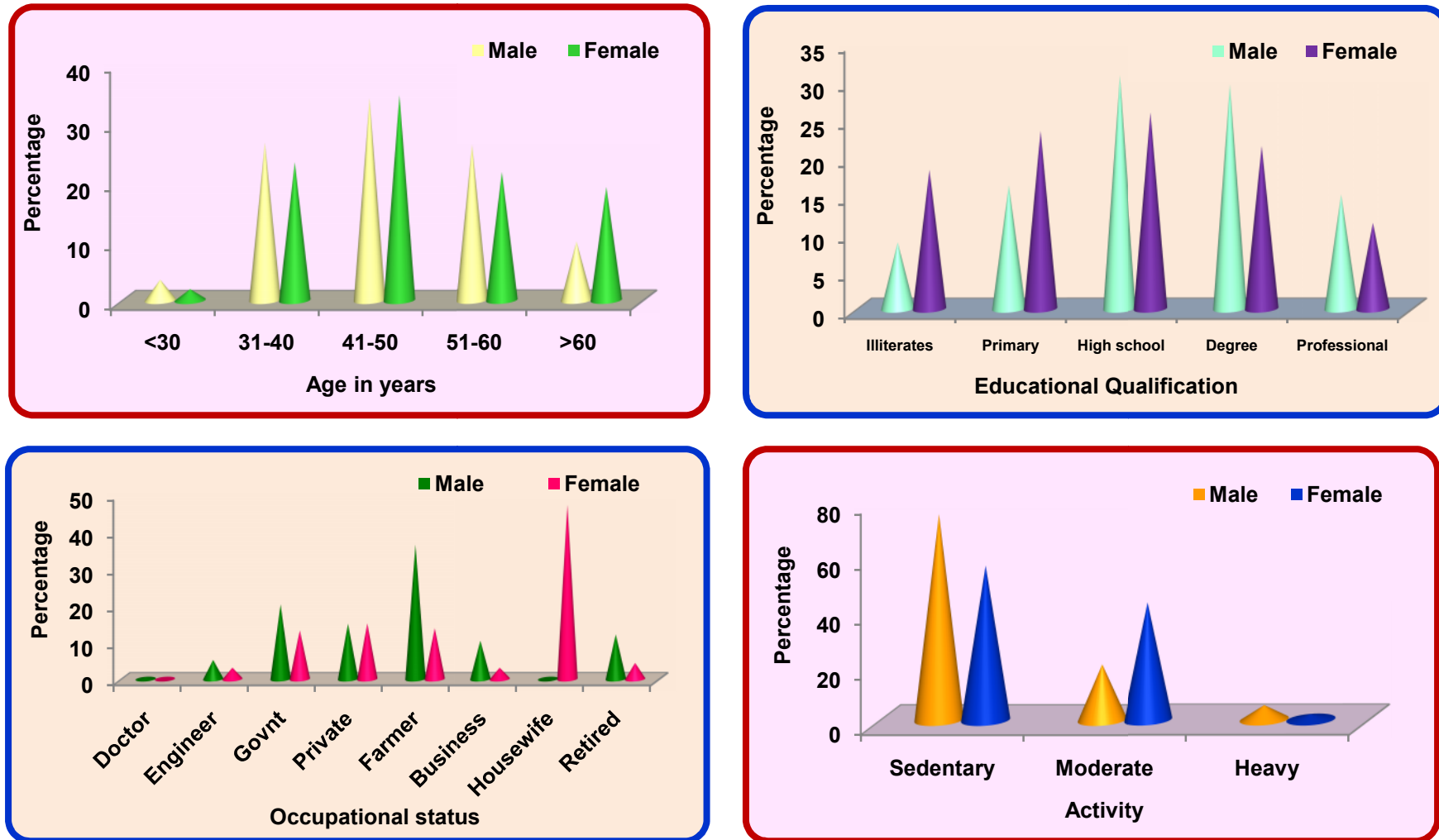


FIGURE 3. DEMOGRAPHIC PROFILE OF THE SELECTED TYPE II DIABETICS

Among the 332 Type II diabetics surveyed, 173 subjects (52.1 per cent) were male and 159 subjects (47.9 per cent) were female.

National Institute for Health Care Excellence (2011) states that being older than 40 years is an important risk factor for developing Type II diabetes and its related health crisis. This is true with the present study that a higher percentage (34.1) of male diabetics were in the age group between 41-50 years. Around 26.6 and 26 per cent of the selected male diabetics were in the age group between 31-40 and 51-60 years respectively. About 9.8 per cent of the male diabetics were elderly with more than 60 years. Only 3.5 per cent of type II diabetics were young adults with 30 years of age and below.

Majority of the selected female Type II diabetics (34.6 per cent) were in the age group between 41-50 years followed by 23.3 and 21.4 per cent in the age group between 31-40 and 51-60 years respectively. About 18.9 per cent of the female Type II diabetics were geriatrics with more than 60 years of age. About 1.9 percentage was less than 30 years of age.

Of the selected 332 Type II diabetics 34.3 per cent were in the age group ranging between 41-50 years. Higher prevalence of diabetes in this younger and economically productive age certainly imposes the burden on financial development of the nation. Diabetes exerts in adults and leads to a significant burden to individual and national income losses by increased morbidity and mortality, decreased life expectancy and reduced quality of life (Mohan *et al.*, 2013). Around 25 and 23.8 per cent of the selected Type II diabetics were in the age group between 31-40 and 51-60 years respectively. Only 14.2 per cent of the Type II diabetics were more than 60 years. Only 2.7 percentage of Type II diabetics were less than 30 years of age.

It was saddening to note that around 13.3 per cent of the selected Type II diabetics were uneducated. About 28.3 per cent were educated up to high school and 25.6 per cent were graduates and 13.3 were highly qualified with a professional degree.

From the 159 female subjects, majority of 25.8 per cent were studied up to high school level. Low educational status was observed among female when

compared to male 23.3 per cent had studied up to primary level, 21.4 per cent were degree holders and 11.3 per cent had studied up to professional level of education. About 18.2 per cent of the female diabetics were illiterates which has strong influence on their blood sugar level (Agardh *et al.*, 2008).

Occupational status has asymmetric effects on health condition. A higher percentage (36.4 per cent) of selected male Type II diabetics were doing farming followed by 20.2 per cent employed in Government offices. Agriculture is the backbone of Indian economy where more than half of the total workforce employed in the agricultural sector (Ramanakumar, 2005). The other occupations by the diabetics were in private industries/companies (15 per cent), retired personnel (12.1 per cent) and doing business (10.4 per cent). Among the surveyed Type II diabetic only one person is a professional doctor.

With regard to the occupation of women, majority (47.2 per cent) of them were housewives. About 15.1 per cent of the female subjects were working in private industries. Similar percentages (13.8 and 13.2) of the female subjects were doing farming and government jobs respectively.

According to Madaan *et al.*, (2014) modernization of life style using modern techniques had made the human population more sedentary, which is one of the main etiological factor for diabetes. This is on par with the present study that the majority (65.7per cent) of Type II diabetics were deskbound with sedentary activity (74.6 per cent male and 56 per cent female). Consequently 20.2 per cent male and 42.1 per cent female diabetics were doing moderate activity. Only a minimum of 5.2 per cent and 1.9 per cent of male and female respectively were doing heavy activity. The rapidly increasing economic status affected the cultural lifestyle during the last decades, pushing towards physical inactivity and sedentary behavior which is a leading cause for the increasing rate of obesity which could also be an important contributing factor for the higher prevalence of metabolic syndrome (Alokail *et al.*, 2010).

### Income level

Income level of the selected diabetics is presented in Table VIII and Figure 4.

TABLE VIII

## INCOME LEVEL OF THE SELECTED TYPE II DIABETICS

Income Level*	Male		Female		Total	
	Number	Per cent	Number	Per cent	Number	Per cent
Economically Weak	18	10.4	32	20.1	50	15.1
Low	28	16.2	30	18.9	58	17.5
Middle	74	42.8	78	49.1	152	45.8
High	53	30.6	19	11.9	72	21.7
Total	173	100.0	159	100.0	332	100.0

\* Twelfth five year plan (2007 - 2012)

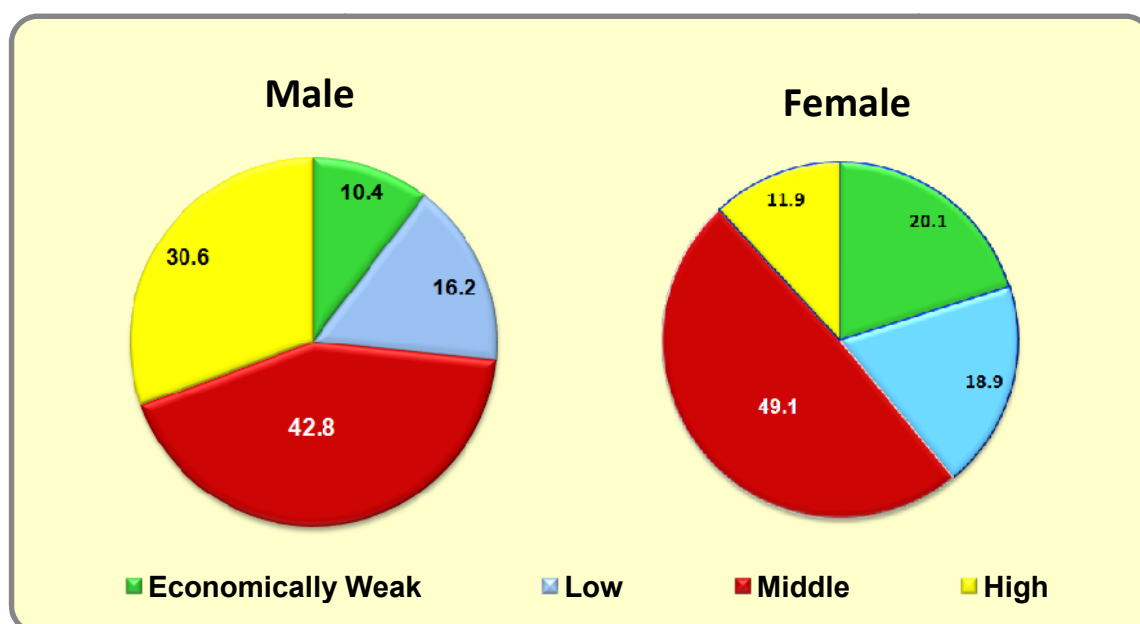


FIGURE 4. INCOME LEVEL OF THE SELECTED TYPE II DIABETICS

Socio Economic Status (SES) may influence access to and quality of care, social support and availability of community resources. It may also influence diabetes-related knowledge, communication with providers, treatment choices and the ability to adhere to recommended medication, exercise and dietary regimens. Thus, low SES could be associated with multiple risks. First, epidemiological studies have repeatedly confirmed the inverse association between Type II diabetes and SES (Espelt *et al.*, 2011).

Majority (45.8 per cent) of the selected diabetics were in the middle income group earning with ₹. 7500-14500 per month as their family income followed by 21.7 per cent in the high income group earning more than ₹.14500 per month. Among the selected diabetics, 17.5 per cent were in the low income group and 15.1 per cent in the economically weaker section. In the present study, the income had an influence on the diabetes management as reported by Corsi and Subramaiyan, (2012) that the household wealth was the strongest socioeconomic factor associated with self-reported diabetes, suggesting that social and behavioral changes associated with diabetes in India may be more closely related to increasing wealth and/or standard of living than educational attainment.

**b. Dietary pattern**

**Dietary habit and meal pattern**

Dietary habit and meal pattern of the Type II diabetics is given in Table IX.

**TABLE IX  
DIETARY HABIT AND MEAL PATTERN**

Dietary habit & Meal pattern	Male		Female		Total	
	Number	Per cent	Number	Per cent	Number	Per cent
<b>Vegetarian</b>	42	24.3	46	28.9	88	26.5
<b>Non vegetarian</b>	131	75.7	113	71.1	244	73.5
<b>Total</b>	173	100.0	159	100.0	332	100.0
<b>No.of meals</b>						
<b>≤2</b>	49	28.3	107	67.3	156	47.0
<b>3</b>	116	67.1	29	18.2	145	43.7
<b>4 and above</b>	8	4.6	23	14.5	31	9.3
<b>Total</b>	173	100.0	159	100.0	332	100.0

Dietary intake is a significant modifiable environmental risk factor in the onset and prevention of Type II diabetes. From the Table it is revealed that around 75.7 per cent male and 71.1 per cent female diabetic subjects were non vegetarians consuming fleshy foods like meat, fish and egg. Around 24.3 and 28.9 percent of male and female diabetics respectively were vegetarians.

It was discouraging to note that 67.3 per cent of females skip their breakfast and are having only two meals a day. Since majority of females were housewives, they had the habit of drinking more number of tea instead of meals. But 67.1 per cent males were consuming 3 meals a day.

About 43.7 per cent of the selected diabetics were having three meals a day regularly and around 9.3 per cent of the diabetics were eating more than three meals. As per the instructions given by the doctors, they were consuming small and frequent meals.

**Type of fats and oils used by the selected Type II diabetics**

Table X and Figure 5 shows the type of fats and oil used by the selected diabetics.

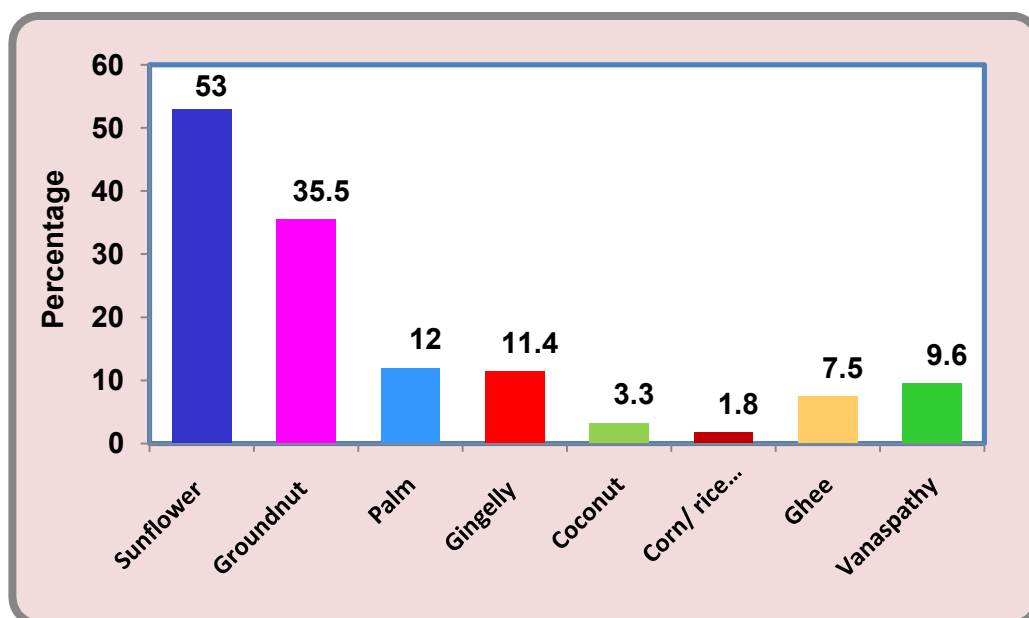
**TABLE X**  
**TYPE OF FATS AND OIL USED BY THE TYPE II DIABETICS**

Type of oil used	Number*	Per cent
Sunflower oil	176	53.0
Groundnut oil	118	35.5
Palm oil	40	12.0
Gingelly oil	37	11.4
Coconut oil	10	3.3
Others (corn, rice bran)	6	1.8
Ghee	25	7.5
Vanaspathy	32	9.6

\*Multiple responses

In recent decades, refined vegetable oils have become more abundant and inexpensive and an increasing number of meals and snacks are being consumed outside the home. Fast and snack foods are generally high in fat and commonly contain trans fats, both of which can contribute to insulin resistance (Colles *et al.*, 2013). This is true with the present study that the refined sunflower oil was preferred and used by 53 per cent of the diabetic subjects followed by 35.5 per cent using

ground nut oil since groundnut is one of the important crop cultivated in their own land or borrowed from neighbours. About 12 per cent of the selected subjects were using palm oil mainly due to the economically weaker section as the palm oil distributed by Government at subsidized rate. Gingelly oil was used by around 11.4, 3.3 and 1.8 per cent of the diabetics were using coconut oil and other oils like corn and rice bran oil respectively. It was noted that the selected diabetics were not particular of using the same oil and were using combinations of oil. They also reported that for some recipes like dosa they used ground nut oil, for few preparations like porriyal coconut oil and for other preparations with tamarind using gingelly oil for better taste.



**FIGURE 5. TYPE OF FATS AND OIL USED BY THE TYPE II DIABETICS**

Economic advancement has also altered eating patterns and food availability. Palm oil consumption increased from 29 per cent to 50 per cent from 2001-2002 to 2011-2012 ( 11 years) while the use of soybean and mustard oils reduced. Around 9.6 per cent of the diabetics were using vanaspathy and 7.5 per cent were using ghee respectively.

### **Food consumption pattern**

The food consumption pattern of the selected diabetics is presented in Table XI.

**TABLE XI**  
**FOOD CONSUMPTION PATTERN OF THE TYPE II DIABETICS**

Foods	No. of servings*/ Day	Male		Female	
		Number	Per cent	Number	Per cent
Cereals	4-6	76	43.9	68	42.8
	6-8	97	56.1	91	57.2
Pulses	< 4	106	61.3	88	55.3
	4-6	67	38.7	71	44.7
Vegetables	< 3	115	66.5	92	57.9
	3-4	47	27.2	58	36.5
	> 4	11	6.3	9	5.6
Fruits	< 2	122	70.5	118	74.2
	2-3	47	27.2	41	25.8
Milk and milk products	> 3	4	2.3	-	-
	< 2	137	79.2	110	69.2
	2-4	33	19.1	38	23.9
Non vegetarian foods	> 4	3	1.7	11	6.9
	No	42	24.3	46	28.9
	2-3	58	33.5	68	42.8
Snacks/ Junk foods	> 3	73	42.2	45	28.3
	<2	42	24.3	65	40.9
	2-3	81	46.8	48	30.2
Water	> 3	50	28.9	40	25.2
	2-4 glasses	38	22.0	26	16.4
	4-8 glasses	92	53.2	84	52.8
	> 8 glasses	43	24.8	49	30.8

\*AHA Note:1 serving =1 slice bread, 1/2 cup cooked rice or grain products, 1cup raw or 1/2 cup cooked vegetables, 1 medium size fruit or ½ cup fruit, 1/2 cup juice, 1 cup milk, 1/3 cup meat, poultry or fish.

Cereals continue to remain by far the most important food source in the world, contributing 50 per cent of calories and as much as 54 per cent in developing countries. Their contribution to energy intake varies markedly between developing and industrial countries. In developing countries such as Africa and parts of Asia, cereals contribute as much as 70 per cent of energy intake, while in industrial

countries, for example, the UK, approximately 30 per cent and 50 per cent of energy intake from available carbohydrates. It is projected that in 2050, the share of calories from cereal food s will declines slowly from 54 per cent in 2001 to 49 per cent in 2030 and 46 per cent in 2050 (Alexandratos, 2006).

From the Table XI, it is evident that 56.1 per cent of males and 57.2 per cent of females consumed 6-8 servings of cereals like rice, wheat, ragi, bajra and more of processed foods. Majority (61.3 per cent males and 55.3 per cent females) of the diabetics consumed less than four servings of pulses.

In case of vegetable consumption among the selected subjects, higher number (male 115, female 92) of the subjects had less than three servings per day. According to NIMS (2009) people consumed vegetables four to seven days in a week and fruits two to three days in a 'week'. Fruit consumption was higher in urban areas but no difference was noticed in vegetable consumption across rural and urban. The proportion of respondents eating less than five servings of fruits and vegetables ranged from 76 per cent in Maharashtra to 99 per cent in Tamil Nadu.

The Green Leafy Vegetables (GLV) consumption was found to be moderate since they consume locally available greens like drumstick leaves, siru keerai etc. The consumption of fruits was found to be very meager and was observed that 70.5 and 74.2 percent of males and females had less than two servings.

With regard to milk and milk products, maximum per cent of diabetics used less than two servings due to tea and coffee consumption. Only very few subjects drink milk regularly.

Majority of male (42.2 per cent) diabetic consumed non vegetarian foods like, egg or chicken more than three servings daily. Around 46.8 per cent of male subjects had two to three servings of snacks like deep fat fried snacks like vadai, bajji, bonda, chips and murrukku along with tea or coffee. About half of the selected subjects drink 4-8 glasses of water regularly.

Bishwajit *et al.*, (2014) discussed about the trends of food consumption and stated that Asian countries have entered a stage of nutrition led by phenomenal economic growth in past few decades. In Asia, rapid nutrition transition is marked by

a declining intake of cereals, legumes, vegetables and an increasing intake of dairy, fish, meat and meat products. Food balance data from the Food and Agriculture Organization (FAO) shows that the change in energy intake in Asian countries have been small but there have been large changes in consumption of animal products, sugars and fats. There appears to be a surge in meat consumption in the Asian countries. Animal protein has become increasingly important in Asian diets over the past decades and the consequences for health have been enormous. In the present study also, the same trend of food consumption like fewer servings of fruit and vegetables and more number of meat and meat products and snacking pattern was observed.

### c. Family and personal history of the disease condition

Diabetes has already been described as an epidemic, but predictions for increases in prevalence, especially in developing countries leads to a major health care crisis for the future. The high costs of treatment of diabetes amongst all socioeconomic patient groups will result in a serious burden on both patients and state resources alike (Tharkar and Devarajan, 2010). Hence details family and personal history related to the present condition, frequency of visit to clinics, monthly expenditure were collected, analysed and discussed below:

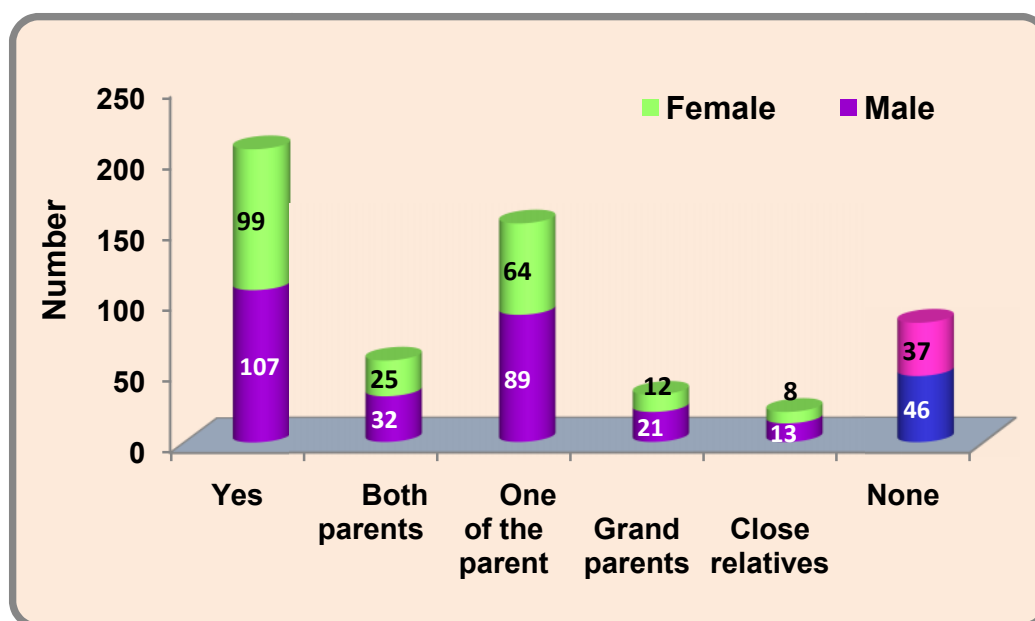
#### Family history of diabetics

Table XII and Figure 6 elucidates the family history of the Type II diabetics.

**TABLE XII**  
**FAMILY HISTORY OF TYPE II DIABETICS**

Family history	Male	Female
<b>Yes*</b>	<b>107</b>	<b>99</b>
<b>Both parents</b>	32	25
<b>One of the parents</b>	89	64
<b>Grand parents</b>	21	12
<b>Close relatives</b>	13	8
<b>No</b>	46	37

\*Multiple responses



**FIGURE 6. FAMILY HISTORY OF TYPE II DIABETICS**

Family history of diabetes is not only a risk factor for the disease but is also positively associated with risk awareness and risk-reducing behaviors. It can provide a useful screening tool for detection and prevention of diabetes (Das *et al.*, 2012).

The lifetime risk of developing the disease is approximately 40 per cent in offspring of one parent with Type II diabetes, greater if the mother is affected, and approaching 70 per cent if both parents have diabetes (Lyssenko and Laakso, 2013). This is on par with the findings of the present study that 107 male and 99 female diabetics were having a history of diabetes in their family. Majority of diabetics (male 89 and female 64) were having a single parental history of this disease.

From the surveyed diabetics, it is inferred that both the parents were affected with diabetics for 32 male and 25 female followed by 89 male and 64 female diabetics with single parental history of the disease. About 21 male and 12 female diabetics grandparents were affected by diabetes. The maternal and paternal relatives of the 13 male and eight female diabetics were having previous episodes of diabetes. Around 46 male and 37 females were not having any family history of diabetics.

### Frequency of visit to clinics by the diabetics

Frequency of visit to clinics by the selected diabetics is given in Table XIII.

**TABLE XIII**  
**FREQUENCY OF VISIT TO CLINICS**

Frequency	Number	Per cent
Monthly	142	42.8
More than six times a year	115	34.6
Two to six times a year	38	11.4
Once a year	22	6.6
Rarely	15	4.5
Total	332	100.0

The above Table reveals that 42.8 per cent of the selected diabetics were health conscious and knew the importance of visiting the clinics regularly and were visiting the clinics once in a month. According to Joshi *et al.*, (2008) wide disparities in socio economic level, educational background and non availability of diabetes care are some of the major hurdles in the management of diabetes or any other chronic diseases in India. Patient-related barriers like lack of awareness, poor motivation, economic constraints, denying risk, stress, fear, confusion, immediate benefits not seen, lack of family and social support, lack of trust in health care providers, changing behavior and sustaining the changes are difficult which results in neglect the management of diabetes. This reflects with the present study that more than 50 per cent of the diabetics were not visiting the clinics regularly.

Around 34.6 per cent of the selected subjects were visiting the hospitals more than six times a year. Only a minimum of 11.4 and 6.6 per cent of the diabetics were going to the hospitals occasionally and once in a year. None of the diabetics visited the doctor every week because most of them got their own glucometer to monitor the blood glucose level and considered it to be economic.

### Monthly expenditure towards the disease condition

Table XIV indicates the medical expenditure details by the Type II diabetics.

**TABLE XIV**  
**MONTHLY EXPENDITURE TOWARDS THE DISEASE CONDITION**

Details	Expenditure per month in ₹.					
	Free	>100	100-500	600-1000	1100-2000	>2000
Diabetic medicine	4	20	82	135	63	28
Visit to the clinic	12	32	254	34	0	0
Analysis of blood profile	28	76	184	27	12	5

It is clear from the Table that out of 332 diabetics about 135 members spent ₹. 600-1000 per month, followed by 82 of them spending ₹. 100-500 per month for diabetic medicines. Around 63 and 28 diabetics spent ₹. 1100-2000 and more than ₹. 2000 towards medications respectively for their diabetic condition along with its other complications.

Long standing diabetes mellitus is associated with an increased prevalence of micro vascular and macro vascular diseases (Soumya and Srilatha, 2011). With the rising prevalence of diabetes, the number suffering from the vascular complications of diabetes will also increase. Government hospitals in the city provide free consultation, blood check up and treatment for the disease condition. This was the main reason for not spending money towards medication, doctors fees and blood analysis among the diabetics by the low income group.

Majority of the diabetics (N-254) spent ₹.100-500 towards doctors fee, 32 diabetics spent less than ₹.100 and only 34 diabetics spent ₹.600-1000 for paying the doctor.

High number (184) of subjects spent ₹.100-500 for blood analysis followed by 76 and 27 diabetics doing blood analysis of the cost less than ₹.100 and ₹. 600-1000 respectively. Only five diabetics spent more than ₹. 2000 due to the other complications.

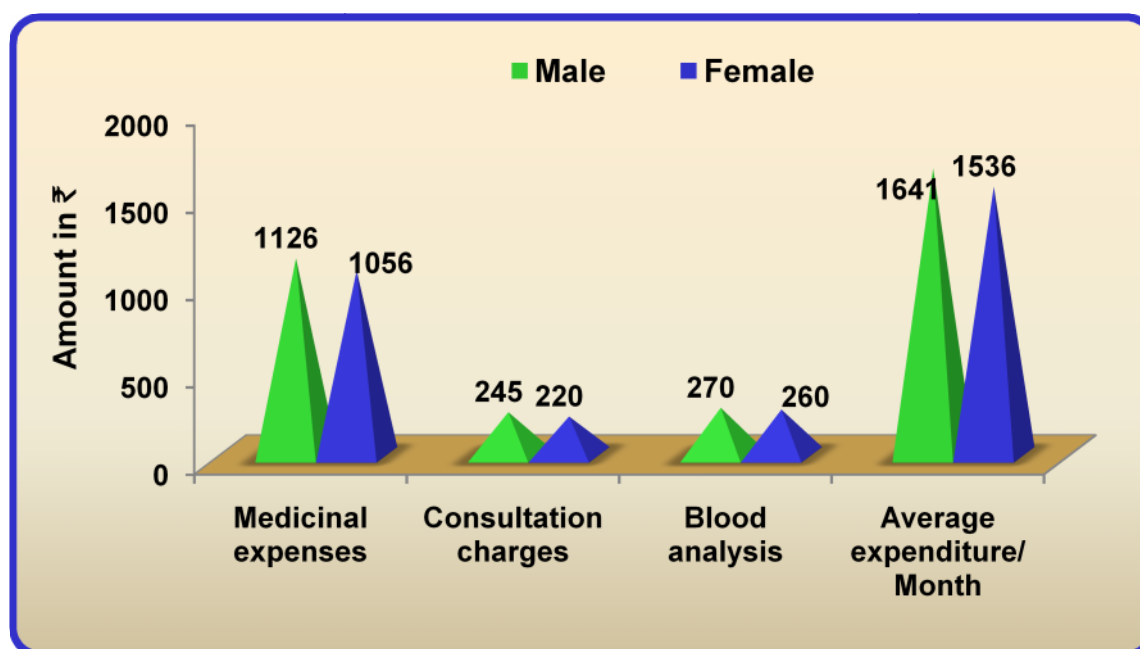
### Medical expenditure of the selected diabetics

Table XV and Figure 7 presents the monthly medical expenditure of the diabetics studied.

**TABLE XV**  
**MEDICAL EXPENDITURE OF THE DIABETICS**

Expenditure (₹)	Male	Female
<b>Medical expenses</b>	1126	1056
<b>Consultation charges</b>	245	220
<b>Blood analysis</b>	270	260
<b>Month medical expenditure</b>	1641	1536
<b>Average monthly income</b>	20,180	13,765
<b>Percentage of income spent per month</b>	<b>12.3</b>	<b>8.98</b>

The above Table highlights that the mean monthly income of the male and female subjects were ₹ 20,180 and ₹ 13765 respectively. The mean expenditure incurred by the male and female diabetes were ₹ 1641 and ₹ 1536 per month respectively.



**FIGURE 7. MEDICAL EXPENDITURE**

About 12.3 per cent and 8.98 per cent of the monthly income was spent towards hypoglycemic drugs, doctors fee and blood analysis by the male and female subjects respectively. Diabetes being a life-long disorder is an expensive ailment for a very large proportion of subjects in developing societies. In India the money was

spent from the family's financial resources. Although the amount spent by the upper and the lower class persons were similar, the percentage of the income spent was higher among the latter which is due to their lower earning (Mohan *et al.*, 2003).

A study from Chennai reported on costs from 2008 and 2009 found that total costs for diabetics without complications were INR 4,493 (USD 92.15) compared to INR 14,691.75 (USD 301.32) for diabetics with complications. Consultation and hospitalization costs were especially higher for diabetics with complications (on average INR 1,085 (USD 22.25) for consultation costs and INR 5,256 (USD 107.80) for hospital costs compared to diabetics without complications INR 350 (USD 7.18) for consultation costs and INR 1,083 (USD 22.21) (Kumapatla *et al.*, 2013).

According to the Cost of Diabetes in India (CODI) and Bangalore Urban District (BUD) diabetes studies, ambulatory care constitutes 65 per cent cost whereas the hospitalization cost is 35 per cent and therapy cost is 31 per cent of which specific anti diabetic drug cost is only 17 per cent. Ambulatory care including monitoring and doctor visits constitute 34 per cent costs (Kapur, 2007).

In a study by Grover *and* Avasthi (2005), the total annual cost of care for 50 patients of the sample population was ₹ 14,508 (263.78 euros). The largest proportion of the total cost was made up of direct costs (68 per cent), followed by indirect costs (28.76 per cent) and provider's costs (2.8 per cent). Drug costs were also high. Total treatment cost was significantly higher in those who were more educated, those who visited the hospital more often, and those receiving a greater number of drugs.

#### **d. Life style pattern**

Lifestyle variables include meal habits, exercise state, drinking state and smoking state. Life style modification can be a very effective way to keep diabetes in control. Improved blood glucose control can slow the progression of long term complications. Multiple small changes can lead to improvements in diabetes control, including a decreased need for medication (Khan, 2012).

Diabetics who consume alcohol may have severe health consequences and so those subjects were excluded from this study. So the smoking pattern and exercise pattern of the 332 diabetics were collected and given below:

### Smoking pattern

Details regarding the smoking pattern of the selected diabetics is given in Table XVI.

**TABLE XVI**  
**SMOKING PATTERN OF THE TYPE II DIABETICS**

Smoking Pattern	Number	Per cent
Yes	81	46.8
No	92	53.2
<b>Chewing tobacco</b>		
Yes	46	28.9
No	113	71.1

Wakabayashi (2014) reported that smokers have 30 per cent to 40 per cent higher risk of diabetes than non smokers. From the 173 male diabetics surveyed, 81 diabetics were having the habit of smoking cigarette or beedi. None of the female diabetics had the habit of smoking. Subjects with diabetes who smoke have double the risk of premature death compared to non-smokers with diabetes. Furthermore, the risk of complications connected with tobacco use and diabetes in combination is nearly 14 times higher than the risk of either smoking or diabetes alone (Haire and Thomas 2005).

Out of 153 female diabetics surveyed, 46 subjects had the habit of chewing betel leaves and tobacco.

### Exercise pattern of Type II diabetics

Lack of exercise is one of the vital cause for the development of Type II diabetes. Table XVII depicts the physical activity pattern of the Type II diabetics.

**TABLE XVII**  
**EXERCISE PATTERN OF TYPE II DIABETICS**

Details	Male		Female		Total	
	Number	Per cent	Number	Per cent	Number	Per cent
<b>Yes</b>	61	35.3	48	30.2	109	32.8
<b>No</b>	112	64.7	111	69.8	223	67.2
<b>Total</b>	173	100.0	159	100.0	332	100.0
<b>Type of Exercise</b>						
<b>Walking</b>	53	30.6	31	19.5	91	27.4
<b>Yoga &amp; meditation</b>	4	2.3	5	3.1	9	2.7
<b>Cycling</b>	14	8.1	2	1.3	16	4.8

Physical activity is a defensive factor for the development of diabetes. Al-Kaabi *et al.*, (2009) reported that not only physical activity, but leisure time activity is also an important factor for the development of Type II diabetes. The prevalence of diabetes among hard working group was lower when compared to sedentary workers. Gill and Cooper (2008) also support the fact that physical activity has a protective role in the development of Type II diabetes. An imbalance between physical activity and calorie intake can lead to obesity, which results in insulin resistance and is common in Type II diabetes (www.niddk.nih.gov, 2014).

In the present study, it is saddening to note that only 35.3 per cent male and 30.2 female diabetics were doing regular exercise. Maximum of 67.2 percentage of the selected diabetics were not doing any kind of exercise which in turn increases the micro vascular and macro vascular complications of diabetes.

Walking is the preferable type of exercise by 30.6 per cent of male and 19.5 percent of female diabetics respectively. Few diabetics (8.1 percent male and 1.3 percent female) were using cycle for daily routine activity. Yoga and meditation were done by 2.7 percentages of diabetics only.

## B. NUTRITIONAL ASSESSMENT OF THE SELECTED TYPE II DIABETICS

Nutritional assessment is one of the important step in the management of diabetes. Anthropometric measurements, dietary survey and biochemical profile were collected and discussed below:

### a. Anthropometric measurements

For all the selected 332 diabetics, anthropometric measurements like height, weight, waist circumference were measured and Body Mass Index (BMI), Waist to Height Ratio (WHtR) and Conicity Index (CI) were calculated, tabulated and discussed below:

#### Height

Height of the selected 332 Type II diabetics is depicted in Table XVIII.

**TABLE XVIII**  
**HEIGHT OF THE SELECTED TYPE II DIABETICS**

Height in cm	Reference value*	Male		Reference value*	Female	
		Number	Per cent		Number	Per cent
141-150		2	1.2		42	26.4
151-160		32	18.5		65	40.9
161-170	172.3 cm	83	48.0	161 cm	38	23.9
>171		56	32.4		14	8.8
<b>Total</b>		173	100.0		159	100.0

#### \*ICMR 2010

Among the 173 selected diabetics maximum of 48 per cent of male diabetics had their height ranging between 161-170 cm which is below the reference value and 32.4 per cent had more than 171 cm as their height. About 18.5 per cent of male had their height in the range of 151-160 cm.

In the case of female diabetics, 40.9 per cent had their height ranging between 151-160 cm that is also below the ICMR reference value and 23.9 per cent of them are having their height ranging between 161 and 170 cm.

## Weight

Weight of the selected 332 Type II diabetics is shown in Table XIX.

**TABLE XIX**  
**WEIGHT OF THE SELECTED TYPE II DIABETICS**

Weight in Kg	Reference value*	Male		Reference value*	Female	
		Number	Per cent		Number	Per cent
41-50	60 kg	8	4.6	55 kg	21	13.2
51-60		19	11.0		56	35.2
61-70		59	34.1		38	23.9
71-80		41	23.7		31	19.5
>81		46	26.6		13	8.2
<b>Total</b>		173	100		159	100

### \*ICMR 2010

Out of 173 male diabetics selected, 34.1 per cent were in the weight range of 61-70 kg followed by 26.6 per cent above 81 kg of body weight and 23.7 per cent had their body weight ranged between 71-80 kg.

In the case of female diabetics, 35.2 per cent were in the weight range of 51-60 kg which is considered as normal as per ICMR reference value. But the mean weight of the screened male and female were 71.37 and 62.59 kg which were well above the standard reference weight as recommended by ICMR (2010) conforming even modest changes in weight was associated with substantial increase in diabetes risk (National Institute for Health and Care Excellence, 2011). It is clear that overweight was predominant among the selected Type II diabetics.

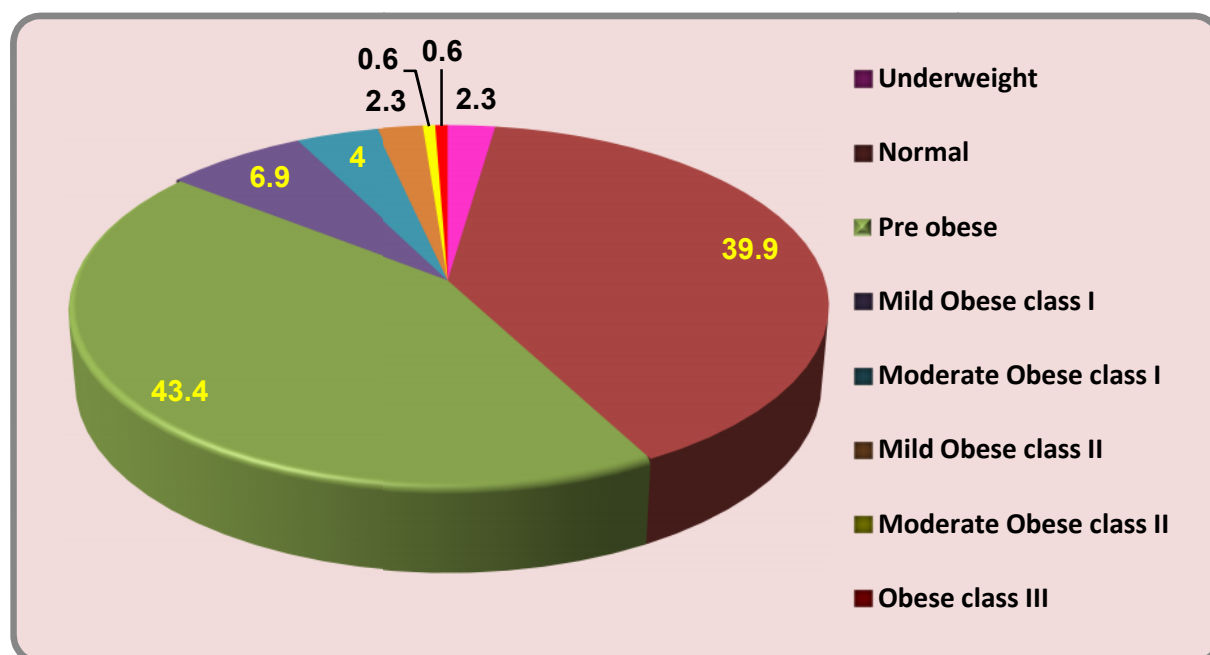
### Body Mass Index

Table XX and Figure 8 represents the body mass index of the selected 332 Type II diabetics.

**TABLE XX**  
**BODY MASS INDEX OF THE SELECTED TYPE II DIABETICS**

BMI Classification*		Male		Female		Total	
		Number	Per cent	Number	Per cent	Number	Per cent
<18.49	Underweight	4	2.3	7	4.4	11	3.3
18.5 – 24.9	Normal	69	39.9	76	47.8	145	43.7
25.0-29.9	Pre obese	75	43.4	58	36.5	133	40.1
30.0- 32.49	Mild obese class I	12	6.9	10	6.3	22	6.6
32.5-34.9	Moderate obese class I	7	4.0	6	3.8	13	3.9
35.0- 37.49	Mild obese class II	4	2.3	2	1.3	6	1.8
37.5-39.9	Moderate obese class II	1	0.6	0	0.0	1	0.3
≥40.0	Obese class III	1	0.6	0	0.0	1	0.3
<b>TOTAL</b>		<b>173</b>	<b>100.0</b>	<b>159</b>	<b>100.0</b>	<b>332</b>	<b>100</b>

\* WHO 2004



**FIGURE 8. BODY MASS INDEX OF THE SELECTED TYPE II DIABETICS**

From the above Table XX, it was noted that among the 173 male diabetics, 43.4 per cent of them were considered as pre obese having BMI ranging from 25 to 29.9 followed by 39.9 per cent had normal BMI of 18.5 to 24.9 and very few of 2.3 per cent of male diabetics were underweight.

Almost 6.9 and four per cent of the selected diabetics were under mild and moderate obese class I category respectively, 2.3 per cent of them were in mild obese class II category and only 0.3 per cent each were in moderate obese class II and obese class III category.

From the above Table it is clear that, among the 159 female diabetics, 47.8 per cent of them had their BMI between 18.5 to 24.99 and are considered normal. Around 36.5 per cent fall under the pre obese category, 6.3 per cent fall under mild obese class I category, 3.8 per cent were under moderate obese class I category, 1.3 per cent fall under mild obese class II category.

From Table XX, it is clearly opined that only 43.7 per cent of the selected diabetics were normal and almost three per cent were underweight, more than 50 per cent were above normal and belong to the category of pre obese and different obesity grades.

Mean body mass index determined for the screened male and female were 26.05 and 25.23 respectively which shows that they were in pre obese category which is also associated with increased risk of diabetes. A multiethnic cohort study identified that incident diabetes risk, adjusted for age, sex, socio demographic characteristics and BMI, was significantly higher for South Asians (20.8/1,000 person-years; HR 3.40), blacks (16.3/1,000; 1.99), and Chinese (9.3/1,000; 1.87), compared with non-Hispanic whites (9.5/1,000) (Chiu *et al.*, 2011).

### **Waist circumference, waist to height ratio and conicity index**

Table XXI depicts waist circumference, waist to height ratio and conicity index of the selected 332 Type II diabetics.

**TABLE XXI**  
**WAIST CIRCUMFERENCE, WHtR AND CI OF TYPE II DIABETICS**

Anthropometric measurements	Male			Female		
	Ref. value	Mean $\pm$ SD	Excess	Ref. value *	Mean $\pm$ SD	Excess
Waist circumference*	<90	92.72 $\pm$ 10.15	+2.72	<80	88.42 $\pm$ 8.73	+8.42
Waist to height ratio**	0.536	0.56 $\pm$ 0.06	+0.024	0.492	0.56 $\pm$ 0.06	+0.068
Conicity Index***	1.25	1.30 $\pm$ 0.10	+0.05	1.18	1.30 $\pm$ 0.15	+0.12

\*ICMR 2010 \*\* (Xin *et al.*, 2012), \*\*\* (Valdez *et al.*, 1993)

The findings of the present study was similar to those of the study conducted by Farzad *et al.*,(2012), in which it was reported that waist circumference and conicity index were superior to BMI for identifying visceral adiposity, metabolic disorders and cardiovascular risk factors. The above table reveals that the mean waist circumference of the female subjects were much higher (8.42) than the reference value. Male diabetics also showed an elevated waist circumference compared to the reference value of <90 cm.

A novel marker of adiposity, the conicity index, was associated with the 10 year risk of fatal coronary heart disease events in patients with Type II diabetes. Conicity index values above 1.35 increased the odds of high coronary heart disease risk by 69 per cent (Tonding *et al.*, 2014).

The above Table clearly says that the female diabetics had higher mean waist to height ratio ( 0.068) and conicity index (0.12) than the desirable levels. The mean waist to height ratio and conicity index of the 173 male diabetics were also faintly higher than that of the reference values.

It is concluded that the anthropometric measurements like waist circumference, waist to height ratio and conicity index of both male and female diabetics of the present study is much elevated when compared to the reference values.

### b. Biochemical estimations

Biochemical parameters like fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin and lipid profile of the selected 332 Type II diabetics were discussed below.

#### Mean blood glucose levels of the selected Type II diabetics

The mean blood glucose levels of the selected 332 Type II diabetics is described in Table XXII and Figure 9.

TABLE XXII

MEAN BLOOD GLUCOSE LEVELS OF THE SELECTED TYPE II DIABETICS

Blood glucose	Desirable level *	Mean $\pm$ SD	
		Male	Female
Fasting Blood Glucose (mg/dl)	$\geq 126$	142.00 $\pm$ 42.73	144.23 $\pm$ 51.70
Postprandial Blood Glucose (mg/dl)	$\geq 200$	224.29 $\pm$ 67.44	226.75 $\pm$ 79.16
Glycosylated hemoglobin HbA1c (per cent)	$\geq 6.5$	8.10 $\pm$ 1.49	8.29 $\pm$ 1.79

\*NDEP2011

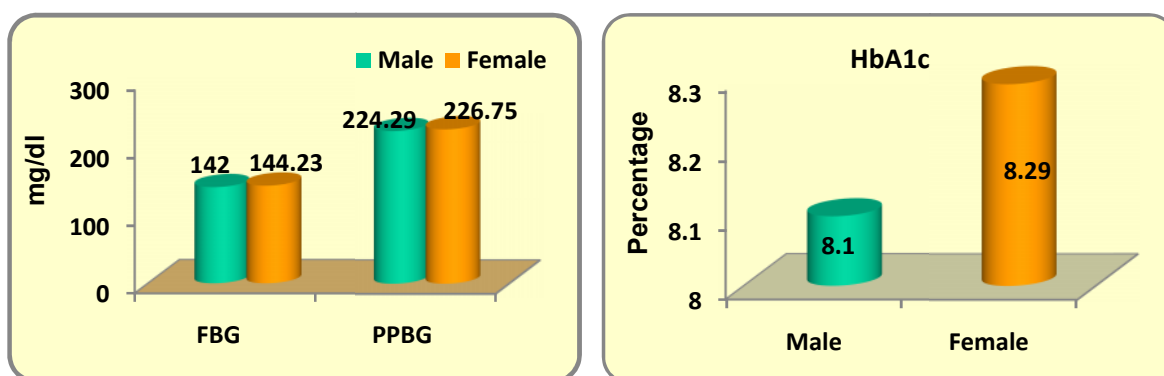


FIGURE 9. MEAN BLOOD GLUCOSE LEVELS OF THE TYPE II DIABETICS

Elevated blood glucose at all times is the commonest finding in Type II diabetic patients. The observed patterns of mean fasting blood glucose in female diabetics were especially higher (144.23 mg/dl) than male diabetics (142 mg/dl) which was well above the reference value. The present study is in accord with the study by Madaan *et al.*, (2014) that the mean fasting plasma glucose in males was

149.36 ± 19.51 mg/dl and females was 147.43 ± 18.19 mg/dl. Mean 2 hour postprandial plasma glucose was 259.94 ± 51.36 mg/dl and 259.65 ± 51.39 mg/dl in male and female respectively.

It is increasingly recognized that postprandial hyperglycemia is an important component of the overall glycemic burden, though there is as yet a paucity of data showing that lowering of Postprandial Plasma Glucose (PPG) reduces risk of Type II diabetes complications (Blevins, 2011). The mean postprandial levels of the male and female subjects were 224.29 and 226.75 mg/dl respectively.

HbA1c values reflect overall glycemic exposure over the past two to three months and are determined by both fasting (FPG) and postprandial plasma glucose levels. Among the 332 surveyed diabetics the mean HbA1c levels were 8.29 per cent for female and 8.10 per cent for male diabetics respectively. This is on par with the preliminary results from the Diabcare India 2011 study in the mean HbA1c of 8.97 ± 2.2 per cent for more than 6000 diabetics in India and shows the poor glycemic control in India (Mohan *et al.*, 2012).

#### Lipid profile of the selected Type II diabetics

The mean lipid profile of the selected 332 Type II diabetics is presented in Table XXIII and Figure 10.

TABLE XXIII

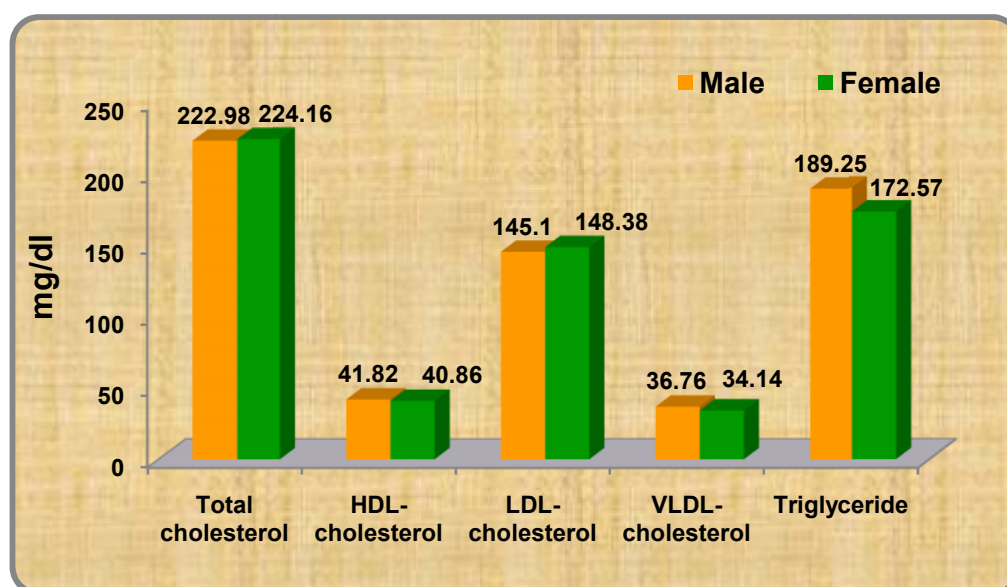
#### MEAN LIPID PROFILE OF THE SELECTED TYPE II DIABETICS

Lipid profile (mg/dl)	Desirable levels *	Mean ±SD	
		Male	Female
Total - cholesterol	< 200	222.98 ± 34.62	224.16 ± 18.84
HDL- cholesterol	> 50	41.82 ± 8.6	40.86 ± 7.27
LDL- cholesterol	< 130	145.1 ± 34.28	148.38 ± 22.11
VLDL- cholesterol	< 30	36.76 ± 16.55	34.14 ± 11.01
Triglyceride	< 150	189.25 ± 98.35	172.57 ± 54.54

\*National Cholesterol Education Program-ATP IV Guidelines (NCEP), 2012

Abnormalities in lipoproteins are very common in non insulin dependent diabetes mellitus. Diabetes leads to changes in the plasma lipid and lipoprotein

profile thereby raise the risk of cardio vascular disease. In subjects with Type II diabetes hyper triglyceridemia and low HDL-cholesterol levels are common (Parmer *et al.*, 2011). The present study support with the above statement that the mean serum total cholesterol of the 173 male subjects were found to have 222.98 mg/dl, mean HDL cholesterol was recorded as 41.82 mg/dl, 145.1 mg/dl as mean LDL cholesterol, 189.25 mg/dl was recorded for triglycerides and as an average of 36.76 mg/dl for VLDL cholesterol.



**FIGURE 10. MEAN LIPID PROFILE OF THE SELECTED TYPE II DIABETICS**

Out of the 159 female subjects, mean total cholesterol level was found to be 224.16 mg/dl, average HDL cholesterol values were found to be 40.86 mg/dl, mean LDL cholesterol was 148.38 mg/dl, triglyceride level was 172.57 mg/dl and the average VLDL cholesterol level recorded was 34.14 mg/dl.

Mean total cholesterol, LDL cholesterol, triglyceride and VLDL cholesterol values of the diabetics were higher than the desirable values. The mean HDL cholesterol values were lower when compared with the desirable values.

### **C. Bitter gourd consumption pattern among Type II diabetics**

Among the selected Type II diabetics, details regarding the mode of purchase, preparations, frequency and quantity of bitter gourd consumption pattern were elicited and presented below.

### a. Purchase of bitter gourd

#### Details on the mode of purchase of bitter gourd

Table XXIV presents the details regarding the mode of purchase of bitter gourd by the selected diabetics

**TABLE XXIV**  
**MODE OF PURCHASE OF BITTER GOURD**

Details	Number*	Per cent
Street vendors	145	43.7
Daily market	124	37.3
Own garden	35	10.5
Super market	22	6.6
Neighbours or friends	18	5.4
Other sources	8	2.4

\* Multiple responses

It is noted from the above Table that 43.7 per cent of diabetics purchased bitter gourd from street vendors because it is easily available at doorsteps. Around 37.3 per cent procured bitter gourd freshly from the daily market. Around 10.5 per cent of the diabetics had bitter gourd creeper in their own garden and cultivated the vegetables and 6.6 per cent of the diabetics purchased from super market.

#### Precooking process done to bitter gourd

Precooking process done to bitter gourd is presented in Table XXV.

**TABLE XXV**  
**PRECOOKING PROCESS DONE TO BITTER GOURD**

Details	Number	Per cent
No treatment	220	66.3
Soak the cut pieces in salt added water	83	25.0
Soak the cut pieces in tamarind juice	56	16.9
Soak the cut pieces in rice washed water	5	1.5
Leave the cut pieces at room temperature	2	0.6

\* Multiple responses

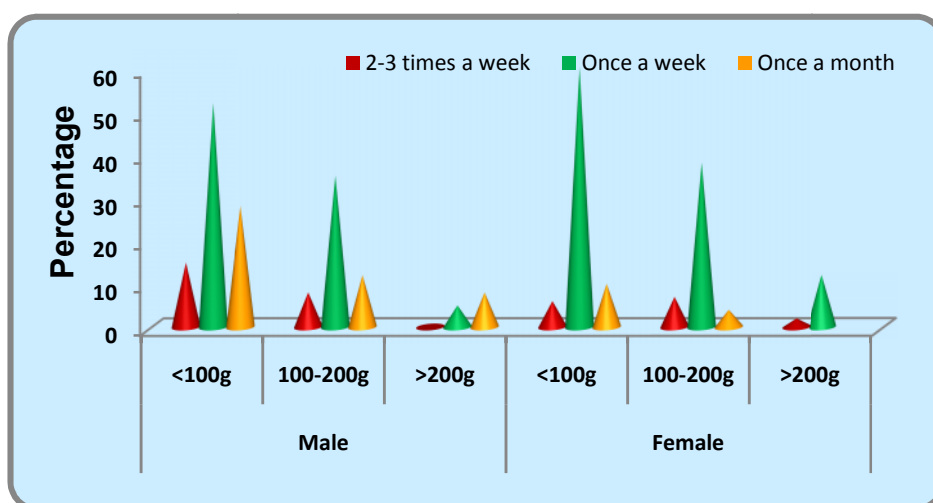
Majority (66.3 per cent) of the subjects were not doing any pre cookery treatment. Around 25 and 16.9 per cent of the diabetics soaked the bitter gourd pieces in salt added water and tamarind juice for 10-20 minutes respectively before cooking to remove bitterness. Only five members soaked the bitter gourd after cutting in rice washed water and two subjects left out the pieces exposing to atmosphere for some time to remove bitterness. In Pakistan, a traditional way to cook bitter gourd curry is to peel off the skin and cut into thin slices and is cooked with lots of onions. It is salted and exposed to direct sunlight for few hours to reduce its bitterness. (<http://www.medicalhealthguide.com/articles/ampalaya.htm>).

**b. Frequency and quantity of bitter gourd consumption**

Table XXVI and Figure 11 explains the quantity and frequency of bitter gourd consumption by the selected Type II diabetics.

**TABLE XXVI**  
**FREQUENCY AND QUANTITY OF BITTER GOURD CONSUMPTION**

Frequency	Male			Female		
	<100g	100-200g	>200g	<100g	100-200g	>200g
2-3 times a week	15	8	-	6	7	2
Once a week	52	35	5	60	38	12
Once a month	28	12	8	10	4	
Never eat		10			14	



**FIGURE 11. FREQUENCY AND QUANTITY OF BITTER GOURD CONSUMPTION**

Out of 332 diabetics surveyed, 60 female and 52 male diabetics were consuming 100 g of bitter gourd once in a week, followed by 38 female and 35 male subjects consuming 100-200 g of bitter gourd once in a week and 12 female and five male subjects were consuming more than 200 g of bitter gourd weekly.

About 28 male and 10 female subjects were consuming less than 100 g followed by 12 male and four female subjects consuming 100-200 g of bitter gourd once in a month. Only eight male diabetics were having more than 200 g bitter gourd monthly.

A least number of subjects 15 male and 6 female subjects consuming 100g of bitter gourd frequently, followed by eight male and seven female subjects consuming 100-200 g of bitter gourd very often, a bare minimum of two female subjects consuming more than 200 g of bitter gourd frequently. From the studied subjects 10 male and 14 female diabetics never like to eat bitter gourd because of its resentment.

**c. Form of bitter gourd consumption**

Table XXVII depicts the form in which the bitter gourd was consumed by the diabetic subjects.

**TABLE XXVII  
FORM OF BITTER GOURD CONSUMPTION**

Mode of preparation	Male	Female
Curry	84	60
Shallow fat fried	47	36
Deep fat fried	38	30
Juice	5	2
Boiled/Cooked	4	-

Majority (84 male and 60 female) of the subjects consumed bitter gourd in the form of gravy or curry. The word “curry” is derived from the Tamil kari, meaning something similar to “sauce”. Bitter gourd is a popular vegetable in Tamil Nadu and

in Kerala. They use it for making a dish called thoran mixed with grated coconut, theyyal and pachadi. This is one of the common medicinal food for patients with diabetes. Popular bitter gourd recipes include curry, deep fry with groundnuts and 'Pachi Pulusu' a kind of soup made up of boiled bitter gourd, fried onions and other spices (Anilakumar *et al.*, 2015).

Study by Snee *et al.*, (2011) reports the similar form of bitter gourd that immature fruits of bitter gourd can be prepared in many ways such as frying or curries. Bitter gourd was usually blanched or soaked in salt water before cooking to reduce the bitter taste.

Shallow fat frying is the next accepted method of cooking bitter gourd by 47 male and three female followed by 38 male and 30 female subjects consuming deep fat fried bitter gourd chips as a snack. Four male diabetics consumed bitter gourd in boiled form and two diabetics were taking raw bitter gourd in the form of salad. In southern part of India, bitter gourd is used by mixing with freshly grated coconut and fried or even added in the popular sambar to make it a healthy and nutritious dish. Bitter gourd fry is best when served with hot tandoori bread, naan, chapatti or rice and lentil.

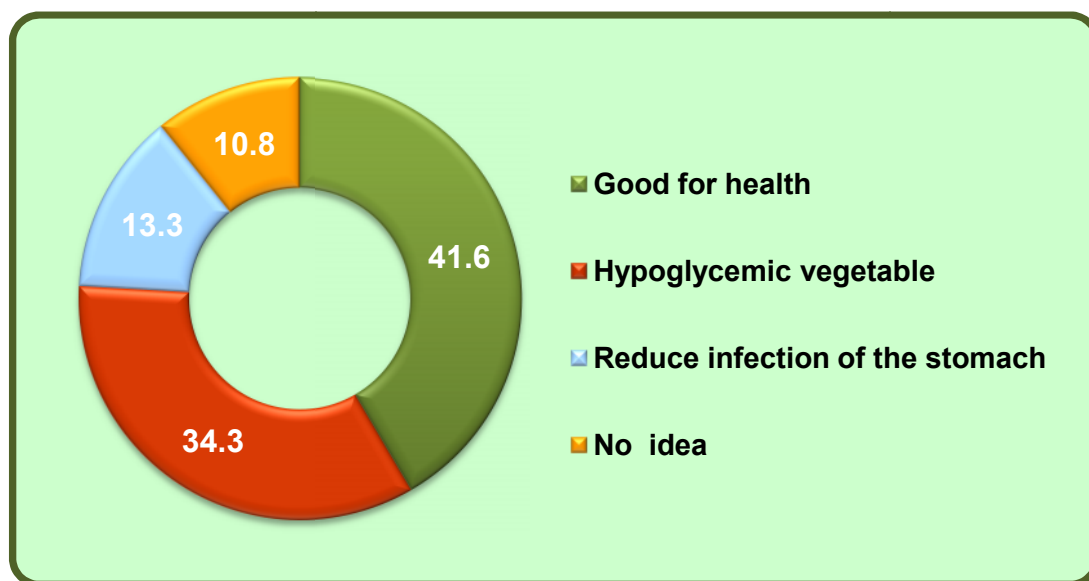
**d. Health benefits of bitter gourd**

Table XXVIII and Figure 12 shows the health benefits of bitter gourd as described by the diabetics.

**TABLE XXVIII**

**HEALTH BENEFITS OF BITTER GOURD**

Details	Number	Per cent
Good for health	138	41.6
Hypoglycemic vegetable	114	34.3
Reduces infection of the stomach	44	13.3
No idea	36	10.8
<b>Total</b>	<b>332</b>	<b>100.0</b>



**FIGURE 12. HEALTH BENEFITS OF BITTER GOURD**

Bitter melon has been used in various Asian traditional medicine systems for a long time. It is evidenced from the Table that 41.6 per cent of the diabetics believed that bitter gourd is good for general health, 34.3 per cent reported that bitter gourd helps to decrease the sugar level and a few (13.3 per cent) members informed that it reduces the stomach infection. In Ayurveda medicine, bitter gourd is considered as stomachic, stimulant, emetic, antibilious, laxative and alterative (Kumar *et al.*, 2010).

### Sources of Information on bitter gourd

Sources of information gained with regard to bitter gourd health benefits by the diabetics is illustrated in Table XXIX.

**TABLE XXIX**

### SOURCES OF INFORMATION GAINED BY THE DIABETICS

Sources	Number*	Per cent
Market/Vegetable shops	8	2.4
Radio and other medias	23	6.9
Neighbours or friends	53	16.0
Family members	218	65.7
Health personnel	73	22.0
Hearsay	27	8.1

\* Multiple responses

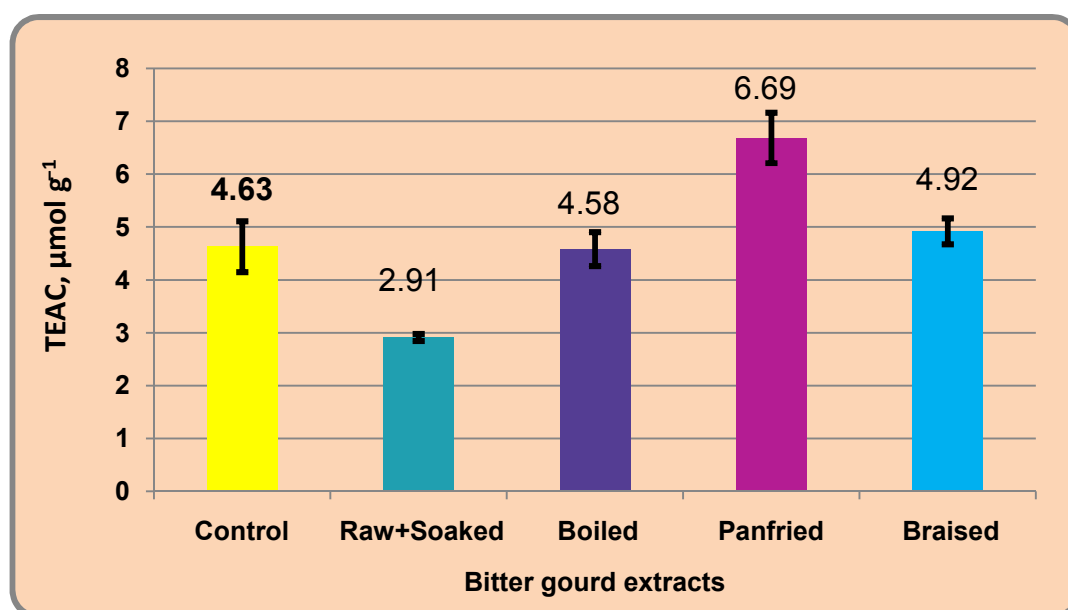
Among the 332 diabetics surveyed, 65.7 per cent obtained the information about the health benefits of bitter gourd from their family members. About 22 per cent of the diabetics gained information from the doctor and 16 per cent of the diabetics received the information from the neighbours and friends. Media played a minute role in spreading the health effects of bitter gourd (6.9 per cent) and the aged population are not computer literates and have minimum access to internet. About 8.1 per cent of the subjects were not able to specify the source and they said word of mouth or hearsay.

## PHASE II

### D. Development and standardisation of bitter gourd recipes

#### a. Analysis of anti oxidant activity of bitter gourd

Bitter gourd samples were prepared using different cooking methods and anti oxidant activity analysed is illustrated in Figure 13.



ANOVA with post hoc  $p \leq 0.001$

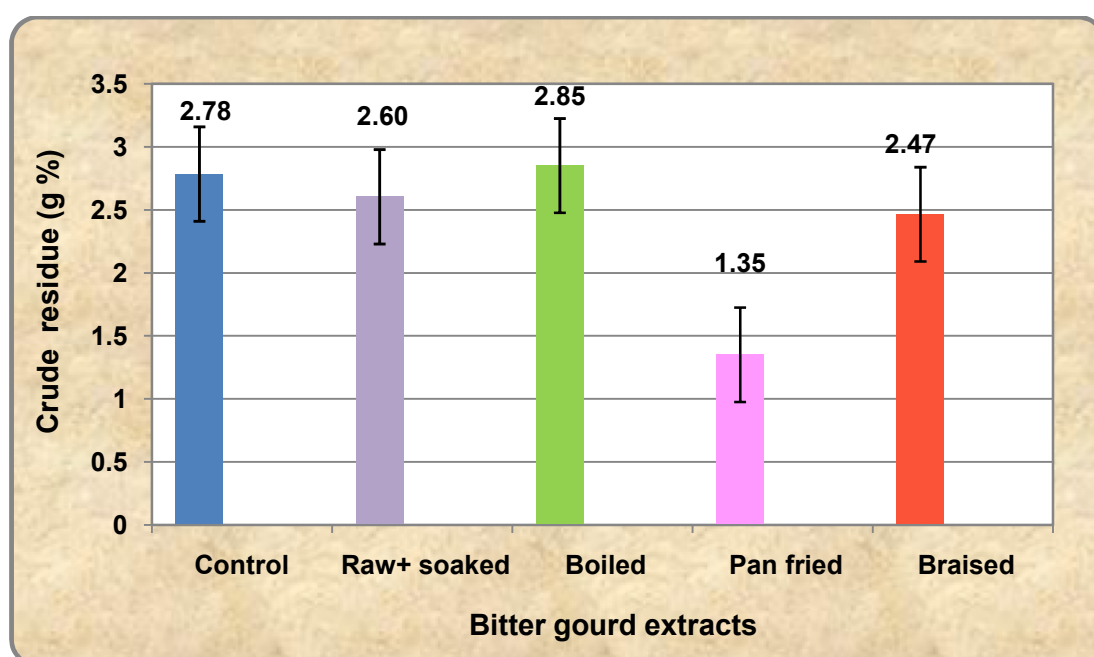
**FIGURE 13. ANTIOXIDANT ACTIVITY OF THE BITTER GOURD EXTRACTS**

Bitter gourd possess potent antioxidant activity, which may be directly or indirectly responsible for its hypoglycemic property. In the present study the anti oxidant activity ranged from 2.91 in raw+soaked samples to 6.69 in pan fried

samples. In raw+soaked as well as boiled samples, the process of cooking reduced the anti oxidant level to the extent 38 per cent and two per cent respectively when compared to control sample. This reduction might be due to the loss of water soluble vitamins which are essential for anti oxidant content of the samples. However the reduction in boiled sample is meager because in this method of cooking, water was not discarded. It was interesting to note that the pan frying method of cooking increased the anti oxidant content to the extent of 45 per cent and braising increased the content to six per cent. The difference in the antioxidant levels of bitter gourd samples with different methods of cooking was found to be statistically significant at ( $p>0.001$ ) level.

#### b. Analysis of crude residue percentage

The crude residue obtained after the bitter gourd extraction using different cooking methods is shown in Figure 14.



**FIGURE 14. CRUDE RESIDUE PERCENTAGE OF THE BITTER GOURD EXTRACTS**

From the figure it is revealed that the crude residue obtained from the bitter gourd extracts ranged from 1.35 to 2.85 g fresh percentage. Raw preparations (2.6 g per cent) and boiled (2.85 g per cent) bitter gourd showed similar crude

residue compared with control (2.78 g per cent) where as the braised (2.47 g per cent) extract showed a reduction in the crude residue weight. The pan fried extract (1.35 g per cent) exhibited a high loss in the crude residue weight.

### c. Organoleptic evaluation of bitter gourd recipes

Table XXX presents the mean acceptability scores of bitter gourd recipes with different cooking methods as assessed by diabetic and non diabetic panels.

Table XXX reveals that among the six methods of cooking, raw and boiling preparations received low mean acceptability scores. For the sensory evaluation of raw preparation, two bitter gourd juices one mixed with amla and other with lemon juice were chosen. As raw and boiled preparations were predominantly bitter, their acceptability scores were low. Acceptability scores for raw preparations given by the diabetic taste panel was significantly greater when compared to that of non diabetics ( $P < 0.05$ ). This might be because they were aware of the health benefits of bitter gourd consumption. Frying method resulted in browning of bitter gourd which received the highest acceptability score for the appearance. The mean scores revealed that the pan fried recipes were well accepted by the diabetic subjects when compared to non diabetics though the difference was not significant. The stir fried recipes namely bitter gourd fried rice, noodles and bitter gourd pachadi received almost similar scores by both the panels.

Using the braising method, three different curries were prepared and almost same acceptability scores were recorded by both the groups of taste panel and the difference was not found to be significant. In these recipes bitter gourd absorbed the taste of the other ingredients and got reduced in the bitterness. Crispy karela, bitter gourd dhal powder and the microwave cooked recipe were well accepted by the non diabetics compared to diabetic taste panel. Except the raw preparations none of the cooking methods brought about significant difference in the total acceptability scores recorded by the diabetic and non diabetic groups of taste panel.

TABLE XXX

MEAN ACCEPTABILITY SCORES OF BITTER GOURD RECIPES COOKED IN DIFFERENT METHODS (Max. scores-9)

Cooking methods	Taste panel	Appearance	Taste/ Flavor	Texture/ Consistency	Aroma/ Smell	Overall Acceptability	't' value for overall acceptability ND Vs D
Raw preparations	Non diabetics (ND)	7.2±1.22	7.2±1.12	7.1±0.99	7.1±1.14	7.1±1.01	1.77*
	Diabetics (D)	7.8±0.89	7.6±0.97	7.6±0.79	7.8±0.89	7.9±0.9	
Boiling method	Non diabetics	7.5±1.2	6.6±1.83	7.2±1.75	6.7±1.95	6.8±1.8	0.849 <sup>NS</sup>
	Diabetics	7.15±1.01	7.1±0.89	7.2±0.98	7.15±1.01	7.2±0.98	
Pan fried	Non diabetics	8.1±0.75	7.83±0.86	7.73±0.93	7.9±0.79	7.83±0.90	1.46 <sup>NS</sup>
	Diabetics	8.13±1.15	8.2±1.01	8.03±1.11	8.13±1.08	8.2±1.01	
Stir fried	Non diabetics	8.33±0.65	8.13±0.99	8.27±0.93	8.17±0.86	8.2±0.9	0.466 <sup>NS</sup>
	Diabetics	8.23±0.84	8.27±0.77	8.33±0.75	8.3±0.74	8.33±0.76	
Braising	Non diabetics	8.07±0.93	8.17±0.97	8.13±0.99	8.07±0.96	8.33±0.88	0.817 <sup>NS</sup>
	Diabetics	8.47±0.62	8.47±0.72	8.5±0.69	8.47±0.67	8.5±0.68	
Microwave	Non diabetics	8.25±0.83	7.95±0.97	8.3±0.71	8.2±0.81	8.25±0.77	0.856 <sup>NS</sup>
	Diabetics	7.95±1.56	7.85±1.62	7.9±1.51	7.8±1.60	7.9±1.61	

NS - Not Significant; \* significant at P&lt;0.05 level.

### Statistical appraisal of overall acceptability scores

Table XXXI gives the result of the statistical appraisal of the different cooking methods used for the bitter gourd.

**TABLE XXXI**

#### STATISTICAL APPRAISAL OF OVERALL ACCEPTABILITY SCORES OBTAINED FOR DIFFERENT METHODS OF COOKING

Methods compared	t value	
	Non diabetics	Diabetics
Raw preparations vs Boiling	0.737 <sup>NS</sup>	1.64 <sup>NS</sup>
Raw preparations vs Pan frying	2.62*	3.39**
Raw preparations vs Stir frying	3.66**	4.54**
Raw preparations vs Braising	3.93**	5.46**
Raw preparations vs Micro wave cooking	3.22**	1.62 <sup>NS</sup>
Boiling vs Pan frying	2.45*	1.75 <sup>NS</sup>
Boiling vs Stir frying	3.92**	2.62*
Boiling vs Braising	4.32**	3.52**
Boiling vs Micro wave cooking	3.77**	0.473 <sup>NS</sup>
Pan frying vs Stir frying	1.71 <sup>NS</sup>	0.571 <sup>NS</sup>
Pan frying vs Braising	2.16*	1.33 <sup>NS</sup>
Pan frying vs Micro wave cooking	1.67 <sup>NS</sup>	0.792 <sup>NS</sup>
Stir Frying vs Braising	0.435 <sup>NS</sup>	0.895 <sup>NS</sup>
Stir frying vs Micro wave cooking	0.675 <sup>NS</sup>	1.26 <sup>NS</sup>
Braising vs Micro Wave Cooking	0.341 <sup>NS</sup>	1.78 <sup>NS</sup>

NS- Not significant; \* significant at P<0.05 level. \*\*significant at P<0.01 level.

The overall acceptability scores recorded for the different methods of cooking were compared statistically and the results revealed that the acceptability of raw preparations vs boiling method, pan frying vs stir fry, pan frying vs microwave cooking, stir frying vs braising, stir frying vs microwave and braising vs microwave

cooking did not differ significantly. The non diabetics and diabetics revealed the same opinion with regard to the cooking methods used for bitter gourd preparations.

Pan frying, stir frying and braising recorded significantly greater overall acceptability scores than the raw preparations by both the groups of taste panel members. Similarly stir frying and braising received significantly greater acceptability scores than the boiling method of preparation.

In most of the cases there was a general agreement in the acceptability of recipes among the non diabetics and diabetics. However the diabetics did not reveal any significant difference in the acceptability of raw preparation vs microwave cooking, boiled preparation vs pan fried recipes, boiled preparation vs microwave cooked recipes while the acceptability differed significantly for non diabetics subjects.

### PHASE III

#### E. Identification and screening of prediabetics by IDRS

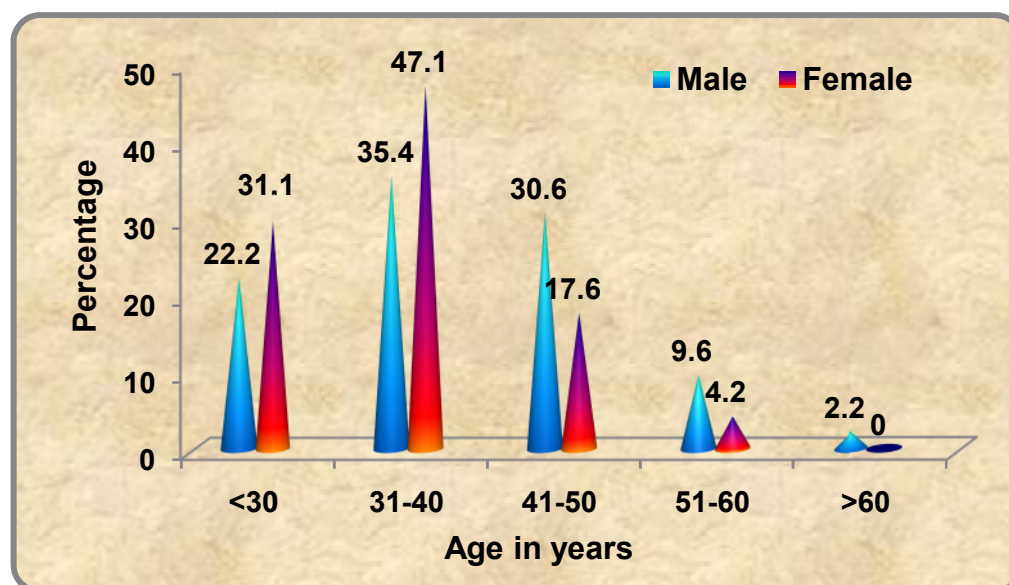
To identify the prediabetics, around 948 participants from different industries were screened using IDRS and their details are furnished below:

##### a. Age and sex wise distribution of the selected participants

Table XXXII and Figure 15 reveals the age and gender wise distribution of the 948 selected population screened using IDRS.

**TABLE XXXII**  
**AGE AND SEX WISE DISTRIBUTION OF THE PARTICIPANTS**

Age in Yrs	Male		Female		Total	
	Number	Per cent	Number	Per cent	Number	Per cent
<30	120	22.2	127	31.1	247	26.1
31-40	191	35.4	192	47.1	383	40.4
41-50	165	30.6	72	17.6	237	25.0
51-60	52	9.6	17	4.2	69	7.3
>60	12	2.2	0	0.0	12	1.3
<b>Total</b>	<b>540</b>	<b>100.0</b>	<b>408</b>	<b>100.0</b>	<b>948</b>	<b>100.0</b>



**FIGURE 15. AGE AND SEX WISE DISTRIBUTION OF THE PARTICIPANTS**

About 948 participants screened, of these 540 (57 per cent) were males and 408 (43 per cent) were females.

A study by Sosale *et al.*, (2014) confirms that the newly diagnosed diabetics were from a younger age between 31-40 years (35 per cent) and almost equal (40 per cent) population was from the age group of 41-50 years. Younger age of onset implies that the most productive years of life is utilized and has a greater chance of rising complications. Both environmental and genetic factors might explain the younger onset of age along with high prevalence of diabetes in the Indian population. Hence the participants aged 25 years onwards were screened to identify the prediabetes.

From the 540 male subjects, most (35.4 per cent) of the selected subjects were in the age group between 31-40 years followed by 30.6 percent were in 41-50 years. Only a minimum of two percent of these selected male subjects were more than 60 years of age.

Among the 408 female subjects screened, a higher percentage (47.1) was in the age between 31-40 years and 31.1 per cent were less than 30 years of age. Around 17.6 per cent and 4.2 per cent were in the age group of 41-50 years and 51-60 years respectively.

## b. Anthropometric measurements of the selected participants

### BMI Classification of participants

Table XXXIII portrays the classification of screened subjects according to their BMI.

**TABLE XXXIII**  
**BMI CLASSIFICATION OF THE PARTICIPANTS**

BMI Classification*		Male		Female		Total	
		Number	Per cent	Number	Per cent	Number	Per cent
<18.49	Underweight	52	9.6	28	6.9	80	8.4
18.5 – 24.9	Normal	304	56.3	168	41.2	472	49.8
25.0-29.9	Pre obese	155	28.7	149	36.5	304	32.1
30.0- 32.49	Mild Obese class I	19	3.5	41	10.0	60	6.3
32.5-34.9	Moderate Obese class I	6	1.1	12	2.9	18	1.9
35.0- 37.49	Mild Obese class II	2	0.4	6	1.5	8	0.8
37.5-39.9	Moderate Obese class II	1	0.2	4	1.0	5	0.5
≥40.0	Obese class III	1	0.2	0	0.0	1	0.1
<b>TOTAL</b>		<b>540</b>	<b>100.0</b>	<b>408</b>	<b>100.0</b>	<b>948</b>	<b>100</b>

\*WHO (2004)

Obesity is one of the key risk factors for diabetes. Despite of having lesser overweight and obesity rates, India has a higher prevalence of diabetes compared to western countries suggesting that diabetes may occur at a much lower body mass index in Indians compared with Europeans (Rao *et al.*, 2011).

Historically, there has been a general acceptance that a BMI cutoff point lower than 25 kg/m<sup>2</sup> would increase the possibility of identifying diabetes or diabetes risk in Asians. Thus in the Diabetes Prevention Program (DPP), a BMI value of 22 kg/m<sup>2</sup> was selected for Asians. American Diabetes Association (2014) indicates that there is compelling evidence that lower BMI cut off points, specifically 24 kg/m<sup>2</sup> in South Asians and 25 kg/m<sup>2</sup> in Chinese, denote increased diabetes risk in some racial and ethnic groups.

It was noticed from the above Table, among the 540 male subjects, 56.3 per cent of them were considered to be normal having BMI ranging from 18.5 - 24.99. Very few of 9.6 per cent of male subjects were underweight. Almost 28.7 per cent of the subjects were in preobese category with the BMI of  $\geq 25$  and are considered to be overweight. 3.5 per cent were under mild obese class I category, 1.1 per cent in moderate obese class I and only 0.2 per cent each in moderate obese class II and obese class III categories respectively.

From the above Table it was clear that, among the 549 female subjects, 41.2 per cent were in normal BMI range between 18.5 - 24.99. Only 6.9 per cent of the females were underweight group whose BMI is  $< 18.49$ . Among these subjects, 36.5 per cent falls under the pre obese category, 10 per cent falls under mild obese class I category, 2.9 per cent were under moderate obese class I category, 1.5 per cent under mild obese class II category and one per cent falls under moderate obese class II category.

### Waist circumference of the selected participants

Classification of screened subjects according to waist circumference is presented in Table XXXIV.

TABLE XXXIV

#### WAIST CIRCUMFERENCE OF THE SELECTED PARTICIPANTS

Waist circumference* (cm)	Male		Waist circumference* (cm)	Female	
	Number	Per cent		Number	Per cent
<90	343	63.5	<80	142	34.8
90-99	138	25.6	80-89	154	37.7
$\geq 100$	59	10.9	$\geq 90$	112	27.5
<b>Total</b>	173	100	<b>Total</b>	159	100

\* WHO (2008)

Among the South Asians, in both men and women, the waist circumference cut-point was consistently lower than in whites which is 102 cm for men or 88 cm for women. Based on findings of Bodicoat *et al.*, (2014) it was recommended a waist circumference threshold of 90 cm for men and 77 cm for women in South Asians.

With regard to waist circumference, a higher percentage (63.5) of the male subjects were in normal range with <90 cm whereas 37.7 per cent of female subjects were having their waist circumference of 80-89 cm and falls in the at risk category. About 27.5 per cent of the female subjects were having  $\geq 90$  cm as their waist circumference in turn increases the metabolic rate.

### c. Physical activity status of the selected participants

Distribution of screened subjects according to their physical activity status of the selected population is given in Table XXXV.

**TABLE XXXV**  
**PHYSICAL ACTIVITY STATUS OF THE SELECTED PARTICIPANTS**

Physical activity	Male		Female		Total	
	Number	Per cent	Number	Per cent	Number	Per cent
Vigorous exercise or manual work at home/work site	0	0.0	1	0.2	1	0.1
Moderate exercise or physical activity at home/work site	15	2.8	6	1.5	21	2.2
Mild exercise or physical activity at home/work site	86	15.9	37	9.1	123	13.0
No exercise and sedentary activities at home/worksite	439	81.3	364	89.2	803	84.7
	540	100	408	100.0	948	100.0

ICMR-INDIAB-5 study by Anjana *et al.*, (2014) revealed that among 14227 individuals studied, 54.4 per cent (n = 7737) were inactive while 31.9 per cent (n = 4537) were active and 13.7 per cent (n = 1953) were highly active. The region-wise prevalence of physical inactivity was as follows: Chandigarh-66.8 per cent, Tamil Nadu- 60.0 per cent, Maharashtra- 55.2 per cent and Jharkhand-34.9 per cent. When extrapolated to the whole country, the estimated number of inactive individuals in India would be 392 million. The present study findings may also

bear same results that higher percent of both male and female (81.3 and 89.2 per cent) of the selected screened subjects were not doing exercise.

About 15.9 percent of male and 9.1 per cent of female belong to mild physical activity category where as 2.8 and 1.5 per cent of the male and female subjects respectively were doing moderate exercise or strenuous work category.

It is very sad to know that about 81.3 per cent of male and 89.2 per cent of female subjects are not doing any exercise and they belong to sedentary activity category which is one of the important risk factor for developing diabetes.

#### d. Family history of the selected participants

Table XXXVI shows the screened subjects according to their family history of diabetes

**TABLE XXXVI**  
**FAMILY HISTORY OF DIABETES**

Family history	Male		Female		Total	
	Number	Per cent	Number	Per cent	Number	Per cent
<b>No genetic history</b>	393	72.8	269	65.9	662	69.8
<b>Single parent</b>	126	23.3	122	29.9	248	26.2
<b>Both parents</b>	21	3.9	17	4.2	38	4.0
<b>Total</b>	540	100	408	100	948	100.0

With regard to the family history, 126 (23.3 per cent) males and 122 (29.9 per cent) females were having positive history of diabetes in one of the parent and 3.9 per cent male and 4.2 per cent female respectively in both parents. Almost similar finding was reported by Kumar *et al.*, (2014) that 32 per cent of the screened subjects were having single parental history and six per cent in both parents.

#### F. Preface data of the selected prediabetics

##### a. Socio - economic status

Socio economic status is a complex indicator of lifestyle, behavior, knowledge of health promotion and access to health services. The age, residence, education and activity of 90 prediabetics selected for clinical trial is presented in Table XXXVII and Figure 16.

**TABLE XXXVII**  
**SOCIO - ECONOMIC BACKGROUND OF THE PREDIABETICS (N=90)**

Socio Economic Details	Male	Female	Total
<b>Age in years</b>			
<30	2	7	9
31-40	19	15	34
41-50	23	10	33
51-60	9	5	14
<b>Area of residence</b>			
Urban	32	22	54
Semi urban	12	7	19
Rural	9	8	17
<b>Education</b>			
Illiterate	6	6	12
Primary	4	5	9
High school	25	13	38
Higher secondary	2	7	9
Graduate	14	5	19
Professional	2	1	3
<b>Activity</b>			
Sedentary	22	22	44
Moderate	23	14	37
Heavy	8	1	9
<b>Type of family</b>			
Nuclear	37	23	60
Joint	16	14	30
<b>Family members</b>			
<3	18	10	28
4-6	31	27	58
>6	4		4
<b>Occupation</b>			
Daily wage	2	8	10
Clerical work/ Helpers	30	4	34
Desk workers	8	6	14
Supervisors	8	3	11
House wife	-	16	16
Others	5	-	5
<b>Nature of job</b>			
Permanent	21	11	32
Temporary	32	10	42
No job	0	16	16
<b>Income level*</b>			
Economically weak	6	3	9
Low	5	7	12
Middle	26	15	41
High	16	12	28

\*Report of technical group[11<sup>th</sup> five year plan2007-2012]

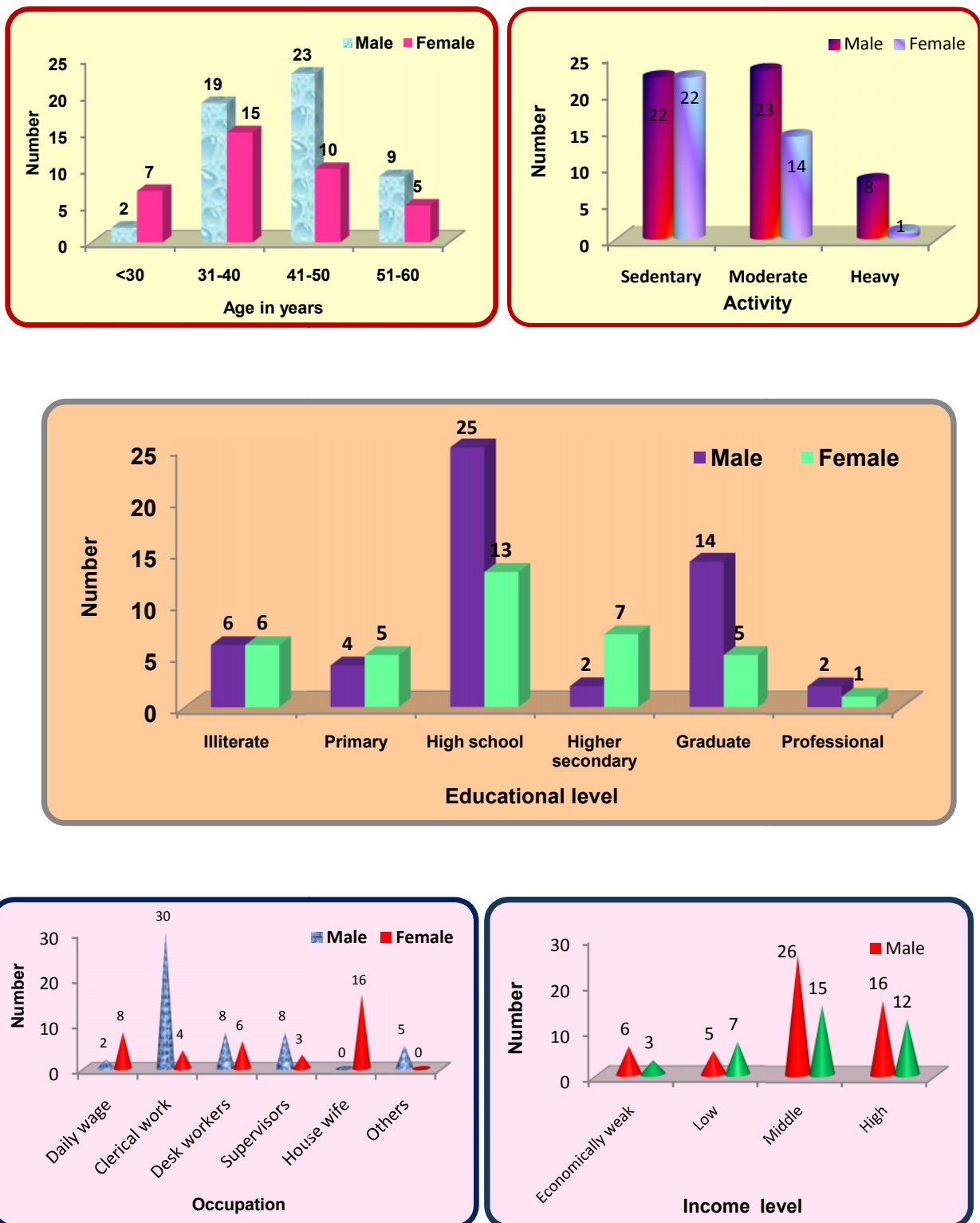


FIGURE 16. SOCIO-ECONOMIC BACKGROUND OF THE PREDIABETICS

The clinical trial conducted on 90 prediabetic subjects consisted of 53 males and 37 females. Table XXXVII revealed that majority (N-23) of the selected male prediabetics were in the age between 41-50 years. Among the female subjects, 15 were in the age range of 31-40 years. Epidemiology study by Mohan and Pradeepa (2009) revealed that Type II diabetes has become prevalent even among younger age groups, which could have long lasting effects on the health of the nation and its economy. In the present study maximum prevalence was recorded among 31-50 years age group. Advanced age (45 years or older) was associated with more than threefold increase in the risk of pre-diabetes compared to age younger than 45 years (OR = 3.29; 95 per cent CI 1.40, 9.45).

Among the prediabetics, most of the male (N-32) and female (N-22) were living in the urban area. This is mainly because the area selected for the study was Coimbatore city. Only a minimum of 9 male and 8 female prediabetics lived in the rural area.

It was noted that 25 male and 13 female prediabetic subjects completed their high school education. Only 14 male and five female prediabetics were graduates. Each of 6 male and female prediabetic subjects respectively were not having any formal education.

It is apparent from the Table that greater number of male prediabetics (N-23) were doing moderate activity whereas around the same number of prediabetics (male and female each N-22) were engaged only in deskbound sedentary work. Sedentary lifestyle increases mortality, double the risk of cardiovascular diseases, diabetes and obesity (Booth *et al.*, 2012). Only eight male and one female prediabetics were doing heavy activity.

Table XXXVII evidenced that the majority of selected prediabetics belonged to nuclear families consisting of 4-6 family members. Banerjee (2010) explains that in Indian cities; families aspire to an improved lifestyle, which they recognize is possible with fewer children. Reflecting the rise of the nuclear family in urban India, these households are small in size, 88 per cent have three to four members and there were no senior citizens in these households.

Most (N-32) of the male selected prediabetics were temporary workers whereas higher number (N-16) of female subjects were home makers and interested in learning handicraft works. With regard to the occupation, majority of male prediabetics (30) were doing clerical work. About eight female prediabetics were working as daily wage earners.

Among the 90 prediabetics, 41 belonged to middle income group followed by 28 prediabetics in high income and nine prediabetics in economically weaker section. The highest prevalence of Type II diabetes in developing countries occurs in the higher socio-economic groups and this is also true for the Indian population.

**b. Dietary pattern**

Dietary pattern is a modifiable risk factor that has been linked to the increased risk of obesity, insulin resistance and Type II diabetes. Hence the dietary habit, meal consumption pattern and types of oil used by the prediabetics were collected and discussed below.

**Dietary habit and meal consumption pattern**

Details regarding the dietary habits and meal pattern of the subjects are displayed in Table XXXVIII.

**TABLE XXXVIII**

**DIETARY HABIT AND MEAL CONSUMPTION PATTERN**

Details	Male	Female	Total
<b>Dietary habit</b>			
<b>Vegetarian</b>	4	4	8
<b>Non Vegetarian</b>	49	31	80
<b>Ova Vegetarian</b>	0	2	2
<b>No. of meals /day</b>			
<b>2</b>	7	13	20
<b>3</b>	45	24	69
<b>&gt; 3</b>	1	0	1

The eating habits in the Indian culture are largely based on religion and tradition. A high-vegetable diet with no beef or pork comes from the Hindu religion (www.ehoe.com). However, with regard to the dietary habit of the selected prediabetics, 49 male and 31 female were found to be non vegetarian consuming only chicken, fish and lamb. Majority of them consumed three meals per day without skipping meals.

### Type of oils used by the prediabetics

Table XXXIX shows the type of oil used by the prediabetics.

**TABLE XXXIX**  
**TYPE OF OIL USED BY THE PREDIABETICS**

Type of oil used*	Number
Sunflower oil	72
Palm oil	15
Gingelly oil	8
Groundnut oil	7
Others (olive, corn, rice bran)	4
Coconut oil	3

\*Multiple responses

Table XXXIX enlightens that sunflower oil was preferred and used by 72 prediabetic subjects followed by 15 prediabetics using palm oil since they belonged to economically weaker section and also this is supplied at subsidized rate by State Government through public distribution system. About eight and seven prediabetics were using gingelly and ground nut oil respectively.

### Food consumption pattern

The food consumption pattern of the selected prediabetics calculated from 24 hours recall method is given in Table XL.

**TABLE XL**  
**FOOD CONSUMPTION PATTERN OF THE PREDIABETICS**

Food groups	No. of servings* / Day	Male	Female	Total
Cereals	4-6	20	27	47
	6-8	31	12	43
Pulses	< 4	30	32	62
	4-6	23	5	28
Vegetables	< 2	34	24	58
	2-4	12	9	21
	> 4	7	4	11
Fruits	< 2	41	32	73
	2-3	9	3	12
	> 3	3	2	5
Milk and milk products	< 2	37	28	65
	2-4	16	8	24
	> 4	-	1	1
Non vegetarian foods	no	38	19	57
	1-2	10	16	26
	> 2	5	2	7
Snacks/ Junk foods	1	12	8	20
	2-3	35	26	61
	> 3	6	2	9
Water	2-4 glasses	12	7	19
	4-8 glasses	28	19	47
	> 8 glasses	13	11	24

\*AHA Note: 1 serving = 1 sl. Bread, 1/2 cup cooked rice or grain products, 1 cup raw or 1/2 cup cooked vegetables, 1 medium size fruit or 1/2 cup fruit, 1/2 cup juice, 1 cup of milk, 1/3 cup meat, poultry or fish.

Of the 90 prediabetics, 31 male and 12 female prediabetics consumed 6-8 servings of cereals. The cereals included rice, wheat, ragi, bajra and other cereal products. Less than four servings of pulses were consumed daily by majority (N-62) of prediabetics. The vegetable consumption among prediabetics was found to be low and higher number (N-58) of the prediabetics had less than two servings per day. The green leafy vegetable consumption was less and they reported that weekly

once or once in two weeks they ate green leafy vegetables. The consumption of fruits was also very meager and majority (N-73) of them ate less than two servings. A very few (N-5) prediabetics consumed more than three servings of fruits daily. Maximum of 65 prediabetics used milk and milk products <2 servings. The work place provided tea with milk and a glass of buttermilk along with lunch every day. Only seven prediabetics consumed non vegetarian foods like, egg or chicken more than two servings daily where as majority (N-57) of the prediabetics were not consuming non vegetarian foods daily and they expressed that they consumed chicken or mutton or egg only on Sundays. Around 61 prediabetics had two to three servings of snacks per day and they ate snacks like bajji, bonda, chips and murrukku along with tea or coffee. Only 24 prediabetics had more than eight glasses of water per day.

**c. Family history**

Table XLI and Figure 17 elucidates the family history of the selected prediabetics.

**TABLE XLI**

**FAMILY HISTORY OF PREDIABETICS**

<b>Occurrence of diabetes</b>	<b>Number*</b>
<b>Yes</b>	<b>51</b>
<b>Both parents</b>	11
<b>One of the parents</b>	34
<b>Grand parents</b>	3
<b>Close relatives</b>	13
<b>No</b>	39

\*Multiple responses

Family studies have revealed that first degree relatives of individuals with Type II diabetes are about three times more likely to develop the disease than individuals without a positive family history of the disease (Flores *et al.*, 2003, Gloyn, 2003 and Hansen, 2003). This is on par with the findings of the present study that 51 selected prediabetics were having a history of diabetes in their family. Majority of

prediabetics (N=34) were having a single parental history of this disease. A study by Mohan *et al.*, (2003) also reported the similar findings that 9.3 per cent of subjects with family history of diabetes had impaired glucose tolerance (IGT- a pre-diabetic stage) compared to five per cent of subjects without a family history.

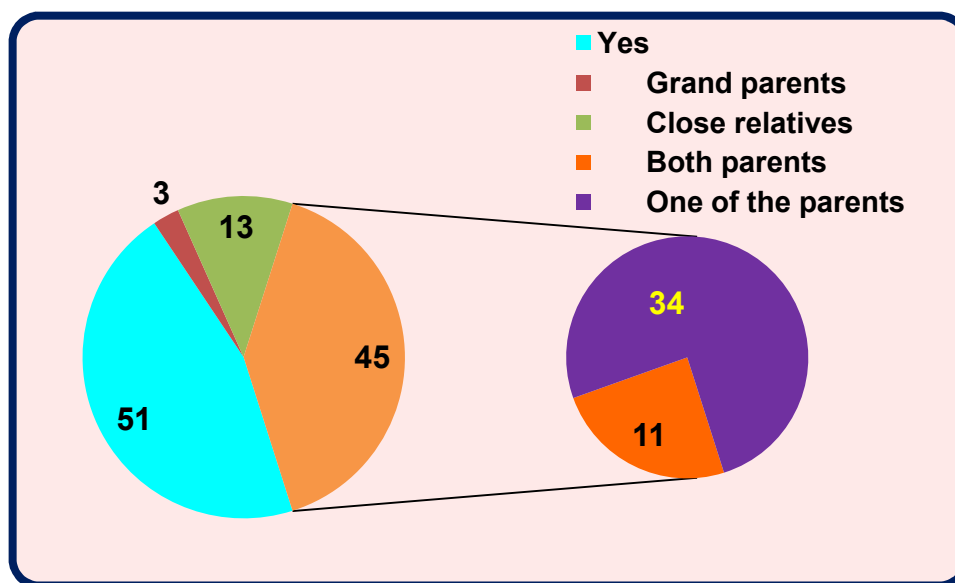


FIGURE 17. FAMILY HISTORY OF PREDIABETICS

d. Life style pattern

Exercise pattern

The type of exercise performed by the prediabetics is provided in Table XLII.

TABLE XLII  
EXERCISE PATTERN

Detail	Male	Female
Yes	21	9
No	32	28
Type of Exercise*		
Walking	15	3
Yoga	7	5
Gardening	3	-
Others	1	1

\*Multiple responses

It was recorded that 60 prediabetics (male 32, female 28) were not doing any regular physical exercise and only 21 male and 9 female prediabetics were doing regular exercise. Of the 30 subjects, 15 male and only three female prediabetics were going for a walk every day. Eleven prediabetics were doing yoga and only three male prediabetic subjects were engaging themselves in gardening activity.

Physical inactivity as an independent factor for the development of Type II diabetes. The availability of motorised transport and a shift in occupations combined with the plethora of television programmes has reduced the physical activity in all groups of populations

### Smoking pattern

Details regarding the smoking pattern of the selected prediabetics is given in Table XLIII.

**TABLE XLIII**  
**SMOKING PATTERN**

Life style	Number	Per cent
<b>Smoking habit</b>		
<b>Yes</b>	16	17.8
<b>No</b>	74	82.2
<b>Tobacco Chewing habit</b>		
<b>Yes</b>	6	6.7
<b>No</b>	84	93.3

Cigarette smoking is an independent risk factor for Type II diabetes. A meta-analysis found that current smokers had a 45 per cent increased risk of developing diabetes compared with nonsmokers (Willi *et al.*, 2007). From the selected 53 male prediabetics, 16 had the habit of smoking cigarette or beedi which is a thin, Indian cigarette filled with tobacco flakes and wrapped in a tendu or possibly even *Piliostigma racemosum* leaf tied with a string at one end. None of the female prediabetics had the habit of smoking. Out of 37 female prediabetics six subjects had the habit of chewing betel leaves with tobacco.

## PHASE IV

**G. Impact of intervention with bitter gourd juice on prediabetics**

The clinical trial was conducted on 90 prediabetics. A dropout of 25 prediabetics happened due to change in their job, unexpected pregnancy and family shift. Hence the trial was ended up with 65 prediabetics consisting of 43 male and 22 female prediabetics. The impact was analysed for these 65 subjects and discussed below.

**a. Anthropometric measurements of prediabetics the intervention****Body weight**

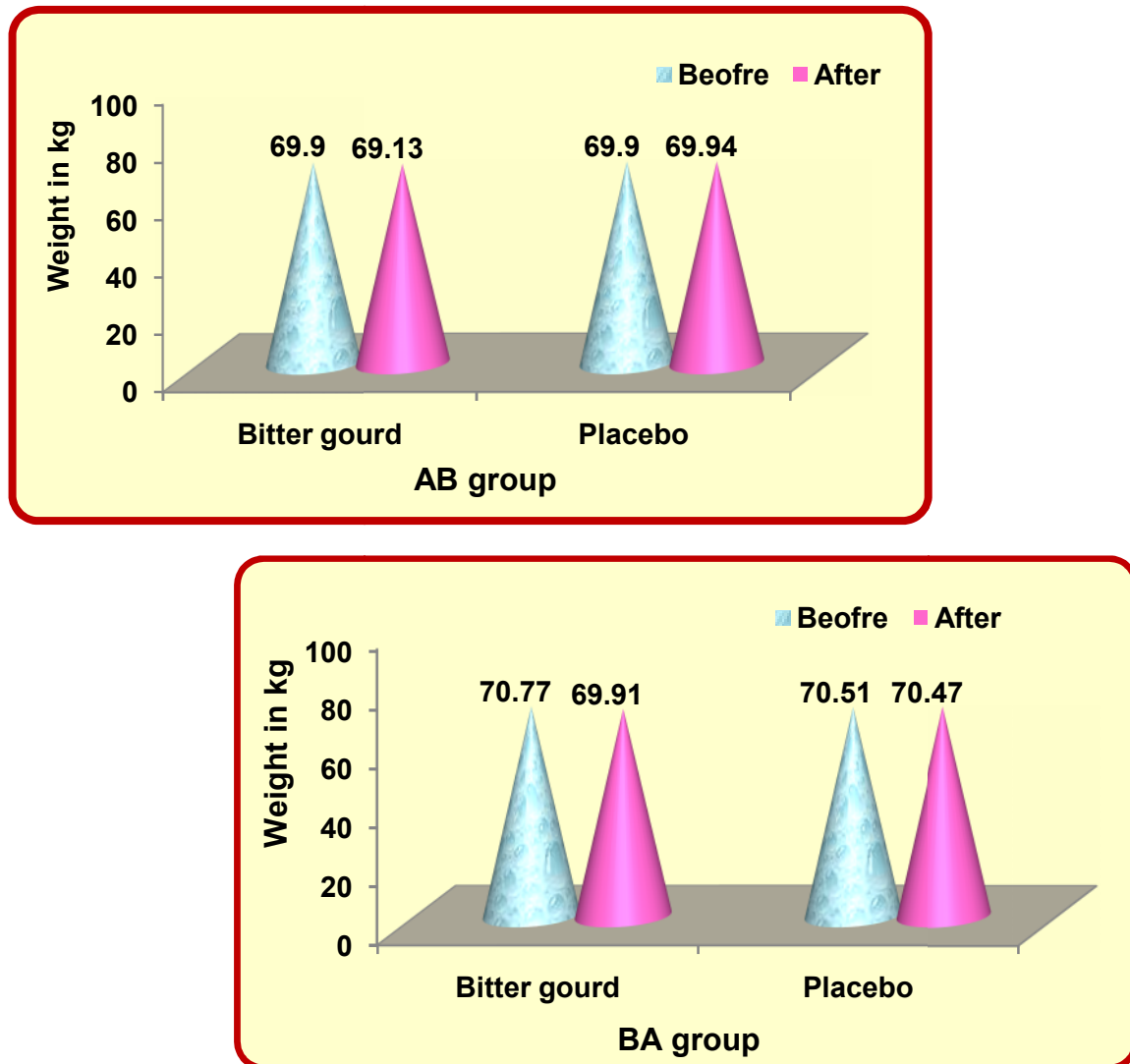
People who are overweight are at a greater risk of developing Type II diabetes than normal weight individuals. Overweight adds pressure on the body's ability to properly control blood sugar using insulin and therefore makes it much more likely for one to develop diabetes (Kelly, 2005). Table XLIV and Figure 18 exhibits the mean body weight of the selected prediabetics before and after the intervention study.

**TABLE XLIV**  
**BODY WEIGHT OF THE PREDIABETICS BEFORE AND AFTER THE INTERVENTION**

Group	Weight in (kg)(Mean ±SD)								‘t’ value (N1 Vs N4)
	Bitter gourd (A)		Diff	‘t’ value	Placebo(B)		Diff	‘t’ value	
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	69.90 ± 12.94	69.13 ± 13.06	- 0.77 ± 0.99	4.585**	69.90 ± 13.25	69.94 ± 13.73	0.04 ± 2.0	0.127	0.111 <sup>NS</sup>
B to A (N-30)	Placebo(B)		Diff	‘t’ value	Bitter gourd(A)		Diff	‘t’ value	(N1Vs N4)
Placebo to bitter gourd	70.51 ± 13.11	70.47 ± 13.27			-0.04 ± 1.23	0.175 <sup>NS</sup>			

NS- Not Significant, \*\* significant at (p<0.01)

From the above table the data revealed that body weight of the bitter gourd juice supplemented group was recorded as 69.9 kg before the supplementation and after the supplementation it got reduced to 69.13 kg. The difference in the body weight was analysed and found to be significant at (p<0.01) level.



**FIGURE 18. BODY WEIGHT OF THE PREDIABETICS BEFORE AND AFTER THE INTERVENTION**

With regard to the group (A to B) started with the placebo supplementation recorded the initial body weight as 70.77 kg and it was reduced to 69.91 kg with the difference of 0.86 kg after the bitter gourd intervention period which showed a significant difference at ( $p < 0.01$ ) level.

From the results, it was clearly depicted that the placebo supplemented group (A to B) the difference in the body weight was only 0.04 kg and the similar difference (0.04 kg) was obtained for placebo group with B to A intervention also. The difference was statistically analysed and found to be not significant in both the groups supplemented with placebo.

*Momordica charantia* or its bioactive ingredients could be used as a dietary adjunct in the control of body weight and lipid profile (Bano *et al.*, 2011). Hence it was concluded that bitter gourd juice supplementation has helped to reduce the body weight among the selected prediabetics.

### Body Mass Index

BMI of the selected prediabetics before and after the intervention period is presented in Table XLV and Figure 19.

**TABLE XLV**

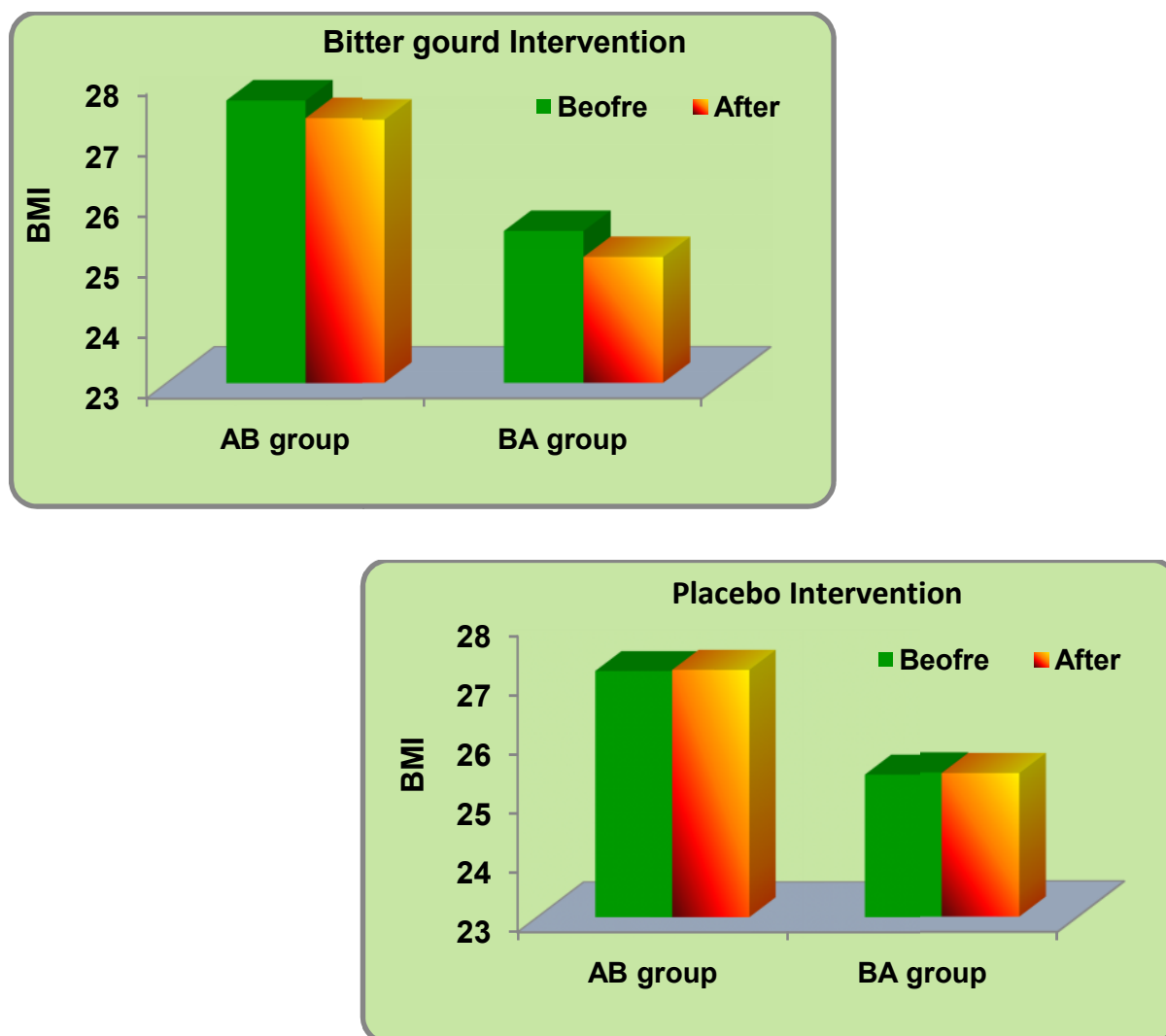
**BMI OF THE PREDIABETICS BEFORE AND AFTER THE INTERVENTION**

Group	BMI (Mean $\pm$ SD)							't' value (N1Vs N4)	
A to B (N-35)	Bitter gourd (A)		Diff	't' value	Placebo(B)		Diff		't' value
	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	27.64 $\pm$ 5.89	27.35 $\pm$ 5.96	-0.3 $\pm$ 0.38	4.554**	27.16 $\pm$ 4.57	27.18 $\pm$ 4.83	0.02 $\pm$ 0.76	0.192 <sup>NS</sup>	0.939 <sup>NS</sup>
B to A (N-30)	Placebo(B)		Diff	't' value	Bitter gourd(A)		Diff	't' value	't' value (N1Vs N4)
Placebo to Bitter gourd	25.41 $\pm$ 3.75	25.40 $\pm$ 3.81	-0.02 $\pm$ 0.46	0.250 <sup>NS</sup>	25.51 $\pm$ 3.77	25.08 $\pm$ 3.82	-0.42 $\pm$ 0.32	7.235**	3.636**

NS- Not Significant, \*- significant ( $p < 0.05$ ), \*\* significant ( $p < 0.01$ ),

From the above Table it was clear that the body mass index of the bitter gourd juice supplementation started group (A to B) showed a significant decline at ( $p < 0.01$ ) level whereas the same group supplemented with placebo the difference in BMI was not significant statistically.

In connection with supplementation of placebo started group (B to A), the difference between initial and final values of BMI was not significant statistically. The same group showed a statistical significant difference ( $p < 0.01$ ) between the value obtained before and after the bitter gourd intervention period.



**FIGURE 19. BMI OF THE PREDIABETICS BEFORE AND AFTER THE INTERVENTION**

It was also revealed that when the statistical appraisal was done between the N1 and N4 values of AB and BA group. In AB group the values are not statistically significant whereas BA group showed the difference which was significant at ( $p < 0.01$ ) level. This concludes that bitter gourd supplemented group was having the effect of reducing BMI only during the period of supplementation.

Huang *et al.*, (2008) also reported that supplementation of bitter gourd significantly decreased the number of large adipocytes ( $>180\mu\text{m}$ ), increased the number of small adipocytes (20–60  $\mu\text{m}$ ) and down regulated the expression of lipogenic genes in adipose tissues.

### Waist circumference

Details regarding the changes in the mean waist circumference of the selected male and female prediabetics is illustrated in Table XLVI and Figure 20.

**TABLE XLVI**  
**WAIST CIRCUMFERENCE OF THE PREDIABETICS BEFORE AND AFTER THE INTERVENTION**

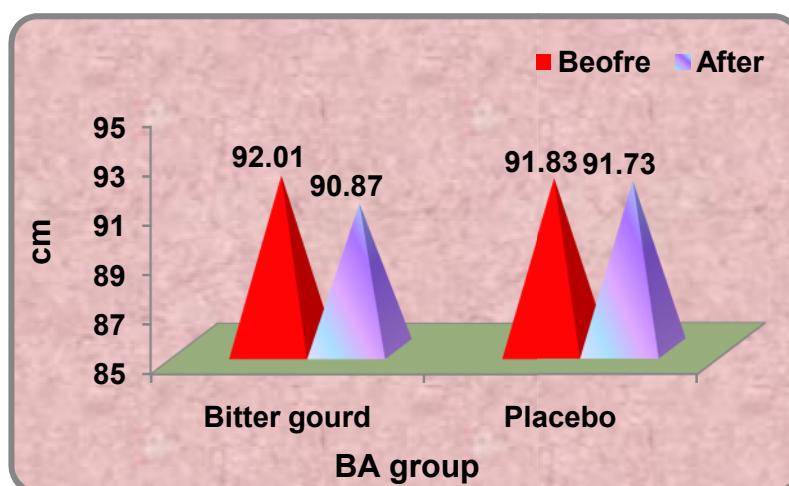
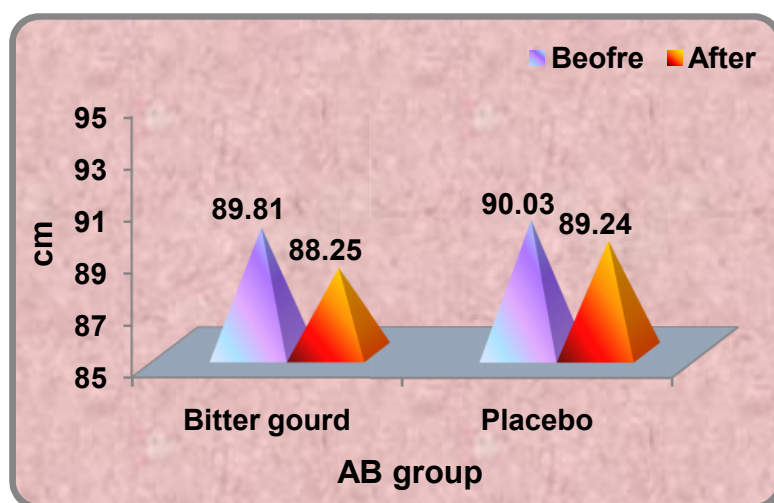
Group	Waist circumference (cm) (Mean $\pm$ SD)							't' value	't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff		
A to B (N-35)	Before (N1)	After (N2)			Diff	't' value		Before (N3)	After (N4)
Bitter gourd to placebo	89.81 $\pm$ 10.86	88.25 $\pm$ 10.55	-1.56 $\pm$ 0.87	10.591**	90.03 $\pm$ 10.56	89.24 $\pm$ 10.6	-0.79 $\pm$ 0.84	5.544**	2.475*
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Placebo to Bitter gourd	91.83 $\pm$ 10.11	91.73 $\pm$ 10.08			-0.11 $\pm$ 0.54	1.068 NS			

NS- Not Significant, \*- significant ( $p < 0.05$ ), \*\* significant ( $p < 0.01$ ),

A large waist circumference is associated with increased likelihood of developing Type II diabetes. Men are at higher risk of Type II diabetes if they have a waist circumference of 94-102 cm and are at very high risk if it is more than 102 cm. Women are at higher risk if they have a waist circumference of 80-88 cm and at very high risk if it is more than 88 cm (National Institute for Health and Care Excellence, 2011).

Prediabetics in AB group showed a decline in their waist circumference during bitter gourd as well as placebo intervention and the difference was found to be statistically significant ( $P < 0.01$ ). This impact could also be attributed to the awareness created among the prediabetics so that they could have included bitter gourd more frequently in their home diets. Similar results were reported by Tsai *et al.*, (2012) in which significant decrease in the waist circumference was observed after the intervention with wild bitter gourd in their study, compared to the

value at the baseline (visit 1), there were significant decreases in the waist circumference at visit 3 ( $p < 0.0001$ ), visit 4 ( $p = 0.002$ ) and visit 5 ( $p = 0.042$ ).



**FIGURE 20. WAIST CIRCUMFERENCE OF THE PREDIABETICS BEFORE AND AFTER THE INTERVENTION**

After the placebo intervention, BA group revealed that no significant change in the waist circumference was noticed whereas during bitter gourd intervention it had reduced from 92.01 cm to 90.87 cm and the difference was statistically significant ( $P < 0.01$ ) level.

### Waist to Height Ratio (WHtR)

Table XLVII reveals the waist to height ratio of the selected prediabetics.

**TABLE XLVII**  
**WHtR OF THE PREDIABETICS BEFORE AND AFTER THE INTERVENTION**

Group	WHtR (Mean $\pm$ SD)							't' value (N1 Vs N4)	
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff		't' value
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	0.565 $\pm$ 0.07	0.554 $\pm$ 0.07	0.011 $\pm$ 0.01	8.18**	0.566 $\pm$ 0.07	0.564 $\pm$ 0.07	0.001 $\pm$ 0.01	4.82**	2.24*
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Placebo to Bitter gourd	0.553 $\pm$ 0.07	0.552 $\pm$ 0.2			0.001 $\pm$ 0.0	1.00 <sup>NS</sup>			

Twenty two prospective analysis showed that WHtR and WC were significant predictors of cardio metabolic outcomes (Browning *et al.*, 2010).

In the case of Waist to Height Ratio of the AB group, initial value ie.0.565 per cent declined to 0.554 per cent after eight weeks of bitter gourd intervention and the difference was found to be significant at ( $p < 0.01$ ) level. The same group after the wash out period, the waist to height ratio reduced from 0.566 to 0.564 per cent which was also found to be significant at ( $p < 0.01$ ) level.

In BA group, the placebo intervention did not show significant reduction in waist to height ratio whereas bitter gourd intervention proved to have an impact on waist to height ratio and the difference was found to be significant at ( $p < 0.01$ ) level.

Final values of both AB and BA group showed a significant reduction ( $p < 0.05$ ) and ( $p < 0.01$ ) reduction from baseline values. The prevalence of diabetes and hypercholesterolemia appeared to be higher with higher WHtR.

### Conicity Index

Conicity index of the selected prediabetics before and after the intervention is depicted in Table XLVIII.

**TABLE XLVIII**  
**CONICITY INDEX OF THE PREDIABETICS BEFORE AND AFTER**  
**THE INTERVENTION**

Group	CI (Mean $\pm$ SD)								't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff	't' value	
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	1.25 $\pm$ 0.11	1.23 $\pm$ 0.11	-0.02 $\pm$ 0.01	9.23**	1.25 $\pm$ 0.11	1.24 $\pm$ 0.11	-0.01 $\pm$ 0.01	4.39**	2.004*
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Placebo to bitter gourd	1.29 $\pm$ 0.09	1.29 $\pm$ 0.09			0	0			

Neufeld *et al.*, (2008) reported the best cut-off points for pre-diabetes status as 27.8 kg/m<sup>2</sup> for BMI, 89.8 cm for waist circumference and 1.28 for conicity index.

From the above table, conicity index of the AB group exhibit a difference of 0.02 from initial value and it was found to be significant at ( $p < 0.01$ ) level during bitter gourd intervention. As well as during placebo intervention the conicity index reduced faintly and the difference was found to be significant at ( $p < 0.01$ ) level.

It is clear in BA group, in the placebo intervention no change in the conicity index whereas bitter gourd intervention had an impact on conicity index and the difference was found to be significant at ( $p < 0.01$ ) level.

#### **Anthropometric measurements of pooled data analysis for the cross over study**

In this study an effort was made to pool both AB and BA groups (N-65) and the impact during the bitter gourd intervention alone was done to find out the impact. Table XLIX gives a picture of the mean anthropometric measurements of the prediabetics during bitter gourd intervention.

**TABLE XLIX**  
**ANTHROPOMETRIC MEASUREMENTS OF PREDIABETICS BEFORE AND AFTER BITTER GOURD INTERVENTION**

Anthropometric measurements	Bitter gourd intervention (Mean $\pm$ SD)		't' value (I Vs F)
	Initial (I)	Final (F)	
Body weight (kg)	70.30 $\pm$ 13.07	69.35 $\pm$ 13.17	7.977**
BMI	26.66 $\pm$ 5.12	26.30 $\pm$ 5.2	7.96**
Waist circumference (cm)	90.82 $\pm$ 10.54	89.46 $\pm$ 10.32	13.124**
Waist to Height Ratio (WHtR)	0.56 $\pm$ 0.69	0.55 $\pm$ 0.66	9.297**
Coicity index	1.27 $\pm$ 0.11	1.25 $\pm$ 0.10	11.516**
Body fat per cent	30.66 $\pm$ 5.26	30.35 $\pm$ 5.28	2.415*

\*- significant (p<0.05) \*\* significant (p<0.01)

Excess body fat is a primary cause of metabolic disturbances such as Type II diabetes mellitus (Wang *et al.*, 2005). As a simple and non-invasive method, anthropometric measurements have been used to assess general obesity (BMI) and central obesity (WC) (Ho *et al.*, 2001). In addition, some studies have shown that a high proportion of abdominal fat, particularly visceral fat, is a major risk factor for Type II diabetes. Therefore, other anthropometric parameters are used to assess excess visceral fat. Also, WC was reported by Ford *et al.*, (2009) as a better predictor than BMI for prediction of metabolic syndrome, diabetes, cardiovascular disease and all-cause mortality.

Anthropometric measures of the pooled data for the AB and BA groups enlighten that bitter gourd intervention had a positive impact with significant (P<0.01) reduction in weight, BMI, waist circumference, waist to height ratio and conicity index. It was also observed that affirmative cutback in body fat was significant at five per cent level.

#### **b. Mean food and nutrient intake of the prediabetics**

##### **Mean food intake of the prediabetics**

The mean food intake of the prediabetics is presented in Table L.

**TABLE L**  
**MEAN FOOD INTAKE OF THE PREDIABETICS**

Food Groups	RDA (ICMR, 2010)	Male		RDA (ICMR, 2010)	Female	
		Actual intake (g)	Excess/deficit (per cent)		Actual intake (g)	Excess/deficit (per cent)
Cereals	375	390	4.0	270	216	-20.0
Pulses	75	46	-38.7	60	38	-36.7
Roots and tubers	200	160	-20.0	200	137	-31.5
GLV	100	70	-30.0	100	39	-61.0
Other vegetables	200	125	-37.5	200	98	-51.0
Fruits	100	68	-32.0	100	32	-68.0
Milk & Milk Products	300	228	-24.0	300	212	-29.3
Fats & Oils	25	36	44.0	20	31	55.0
Sugar & jaggery	20	47	135.0	20	33	65.0

With regard to the food intake of the selected male prediabetics it was recorded that intake of pulses was deficit by 38.7 per cent, roots and tubers by 20 per cent deficit. 30, 37.5, 32 and 24 per cent deficit was recorded for green leafy vegetables other vegetables, fruits and milk and milk products respectively. The intake of cereals and fats and oils was excess by 4 per cent and 44 per cent respectively. It was shocking to note that the intake of sugar and jaggery was excess by 135 per cent when compared with RDA.

In case of female prediabetcs, the actual intake of food was recorded as 20 per cent deficit for cereals, 36.7 per cent deficit for pulses, 31.5 per cent deficit for roots and tubers, 61 per cent deficit for green leafy vegetables, other vegetables by 51 per cent, fruits by 68 per cent, and milk and milk products by 29.3 per cent deficit. The results showed that the intake of fats and oils and sugar and jaggery were excess by 55 per cent and 65 per cent. In general it was observed from the Table that both male and female prediabetics has very poor food choice, low in fruit and vegetables and high in fats and oils.

### Mean nutrient intake of the prediabetics

Mean nutrient intake of the selected prediabetics is shown in Table LI.

**TABLE LI**  
**MEAN NUTRIENT INTAKE OF THE PREDIABETICS**

Nutrients	RDA (ICMR, 2010)	Male		RDA (ICMR, 2010)	Female	
		Actual intake	Excess/ deficit (per cent)		Actual intake	Excess/ deficit (per cent)
Energy (Kcal)	2320	2190	-5.6	1900	1710	-10.0
Protein (g)	60	48	-20.0	55	42	-23.6
Fat (g)	25	45	80.0	20	32	60.0
Fibre (g)	40	23	-42.5	40	18	-55.0
Calcium (mg)	600	419	-30.2	600	440	-26.7
Iron (mg)	17	20	17.6	17	14	-17.6
Beta carotene (µg)	4800	3225	-32.8	4800	2840	-40.8
Thiamine (mg)	1.2	1.3	8.3	1.0	1.1	10.0
Riboflavin (mg)	1.4	1.6	14.3	1.1	1.2	9.1
Niacin (mg)	16	14	-12.5	12	11	-8.3
Vitamin-C (mg)	40	58	45.0	40	46	15.0

Mean nutrient intake of the male prediabetic subjects revealed that all the nutrients recorded were excess apart from energy, pulses, fibre, calcium, beta carotene and niacin which was deficit by 5.6 per cent, 20 per cent, 42.5 per cent, 30.2 per cent, 32.8 per cent and 12.5 per cent respectively. The nutrient intake of fat, iron, thiamine, riboflavin and vitamin C were deficit by 80 per cent, 17.6 per cent, 8.3 per cent, 14.3 per cent and 45 per cent respectively.

Same trend was also observed among the female prediabetic subjects. The main reason for inadequacy of nutrients among male and female prediabetics is

inadequate intake of food, poor eating habits and lack of nutritional knowledge which results in faulty dietary habits and unawareness over the selection of foods.

Consumption of animal foods, sugar (especially sweetened, carbonated beverages) and traditional Indian energy-dense foods has increased. The diets of all income groups have moved away from wholegrain cereals to other food groups (Misra *et al.*, 2011).

Joshi *et al.*, (2012) explains that the carbohydrates remain the major source of energy in Indian diets, the percentage of total energy intake derived from carbohydrates has declined (1975–1979, 80.3 per cent; 2001, 75.5 per cent); however, the quality of carbohydrates has changed from the traditional high-fiber carbohydrates to the low-fiber carbohydrates such as polished white rice, which has a higher glycemic index. There is also an increase in the percentage of energy coming from dietary fats (1975–1979, 8.9 per cent; 2001, 13.9 per cent).

### **c. Measurement of blood pressure and body fat percentage**

#### **Blood pressure**

Table LII depicts the changes in the mean blood pressure of the selected prediabetics.

**TABLE LII**  
**EFFECT OF INTERVENTION ON THE BLOOD PRESSURE OF THE PREDIABETICS**

Group	Blood pressure (Mean ±SD)								't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff	Diff	
AB (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Diastolic pressure	74.66±10.26	75.43±9.61	0.77±8.53	0.535 <sup>NS</sup>	76.83±9.84	76.43±9.09	-0.40±8.14	0.291 <sup>NS</sup>	0.916 <sup>NS</sup>
Systolic pressure	119.37±23.39	120.09±13.20	0.71±23.13	0.183 <sup>NS</sup>	119.03±23.39	121.03±13.39	2.0±22.00	0.538 <sup>NS</sup>	0.401 <sup>NS</sup>
BA (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Diastolic pressure	75.60±12.60	75.23±12.85			-0.37±6.00	0.329 <sup>NS</sup>			
Systolic pressure	127.37±18.24	122.80±17.73	-4.57±7.92	3.105 <sup>**</sup>	127.70±17.27	123.47±17.82	-4.23±7.83	2.913 <sup>**</sup>	2.671 <sup>**</sup>

NS- Not Significant, \*- significant (p<0.05), \*\* significant (p<0.01)

With regard to changes in the blood pressure of subjects in the AB group, diastolic pressure and systolic pressure showed a difference of 1-3 mmHg during bitter gourd as well as placebo intervention. Similarly, in case of BA group, it showed a difference of 2-4 mmHg of diastolic and systolic pressure during the period of 16 weeks of bitter gourd and placebo intervention. In general there was no trend in the reduction or increase in blood pressure among the subjects in both AB and BA groups. The minor changes recorded could be attributed to various other reasons.

**Body fat percentage**

Elevated abdominal fat has been shown to significantly increase the risk of developing resistance to insulin, which can lead to diabetes. Table LIII depicts the mean body fat percentage of the selected male and female prediabetics.

**TABLE LIII**  
**EFFECT OF INTERVENTION ON THE BODY FAT PERCENTAGE**

Group	Mean body fat percentage (Mean ±SD)								't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff	't' value	
AB (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	31.62 ±6.22	31.19 ±6.32	-0.43 ± 0.68	3.732**	32.02 ±6.27	31.86 ±5.86	- 0.16 ±0.92	1.006 <sup>NS</sup>	0.704 <sup>NS</sup>
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Placebo to bitter gourd	30.04 ±3.34	29.97 ±3.48			-0.08 ±0.67	0.662 <sup>NS</sup>			

NS- Not Significant, \*\* significant (p<0.01)

According to Chen and Li (2005) *Momordica charantia* leads to a general decrease in tissue fat accumulation and that such an effect is mediated in part by enhanced sympathetic activity and lipolysis. Similar trends in the present study was also noted that the mean body fat percentage of the selected prediabetics showed significant reduction (P<0.01) during bitter gourd intervention and no significant difference in case of placebo intervention in AB group.

BA group did not show any significant difference with regard to bitter gourd as well as placebo intervention. However the overall reduction recorded in BA group was significant at ( $P < 0.01$ ) level.

#### d. Biochemical profile of the prediabetics

##### Mean fasting blood glucose level

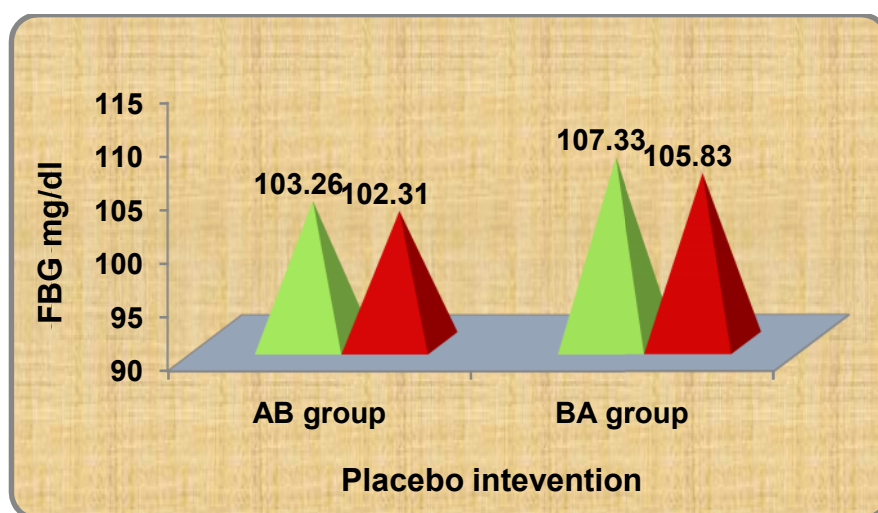
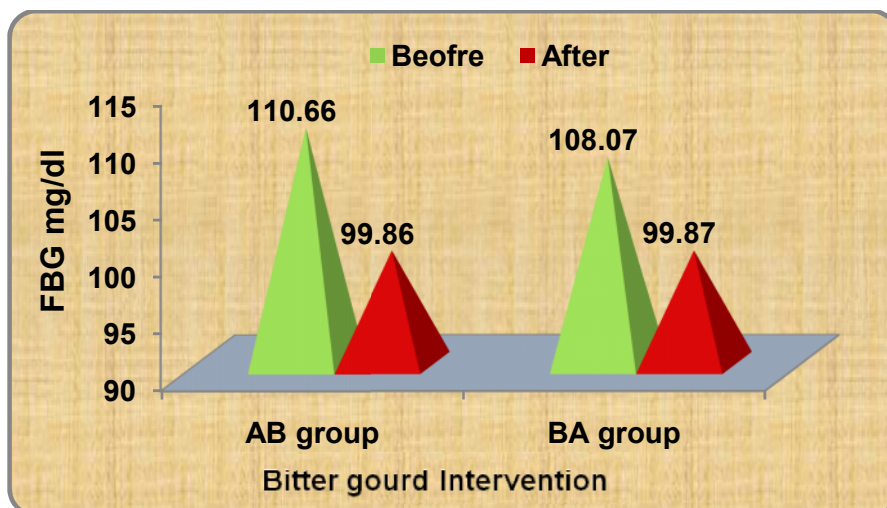
Details regarding changes in the mean fasting blood glucose level of the prediabetics are depicted in Table LIV and Figures 21.

**TABLE LIV**  
**EFFECT OF INTERVENTION ON THE FASTING BLOOD GLUCOSE LEVEL**

Group	Fasting blood glucose (mg/dl) (Mean $\pm$ SD)								't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff	't' value	
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	110.66 $\pm$ 8.66	99.86 $\pm$ 5.59	-10.8 $\pm$ 11.76	5.432**	103.26 $\pm$ 6.84	102.31 $\pm$ 6.74	-0.94 $\pm$ 5.36	1.04 <sup>NS</sup>	4.402**
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Placebo to bitter gourd	107.33 $\pm$ 6.41	105.83 $\pm$ 12.33			-1.13 $\pm$ 10.79	0.729 <sup>NS</sup>			

NS- Not Significant, \*\* significant ( $p < 0.01$ )

The mean initial blood glucose level of prediabetics in AB group was 110.66 mg/dl which was reduced significantly ( $P < 0.01$ ) to 99.86 mg/dl at the end of bitter gourd intervention. After the cross over (four weeks of wash out period), during the placebo intervention the mean initial FBG level was 103.26 mg/dl and the final FBG level was 102.31 mg/dl, which was slightly lower than the initial value and the difference was not found to be statistically significant. However after the termination of the bitter gourd treatment slow elevation of FBG was seen and hence N1 Vs N4 showed significance even at the end of 20 weeks period.

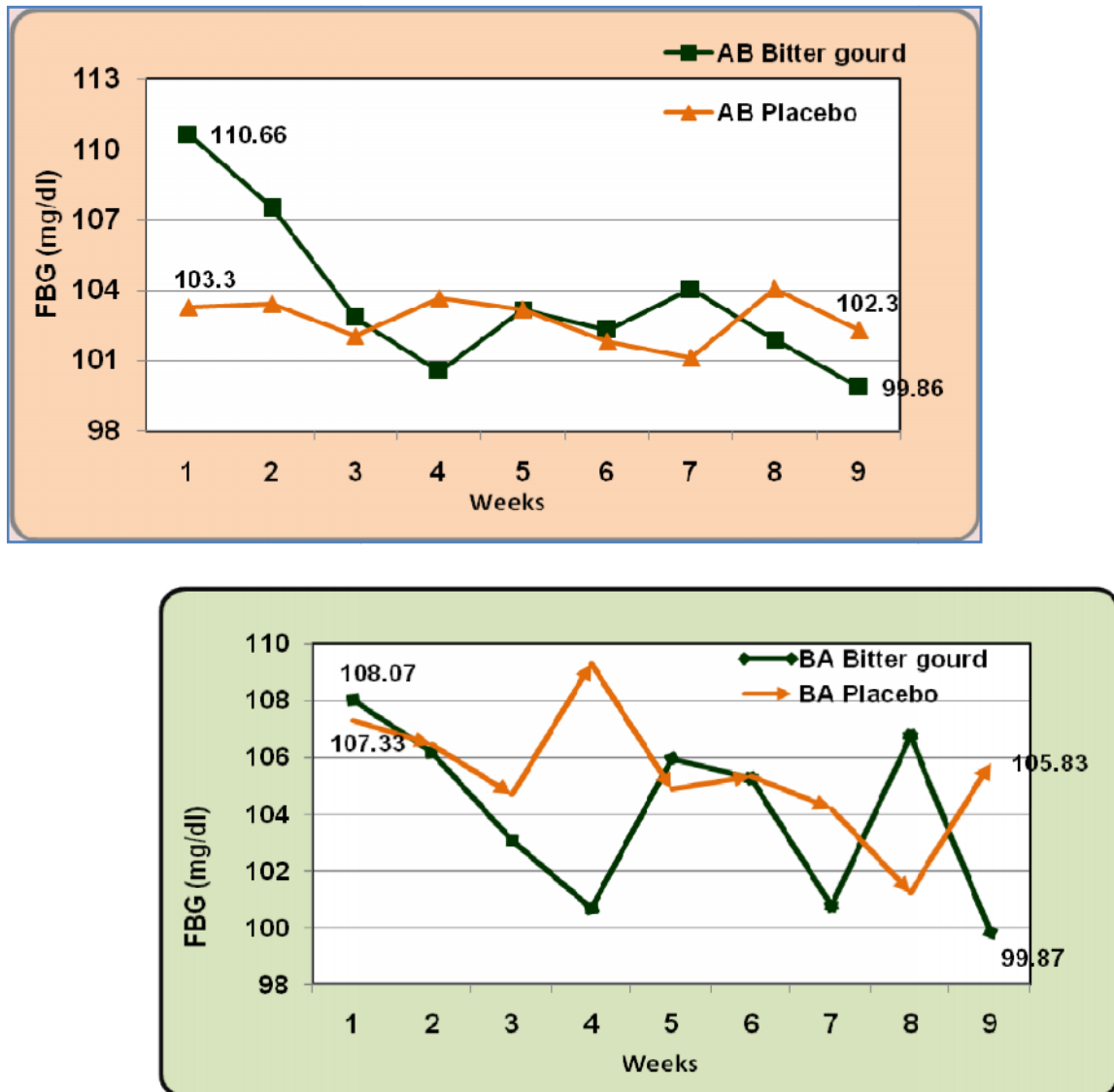


**FIGURE 21. EFFECT OF INTERVENTION ON THE FASTING BLOOD GLUCOSE LEVEL**

In the case of BA group the placebo treatment did not bringforth any appreciable change in FBG whereas the bitter gourd treatment as well as N1 Vs N4 comparisons were found to be significant. The results of the present study was in accordance with the study by Waheed *et al.*, (2008) that consumption of dried powder of *M. charantia* fruit showed reduction in FBG for 10 Type II diabetic patients with no history of previous medication and 10 Type II diabetic patients with history of taking oral hypoglycemic agents. The same effect was also obtained with aqueous and alcoholic extracts of *M. charantia*.

### Periodic fasting blood glucose of the prediabetics

Fasting blood glucose level of prediabetics in AB group and BA group during the eight weeks of intervention period is depicted in Figure 22.



**FIGURE 22. PERIODIC FASTING BLOOD GLUCOSE LEVELS IN AB AND BA GROUP**

The weekly fasting blood glucose values indicate that AB group which had 110.66 mg/dl at the start of the bitter gourd intervention showed a rapid decrease in the value over a period of three weeks and there after the values showed nearly normal fluctuations. In case of BA group the weekly FBG were too high. These fluctuations reflected the festival seasons and family functions when the subjects tend to overeat and also consume more sweets.

During the placebo intervention, with regard to AB group the weekly fasting blood glucose level was slightly up and down with minimum fluctuations, whereas in the BA group after the third week a rapid increase was recorded which was slightly lowered and attained the normal level after eight week period.

The beneficial effect of dried bitter gourd powder could be attributed to its high fibre content (31 per cent insoluble and 17 per cent soluble) or it could be due to its bioactive components. It is well known that dietary fibre facilitates slow absorption of glucose along the passage through gastrointestinal. Singh *et al.*, (2011) reported that the hypoglycemic effect of bitter gourd is due to suppression of key gluconeogenic enzymes such as glucose-6-phosphatase and fructose-1,6-bisphosphatase on one hand and an accelerated glucose metabolism through glucose-6-phosphate dehydrogenase on the other hand.

### Mean glycosylated haemoglobin level

Details regarding mean glycosylated haemoglobin level of the prediabetics is presented in Table LV.

TABLE LV

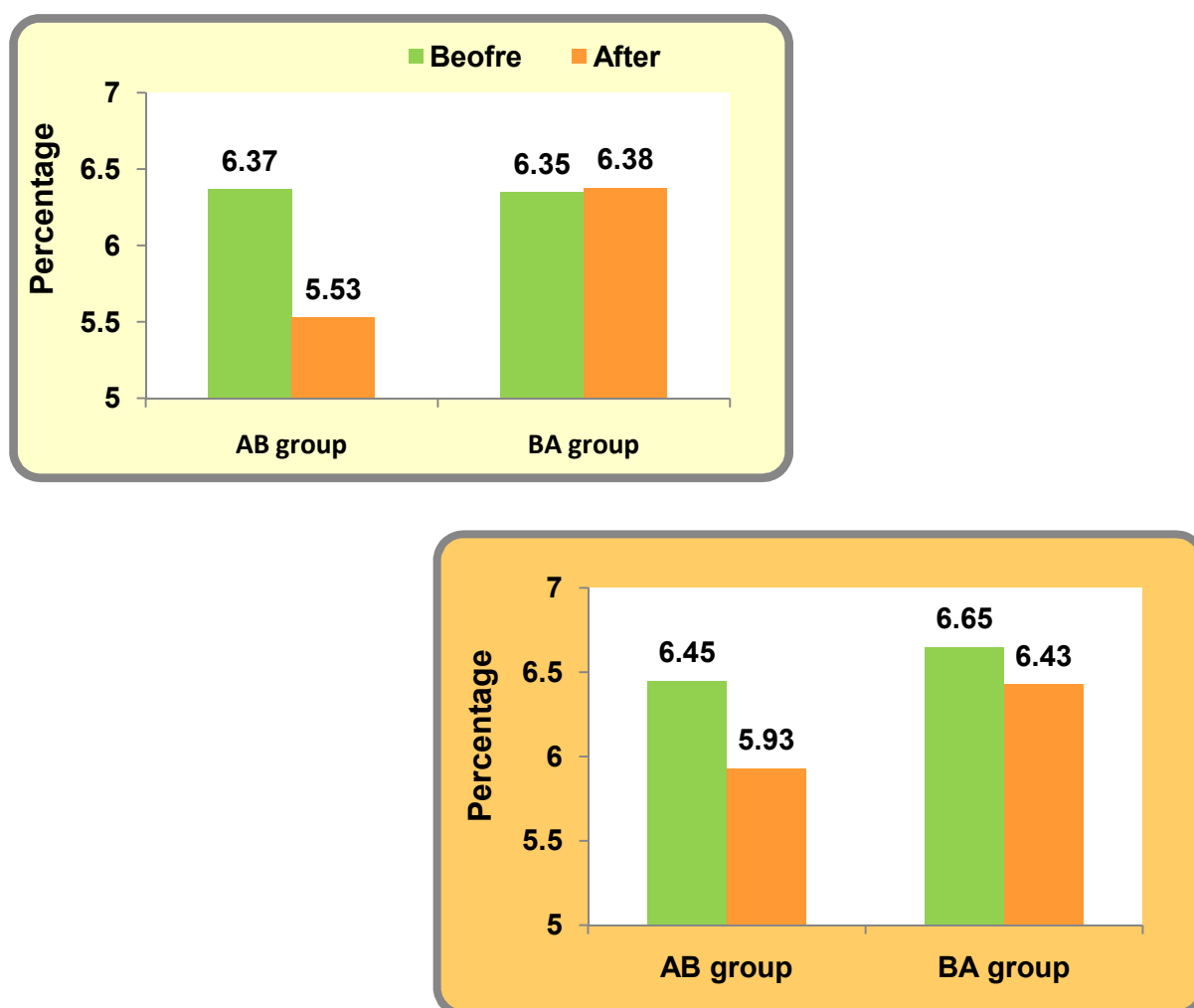
#### EFFECT OF INTERVENTION ON GLYCOSYLATED HAEMOGLOBIN LEVEL

Group	HbA1c (per cent) (Mean ±SD)								't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff	't' value	
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	6.37 ±0.44	5.53 ±0.39	-0.84± 0.5	9.858**	6.45 ±0.56	5.93 ±0.35	-0.52 ±0.64	4.819**	5.449**
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Placebo to bitter gourd	6.65 ±0.73	6.43 ±0.53			-0.23 ±0.81	1.535 <sup>NS</sup>			

NS- Not Significant, \* significant (p<0.05) \*\* significant (p<0.01)

With respect to the glycosylated hemoglobin level of the AB group, initial value 6.37 per cent trimmed down to 5.53 per cent after eight weeks of bitter gourd intervention with a statistical significant at (p<0.01) level. The same group after the

wash out period is given the placebo intervention, in that the glycosylated hemoglobin reduced from 6.45 to 5.93 per cent which was also significant at ( $p < 0.01$ ) level. After the washout period the HbA1c per cent of AB group increased from the N2 value there after again decreased during the placebo period which may be due to the effect of bitter gourd intervention in the earlier period. The difference in the mean value for N1 and N4 was found to be significant ( $p < 0.01$ ), which confirms that bitter gourd intervention is playing an important role in lowering blood glucose and glycosylated hemoglobin. Rahman *et al.*, (2011) also reported similar findings that the freeze-dried bitter melon juice in a dose of 1 g/d along with diet control showed a significant ( $p < 0.01$ ) reduction in HbA1c levels when compared to only diet control group (Figure 23).



**FIGURE 23. EFFECT OF INTERVENTION ON THE GLYCOSYLATED HAEMOGLOBIN LEVEL**

In case of BA group, no significant difference was observed both during placebo and bitter gourd treatment, however when compared to the initial and final glycosylated hemoglobin level of the group after the intervention period of five months there was significant ( $p < 0.05$ ) reduction in HbA1c level. It could be inferred that the HbA1c levels reflect the blood sugar levels of past three months. Hence every measurement reflects the impact of intervention as well as the past values.

### Mean fructosamine level

Table LVI presents the details regarding the mean fructosamine level of the prediabetics.

**TABLE LVI**  
**EFFECT OF INTERVENTION ON THE FRUCTOSAMINE LEVEL**

Group	Fructosamine ( $\mu\text{mol/dl}$ ) (Mean $\pm$ SD)								't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff	't' value	
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	248.29 $\pm 20.09$	252.29 $\pm 20.2$	4.00 $\pm 12.36$	1.91 <sup>NS</sup>	230.00 $\pm 20.68$	235.97 $\pm 22.16$	5.97 $\pm 11.99$	2.946 <sup>**</sup>	5.483 <sup>**</sup>
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
Placebo to bitter gourd	263.5 $\pm 25.97$	271.6 $\pm 29.72$			8.10 $\pm 14.89$	3.086 <sup>**</sup>			

NS- Not Significant, \* significant ( $p < 0.05$ ) \*\* significant ( $p < 0.01$ )

Fructosamine (glycated albumin) measures short term control of blood sugar for the past one to three weeks. The reference range is 202-282  $\mu\text{mol/dl}$ . It is inferred from the above Table that the mean fructosamine level did not significantly change during bitter gourd intervention but significant increase was noted during placebo treatment in AB group as well as in BA group.

Significant reduction ( $p < 0.01$ ) was observed from the baseline to the final level of fructosamine in both the groups. This is in line with the study by

Fuangchan *et al.*, (2011), that significant reduction in fructosamine levels from baseline among patients with Type II diabetics who received metformin and bitter melon 2000 mg/day was demonstrated.

### Mean Insulin Level

Mean insulin level of the prediabetics during the intervention is given in Table LVII and Figure 24.

**TABLE LVII**  
**EFFECT OF INTERVENTION ON THE INSULIN LEVEL**

Group	Insulin ( $\mu\text{U/dl}$ )(Mean $\pm$ SD)								't' value (N1Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo(B)		Diff	't' value	
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
Bitter gourd to placebo	9.55 $\pm$ 7.11	10.57 $\pm$ 6.49	1.02 $\pm$ 6.62	0.912 <sup>NS</sup>	10.84 $\pm$ 5.69	10.51 $\pm$ 4.73	-0.33 $\pm$ 3.45	0.568 <sup>NS</sup>	0.815 <sup>NS</sup>
B to A (N-30)	Placebo(B)		Diff	't' value	Bitter gourd(A)		Diff	't' value	't' value (N1Vs N4)
Placebo to bitter gourd	7.62 $\pm$ 4.99	9.82 $\pm$ 7.14			2.2 $\pm$ 7.29	1.657 <sup>NS</sup>			

NS- Not Significant

From the Table it is evident that AB group showed an increase in insulin level from 9.55 to 10.57 $\mu\text{U/dl}$  during bitter gourd intervention and a reduction of 0.33  $\mu\text{U/dl}$  during the placebo treatment. A study by Mohammady *et al.*, (2012) reported that the significant increase in serum insulin concentration of diabetic rats after bitter melon treatment might be ascribed to the ability of this agent to stimulate the spontaneous recovery of  $\beta$  cells of the islets of Langerhans. *In vitro* studies using isolated islets of Langerhans demonstrated that bitter melon induced a significant increase in insulin release. The work of Fernandes *et al.*, (2007) and Singh and Gupta (2007) also supports this finding. However insulin level showed 0.33  $\mu\text{U/dl}$  reduction during placebo intervention. Bitter gourd can also improve insulin

sensitivity by increasing insulin-stimulated insulin receptor substrate-1 (IRS1) tyrosine phosphorylation (Sridhar *et al.*, 2008).

In BA group, there was an increase in insulin levels with no significant difference during placebo treatment. But during bitter gourd intervention, the level was steady at 8.24  $\mu\text{U}/\text{dl}$ . None of the changes were statistically significant. May be the duration of treatment was too low to evince any significant results in insulin levels.

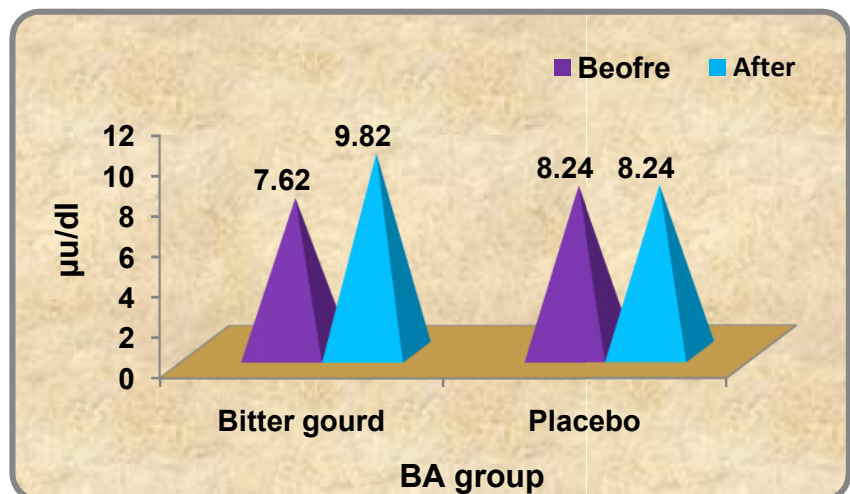
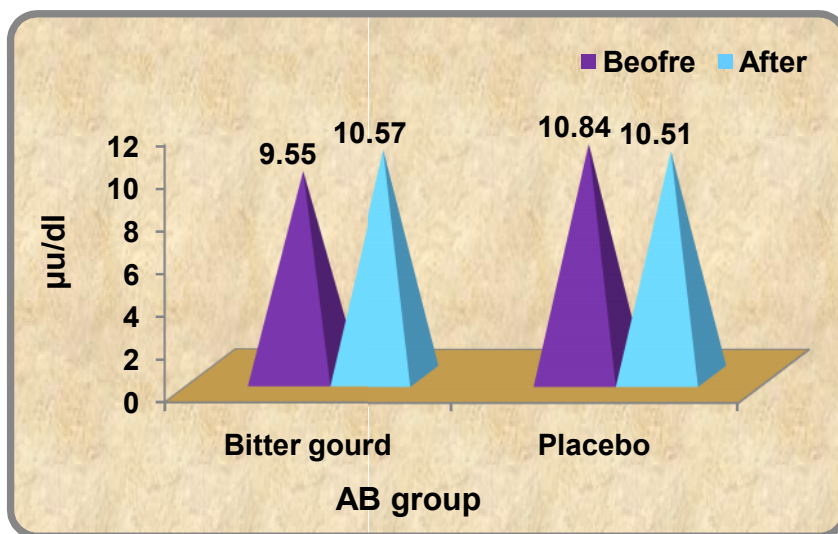


FIGURE 24. EFFECT OF INTERVENTION ON THE INSULIN LEVEL

### Lipid profile

Mean lipid profile of the prediabetics is revealed in Table LVIII and Figure 25.

**TABLE LVIII**  
**EFFECT OF INTERVENTION ON THE LIPID PROFILE OF THE PREDIABETICS**

Lipid profile(mg/dl)	Lipid profile (mg/dl) (Mean ±SD)								't' value (N1 Vs N4)
	Bitter gourd (A)		Diff	't' value	Placebo (B)		Diff	't' value	
A to B (N-35)	Before (N1)	After (N2)			Before (N3)	After (N4)			
<b>Total cholesterol</b>	191.17±36.57	182.43±36.94	-8.74±20.39	2.42*	188±37.78	177.89±31.37	-10.31±25.02	2.40*	4.08**
<b>HDL- cholesterol</b>	40.20±6.68	40.31±6.97	0.11±5.49	0.12 <sup>NS</sup>	39.94±7.6	38.4±7.44	-1.54±4.44	2.025*	2.196*
<b>LDL- cholesterol</b>	27.49±15.15	24.65±15.01	-2.85±7.51	1.96 <sup>NS</sup>	29.09±18.24	29.17±17.16	0.09±16.39	0.02 <sup>NS</sup>	1.80 <sup>NS</sup>
<b>VLDL- cholesterol</b>	132.91±29.04	116.86±36.83	-16.06±22.11	4.234**	121.29±31.79	110.20±29.75	-11.09±22.9	2.812**	7.634**
<b>Triglyceride</b>	147.17±102.98	121.69±76.74	-25.49±67.54	2.2*	136.83±79.93	145.94±85.94	9.11±53.99	0.984 <sup>NS</sup>	0.804 <sup>NS</sup>
B to A (N-30)	Placebo (B)		Diff	't' value	Bitter gourd (A)		Diff	't' value	't' value (N1 Vs N4)
<b>Total cholesterol</b>	164.1±90.09	142.43±48.77			-21.67±84.33	1.166 <sup>NS</sup>			
<b>HDL- cholesterol</b>	41.57±9.48	40.77±10.36	-0.8±4.63	0.851 <sup>NS</sup>	39.2±8.98	40.77±13.03	1.57±7.97	1.077 <sup>NS</sup>	0.566 <sup>NS</sup>
<b>LDL- cholesterol</b>	31.37±12.78	28.49±9.74	-2.88±10.64	1.482 <sup>NS</sup>	34.29±19.12	31.87±20.03	-2.42±14.93	0.762 <sup>NS</sup>	0.084 <sup>NS</sup>
<b>VLDL- cholesterol</b>	123.67±34.5	115.37±32.25	-8.29±19.25	2.359*	114.11±33.01	112.41±31.01	-1.7±27.73	0.335 <sup>NS</sup>	2.129 <sup>NS</sup>
<b>Triglyceride</b>	196.63±36.16	184.67±32.24	-11.97±25.29	2.591*	188.37±35.51	183.1±41.6	-5.27±26.25	1.099 <sup>NS</sup>	2.214*

NS- Not Significant, \*- significant (p<0.05), \*\* significant (p<0.01)

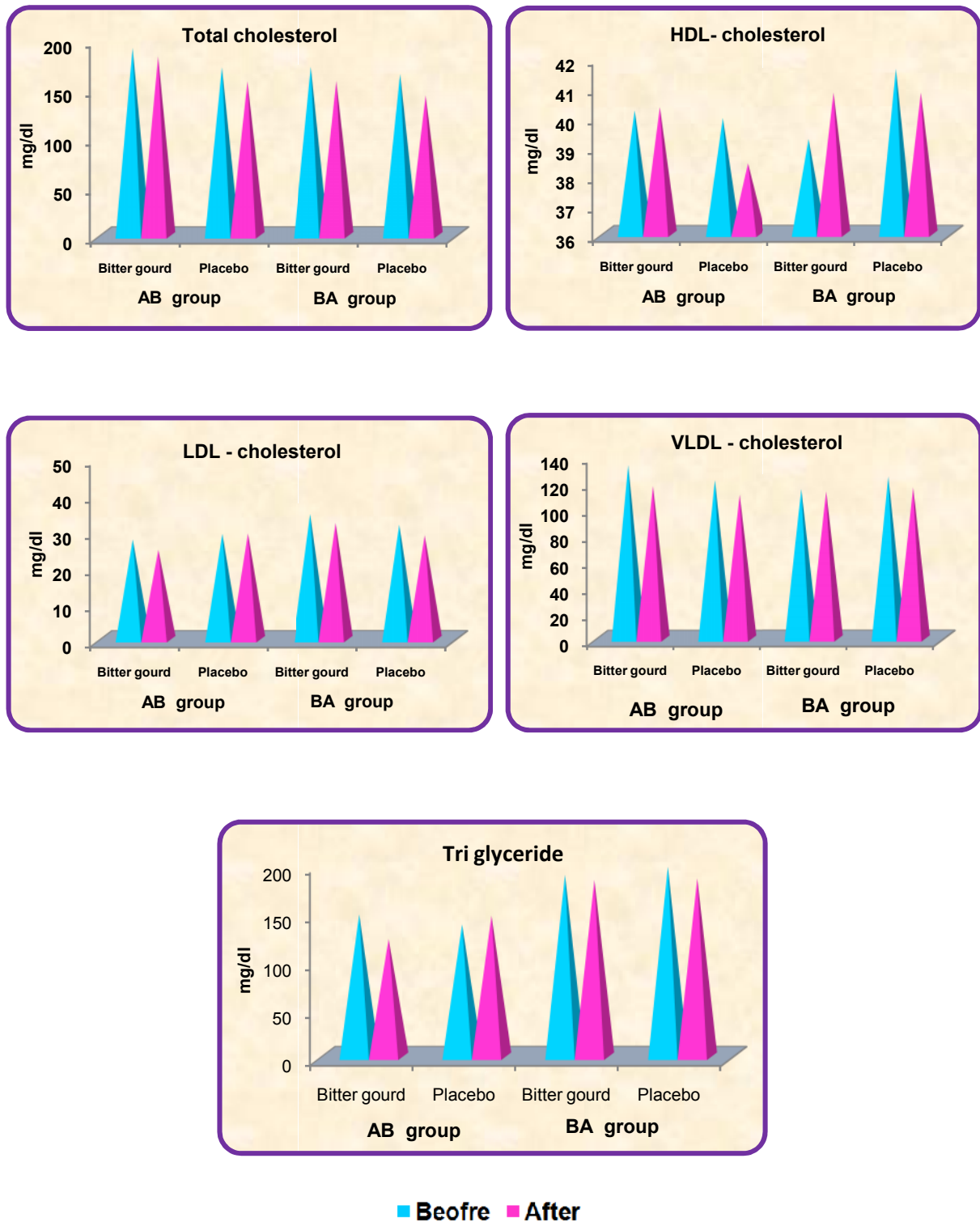


FIGURE 25. EFFECT OF INTERVENTION ON THE LIPID PROFILE

Bitter melon juice is a potent inhibitor of lipogenesis and stimulator of lipolysis activity in human adipocytes and proves to be an effective complementary or alternative therapy to reduce adipogenesis in human (**Nerurkar *et al.*, 2010**).

With regard to the total cholesterol level of AB group, the mean reduction observed was 8.74 mg/dl and 10.31 mg/dl respectively during bitter gourd and placebo intervention. Both bitter gourd and placebo intervention showed a significant difference ( $p < 0.05$ ). A study by Parmer *et al.*, (2011) reported similar findings that in addition to the hypoglycemic activity of bitter gourd fruit juice, it also possesses lipid lowering properties in diabetic animals. Serum cholesterol and triglyceride levels of diabetic rats were found to be significantly decreased by the treatment with 50 per cent bitter gourd juice.

The LDL cholesterol and TG showed significant ( $p < 0.01$ ) reduction during bitter gourd intervention as well as placebo intervention in AB group. In BA group, the reduction was significant only for LDL cholesterol during the bitter gourd intervention.

There was an insignificant reduction in the mean triglyceride, total cholesterol, VLDL cholesterol and LDL cholesterol levels in AB as well as BA groups during the bitter gourd intervention. However in both groups increase in HDL cholesterol level could not be observed during the bitter gourd intervention. May be the intervention period was too short to bring out the changes in the fat metabolism.

Table LVIII, indicates that there was a reduction in the triglyceride level from 147.17 to 121.69 mg/dl during the eight weeks of bitter gourd intervention and the difference was found to be significant at ( $p < 0.05$ ) level in AB group. Whereas in placebo treatment, there was an increase at final level (145.94 mg/dl) when compared with initial level (136.83 mg/dl). But the difference was in significant statistically.

It was also observed that in AB group which started with the bitter gourd intervention, even after wash out period and placebo treatment lowering of the total cholesterol and LDL cholesterol level were recorded. The results of the present study is on par with the study by Hasan and Khatoon (2012) wherein six gram of shade dried Bitter Gourd Tablets (BGT) for 12 weeks showed a significant ( $p < 0.05$ )

reduction in total cholesterol, VLDL and triglyceride levels in diabetic patients and increased the HDL-cholesterol levels among Type II diabetics.

### Bio chemical parameters of pooled data for the cross over study

Table LIX and Figure 26 depicts the mean bio chemical parameters of the prediabetics during bitter gourd intervention for both AB and BA group pooled data.

TABLE LIX

### BIO CHEMICAL PARAMETERS OF THE PREDIABETICS BEFORE AND AFTER BITTER GOURD INTERVENTION

Bio chemical parameters	Bitter gourd Intervention (Mean $\pm$ SD)		't' value
	Initial	Final	
FBG (mg/dl)	109.46 $\pm$ 8.09	99.86 $\pm$ 7.25	7.579**
HbA <sub>1c</sub> (per cent)	6.36 $\pm$ 0.48	5.92 $\pm$ 0.59	5.567**
Fructosamine ( $\mu$ mol/dl)	246.55 $\pm$ 20.9	251.63 $\pm$ 22.13	2.658*
Insulin ( $\mu$ U/dl)	9.25 $\pm$ 6.44	9.49 $\pm$ 5.63	0.328 <sup>NS</sup>

NS- Not Significant, \*- significant ( $p < 0.05$ ), \*\* significant ( $p < 0.01$ )

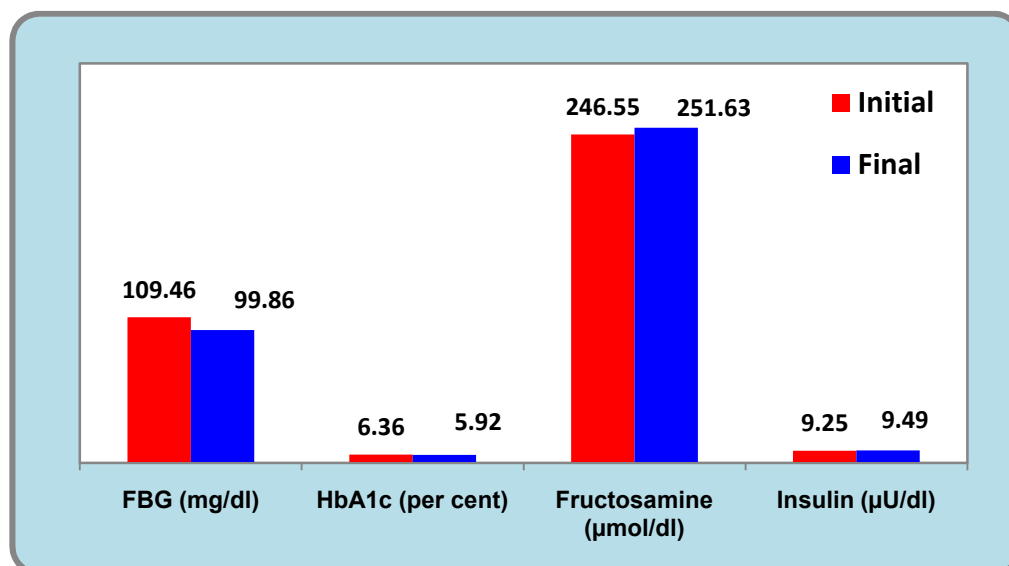


FIGURE 26. BIO CHEMICAL PARAMETERS OF THE PREDIABETICS BEFORE AND AFTER THE BITTER GOURD INTERVENTION

With regard to the fasting blood glucose level and glycosylated hemoglobin in the bitter gourd intervention showed a significant ( $p < 0.01$ ) reduction whereas

contradictory increase in fructosamine level was noticed. In case of insulin, slight increase was found with no statistical significance. Shetty *et al.*, (2005) reported that the edible portion of bitter melon at 10 per cent level in the diet STZ-induced diabetic rats, an amelioration of about 30 per cent in fasting blood glucose was observed.

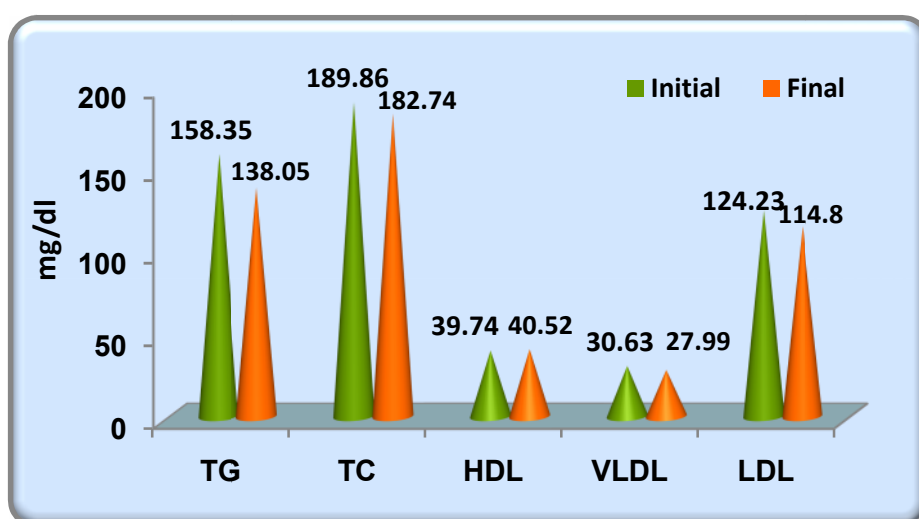
**Lipid profile**

Table LX and Figure 27 presents of the mean bio chemical parameters of the prediabetics during bitter gourd intervention for AB group and BA group for pooled data.

**TABLE LX**  
**LIPID PROFILE OF THE PREDIABETICS BEFORE AND AFTER BITTER GOURD INTERVENTION**

Lipid profile (mg/dl)	Bitter gourd Intervention (Mean ±SD)		't' value
	Initial	Final	
Total cholesterol	189.86±35.95	182.74±39.12	2.4**
HDL- cholesterol	39.74±7.82	40.52±10.18	0.94 <sup>NS</sup>
LDL- cholesterol	124.23±32.31	114.80±34.39	2.9**
VLDL- cholesterol	30.63±17.76	27.99±17.98	1.85 <sup>NS</sup>
Triglyceride	158.35±100.48	138.05±95.37	2.2*

NS- Not Significant, \* significant (p<0.05), \*\* significant (p<0.01)



**FIGURE 27. LIPID PROFILE OF THE PREDIABETICS BEFORE AND AFTER BITTER GOURD INTERVENTION**

The pooled data reveals that triglyceride ( $p < 0.05$ ), total cholesterol ( $p < 0.01$ ) and low density lipoprotein cholesterol ( $p < 0.01$ ) reduced significantly whereas HDL cholesterol increased and VLDL cholesterol reduced without any significant impact due to bitter gourd treatment. Bitter melon has reduced blood glucose and lipids in both normal and diabetic animals by protecting the beta cells, enhancing insulin sensitivity and reducing the oxidative stress (Shih *et al.*, 2009). *Momordica* also contains an insulin like polypeptide, polypeptide-p, which lowers blood sugar levels when injected subcutaneously into Type I diabetic patient. Polypeptide-p, a plant insulin, charantin, vicine, glycosides, and karavilosides reduce blood sugar levels by increasing glucose uptake and glycogen synthesis in the liver, muscles and fat cells (Yadav *et al.*, 2005).

**Correlation analysis**

Table LXI and Figures 28 and 29 depicts the correlation analysis done with body measures with the biochemical parameters.

**TABLE LXI**  
**CORRELATION BETWEEN BODY MEASURES AND BIOCHEMICAL PARAMETERS**

Parameters	Correlation Co-efficient		
	FBG (mg/dl)	HbA1c (per cent)	TC (mg/dl)
Body weight (kg)	+0.124	-0.004	+0.044
BMI	+0.274	-0.103	-0.002
Waist circumference (cm)	+0.135	-0.049	+ 0.161
Waist to Height Ratio	+0.134	-0.026	+0.101
Conicity index	-0.002	+0.038	+0.183
Body fat per cent	+0.071	-0.178	+0.047

The body weight had a positive correlation with fasting blood glucose and total cholesterol whereas the glycosylated haemoglobin was negatively correlated.

In case of BMI a positive association was found with fasting blood glucose and negative association was observed with glycosylated haemoglobin and total cholesterol.

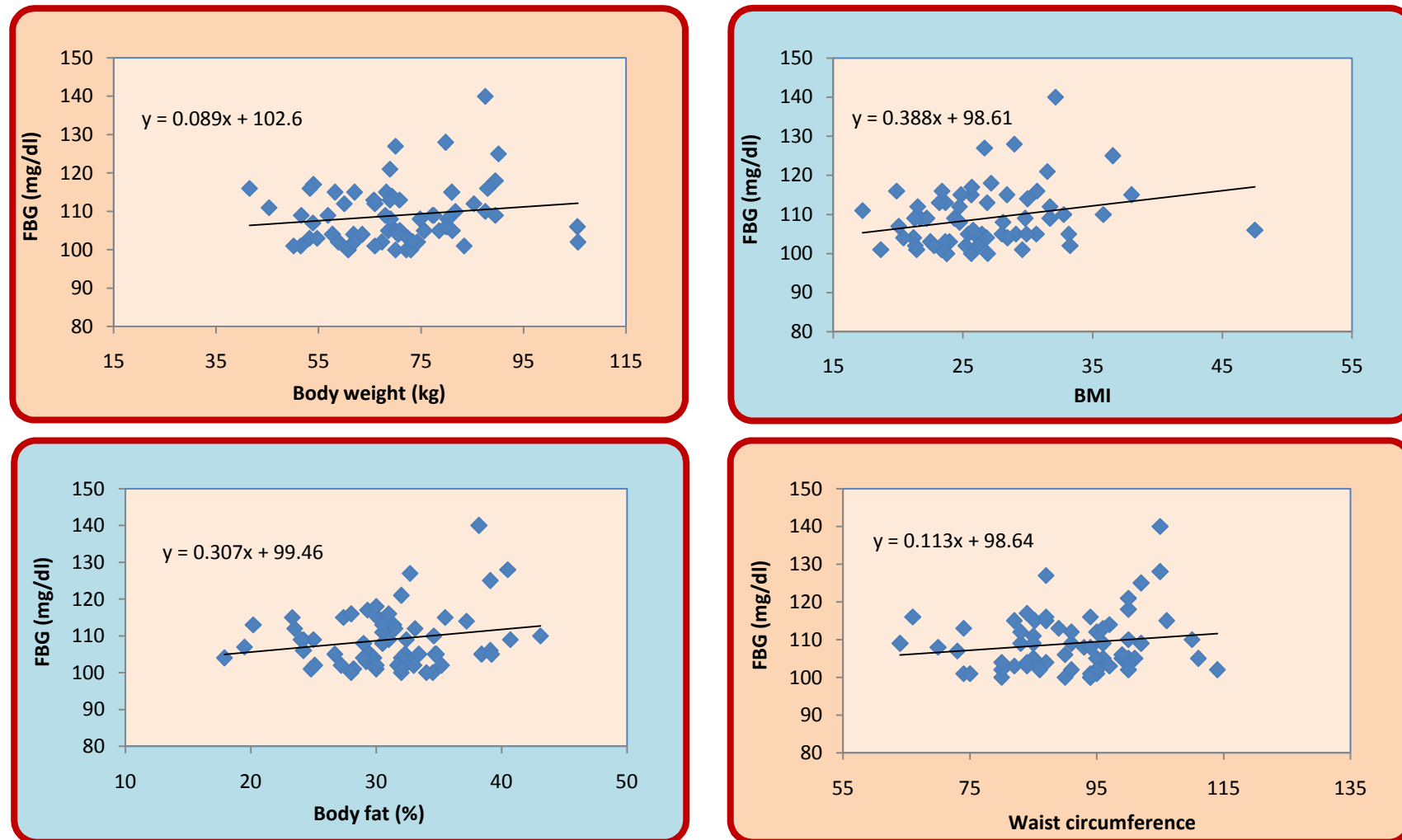
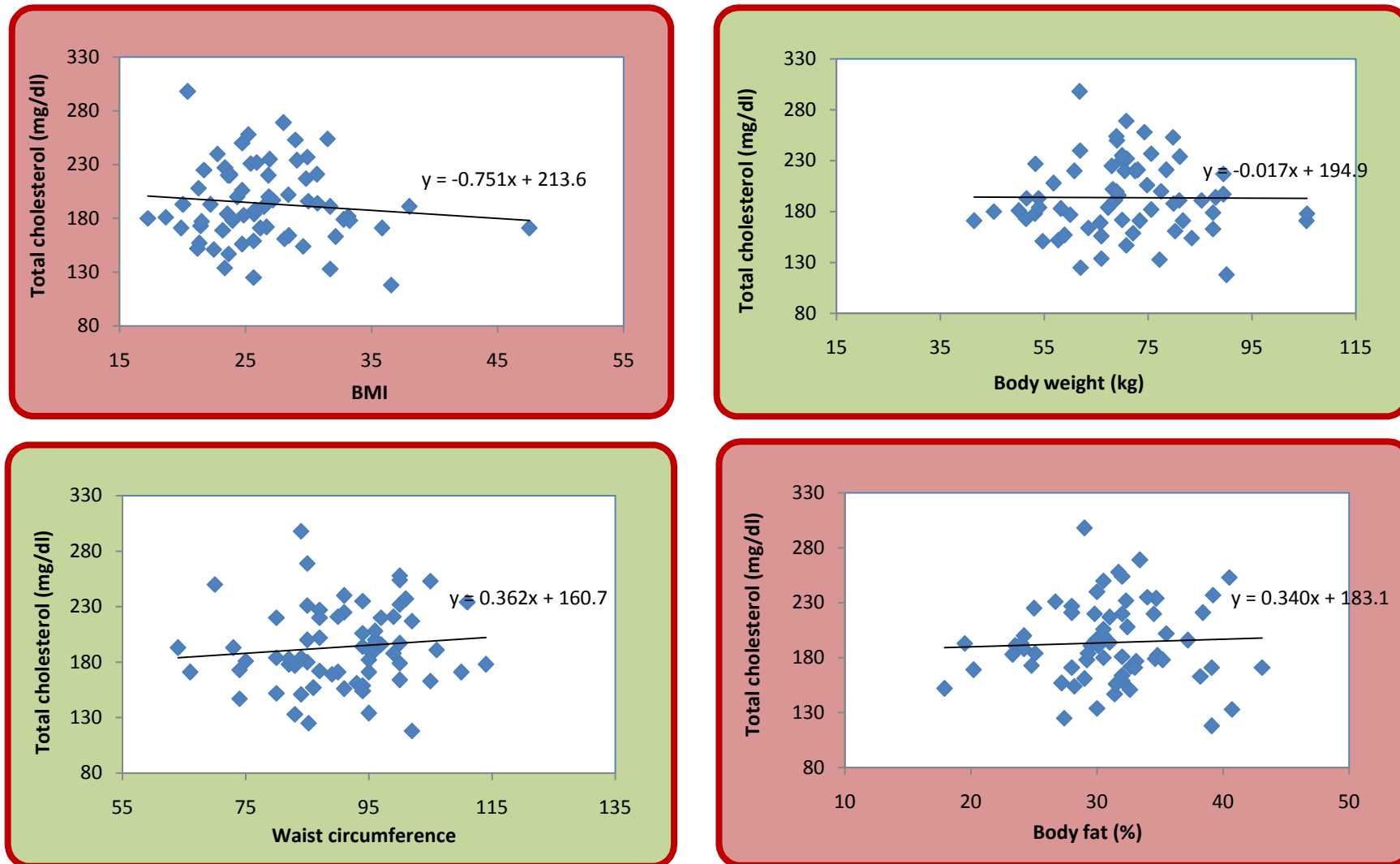


FIGURE 28. CORRELATION BETWEEN BODY MEASURES AND FBG



**FIGURE 29. CORRELATION BETWEEN BODY MEASURES AND TOTAL CHOLESTEROL**

The waist circumference also showed a positive correlation with fasting blood glucose and total cholesterol. A study by Veghari *et al.*, (2014) reported that a positive correlation between FBG and WC was seen in both genders. The cut-off point of WC for detecting of diabetes obtained 89 cm and 107 cm in men and women, respectively.

Waist to height ratio had a positive correlation with glycosylated haemoglobin and total cholesterol whereas the fasting blood glucose was negatively correlated.

With regard to conicity index a positive association was found with fasting blood glucose and negative association was observed with glycosylated haemoglobin and total cholesterol.

From the foregoing discussions, it could be concluded that the intervention with bitter gourd on prediabetics had brought about a very significant and desirable impact on blood parameters, body fat as well as body measurements. Efforts needs to be strengthened to popularize these findings among the public and help to promote the cultivation, processing and consumption of this vegetable among the diabetics and prediabetics.

### PHASE V

#### H. Effect of supplementation of bitter gourd on Type II diabetics

##### a. Anthropometric measurements before and after the supplementation

Table LXII and Figure 30 reveals the mean anthropometric changes before and after supplementation of bitter gourd dhal powder.

From the Table it is evident that the experimental group supplemented with bitter gourd dhal powder showed a significant ( $p < 0.01$ ) body weight reduction after 60 days of supplementation whereas the control group did not show any significant weight reduction. The aqueous extract of bitter gourd is known to significantly ( $p > 0.01$ ) reduce body weight (16 per cent) by increasing the Adenosine 5 MonoPhosphate Kinase (AMPK) enzyme activity that facilitates cellular glucose uptake and fatty acid oxidation. This increased fatty acid oxidation eventually leads to weight loss (Bano *et al.*, 2011).

**TABLE LXII**  
**MEAN ANTHROPOMETRIC MEASUREMENTS OF TYPE II DIABETICS**

Anthropometric measurements	Experimental group				Control Group				E Vs C
	Before	After	Diff.	't' value	Before	After	Diff.	't' value	
Weight (Kg)	67.5±8.53	66.8±8.24	0.7±0.9	3.697**	73.04±11.55	72.97±11.62	0.1	0.846 <sup>NS</sup>	1.776 <sup>NS</sup>
BMI (kg/m <sup>2</sup> )	26.22±2.70	25.92±2.62	1.0±5.67	3.724**	26.26±3.9	26.24±3.94	0.02±0.13	0.608 <sup>NS</sup>	0.223 <sup>NS</sup>
Waist circumference (cm)ssss	91.06±2.1	90.22±2.16	0.08±0.6	6.114**	94.34±8.16	94.38±8.18	0.23±0.71	0.336 <sup>NS</sup>	1.138 <sup>NS</sup>
Waist to height ratio	0.57±0.06	0.56±0.06	0.01	2.99**	0.57±0.06	0.57±0.06	0	0	0.025 <sup>NS</sup>
Conicity Index	1.29±0.10	1.28±0.11	0.01	2.292*	1.315±0.097	1.317±0.098	0	0.677 <sup>NS</sup>	0.749 <sup>NS</sup>

NS- Not Significant, \* significant (p<0.05), \*\* significant (p<0.01)

The mean body weight of the experimental group was 67.5 kg before the intervention and was reduced to 66.8 kg after the intervention period. The difference between the initial and final body weight were statistically analyzed and recorded to be significant at ( $p < 0.01$ ) level. Body weight changes also resulted in significant ( $p < 0.01$ ) BMI reduction in the experimental group after the intervention.

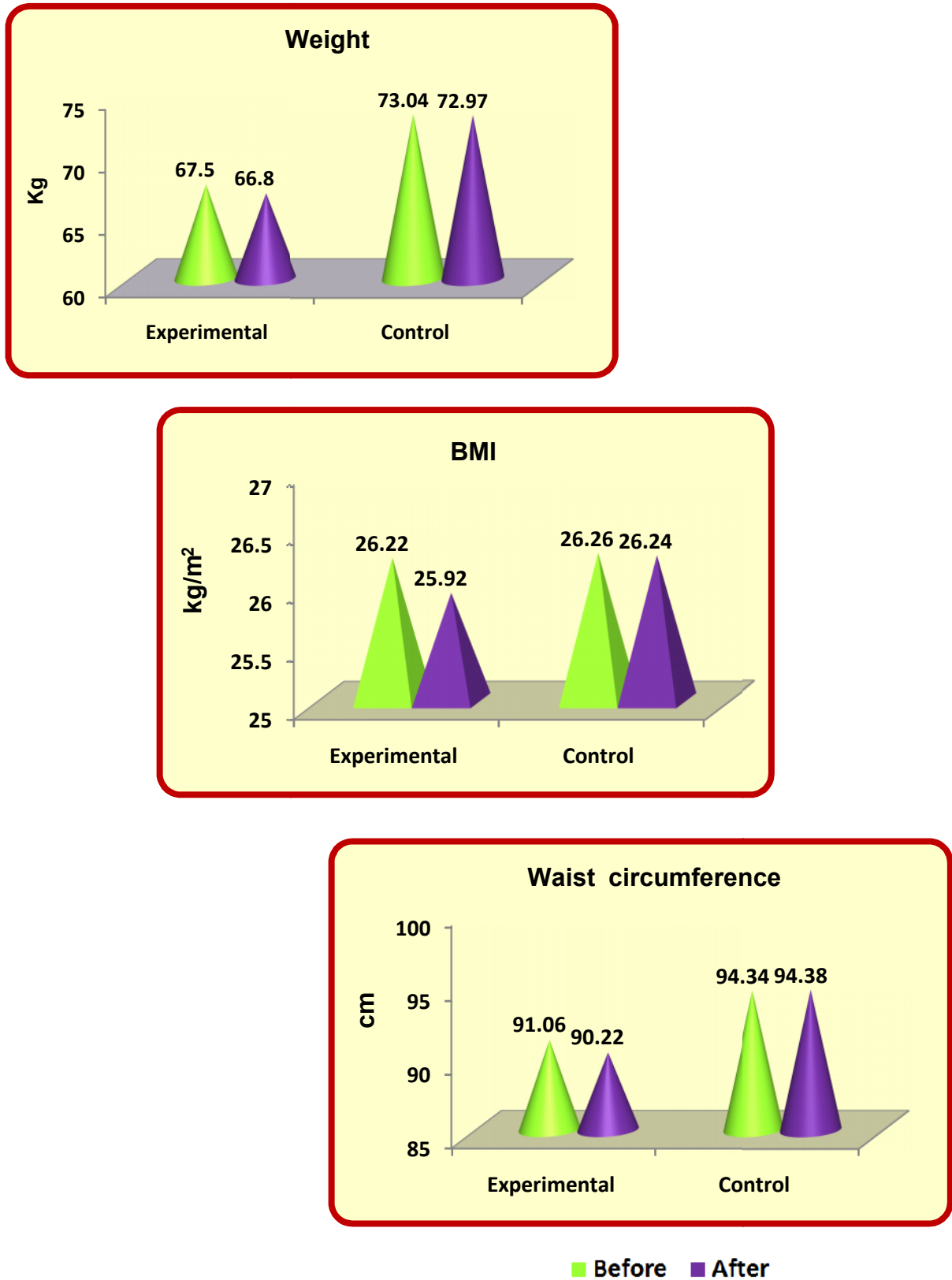
In case of control group, the mean body weight was 73.04 kg at the start of the intervention and had decreased to 72.97 kg after the supplementation period. The reduction was not found to be statistically significant.

Bitter gourd is known to reduce the accumulation of visceral fat in high fat diet-fed rats, and it was suggested that the insulin-sensitising and glucose-lowering properties of bitter gourd might be due to this anti-adiposity effect (Chen and Li, 2005).

The mean waist circumference was 91.06 cm before supplementation which decreased to 90.22 cm after the supplementation and the difference between two levels was found to be statistically significant ( $p < 0.01$ ) whereas the control group did not show any significant reduction in waist circumference.

The same trend of difference (0.01) was observed with waist to height ratio and conicity index before and after the bitter gourd supplementation in the experimental group. A recent study by Chen *et al.*, (2012) revealed that bitter melon seed oil supplementation reduced body weight and fat mass in high fat diet fed mice. According to Huang *et al.*, (2008) adipose tissues also play an important role in obesity. Bitter gourd supplementation is found to suppress the visceral fat accumulation and inhibit adipocyte hypertrophy probably by lowering mRNA levels of fatty acid synthase, acetyl-CoA carboxylase-1, lipoprotein lipase, and adipocyte fatty acid-binding protein, down regulating lipogenic genes in adipose tissues in rats fed high fat diet.

This shows that bitter gourd is effective in lowering the BMI as well as waist circumference and thereby improves the insulin sensitivity and further reduces the complications of diabetes.



**FIGURE 30. MEAN ANTHROPOMETRIC MEASUREMENTS OF TYPE II DIABETICS**

## b. Dietary survey of Type II diabetics

### Mean food intake of the male Type II diabetics

The mean food intake of the Type II diabetics is presented in Table LXII

**TABLE LXIII**  
**MEAN FOOD INTAKE OF THE TYPE II DIABETICS (MALE)**

Food groups	RDA (ICMR, 2010)*	Experimental group		Control group	
		Actual intake (g)	Excess/ deficit (%)	Actual intake (g)	Excess/ deficit (%)
Cereals	375	325.2	-13.3	330	-12.0
Pulses	75	54.0	-28.0	55.2	-26.4
Roots & Tubers	200	140.5	-29.8	142.4	-28.8
GLV	100	42.5	-57.5	43.0	-57
Other vegetables	200	136.0	-32.0	132.3	-33.9
Fruits	100	62.5	-37.5	58.2	-41.8
Milk & Milk Products	300	186.4	-37.9	185.5	-38.2
Fats & Oils	25	33.8	35.2	30.8	23.2
Sugar & jaggery	20	17.4	-13.0	18.5	-7.5

The food intake recorded through 24 hours recall method revealed that male diabetic subjects in experimental group, deficit was observed in cereals (13.3 per cent), pulses (28 per cent), roots and tuber (29.8 per cent), green leafy vegetables (57.5 per cent), other vegetables (32 per cent), fruits (37.5 per cent), milk and milk products (37.9 per cent) and sugar and jaggery (13 per cent) except fats and oils (35.2 per cent) which was in excess compared to the daily recommended dietary allowances.

Similar trend was found in the case of male diabetics in the control group, intake of roots and tubers, green leafy vegetables, other vegetables, fruits and milk and milk products and sugar and jaggery were deficient whereas fats and oils were excess when compared to RDA.

In general, it was observed from the Table that diabetic subjects in both experimental and control group has very poor food choice, eating habits that is low intake of fruits and vegetables and high intake of fats and oils.

### Mean nutrient intake of the male Type II diabetics

Mean nutrient intake of the Type II diabetics is shown in Table LXIII.

**TABLE LXIV**

#### MEAN NUTRIENT INTAKE OF THE TYPE II DIABETICS (MALE)

Nutrients	RDA (ICMR, 2010)*	Experimental group		Control group	
		Actual intake (g)	Excess/ deficit (%)	Actual intake (g)	Excess/ deficit (%)
Energy (Kcal)	2320	2057	-11.3	2111	-9.0
Protein (g)	60	51	-15.0	45	-25.0
Fat (g)	25	32	28.0	35	40.0
Fibre (g)	40	22	-45.0	18	-55.0
Calcium (mg)	600	470	-21.7	520	-13.3
Iron (mg)	17	13	-23.5	10	-41.2
Beta carotene (µg)	4800	3200	-33.3	3254	-32.2
Thiamine (mg)	1.2	1.1	-8.3	1.2	0.0
Riboflavin (mg)	1.4	1.5	7.1	1.4	0.0
Niacin (mg)	16	13.0	-18.8	14	-12.5
Vitamin C (mg)	40	52	30.0	43	7.5

Male Type II diabetics in the experimental group showed deficit in energy intake by 11.3 per cent, protein by 15 per cent, fibre by 45 per cent, calcium by 21.7 per cent, iron by 23.5 per cent, beta carotene by 33.3 per cent, thiamine by 8.3 per cent and niacin by 18.8 per cent. In the case of other nutrients namely fat, riboflavin and ascorbic acid are excess by 28, 7.1 and 30 per cent respectively.

The intake of nutrients by the male Type II diabetics in the control group showed a deficit of 9, 15.3, 25, 55, 13.3, 41.2, 32.2 and 12.5 per cent respectively for energy, protein, fibre, calcium, iron, beta carotene and niacin respectively. Whereas fat and ascorbic acid were excess by 40 and 7.5 per cent respectively when compared to recommended dietary allowances.

### Mean food intake of the female Type II diabetics

Table LXIV shows the mean food intake of the Type II diabetics.

**TABLE LXV**  
**MEAN FOOD INTAKE OF THE TYPE II DIABETICS (FEMALE)**

Food groups	RDA (ICMR, 2010)*	Experimental group		Control group	
		Actual intake (g)	Excess/deficit (%)	Actual intake (g)	Excess/deficit (%)
Cereals	270	217	-19.6	225	-16.7
Pulses	60	40	-33.3	50	-16.7
Roots & Tubers	200	120	-40.0	150	-25.0
GLV	100	65	-35.0	72	-28.0
Other vegetables	200	170	-15.0	155	-22.5
Fruits	100	62	-38.0	70	-30.0
Milk & Milk Products	300	225	-25.0	240	-20.0
Fats & Oils	20	32	60.0	34	70.0
Sugar & jaggery	20	24	20.0	25	25.0

\*ICMR, 2010

The mean intake of cereals among the female Type II diabetics in the experimental and control group was 217 g and 225 g respectively. When compared with the recommended dietary allowances, the intake of cereals was deficit by 19.6 and 16.7 per cent in experimental and control group respectively.

With regard to the experimental group, the intake of pulses, roots and tuber, green leafy vegetables, other vegetables, fruits and milk and milk products were deficit by 33.3, 40, 35, 15, 38 and 25 per cent respectively. In the control, group also all the above-mentioned food groups were also deficit when compared to RDA. In experimental group, the consumption of fats and oils and sugar and jaggery exceeded the RDA by 60 and 20 per cent respectively, while in the control group, the deficit was observed to the tune of 70 and 75 per cent respectively.

### Mean nutrient Intake of the female Type II diabetics

Table LXV shows the mean nutrient intake of the female Type II diabetics.

TABLE LXVI

## MEAN NUTRIENT INTAKE OF THE TYPE II DIABETICS (FEMALE)

Nutrients	RDA (ICMR, 2010)*	Experimental group		Control group	
		Actual intake (g)	Excess/ deficit (%)	Actual intake (g)	Excess/ deficit (%)
Energy (Kcal)	1900	1830	-3.7	1760	-7.4
Protein (g)	55	42	-23.6	38	-30.9
Fat (g)	20	32	60.0	39	95.0
Fibre (g)	40	18	-55.0	22	-45.0
Calcium (mg)	600	430	-28.3	490	-18.3
Iron (mg)	17	14	-17.6	12	-29.4
Beta carotene (µg)	4800	3318	-30.9	3256	-32.2
Thiamine (mg)	1.0	0.9	-10.0	1.1	10.0
Riboflavin (mg)	1.1	1.2	9.1	1.2	9.1
Niacin (mg)	12	10	-16.7	11	-8.3
Vitamin C (mg)	40	63	57.5	56	40.0

\*ICMR, 2010

From the Table it is clear that in experimental group, intake was deficit by 3.7 per cent, 23 per cent, 55 per cent, 28.3 per cent, 17.6 per cent, 30.9 per cent, 10 per cent and 66.7 per cent for energy, protein, fibre, iron,  $\beta$ -carotene, thiamine and niacin respectively. However, the intake of other nutrients such as fat, riboflavin and vitamin c were in exceed to RDA.

In control group, intake deficit was observed for energy (7.4 per cent), protein (30.9 per cent), fibre (45 per cent), iron, (29.4 per cent)  $\beta$ -carotene (32.2 per cent) and niacin (6.3 per cent).

It is evident from the table that the energy intake was almost on par with the recommended dietary allowances while inadequate fibre would lead to accumulation of fat in the adipose tissue that results in complications such as metabolic syndrome, diabetes and cardiovascular disease.

### c. Biochemical profile of the diabetics before and after the supplementation

Table LXVI and Figure 31 illustrates the changes in biochemical parameters before and after the bitter gourd intervention among diabetics.

TABLE LXVII

## MEAN BLOOD GLUCOSE LEVELS OF TYPE II DIABETICS

Blood glucose	Experimental group				Control group				E Vs C
	Before	After	Diff	't' value	Before	After	Diff	't' value	
FBG (mg/dl)	159.85±29.72	150.9±22.21	-8.95±14.34	2.72**	162.81±22.22	167.32±20.0	5.58±9.62	2.529*	5.269**
PPBG (mg/dl)	231±50.81	221.05±42.86	-9.95±22.72	1.909 <sup>ns</sup>	240.38±46.19	255.26±45.58	13.16±17.02	3.37**	12.94**
HbA1c (per cent)	7.53±0.55	7.29±0.49	-0.25±0.27	3.97**	7.88±0.68	7.79±0.67	-0.13±0.49	1.122 <sup>NS</sup>	2.599**

NS- Not Significant, \* significant (p<0.05), \*\* significant (p<0.01)

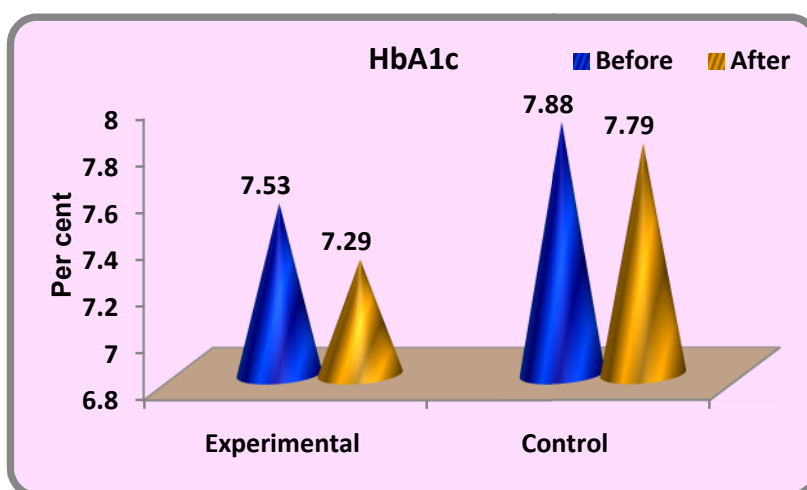
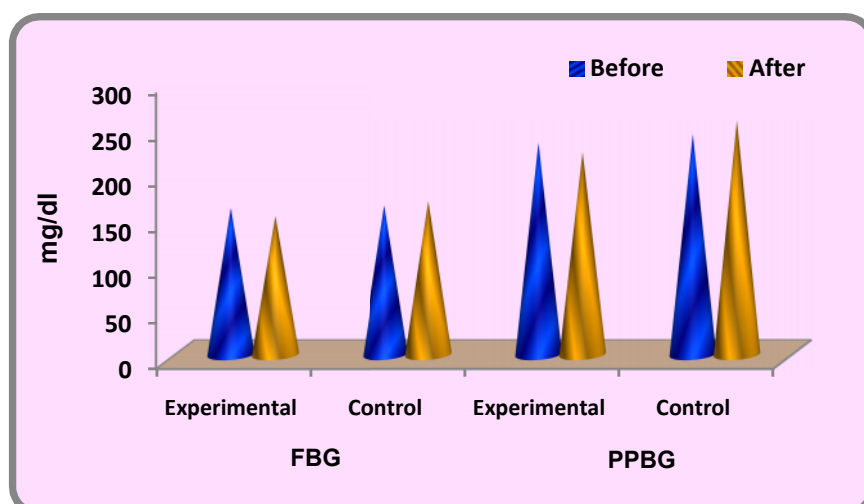


FIGURE 31. MEAN BLOOD GLUCOSE LEVELS OF TYPE II DIABETICS

Efird *et al.*, (2011) declared that the fresh (raw) bitter gourd juice significantly reduce mean blood sugar levels and correspondingly increase mean insulin levels during a 50 g oral glucose test, compared with standard test of distilled water ( $p < 0.05$ ) among non-insulin-dependent diabetics.

Frozen bitter melon pulp juice manifested equally positive results in studies of diabetics (Narayanappa *et al.*, 2010). This observation is also in accordance with the present study that the diabetic subjects were found to exhibit significant ( $p < 0.01$ ) hypoglycemic effect compared to control groups. Table LXVII showed that the mean fasting blood glucose level of the experimental group was 159.85 mg/dl which had reduced to 150.9 mg/dl after intervention with bitter gourd for a period of two months. The initial and final values were analyzed statistically and found to be significant at ( $p < 0.01$ ) level. In the control group, there was a significant increase between the initial (162.81 mg/dl) and final (167.32 mg/dl) levels of fasting blood glucose. Significant difference was observed between experimental and control at ( $p < 0.01$ ) level and when initial values of the experimental and control group were compared, it showed significant difference at ( $p < 0.01$ ) level. This kind of difference in control group might be due to consumption of excess non vegetarian food during their local festival.

Studies have reported that the compound charantin in bitter gourd is more effective than the oral hypoglycemic agent tolbutamide. Charantin-rich extract is considered as a potential agent for improving insulin sensitivity in Type II diabetic patients rather than for protecting patients with Type I diabetics against  $\beta$ -cell dysfunction (Wang *et al.*, 2014).

The mean post prandial blood glucose level of experimental group before supplementation was 231 mg/dl and had reduced to 221.05 mg/dl after supplementation for 60 days. The mean post prandial blood glucose level of control group was 240.38 mg/dl before supplementation and it was 255.26 mg/dl after supplementation which reveals a statistical significant increase.

Glycosylated hemoglobin testing also measures chronic glucose exposure over two-to-three month period and is less influenced by internal factors including

stress and/or illness. The glycosylated hemoglobin level before supplementation was 7.53 per cent and declined to 7.29 per cent after the bitter gourd supplementation. The difference was found to be statistically significant at ( $p < 0.01$ ) level. In case of control group glycosylated hemoglobin was reduced however without any statistical significance.

From the above result, it was concluded that bitter gourd is having hypoglycemic effect by lowering fasting blood glucose, post prandial blood glucose and glycosylated hemoglobin for the diabetes subjects.

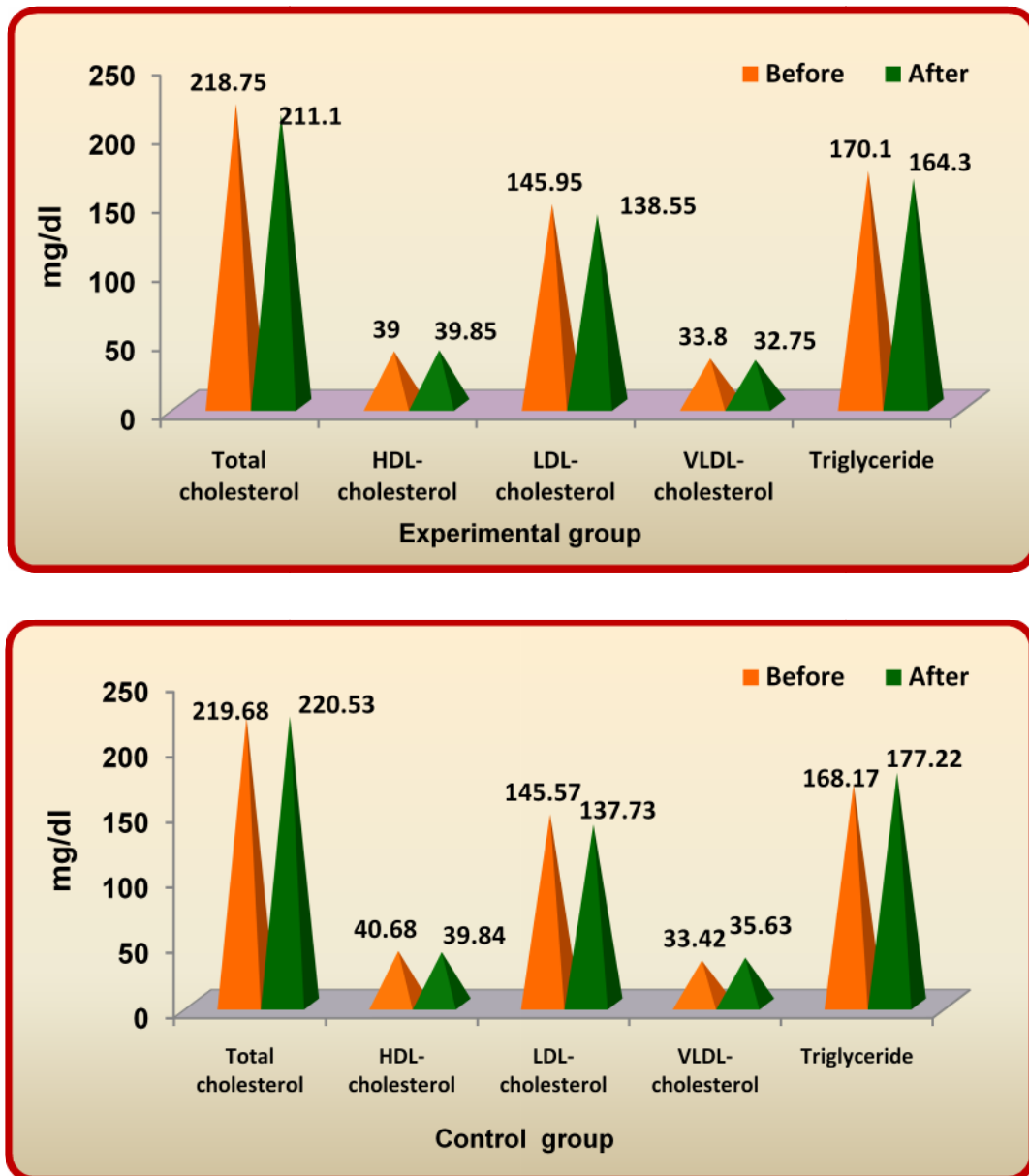
### **Lipid profile**

Table LXVII and Figure 32 exhibits the changes in lipid profile before and after the bitter gourd intervention among diabetics.

**TABLE LXVIII**  
**MEAN LIPID PROFILE OF TYPE II DIABETICS**

Lipid profile (mg/dl)	Experimental				Control				E Vs C
	Before	After	Diff	't' value	Before	After	Diff	't' value	
Total cholesterol	218.75 ± 41.58	211.10±38.10	-7.65±7.16	4.659**	219.68±33.39	220.53±25	0.84±28.84	0.127 <sub>NS</sub>	0.971 <sub>NS</sub>
HDL - cholesterol	39 ± 8.27	39.85±6.18	0.85±4.07	0.911 <sub>NS</sub>	40.68±7.17	39.84±7.16	-0.84±5.15	0.713 <sub>NS</sub>	0.061 <sub>NS</sub>
LDL - cholesterol	145.95 ± 35.05	138.55±32.14	-7.4±6.83	4.723**	145.57±27.77	137.73±21.46	-7.73±25.58	1.34 <sub>NS</sub>	0
VLDL - cholesterol	33.8 ± 19.33	32.75±17.76	-1.05±2.42	1.893 <sub>NS</sub>	33.42±12.61	35.63±12.45	2.03±6.83	1.421 <sub>NS</sub>	0.651 <sub>NS</sub>
Triglyceride	170.10±97.18	164.3±88.74	-5.8±12.58	20.01**	168.17±64.93	177.22±64.29	9.79±34.65	0.451 <sub>NS</sub>	0.752 <sub>NS</sub>

NS- Not Significant, \* significant (p<0.05), \*\* significant (p<0.01)



**FIGURE 32. MEAN LIPID PROFILE OF TYPE II DIABETICS**

From Table, it was apparent that the mean total cholesterol level of the experimental group was 218.75mg/dl and reduced to 211.10 mg/dl after the intervention period and found to be statistically significant at ( $p < 0.01$ ) level. No significant difference was found between the initial (219.68 mg/dl) and final (220.53 mg/dl) levels of the total cholesterol with regard to the control group.

With regard to the mean HDL cholesterol level of experimental group, it was recorded as 39 mg/dl before the intervention and it had been increased to 39.85 mg/dl after the end of the intervention period without any statistical significance.

The mean LDL cholesterol level of experimental group had declined significantly ( $p < 0.01$ ) from 145.95 mg/dl to 138.55 mg/dl. Though there was an decrease from 145.57 mg/dl to 137.73 mg/dl in the control group, the difference was found to be not significant between the initial and final levels.

The VLDL cholesterol level depends on the level of triglyceride. In experimental, VLDL showed a reduction of 1.05 mg/dl difference. However there was no significant difference between the initial and final levels of the control group during the intervention period.

The mean triglyceride level of the experimental group of the selected diabetics was found to be decreased (5.8 mg/dl) after the intervention with a statistical significant difference at ( $p < 0.01$ ) level. In case of control group, no significant difference was observed between the initial and final levels after the intervention period. The decrease in lipid profile seen in this study is in agreement with the earlier study by Bano *et al.*, (2011) that five week oral administration of aqueous extract of *Momordica charantia* showed significant decrease in cholesterol (21 per cent) ( $p < 0.01$ ), triglycerides (20 per cent) ( $p < 0.01$ ), LDL cholesterol (20 per cent) ( $p < 0.01$ ) and increase in HDL (4 per cent) ( $p < 0.05$ ).

The above results accomplished that the bitter gourd intervention might have a hypoglycemic effect along with a hypolipidemic effect which in turn helps to reduce the macro and micro vascular complications of diabetes.