4

RESULTS AND DISCUSSION

The results of the study **"Efficacy of prebiotic food in the management of hyperlipidemia"** is discussed under the following phases:

4.1. PHASE I

Details on awareness knowledge and practice of prebiotic food consumption pattern

4.1.1. Background details ofthe subjects

4.1.2 Awareness on prebiotics

4.1.3 Perception about prebiotic foods

4.1. 4. Practice in the useof prebiotic foods

4.2. PHASE II

Formulation and standardisation of a prebiotic food

4.2.1. Prebiotic products available in the market

4.2.2. Snacking pattern of the subjects

4.2.3. Details on standardization of the developed prebiotic product

4.2.4. Product characteristics

4.2.5. Nutrient content of the prebiotic biscuits

4.2.6. Sensory evaluation of the prebiotic biscuits

4.2.7. Microbial safety

4.2.8. Cost estimation of the selected biscuit

4.3. PHASE III

Details of subjects screened for hyperlipidemia

4.3.1. Demographic details of the subjects

4.3.2 Lipid profile of the subjects

4.3.3. Association of demographic factors with lipid profile

4.4. PHASE IV

Impact of the developed prebiotic food product on hyperlipidemics

4.4.1. Background details of the hyperlipidemic subjects

4.4.2.Details on anthropometric measurementand blood pressure

4.4.3. Dietary pattern of the subjects

4.4.4. Lipid profile of the hyperlipidimic subjects

4.4.5. Effect of supplementation on serum lipid parameters

4.1 PHASE I

Details on awareness knowledge and practice of prebiotic food consumption pattern

4.1.1 Background details of the subjects

A. Age and gender distribution

The age and gender distribution of the selected subjects is shown in Table IV

TABLE IV

AGE AND GENDER DISTRIBUTION

Subjects	Age (years)	Gender	N=1400	
			N	%
Adolescents	10-14	M*	55	4
		F**	44	3
	15 -19	M	118	8
		F	231	17
Adults	20 - 29	M	74	5
		F	128	9
	30 - 39	M	91	7
		F	153	11
	40 - 49	M	61	4
		F	99	7
	50 -59	M	52	4
		F	83	6
Elderly	60-75	M	98	7
		F	113	8

***M-Males; **F-Females**

The age of the selected 1400 subjects ranged from 10-75 years and hence adolescents, adults and elderly were seen among the selected population and gender distribution showed that 61 per cent were females and the rest 39 per cent were males. Fifty three per cent were adults who predominated the group while 32 per cent were adolescents and 15 per cent were elderly subjects.

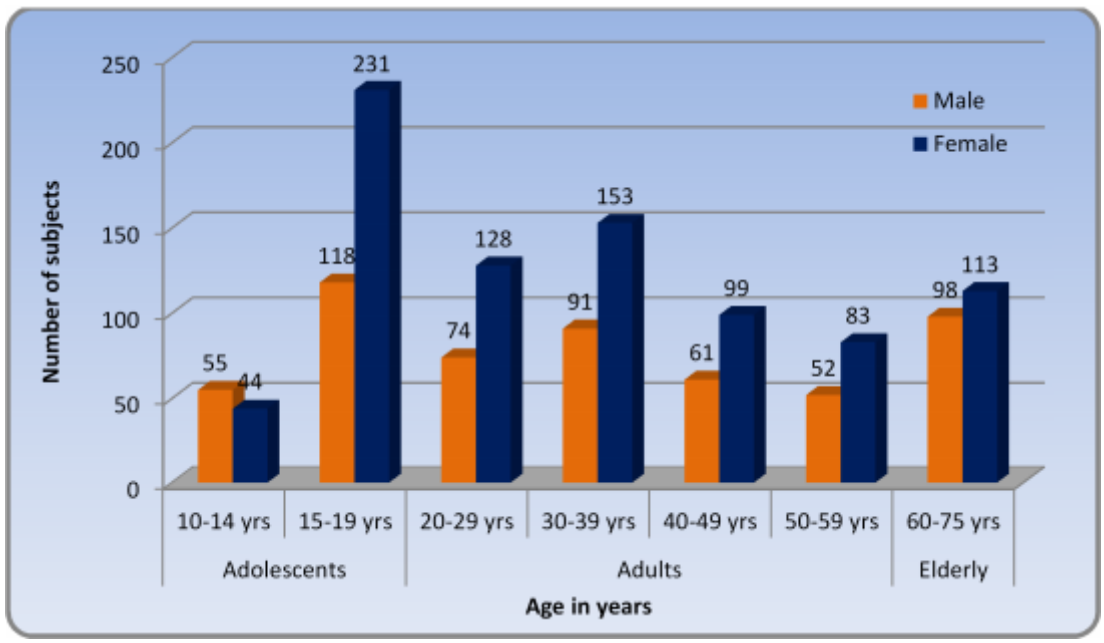


Figure7

Age and gender distribution of selected subjects

B. Education status

The education status of the subjects is given in Table V.

TABLE V

EDUCATION STATUS

Education	Males N=552		Females N=848	
	No.	%	No.	%
Higher secondary	59	11	44	5
Diploma	45	8	18	2
Undergraduates	117	21	284	33
Post-graduate	290	53	429	51
Professional courses	41	7	73	9

The education status of the subjects showed that 51 per cent females and 53 per cent males were post graduates. Twenty one per cent males and 33 per cent females were graduates. It was noted that only eight per cent females and two per cent of the male subjects were diploma holders while seven per cent and nine per cent of the male and female subjects undertook professional courses.

C. Occupation status

TABLE VI

OCCUPATION STATUS

Occupation	Males N=378		Females N=518	
	No.	%	No.	%
Teachers	nil	nil	59	11
Healthcare	21	6	10	2
Banking	47	12	42	8
IT sector	52	14	14	3
Govt. Employee	205	54	262	51
Housewives	nil	nil	92	18
Self employed	37	10	20	4
Others	16	4	19	3

Table VI shows the occupation status of the subjects and it showed that except for 36 per cent (504) all the others were employed. Thirty two per cent were adolescents and hence were studying and the rest four per cent were in the elderly group. Fifty two per cent of the subjects were employed in government sector performing jobs like accounts and clerical and they were also cashiers.

Ten per cent were in bank services and seven per cent were in teaching profession working in school and colleges as faculties. Six per cent were self-employed whereas four per cent were shop keepers and technicians

D. Family Income status

The family income status of the subjects is given in Table VII.

TABLE VII

FAMILY INCOME STATUS

Income per month*(Rs)	Males N=552		Females N=848	
	No.	%	No.	%
<5000 (EWS)	5	1	8	1
5001-10000 (LIG)	47	9	89	10
>10000(HIG)	500	90	751	89

***HUDCO 2010, EWS-Economically Weaker Section,**
LIG-Low Income Group, HIG – High income group

Majority of the subjects (89 per cent) were in high income group (HIG).The economically weaker section earning income of less than Rs.5000 was noted among one per cent each of male and female subjects.

Regarding the type of family 88 per cent of the subjects were in nuclear type and 73 per cent had a family size of 3-4 members.

4.1.2 Awareness on prebiotics

Table VIII presents the awareness of prebiotic foods among the subjects

TABLE VIII

AWARENESS ON PREBIOTIC CONCEPT

Subjects		Aware n=348		Unaware n = 1052	
		N	%	N	%
Adolescents	**M***	65	19	122	12
	F**	76	22	220	21
Adults	**M**	71	20	205	19
	F	107	31	323	31
Elderly	**M**	14	4	84	8
	F	15	4	98	9

***M-Males; **F-Females**

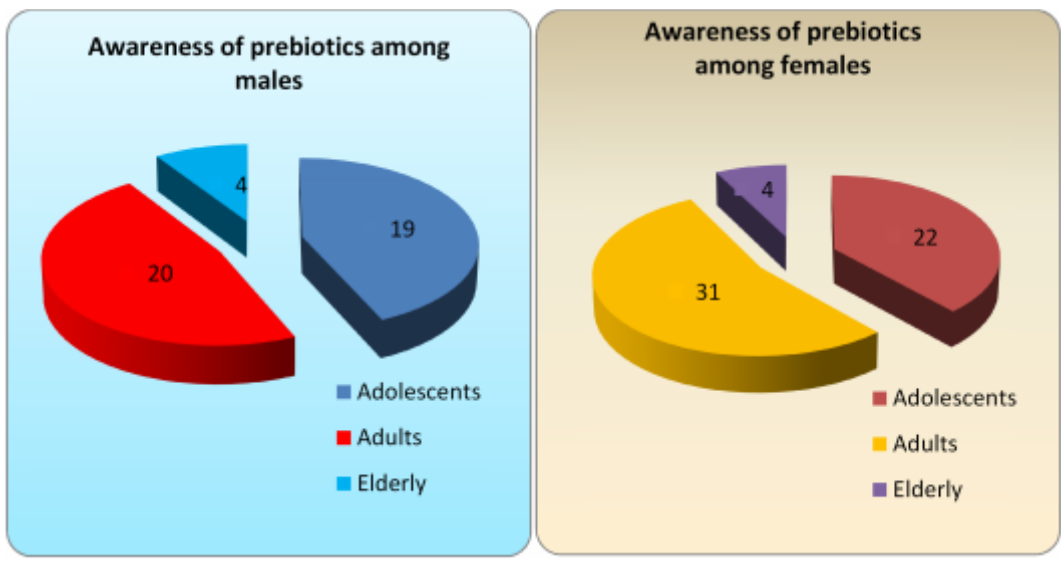


Figure 8

Awareness of prebiotic concept

Among the 1400 subjects, 25 per cent of the subjects responded that they were aware of prebiotics. Majority (75 per cent) were unaware of prebiotics and responded that they have not heard or read about it.

Among the three age groups, it was noticed that to a certain extent i.e 19 per cent males and 22 per cent female adolescents were aware of prebiotics comparatively while the elderly were mostly unaware. Females were better informed than the males.

According to Büyükkaragöz *et al.,* 2014 female respondents were nearly three times more aware of functional food than the male respondents.

4.1.2.1. Sources of information

Table VIII gives the sources of information from which the subjects got to know about prebiotics.

TABLE IX

SOURCES OF INFORMATION

Details*	Subjects	
	N = 348	%
Internet	93	27
Health Magazines	112	32
Newspapers	73	21
TV/Radio	55	16
Doctors/Dietitian	61	17.5
Lectures from experts	68	19.5
Friends/Colleagues	8	2
Others	28	8

***Multiple response**

The awareness of prebiotic information was mainly from magazines (32 per cent), internet (27 per cent) and newspapers (21 per cent). It was the net and social media which played an important role in creating awareness about prebiotics.

According to Charlton *et al.,* 2004; Venter and Hanekom, (2010), media is a major nutritional health information source.

Health professionals such as doctors and dietitians are credible sources of information pertaining to nutrition and health (Landstrom *et al.,*2009 and Lalor *et al.,* 2011) however the information on prebiotics foods from medical fraternity namely doctors and dietitians was only 17.5 per cent.

Scientific lectures from experts created awareness among 19.5 per cent of the subjects. Since the social media is mostly accessed by the adolescents and the adult age group it is obvious that media is their source of information.

4.1.2.2. Association of awareness of prebiotics with gender

TABLE X
ASSOCIATION OF AWARENESS
WITH GENDER

Gender	AWARENESS			
	Unaware N=1052		Aware N=348	
	No.	%	No.	%
Male	424	40	128	37
Female	628	60	220	63
Chi-square	Value			
	1.215^{NS}			

Table X shows the association of awareness with gender. Awareness among the females were higher as compared to the males and it was found to be 63 per cent. Forty per cent of males were found to be unaware of prebiotics. The association between gender and awareness showed no significant relationship.

4.1.2.3. Association of awareness of prebiotics with education

Table XI shows the association of awareness with education

TABLE XI

ASSOCIATION OF AWARENESS

WITH EDUCATION

Education	Awareness			
	Unaware N=1052		Aware N=348	
	No.	%	No.	%
Higher secondary	72	7	31	9
Diploma	45	4	18	5
Undergraduates	299	28	102	30
Post-graduate	540	52	179	51
Professional courses	96	9	18	5
Chi -Square	**Value**			
	7.070^{NS}			

Ns- Not- significant

The table shows the association of education with awareness and it was found that awareness of prebiotics among the postgraduates were higher i.e. 51 per cent compared to other education levels. Thirty per cent of the undergraduates was observed to were found to be aware of prebiotics. Association between education and awareness was not significant.

4.1.2.4. Association of awareness of prebiotics with occupation

Table XII shows the association of awareness with occupation

TABLE XII

ASSOCIATION OF AWARENESS WITH OCCUPATION

Occupation	Awareness			
	Unaware N=1052		Aware N=348	
	No.	%	No.	%
Teachers	49	5	10	3
Healthcare	21	2	10	3
Bankers	72	6	17	5
IT sector	52	5	12	3
Govt. Employee	375	36	94	27
Housewives	65	6	27	8
Student	336	32	168	48
Self employed	53	5	4	1
Others	29	3	6	2
Chi- square		**Value**		
		42.768**		

****- Significant at one per cent level**

. Awareness among the subjects with different occupation shows that subjects who were self employed were least aware. Students had the highest awareness level compared to the other groups and was found to be 48 per cent. Twenty seven per cent of the subjects who were aware were government employees. The association between the occupation and awareness showed a significant relationship at one per cent level.

4.1.2.5. Association of awareness of prebiotics with income

Table XIII shows the association of income with the awareness of prebiotic concept

TABLE XIII

ASSOCIATION OF AWARENESS WITH INCOME

Income per month*(Rs)	Unaware N=1052		Aware N=348	
	No.	%	No.	%
<5000 (EWS)	10	1	3	1
5001-10000 (LIG)	103	10	33	9
>10000(HIG)	939	89	312	90
Chi-square	Value			
	47.877**			

****- Significant at one per cent level**

. It is evident from the table that awareness of prebiotics has a significant relationship with the income of the subjects. Higher income group were found to be more aware of prebiotics than the lower income group. Factors such internet and media among other reasons can be contributory to the increase awareness among the high income group. Income of the subjects was found to have a significant relationship with awareness of prebiotics concept (Chi-square value - 47.877)

4.1.3 Perception about prebiotic foods

TABLE XIV

PERCEPTION ON PREBIOTIC FOODS

Perception about definition of the term prebiotics	N=348#					
	Adolescents N=141		Adults N=178		Elderly N=29	
	N	%	N	%	N	%
Do not Know	40	28	103	58	18	62
Foods similar to probiotics	26	18.5	38	21	11	38
Foods that promote health	57	40	10	6	nil	nil
Foods that stimulate colon activity	5	4	26	15	nil	nil
Non digestible food ingredients	13	9.5	1	0.6	nil	nil

 # -consumers who are aware of prebiotics

Table XIV gives the perception of the subjects on prebiotic foods. Twenty eight per cent of the adolescents, 58 per cent adults and 62 per cent elderly age group did not have knowledge about the meaning of the term prebiotic food. Interestingly, 21 per cent of adults, 18.5 per cent of adolescents and 38 per cent of elderly said that prebiotic foods were similar to probiotics. Only the adolescent and the adult age group responded that prebiotics can promote health and it stimulates colon activity.

The consumption of prebiotic foods even among those who were aware of it was only 58 per cent but on the contrary whether aware or unaware everyone was consuming wheat, onion, garlic, tomato and banana on a regular basis which are the common prebiotic foods.

4.1.3.1 Association of perception of prebiotics with gender

TABLE XV

ASSOCIATION OF PERCEPTION OF PREBIOTICS WITH GENDER

Perception about definition of the term prebiotics	N=348#				Chi-square value
	Males n=128		Females n=220		
	N	%	N	%	
Do not Know	60	47	101	46	2.075^{NS}
Foods similar to probiotics	28	22	47	21	
Foods that promote health	27	22	40	18	
Foods that stimulate colon activity	10	8	21	10	
Non digestible food ingredients	3	2	11	5	

 # -consumers who are aware of prebiotics; **NS- not significant**

Table XV shows the association of gender with perception of the term prebiotics. It is clear from the table that among 348 subjects who were aware of prebiotics 220 subjects were females and 128 were males. Although 25 per cent of the total subjects (348) were aware of prebiotics, 47 per cent males and 46 per cent females did not know the term prebiotics. While it was observed that females with 5 per cent knew the correct definition of prebiotics that is non- digestible food ingredients. However many of the subjects did not have the correct perception on prebiotics. The relationship between knowledge of prebiotic term with gender was not significant statistically.

4.1.3.2. Association of perception of prebiotics with education

Table XVI gives the association of perception of prebiotics with education.

TABLE XVI

ASSOCIATION OF PERCEPTION OF PREBIOTICS WITH EDUCATION

Occupation	Do not Know N=161		Foods similar to probiotics N=75		Foods that promote health N=67		Foods that simulate colon activity N=31		Non digestible food ingredients N=14		Chi-square
	No.	%	No.	%	No.	%	No.	%	No.	%	
Higher Secondary	7	22.6	4	12.9	14	45.2	1	3.2	5	16.1	
Diploma	12	66.7	4	22.2	1	5.6			1	5.6	
Under graduates	51	50.0	23	22.5	18	17.6	8	7.8	2	2.0	43.383**
Post-graduate	78	43.6	42	23.5	33	18.4	21	11.7	5	2.8	
Professional courses	13	72.2	2	11.1	1	5.6	1	5.6	1	5.6	

****- Significant at one per cent level**

It was noted that 44 per cent of the postgraduates (78 subjects) who were aware of prebiotics did not know the term prebiotics. Suprisingly, 16 per cent of subjects who had higher secondary education knew about the term prebiotics while only six per cent of the diploma holders and three per cent of the postgraduates had the correct perception of prebiotics i.e. non –digestible food ingredient. Education was found to have significant relationship with perception of prebiotics and was found to be significant at one per cent level.

4.1.3.3. Association of prebiotic perception with occupation

Table XVII shows the association of knowledge of prebiotic term with occupation

TABLE XVII

ASSOCIATION OF PREBIOTIC PERCEPTION WITH OCCUPATION

Occupation	Do not Know N=161		Foods similar to probiotics N=75		Foods that promote health N=67		Foods that simulate colon activity N=31		Non digestible food ingredients N=14		Chi-square value
	N.	%	No.	%	No.	%	No.	%	No.	%	
Teachers	6	60	3	30	1	10	nil	nil	nil	nil	**80.672****
Healthcare	6	60	1	10	1	10	2	20	nil	nil	
Financial	10	59	4	23	1	6	2	12	nil	nil	
IT sector	4	33	4	33	1	8	3	25	nil	nil	
Govt. Employee	57	61	21	22	5	5	10	11	1	1	
Housewives	20	74	4	15	1	4	2	7	nil	nil	
Student	53	31	33	20	57	34	12	7	13	8	
Self employed	2	50	2	50	nil	nil	nil	nil	nil	nil	
Others	3	50	3	50	nil	nil	nil	nil	nil	nil	

****- Significant at one per cent level**

. It was found that among 348 subjects who are aware of prebiotics, 168 subjects were students and 94 subjects were govt employees. Forty six per cent of the subjects (161 subjects) did not know the term prebiotics. Only four per cent of the subjects (14 subjects) who were aware of prebiotics had the correct perception of prebiotic foods.

This finding is supported by Bogue *et al.* 2005 and Büyükkaragöz *et al.,* 2014 who identified socio-demographic characteristics as important indicators influencing consumers' awareness and consumption of functional foods. Consumers of higher socio-economic groups were observed with higher intake of health-enhancing foods and were more aware of about the health benefits of health-enhancing foods than the lower socio-economic groups

Seechurn *et al.,* (2009); Stewart-Knox (2006) and Wahba *et al.,* (2006) found that people with higher level of education were more aware of functional foods.

According to Niva, 2006; G. Rezai *et al.,* 2012, consumption of functional foodswas related with good socioeconomic status.

4.1.4. Practice in the usage of prebiotic foods

A. Frequency of consumption of prebiotic foods

Frequency of consumption of prebiotic foods is shown in Table XVIII

TABLE XVIII

FREQUENCY OF CONSUMPTION OF PREBIOTIC FOODS

Food* groups	Frequency	Adolescents N=448		Adults N=741		Elderly N=211	
		N	%	No.	%	N.	%
Cereals	Daily	76	17	55	7	6	3
	Weekly	57	13	104	14	49	23
	Monthly	63	14	242	33	73	35
	Occasionally	nil	nil	296	40	3	1
	Never	252	56	44	6	80	38
Vegetables group 1	Daily	180	40	166	22.4	44	21
	Weekly	5	1	82	11	13	6
	Monthly	44	10	135	18.3	53	25
	Occasionally	219	49	358	48.3	101	48
Vegetables group 2	Never	448	100	741	100	211	100
Greens	Daily	32	7.1	56	7.5	11	5
	Weekly	32	7.1	69	9	21	10
	Monthly	1	0.3	59	8	16	8
	Occasionally	nil	nil	12	2	2	1
	Never	383	85.5	545	73.5	161	76
Fruits	Daily	41	9	36	5	8	4
	Weekly	156	35	175	24	47	22
	Monthly	211	47	396	53	96	46
	Occasionally	40	9	134	18	60	28
Coffee (chicory added)	Daily	290	65	555	75	154	73
	Weekly	158	35	186	25	57	27

Cereals - Wheat, Barley; Vegetable G1- Onion, Garlic; Vegetable G2- Artichoke; GLV- Leeks; Fruit- banana ; Coffee

Prebiotic foods in the cereal food groups like wheat, barley were consumed on daily and weekly basis. In vegetable group 2, artichoke was new and no subject consumed it. Chicory added in coffee powder is a prebiotic ingredient and it was noted that all the three age groups consumed coffee daily the percent being 65 among adolescents, 75 among adults and 73 among elderly.

4.2. PHASE II

Formulation and standardisation of prebiotic food

4.2.1. Prebiotic products available in the market

Functional foods increase consumer choice by addition of healthy ingredient to every day food items providing additional benefits that cannot be found in conventional low fat foods for the management of chronic diseases.

Table XIX gives the result of the market survey.

TABLE XIX

PREBIOTIC FOODS AVAILABLE IN MARKET

Prebiotic ingredient used	Biscuits
Inulin	2
Oligofructose	4

It was observed that prebiotic food ingredients such as inulin, fructo-oligosaccharides and mannan oligosaccharides are prebiotic foods commonly incorporated in and biscuits. Four biscuits brands with low-sugar branding had oligofructose as an ingredient. The ingredients were used in the formulation which must have been added as an additional fibre or as a sugar substitute in the products.

4.2.2. Snacking pattern of subjects

Snacking pattern of the subjects is shown in Table XX

TABLE XX

ENERGY CONTRIBUTION OF SNACKS CONSUMED

Snack item	No.	*Kcal	Per cent kcal contribution to RDA	
			Males** 2320kcal	Females** 1900 kcal
Bajji/ pakora	4	140	6	7.3
Vada	4	280	12	15
Potato bonda	4	400	17.2	21
Samosa	2	400	17.2	21
Cake	2	540	23.3	28.4
Vegetable puff	2	400	17.2	21

***ICMR Dietary guidelines for India, 2011**

**** Recommended Dietary Allowances, ICMR 2010**

Evaluation of the snacking pattern of the subjects showed that fried foods like vada, bonda, bajji, puffs and were the common snacks consumed. The contribution of energy from these snacks towards the total calorie intake was found to be 6 -28 per cent.

Snacks are usually high in fat and sugar and hence energy dense and not conducive for healthy eating. Snacking patterns have association with energy and nutrient intakes (Astrup *et al.,* 2006 and Boon *et. al*, 2012)

According to the Booth Hypothesis which states that multiple eating episodes between meals rather than the traditional pattern of three meals per day is a major factor that contributes to obesity (Booth, 1988; Miller *et al.,* 2013) and obesity is a major risk factor for cardiovascular diseases. The findings of the pilot study points out that the snacking behavior can be a strong contributory factor to health and consumption of unhealthy energy dense and high fat snacks

is the culprit which can be changed by adding a functional food which can make snacking behaviour healthier.

4.2.3. Details on standardization of the developed prebiotic product

In cake formulation addition of inulin caused increased crumb density and volume was decreased and was not a favourable end product after sensory evaluation hence biscuits were developed.

The formulation of prebiotic biscuits is shown in Table XXI

TABLE XXI

FORMULATION OF BISCUITS

Ingredients	Standard gm	P 1 Fat and sugar removed	P2 Fat replaced and sugar removed	P 3 Fat replaced
Wheat flour	100	100	100	100
Olive oil	nil	15	nil	nil
Inulin	nil	10	50	30
Butter	80	nil	30	50
Milk powder	2	2	2	2
Sugar	25	nil	nil	25
Baking powder	1/2 tsp	1/2 tsp	1/2 tsp	1/2 tsp

The biscuits were developed and standardised through trial and retried three times for all the variations to get consistent final products in terms of quality and yield and a final standardised product was developed.

It was noted that addition of inulin changes the physical characteristics of the biscuits. Similar findings by Kuntz *et al.,* 2013 demonstrated that addition of inulin alters the physiochemical and sensory characteristics in foods

4.2.4 Product characteristics

Product characteristics of the prebiotic biscuit is given in table XXII

TABLE XXII

PRODUCT CHARACTERISTICS OF THE BISCUITS

Characteristics	***Details***
Weight	*16 gm*
Height	*<10mm*
Diameter	*4.8 to 5.0 cm*
Appearance	*Circular shape, smooth and brown*
Flavour/Aroma	*Vanilla flavour*
Taste/mouthfeel	*Crumbly and crunchy*
Moisture content	*<4%*

The biscuits were circular in shape with a crumby texture. Moisture content was found to be less than four per cent.

4.2.5. Nutrient content of the prebiotic biscuits

Nutrient content of the prebiotic biscuits is shown in Table XXIII

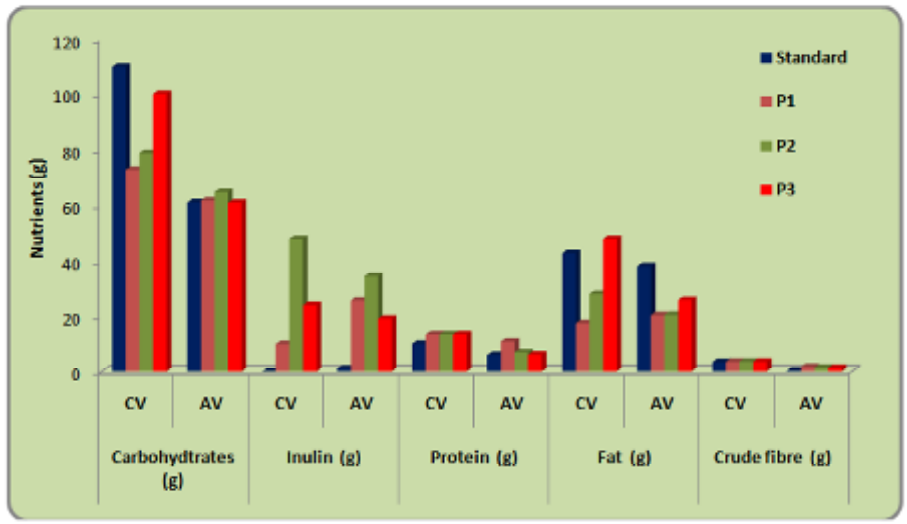
TABLE XXIII

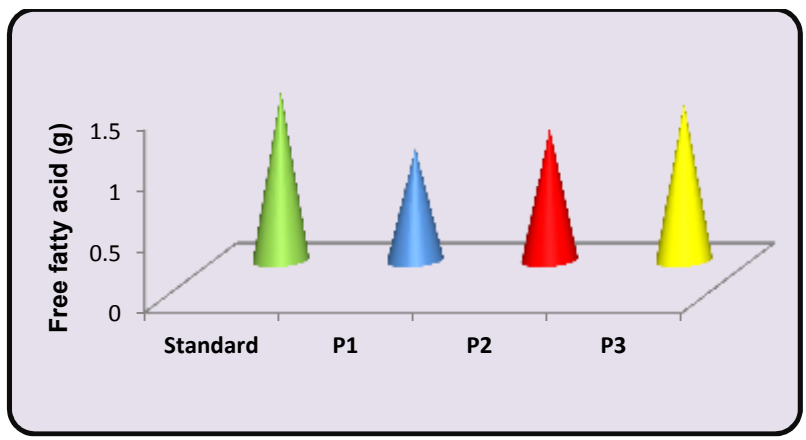
NUTRIENT CONTENT OF BISCUITS

PARAMETERS (100gm)	Standard		P1		P2		P3	
	C V*	AV	C V*	AV	C V*	AV	C V*	AV
Energy(kcal)	578	566	565	541	567	543	572	546
Carbohydrates (g)	110	61.1	73	61.8	79	64.9	100	61.0
Inulin (g)	nil	1.1	10	25.7	48	34.5	24	19.1
Protein (g)	10.18	6.06	13.5	11	13.5	7.08	13.5	6.26
Fat (g)	43	38.2	17.5	20.4	28	20.5	48	25.88
Free fatty acid(mg)	nil	1.40	nil	0.93	nil	1.09	nil	1.30
Crude fibre (g)	3.5	0.45	3.6	1.8	3.7	1.58	3.6	1.39
Total antioxidant activity (µg)	nil	102.8	nil	198.6	nil	229.54	nil	214.96

CV- Computed value; ICMR 2010 Nutritive value of Indian foods; AV- Analysed value

P1 –Fat and sugar removed; P2- Fat replaced and sugar removed; P3-Fat replaced





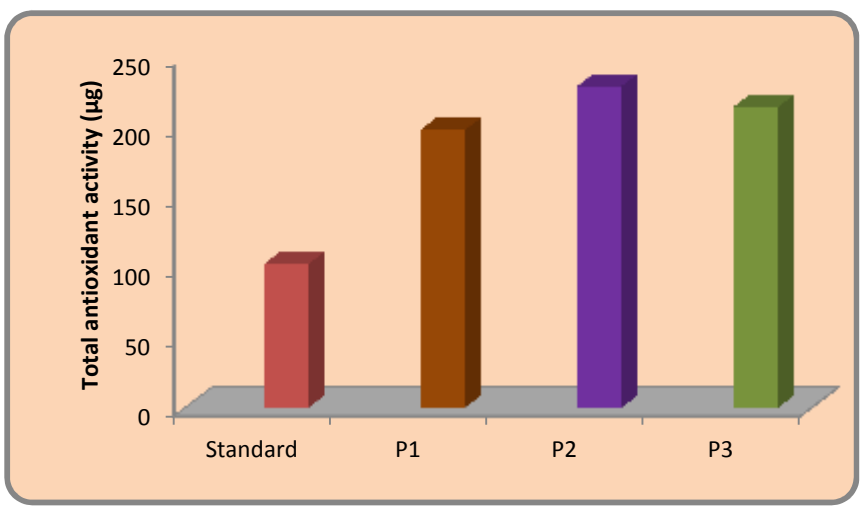


Figure 9

Nutrient content of prebiotic biscuits

The inulin content in P1, P2 and P3 was 25.7gm, 34.5gm and 19.1 gm respectively.The difference in the values may be attributed to the amount of inulin used in the formulation. Antioxidant activity was also observed in all the biscuitsand activity was highest in P2 (229.54 µg).

This observation is in line with a study by Pasqualetti *et al.,* 2014 which showed that antioxidant activity of inulin was significantly higher compared to simple sugars. The study concluded that effects of inulin on the health of the host are attributable not only to its bifidogenic action but also to its antioxidant properties.

4.2.6. Sensory evaluation of the prebiotic biscuits

The oraganoleptic quality of the biscuits is presented in Table XXIV

TABLE XXIV

MEAN ACCEPTABILITY SCORES OF PREBIOTIC BISCUITS

Biscuit	Appearance	Colour	Taste	Texture	Aroma	Overall acceptibility
Standard	7.50±0.51	7.35±0.59	7.85±0.67	7.60±0.51	7.40±0.60	7.41±0.14
P1 n=15	7.20±0.62	7.60±0.75	7.45±0.51	7.25±0.64	7.30±0.83	7.40±0.17
P2 n=15	7.45±0.69	7.65±0.51	7.80±0.60	7.45±0.44	7.30±0.70	7.45±0.0.39
P3 n=15	6.75±0.44	7.75±0.44	5.75±0.44	6.75±0.44	7.25±0.44	7.18±0.60

Values are mean± SD of the scores obtained

P1 –Fat and sugar removed; P2- Fat replaced and sugar removed; P3-Fat replaced

It can be observed that P2 was acceptable with a high score for overall acceptability (7.45±0.39) among the three. The attributes for appearance, taste and texture was comparatively high.Hence P2 (Fat replaced and sugar removed)presented similar results to the standardand was accepted.

This result is supported by findings of a study by Lourencetti *et al.,* 2013 where with 50% replacement of fat in formulation showed similar results with the standard product.

Therefore, inulin can be considered as a fat mimic which can be efficiently utilized for formulations of biscuits, as it contributes to physical attributes as well as nutritional properties

TABLE XXV

NUTRIENT CONTENT OF THE SELECTED PREBIOTIC BISCUIT PER SERVING

PARAMETERS	P2*	
	100gm	Per serving (16gm)
Carbohydrates(g)	64.9	10.3
Inulin (g)	34.5	5.52
Protein(g)	7.08	1.1
Fat(g)	20.5	3.28
Fibre(g)	1.09	0.17
Total antioxidant activity (µg)	229.54	36.7
Energy (Kcal)	543	86.8

***P2- Fat replaced and sugar removed**

Table XXV shows the nutrient content of the selected prebiotic biscuit. Each serving of 16gm biscuits provided 86.8 kcal, 5.52 gm of inulin, 3.28 gm of fat and 0.17 gm of fibre.

4.2.7. Microbial safety

Table XXVI gives the result of the microbial count of the biscuits

Table XXVI

Microbial count (g/100 g) of the developed biscuits

Samples (10^5)g/cfu	Total plate count (cfu/100g)		Mould count cfu/g(100g)	
	0 day	7^{th}day	0 day	7^{th}day
Standard	nil	27.1	nil	3.50
P1	nil	26.9	nil	3.45
P2	nil	25.8	nil	3.35
P3	nil	25.9	nil	3.40

The total viable count at room temperature was within the standard limits on initial and seven days. Though there was an increase in the count as the period increased, the viable count was within the desirable limits.

Therefore based on the results of sensory evaluation, nutrient content and microbial safety of the prebiotic biscuits, P-2 (Fat replaced and sugar removed) was selected for the study.

4.2.8. Estimation of cost

The estimated cost of the selected biscuit is shown in Table XXVII.

TABLE XXVII

COST ESTIMATION OF THE SELECTED PREBIOTIC BISCUIT

Raw materials	**Cost (Rs.)**
Cost per 100gm	36
Cost per 32 gm	11.5

Total cost in the preparation of the biscuits was Rs.36 per 100g and the cost of 32g of prebiotic biscuit was Rs.11.5. Hence, the formulated biscuits are economical and affordable.

4.3. PHASE III:

Details of the subjects screened for hyperlipidemia

4.3.1. Demographic details of the subjects

The demographic details of the subjects who were screened for hyperlipidemia is given in Table XXVIII.

Table XXVIII

DEMOGRAPHIC DETAILS OF SUBJECTS SCREENED FOR HYPERLIPIDEMIA

Demographic profile	Details	N=204			
		Male (n=77)		Female (n=127)	
		N	%	N	%
Age (in years)	30-40	3	4	9	7
	41-50	29	37.5	15	12
	51-60	45	58.5	103	81
Types of family	Nuclear	65	84.5	115	90.5
	Joint	10	13	12	9.5
Family size	2-3	37	48	67	52.5
	3-4	28	36.5	42	33
	>4	12	15.5	18	14
Education status	12^{th}	6	8	5	4
	Ug	32	41.5	37	29
	Pg	23	30	61	48
	Others	16	21	24	19
Occupation status	Government employee	71	92	122	96
	Contract employees	6	8	5	4
Family income	5001-10000 (LIG)	4	5	5	4
	>10000(HIG)	73	95	122	96

The background details of subject screened for hyperlipidemia in the age group of 30-60 years showed that 58 per cent males and 81 per cent females were in the 51-60 years age group.

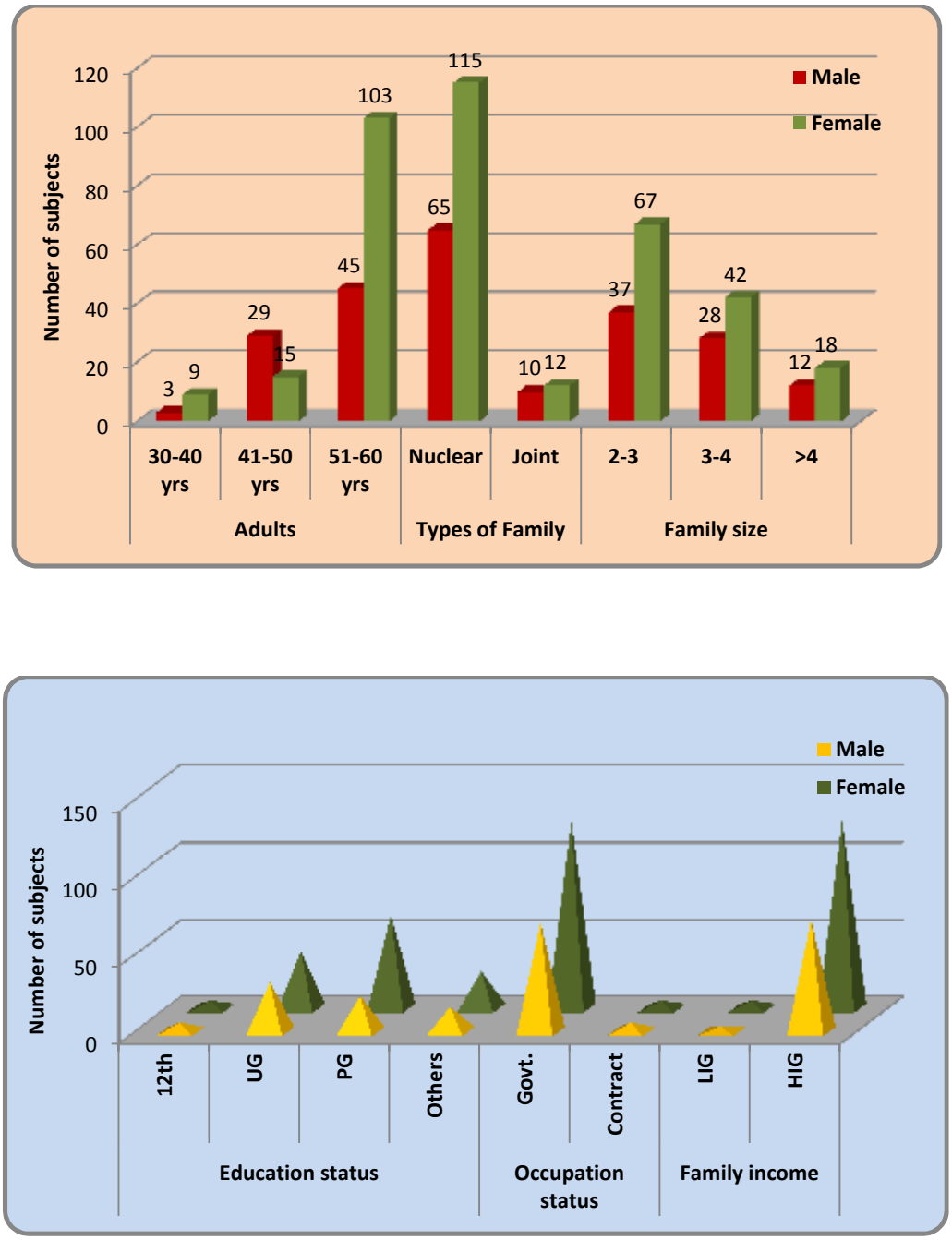


FIGURE 10

DEMOGRAPHIC PROFILE OF THE SCREENED SUBJECTS

Majority had a family size of 2-3 and the education of the subject showed that 41 per cent and 30 per cent of males were undergraduates and post graduates respectively. Forty eight per cent of females were post graduate indicating that literacy status of women is rising 92 per cent and 96 per cent of males and females respectively worked in government sector and had an income of 10000 per month making them a high income.

Many studies have highlighted that education proceeds proportionally to diet quality and vice versa. (Hiza *et al.,* 2013; Sijtsma*et al.,*2012; Manios *et al.,* 2007).However by Kirkpatrick *et al*., 2003 pointed out that higher educational level could be related to occupation that is more stressful hence less available time for cooking and consequently with a bigger trend for consumption of ready-to eat food or fast-food habits.

4.3.2. Details on anthropometry measurements of the screened subjects

A. Body Mass Index

The body mass index of the screened subjects is given in Table XXIX

TABLE XXIX

BODY MASS INDEX OF SELECTED SUBJECTS

Age years	BMI*											
	Normal (N=36)				Overweight (N=98)				Obesity (N=70)			
	M N=29	%	F N=35	%	M n=22	%	F n=61	%	M n=26	%	F n=31	%
30–40	1	3	5	14	2	9	2	3	nil	-	2	6
40–50	15	52	6	17	6	27	6	10	8	30	3	10
50–60	13	45	24	69	14	64	53	87	18	70	26	84

***WHO 2004**

The body mass index of subject secured for hyperlipidemia showed that 48 per cent (98) were overweight, while 34 per cent (70 subjects) were obese. The obese subject were found to be more with 30 per cent while among the obese subject, 13 per cent of males and 15 per cent of females were found to be obese.

B. Waist to hip ratio

Table XXX gives the waist hip ratio of the screened subjects

TABLE XXX

WAIST HIP RATIO

Age (years)	WHR							
	Normal (N=30)				At risk (N=174)			
	M N=10	%	F N=20	%	M N=67	%	F N=107	%
30 – 40	1	10	3	15	2	3	6	6
40 –50	7	70	3	15	22	33	12	11
50 –60	2	20	14	70	43	64	89	83

The WHR of the subject showed that the people at risk for CVD were higher in 33% to males (67) and 52% to females (107) were found to be at high risk with a 0.9 and >1.

4.3.3. Lipid profile of the subjects

TABLE XXXI

SCREENING OF LIPID PROFILE AMONG THE SUBJECTS

Lipid fractions*	N=204			
	Males		Females	
	N	%	N	%
Total Cholesterol				
Normal <200	40	20	78	38
Borderline 200-239	27	13	32	16
High >239	10	5	17	8
Triglycerides				
Normal	40	20	78	38

Lipid fractions*	N=204			
	Males		Females	
	N	%	N	%
<150				
Borderline 150-199	21	10	22	11
High >200	16	8	27	13
HDL-C				
Low <60	37	18	49	24
Desirable >60	40	20	78	38
LDL-C				
Normal <100	40	20	78	38
Borderline 100-129	18	9	43	21
High >130	19	9	6	3
VLDL-C				
Normal <30	40	20	78	38
High >30	37	18	49	24

The results of screening of lipid profile among 204 adults subjects is given in Table XXXI.

Among the total of 204 screened subjects, hyperlidemia was seen among 42 per cent (86 subjects) of the subjects where 57 per cent (49) were females and 43 per cent (37) weremales and they exhibited serum cholesterol level, serum triglycerides levels, HDL cholesterol and LDL cholesterol above the desirable levels (i.e borderline and high). Fifty eight per cent (118 subjects) with 34 per cent males and 66 per cent females was found to be normolipidemic.

Twenty nine per cent of the subjects were categorized with borderline cholesterol level of 200-39mg/dL with female subjects being 16 per cent (32)

and males being 13 per cent (27). Among females 13 per cent had triglyceride level > 200mg/dL which is high and 11 per cent were in borderline level of 150-199mg/dL. Ten per cent males had triglyceride level in borderline category while eight per cent were in high category.HDL cholesterol pattern among the subjects showed that 58 per cent had levels below above desirable level with 38 per cent females and 20 per cent males with HDLc levels <60 mg/dL. Nine per cent of male subjects had high LDL cholesterol while three per cent females were observed to be in the high LDL cholesterol category. HDL cholesterol was found to be low among 29 per cent of the subjects (31 males and 24 females).

4.3.4. Association of demographic factors with lipid profile

Table XXXII gives the association of demographic factors with lipid profile

TABLE XXXII

ASSOCIATION OF DEMOGRAPHIC FACTORS WITH LIPID PROFILE

Demographic factors N=204	Chi-square value
Age	10.233**
Gender	1.763 NS
Education	10.097*
Occupation	42.768**
Income	47.877NS

Ns- Not- significant,

****- Significant at 1 per cent level**

***- Significant at 5 per cent level**

The association of age distribution and lipid profile of the screened subjects showed a significant relationship at one per cent level ($p<0.001$) and the chi square value being 10.233. Education and occupation of the subjects was found to be associated with lipid profile and was significant at 5 per cent ($p<0.05$)

and one per cent level ($p<0.001$).No significant relationship was noted for gender and income with lipid profile.

4.4. PHASE IV

Impact of the developed prebiotic food product on hyperlipidemics

4.4.1. Background details of the hyperlipidemic subjects

The age and gender distributionof the experiment and control subjects is given in Table XXXIII

TABLE XXXIII

AGE AND GENDER DISTRIBUTION OF THE EXPERIMENT AND CONTROL SUBJECTS

Age (Years)	Gender	Experiment N=30		Control N=30	
		N	%	N	%
30-40 years	M	1	3.3	1	3.3
	F	1	3.3	1	3.3
41-50 years	M	9	30	7	23.3
	F	6	20	2	6.7
51-60 years	M	3	10	8	26.7
	F	10	33.4	11	36.7

All the subjects were in the age group of 30-60 years and majority of these subjects were in the age group of 51-60 years. In the experiment group 13 males and 17 females selected and in the control group had 16 males and 14 females were selected.

Females are associated with a longer life expectancy than males hence they constitute a larger proportion of the elderly population in which the prevalence of CVD is greatest (Maas and Appleman, 2010). Alarming statistics

among younger women 35 to 44 years of age show that CHD mortality risks have increased (Mageshwari *et al.,* 2014).

4.4.2. Details on anthropometric measurement and blood pressure

A. Body Mass Index

TABLE XXXIV

MEAN BODY MASS INDEX OF SELECTED SUBJECTS

Groups	Gender	Body Mass Index* N=60		
		Pre-intervention	Post-intervention	
		0 Day Mean±SD	30th Day Mean±SD	60th Day Mean±SD
Experiment	M n =13	27±3.13	26.9±3.159	26.9±3.03
	F n=17	29.2±4.298	29.07±4.131	29±0.98
Control	M n=16	29.9±4.101	29.9±4.153	29.9±4.02
	F n=14	29.7±2.65	29.6±2.684	29.6±2.718

***WHO (2004)**

Table XXXIV represents the mean body mass index of the experiment and control subjects pre and post intervention.

All the subjects in both groups had mean body mass index between 26.9 to 29.9 and falls under the overweight category of BMI classification i.e 25-29.9. Body mass index values did not differ significantly among the periods (0^{th} day, 30^{th} day and 60^{th} day). Hence it can be concluded that inulin supplementation did not show any effect on the BMI values of the experiment subjects.

B. Waist hip ratio

TABLE XXXV

MEAN WAIST TO HIP RATIO OF SELECTED SUBJECTS

Groups	Gender	WAIST HIP RATIO* N=60		
		Pre-intervention	Post-intervention	
		0 Day Mean±SD	30th Day Mean±SD	60th Day Mean±SD
Experiment	M	0.97±0.05	0.97±0.04	0.964±0.05
	F	0.94±0.06	0.93±0.05	0.93±0.05
Control	M	0.97±0.04	0.973±004	0.970±0.04
	F	0.88±0.026	0.88±0.027	0.88±0.028

***WHO (2008)**

Table XXXV shows the mean values of waist hip ratio of the experiment and control subjects pre and post intervention. It was observed that all the subjects in both groups had high waist hip ratio (>0.9 for males; >0.85 for females) and the mean values of waist hip ratio in experiment females were higher than the control females.

Post intervention values of waist hip ratio showed no significant changes in the experiment subjects.

C. Blood pressure

The mean blood pressure level of the selected subjects is shown in Table XXXVI

TABLE XXXVI

MEAN BLOOD PRESSURE LEVELS OF THE SELECTED SUBJECTS

Groups	Gender	Blood Pressure mm/Hg					
		Pre-intervention		Post-intervention			
		0 Day Mean±SD		30^{th} Day Mean±SD		60^{th} Day Mean±SD	
		Systolic	Diastolic	Systolic	Diastolic	Systolic	Diastolic
Experiment	M	155.8±15.01	102±8.611	155±15.33	101.6±9.10	154.7±15.18	101.4±8.903
	F	150.7±16.31	97.5±11.17	149.8±16.35	96.9±11.11	149.2±16.82	96.1±13.12
Control	M	147.7±15.00	96.4±10.67	146.5±15.244	95.2±11.10	146.6±15.41	95.1±11.14
	F	148.7±16.87	96.5±12.15	147.7±17.66	95.6±12.54	147.2±17.58	96.0±11.94

The mean systolic values of the experiment males at 0 day was 155.8±15.01 mm/Hg and at 60th day it was 154.7±15.18 mm/Hg while diastolic values were 102±8.611 mm/Hg at 0day and 101.4±8.903 mm/Hg at 60th day. In females mean systolic values were 150.7±16.31 mm/Hg and 149.2±16.82 mm/Hg at 0 day and 60th day respectively while diastolic values were 97.5±11.17 mm/Hg and 96.1±13.12 mm/Hg. The results showed no significant differences in the mean systolic and diastolic values in the experiment subjects.

Similar trend in the mean values of systolic and diastolic pressure was observed among the control subjects in all the three periods.

4.4.3. Dietary pattern of thesubjects

A. Diet pattern

The details on diet pattern of the experiment and control subjects is discussed in Table XXXVII

TABLE XXXVII

DIET PATTERN

Age	Gender	Experiment N=30		Control N=30	
		N	%	N	%
Vegetarians	M	1	3.3	2	7
	F	1	3.3	nil	nil
Non-Vegetarians	M	12	40	14	47
	F	15	50	13	43
Ova vegetarians	M	nil	nil	nil	nil
	F	1	3.3	1	3

It was also noted that 10 per cent of the subjects 3.3 in experiment group and 7 in control group were vegetarians. Two subjects one in each group were ova vegetarians.

Vegetarian diets is often associated with lower CVD risk although contradictory results are also likewise indicated in many studies (Fraser *et al.,* 2015; Verma *et al*., 2015; Shridhar *et al.,*2014)

B. Consumption of fats and oils

Table XXXVIII represents the consumption of fats and oils among the subjects.

TABLE XXXVIII

CONSUMPTION OF FATS AND OILS

Fat / Oil#	EXPERIMENTAL N=30				CONTROL N=30			
	M		F		M		F	
	N	%	N	%	N	%	N	%
Butter	13	43.3	11	36.6	13	43.3	14	46.7
Ghee	13	43.3	17	56.6	16	53.3	14	46.7
Gingelly oil	13	43.3	17	56.6	16	53.3	14	46.7
Rice bran oil	1	3.3	2	6.6	-		1	3.3
Coconut oil	13	43.3	17	56.6	16	53.3	14	46.7
Canola oil	-		1	3.3	-	-	-	
Soyabean oil	1	3.3	2	6.6	-		-	
Refine vegetable oil	13	43.3	17	56.6	16	53.3	14	46.7

#Multiple response

Fat and oil consumption pattern among the subjects showed that butter, ghee, coconut oil and refine vegetable oil were consumed by all the subjects in both the groups. It was noted that fats like soyabean oil (10 percent) canola oil (3.3 per cent) and rice bran (8.3 per cent) and were least consumed although these type of oils are rich in MUFA and PUFA

C. Frequency of consumption of fats and oils

TABLE XXXIX

FREQUENCY OF CONSUMPTION OF FATS AND OILS

Food* groups	Frequency	EXPERIMENTAL				CONTROL			
		Males n = 13		Females n = 17		Males n=16		Females n = 14	
		N	%	N	%	N	%	N	%
Butter	Weekly	2	15.3	3	18	nil	nil	4	28.5
	Occasionally	11	84.7	8	47	13	81.2	10	71.5
	Never	nil	nil	6	35	3	18.8	nil	nil
Ghee	Occasionally	13	100	17	100	16	100	14	100
Gingelly oil	Daily	3	23	3	17.6	nil	nil	nil	nil
	Weekly	10	77	14	82.4	16	100	14	100
Rice bran oil	Occasionally	1	8	2	11.8	nil	nil	1	7
	Never	12	92	15	88.2	16	100	13	93
Coconut oil	Daily	4	31	3	17.6	16	100	nil	nil
	Weekly	9	69	14	82.4	nil	nil	14	100
Canola oil	Occasionally	nil	nil	1	6	nil	nil	nil	nil
	Never	13	100	16	94	16	100	14	100
Soyabean oil	Occasionally	1	8	2	11.8	nil	nil	nil	nil
	Never	12	92	15	88.2	16	100	14	100
Refined vegetable oil	Daily	7	54	11	65	nil	nil	14	100
	weekly	6	46	6	35	16	100	nil	nil

***Multiple response**

The frequency of fat and oil consumption among the subjects is shown in Table XXXIX. Ghee was seen to be consumed on occasional basis. Coconut oil was found to be taken daily by all males in control group and in experiment group 17.6 per cent females and 31 per cent males consume coconut oil daily.

Higher dietary intakes of major SFAs are associated with an increased risk of coronary heart disease. Risk of coronary heart disease is significantly lower when replacing the saturated fatty acids with polyunsaturated fat, whole grain carbohydrates, or plant proteins (Zong *et al*., 2016). However, the relationship between saturated fatty acid intake and cardiovascular risk is still contradictory.

D. Consumption of coffee

Table XL shows the consumption pattern of coffee among the selected subject

TABLE XL

CONSUMPTION OF COFFEE

Coffee consumption*	Experimental n =30				Control n =30			
	M		F		M		F	
	N	%	N	%	N	%	N	%
< 3 cups / day	10	33.4	12	40	12	40	10	33.4
3- 5 cups/day	3	10	3	10	3	10	4	13.3
> 5 cups / day	nil	nil	2	6.6	1	3.3	nil	nil
Mean Inulin intake from coffee	**3.4**		**3.4**		**3.2**		**3.1**	

***1gm coffee gives 0.17 gm of inulin**

Consumption of coffee among the subjects shows that maximum (40 per cent) of the male subjects in the control group consume less than 3 cups of coffee a day while 13.3 per cent females and 10 per cent males consume 3-5 cups a day.

Twenty per cent (10 per cent males and 10 per cent females) consume 3-5 cups of coffee per day. Least per cent of 3.3 control male subjects and 6.6 experiment female subjects consume more than 5 cups of coffee a day.

According to Ding *et al.,* 2014, moderate coffee consumption was inversely significantly associated with CVD risk, with the lowest CVD risk at 3 to 5 cups per day.

It is evident from the table that mean intake of coffee eventually inulin contribution from coffee is higher in experiment group and compared with the control and the intake was found to 3.4gm in both experiment males and females.

E. Consumption of prebiotic foods

Table XLI shows the consumption of prebiotic foods among the selected subjects

TABLE XLI

CONSUMPTION OF PREBIOTIC FOODS

Food groups	Frequency	Experimental N=30		Control N=30	
		N	%	N	%
Cereals	Daily	8	26.5	nil	nil
	Weekly	10	33.5	12	40
	Occasionally	8	26.5	13	43
	Never	4	13.5	5	17
Vegetables1	Daily	14	46.5	10	33.5
	Weekly	6	20	11	36.5
	Occasionally	10	33.5	9	30
Vegetables2	Never	30	100	30	100
Greens	Daily	Nil	nil	nil	nil
	Weekly	6	20	nil	nil
	Occasionally	16	53.5	21	73
	Never	8	26.5	8	26.5
Fruits	Daily	2	6.5	nil	nil
	Weekly	6	20	10	33.5
	Occasionally	22	73.5	20	67
Coffee	Daily	30	100	30	100

***Cereals – wheat, barley; Vegetable group 1- onion, garlic; Vegetable group 2- artichoke; Green leafy vegetables -Leeks ; Fruit- banana ; Coffee- chicory added coffee**

The consumption pattern of prebiotic foods among the experiment and control showed that the common prebiotic foods were wheat, onion, garlic and banana. Among the experiment group onion and garlic were found to be mostly consumed as they are common spices and condiments added to almost all preparations in the daily diet.

F. Dietary inulin availability

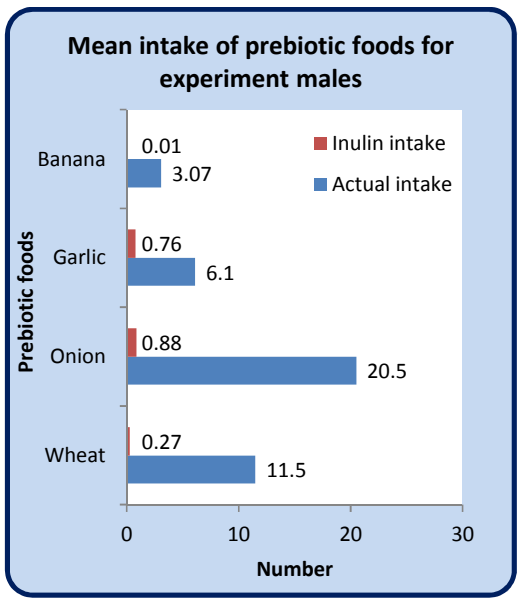
TABLE XLII

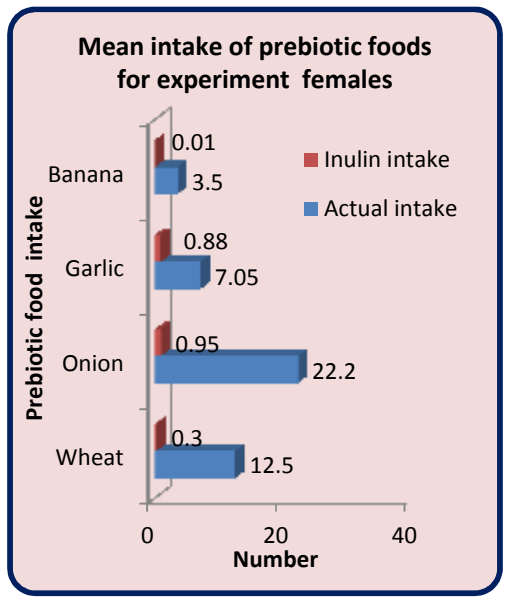
DIETARY INULIN AVAILABILITY FROM THE CONSUMED PREBIOTIC FOODS

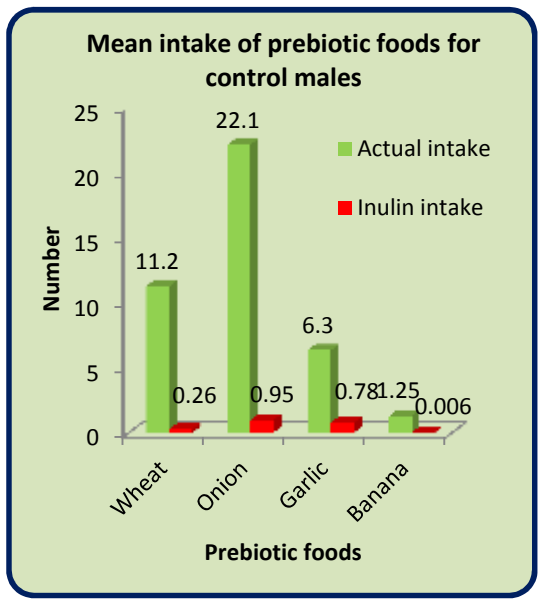
Prebiotic food intake (gm)	Mean intake of prebiotic foods							
	Experiment				Control			
	Males		Females		Males		Females	
	Actual intake	Inulin intake	Actual intake	Inulin intake	Actual intake	Inulin intake	Actual intake	Inulin intake
Wheat	11.5	0.27	12.5	0.3	11.2	0.26	10.4	0.24
Onion	20.5	0.88	22.2	0.95	22.1	0.95	22.2	0.95
Garlic	6.1	0.76	7.05	0.88	6.3	0.78	6.81	0.85
Banana	3.07	0.01	3.5	0.01	1.25	0.006	1.4	0.007
Total inulin intake	**1.92**		**2.14**		**1.2**		**2**	

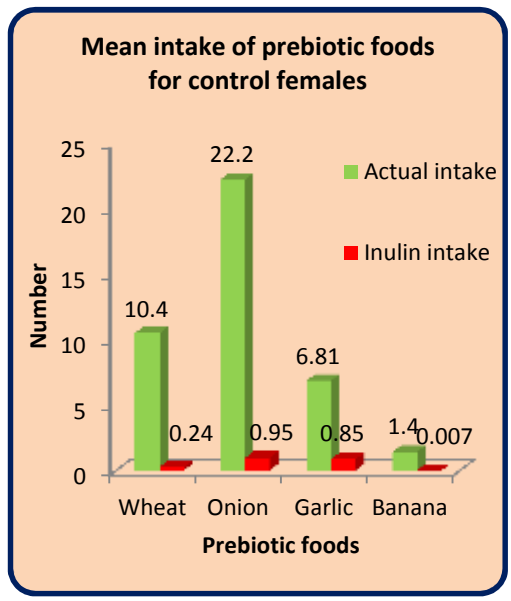
Table XLII gives the dietary inulin availability of prebiotics foods consumed by the selected subjects.

The intake range from 3.07 gm to 20.5 gm in males and 3.5 gm to 22.2 gm in females. The inulin intake ranged from 0.01 gm to 0.88 gm for males and 0.01 gm to 0.95 gm for females. Among the control group inulin intake ranged from 0.006 gm to 0.95 gm in males and 0.007 gm to 0.95 gm in females. This points out that the intake of prebiotic foods among the selected group is highly negligible. Inulin contribution from onions was highest in both males and females. Total inulin intake was highest in females of experiment group and was found to be 2.14 gm.









MEAN INTAKE OF PREBIOTIC FOODS

FIGURE 11

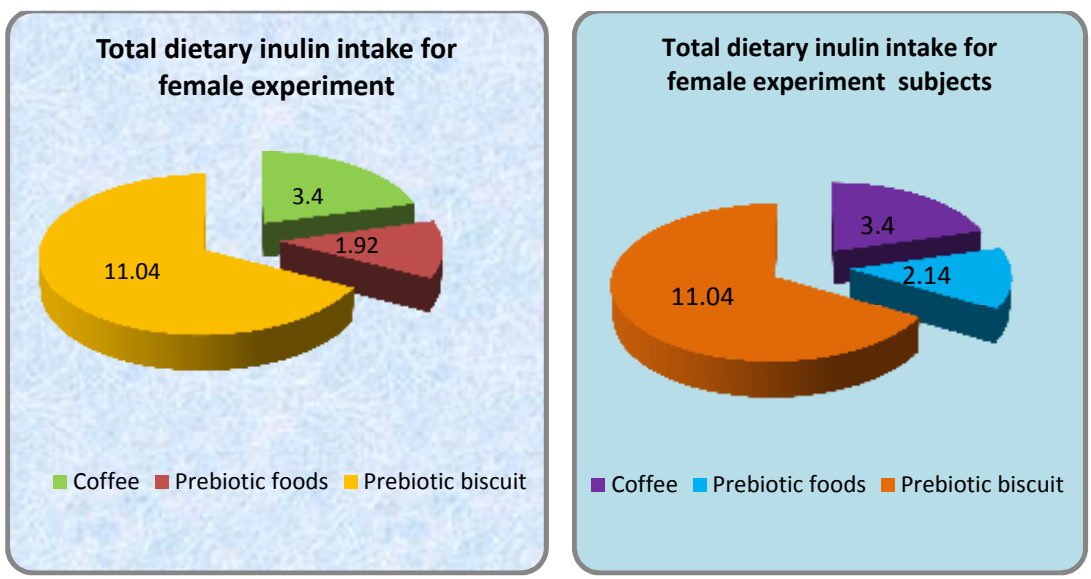
G. Total dietary inulin intake of experiment subjects

TABLE XLIII

TOTAL DIETARY INULIN INTAKE

Details	Experiment subjects N=30	
	Males	Females
Coffee	3.4	3.4
Prebiotic foods	1.92	2.14
Prebiotic biscuit	11.04	11.04
Total inulin Intake (gm)	**16.36**	**16.58**

Table XLIII gives the total dietary inulin intake of the experiment subjects. It was noted that inulin intake of the experiment subjects from coffee, prebiotic foods and the inulin from the prebiotic biscuit supplement was almost similar in both males and females and was found to be 16.36 gm and 16.58 gm respectively.



TOTAL DIETARY INULIN INTAKE

FIGURE 12

H. Mean nutrient intake of experiment and control subjects

The mean nutrient intake of the subjects in experiment and control is shown in Table XLIV and XLV

TABLE XLIV

MEAN NURTIENT INTAKE OF EXPERIMENTAL SUBJECTS

Nutrient	Males			Females		
	RDA	Mean intake ±SD	% excess/ deficit	RDA	Mean intake ±SD	% excess/ deficit
Energy (Kcal)	2320	2728±297.06	+17.5	1900	2240±228.11	+17.9
Protein (g)	60	49.3±7.498	-17.8	55	46.3±6.39	-15.8
Fat (g)	25	43.05±7.534	+72	20	41±6.39	+64
Carbohydrate (g)	300	384±.57.13	+28	300	347±51.04	+15.6
Fibre (g)	40	10.7±316.88	-73.2	40	11.7±3.138	-70.75

The mean nutrient intake of the experiment subjects is shown in Table XLIV. The mean energy intake of male subjects was found to be 2728±297.06 and there is an excess intake of 17.5 per cent was noted while females had an excess of 17.9 per cent when compared with the recommended dietary allowances.

Protein intake was found to be deficit by 17.8 per cent and 15.8 per cent among males and female subjects respectively.

The mean fat intake of the experiment group was higher compared to the control group and was to the extent of an excess of 72 per cent for males and 64 per cent for the females.

Dietary fibre intake of subjects did not meet the recommended dietary allowances and was found to be deficit by 73.2 per cent and 70.75 in females when compared with RDA i.e 40gm /day.

Table XLV shows the mean nutrient intake of the control subjects

TABLE XLV

MEAN NURTIENT INTAKE OF CONTROL SUBJECTS

Nutrient	Males			Females		
	RDA#	Mean intake ±SD	% excess/ deficit	RDA	Mean intake ±SD	% excess/ deficit
Energy (Kcal)	2320	2788±141.94	+21	1900	2342±247.85	+23.6
Protein (g)	60	47±13.74	-21.6	55	42±5.256	-23.6
Fat (g)	25	36.8±213.25	+47.2	20	33.5±1.543	+67.5
Carbohydrate (g)	300	432±14.4	+44	300	365±68.17	+21.6
Fibre (g)	40	11.3±2.746	-71.7	40	12.1±2.780	-69.7

#Reccomended Dietary Allowances

The mean intake of energy in control group was found to be 2788±141.94 among males and 2342±247.85 among females with an excess of 21 per cent and 23.6 per cent respectively when compared with the RDA. Fat intake was seen to be in excess of 47.2 among males and 67.5 among females. A deficit in the dietary fibre intake was seen in both subjects (71.7 per cent males and 69.7 per cent females).

According to Wang *et al*., 2010, the effects of BP on CVD risk was shown to increase with the increasing BMI levels.

Combined hyperlipidemia is a commonly occurring form of hypercholesterolemia characterised by increased LDL and triglyceride concentrations, often accompanied by decreased HDL. It was seen among 86 per cent of the subjects with female subjects having a maximum of 59 per cent (44) and males with 41 per cent (30). Dyslipidemia which is elevation of serum cholesterol, triglycerides (TGs) or both or a low high-density lipoprotein level was noted among 14 per cent of the subjects

According to Babu *et al.,* 2016 and Björkelund *et al.,* 2008, females are more prone to be in high-risk categories of all lipoprotein fractions and this is attributed to the menopausal status of women.

4.4.4 Lipid profile of the hyperlipidimic subjects

Table XLVII gives the mean serum lipid profile of the hyperlipidemic subjects

TABLE XLVI

MEAN SERUM LIPID PATTERN OF THE HYPERLIPIDEMIC SUBJECTS

Lipid fractions mg/dL	N=86 Mean±SD	
	Males	Females
Total cholesterol	226.7 ± 25.71	227.± 23.95
Triglycerides	240.4±119.22	235.2±77.58
HDL-c	45.6±11.33	43±7.712
LDL-c	115.8±19.78	114±14.13
VLDL-c	48±14	47.8±15.10

The mean serum total cholesterol levels in males and females were 226.7±25.71 and 227.±23.95 respectively. The mean triglycerides level for triglycerides, LDL-c and VLDL-c in males were higher than females. HDL-c levels were lower in females (43±7.712) compared to males (45.6±11.33).

Table XLVII shows the trends in hyperlipidemic condition among the subjects

TABLE XLVII

TRENDS IN HYPERLIPIDEMIC CONDITION

Lipid profile	N=86			
	Males n =37		Females n =49	
	N	%	N	%
Combined hyperlipidemia	30	35	44	51
Dyslipidemia	7	8	5	6

Combined hyperlipidemia is a commonly occurring form of hypercholesterolemia characterised by increased LDL and triglyceride concentrations, often accompanied by decreased HDL. It was seen among 86 per cent of the subjects with female subjects having a maximum of 59 per cent (44) and males with 41 per cent (30). Dyslipidemiawhich is elevation of serum cholesterol, triglycerides (TGs) or both or a low high-density lipoprotein level was noted among 14 per cent of the subjects.

According to Björkelund *et al.,* 2008 , females are more prone to be in high-risk categories of all lipoprotein fractions and this is attributed to the menopausal status of women.

He *et al.,* 2016 studied the association of menopausal status with cardiovascular disease (CVD) and related metabolic disorders in Chinese females aged 45-59 years showed significant relationship and the findings suggests that menopausal status of women might aggravate the cardiovascular risk factor epidemic and increase the risk of cardiovascular disease beyond effects of aging.

4.4.5. Effect of supplementation on serum lipid parameters

The effect of supplementation on the serum lipid parameters is shown in Table XLVIII

TABLE XLVIII

EFFECT OF SUPPLEMENTATION ON MEAN LIPID PROFILE PARAMETERS OF EXPERIMENT AND CONTROL SUBJECTS

Parameters mg/dL.	Pre-intervention		Post-intervention			
	0day Mean ±SD		30th day Mean ±SD		60th day Mean±SD	
	Males	Females	Males	Females	Males	Females
Total Cholesterol						
Experimental	229±20.90	221.53±14.71	226.77±20.93	218.79±15.27	219.07±19.07	214.42±14.97
Control	217.06± 15.94	249.64±27.39	215.25±16.87	249.21±26.42	218.44±16.97	249.97±26.24
Triglycerides						
Experimental	299.08±173.08	279.76±88.85	249.27±63.63	274.35±87.81	239.45±60.74	268.02±86.91
Control	219.14±50.68	236.21±67.37	220.16±42.75	235.07±47.80	223.69±60.74	235.71±47.69
HDL-C						
Experimental	48.03±8.24	45.65±7.99	48.26±8.45	46.76±7.60	50.06±8.06	48.58±7.56
Control	40.25±10.41	42.34±8.63	38.88±9.97	42.21±8.70	39.60±10.41	42.36±8.03
LDL-C						
Experimental	111.42±7.27	114.81±14.07	107.50±7.68	108.51±15.08	102.84±7.35	104.55±14.15
Control	115.07±12.65	108.79±9.33	116.19±11.78	109±7.83	116.91±12.32	109.76±8.18
VLDL-C						
Experimental	50.88±13.81	55.95±17.77	49.85±12.72	54.87±17.56	47.84±12.12	53.57±17.41
Control	43.56±10.15	47.24±13.48	44.03±8.55	47.01±9.56	44.74±8.42	47.20±9.60

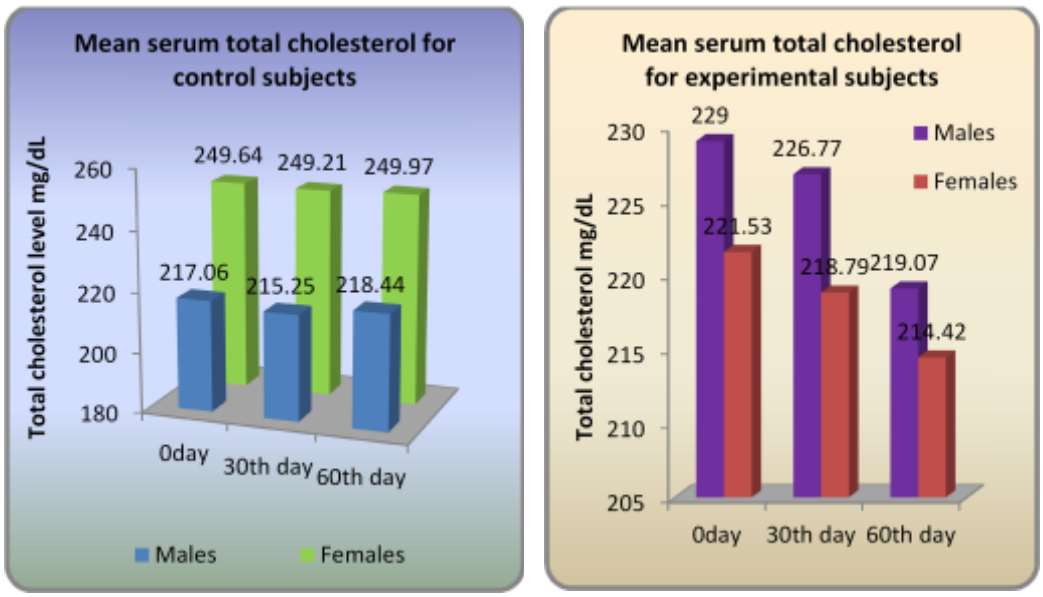


Figure 13

Mean serum lipid profile of experiment subjects

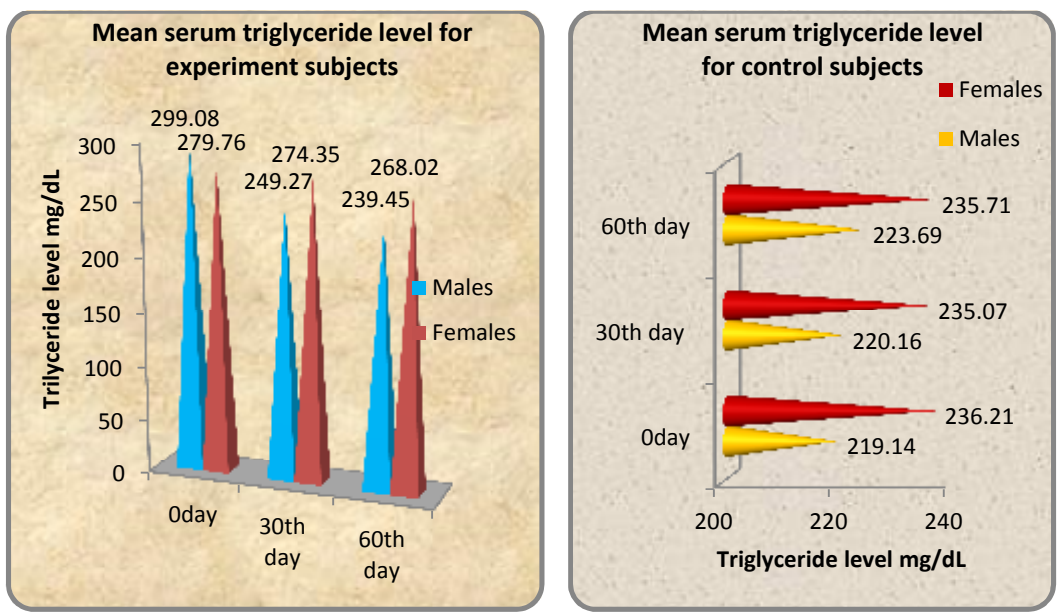


Figure 14

Mean serum lipid profile of control subjects

Cholesterol levels of the experiment male subjects showed a decrease from 229±20.90 mg/dL to 219.07±19.07 mg/dL. In the female subjects it decreased from 221.53±14.71 mg/dL to 214.42±14.97 mg/dL. There was not much differences noted for cholesterol levels among the control.

The lipid fraction triglycerides in males showed a decrease of 60 mg/dL from 299.08±173.08 mg/dL at 0 day to 239.45±60.74 mg/dL at 60^{th} day. The females also recorded a considerable decrease in the triglyceride levels from 279.76±88.85 mg/dL at 0 day to 268.02±86.91 mg/dL at 60^{th} day. However, there was no change noticed for the control subjects. HDL-c levels increased from 48.03±8.24 mg/dL to 50.06±8.06 mg/dL in males subjects and in females it increased from 45.65±7.99 mg/dL to 48.58±7.56 mg/dL. LDL-c levels decreased from 111.42±7.27 mg/dL to 102.84±7.35 mg/dL in males and 114.81±14.07mg/dL to 104.55±14.15 mg/dL and VLDL-c levels did not show any significant changes.

.In order to identify whether the serum lipid values differ significantly between control and experiment group and between males and female groups post intervention Analysis of Co-Variance (ANACOVA) was used. The results are given below.

Table XLIX shows the results of ANACOVA for lipid profile for the selected subjects

TABLE XLIX

ANACOVA FOR LIPID PROFILE AT 60TH DAY FOR MALE AND FEMALE SUBJECTS

Criteria	Co Variate-0 day				Between Groups				Between Gender			
	Sum of squares	df	Mean Squares	F	Sum of squares	df	Mean Squares	F	Sum of squares	df	Mean Squares	F
TC	30494.087	1	30494.087	1099.407**	1342.136	1	1342.136	48.388**	36.471	1	36.471	1.315^{NS}
TGL	140827.605	1	140827.60	88.798**	79.050	1	79.050	57.050**	6362.057	1	6362.057	4.012*
HDL – c	4596.087	1	4596.087	495.531**	156.407	1	156.407	16.863**	8.905	1	8.905	.960^{NS}
LDL- c	6774.559	1	6774.559	1513.30**	1779.509	1	1779.509	397.507**	26.198	1	26.198	5.852*
VLDL- c	7379.604	1	7379.604	190.504**	26.885	1	26.885	.694^{NS}	7.028	1	7.028	.181^{NS}

****Significant at 1 per cent level * Significant at 5 per cent level**

Since the differences in the initial values will also be carried over to the final values, ANACOVA was used to remove the effect and test for significant differences between the age groups and gender

The ANACOVA results shows that the co-variates (lipid fractions at 0 day) has significant effect since the F ratio value (1099.407 for TC; 88.798 for triglycerides; 495.531 for HDL-c; 1513.303 for LDL-c and 190.504 for VLDL-c) is significant at 1 per cent level for all the lipid profiles.

Between control and experiment groups, there was a significant difference since the F value (48.388 for cholesterol; 57.050 for triglycerides; 16.863 for HDL-c; 397.507 for LDL-c) is significant at 1 per cent level. However F-value ratio for VLDL-c was not significant.

The F–value comparing between gender for TGL and LDL was found to be significant at 5 per cent level (4.012 for TGL; 5.852 for LDL-c) while F – value for TC, HDL-c and VLDL –c was not significant.

Table L and Table LI shows the results of repeated measures of ANOVA for lipid profile of male and female subjects.

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TABLE L

REPEATED MEASURES OF ANOVA FOR LIPID PROFILE OF MALE SUBJECTS

Criteria	Between Groups				Days				Interaction between days and groups			
	Sum of squares	df	Mean Squares	F	Sum of squares	df	Mean Squares	F	Sum of squares	df	Mean Squares	F
TC	462.425	1	462.425	1.400^{NS}	198.221	2	99.110	5.735**	589.412	2	294.706	17.053**
TGL	12414.779	1	12414.779	2.582^{NS}	10309.893	2	5154.946	14.791**	16444.447	2	8222.224	15.857**
HDL -c	608.343	1	608.343	7.152*	21.172	2	10.586	1.870^{NS}	26.109	2	13.055	2.306^{NS}
LDL- c	556.059	1	556.059	5.211*	117.969	2	58.984	31.409**	388.642	2	194.321	103.475**
VLDL- c	210.092	1	210.092	2.068 ^{NS}	7.823	2	3.911	.144 ^{NS}	65.466	2	32.733	1.204 ^{NS}

****Significant at 1 per cent level; * Significant at 5 per cent level**

Repeated measures of ANOVA was used to test significant differences between the periods (0 day, 30th day and 60th day) and between the groups. The ANOVA results shows that the F ratio comparing the TC, TGL and VLDL-c levels between groups is 1.400, 2.582 and 2.068 which was not significant. However, HDL-c and LDL-c levels were significant at 5 per cent level.

The interaction effect testing whether the group differences exist on all the periods (0 day, 30th day and 60th day) for TC, TGL and LDL-c is 17.053, 2.857 and 103 .475 respectively which is found to be significant at 1 per cent level. However HDL-c and VDL-c was not significant.

This shows that for males the inulin induced effect had significant effect over the three periods (0day, 30th day and 60th day) for C, TGL and LDL.

TABLE LI

REPEATED MEASURES OF ANOVA FOR LIPID PROFILE OF FEMALE SUBJECTS

Criteria	Between Groups				Days				Interaction between days and groups			
	Sum of squares	df	Mean Squares	F	Sum of squares	df	Mean Squares	F	Sum of squares	df	Mean Squares	F
TC	7550.598	1	7550.598	17.129**	218.456	2	109.228	30.334**	222.353	2	111.176	30.875**
TGL	11308.102	1	11308.102	2.049^{NS}	689.576	2	344.788	2.291*	494.975	2	247.487	1.644*
HDL –c	169.281	1	169.281	2.638 ^{NS}	41.954	2	20.977	17.927**	32.836	2	16.418	14.030**
LDL- c	.088	1	.088	.001 ^{NS}	429.122	2	214.561	88.757**	487.089	2	243.544	100.746**
VLDL- c	448.792	1	448.792	2.029 ^{NS}	27.269	2	13.635	2.335 ^{NS}	21.521	2	10.761	1.843 ^{NS}

****Significant at 1 per cent level; * Significant at 5 per cent level**

Table LI shows the significant differences between the periods (0^{th} day, 30^{th} day and 60^{th} day) and between the groups was observed for the female subjects. The F-ratio value comparing the TC levels between groups was 17.129 which was significant at 1 per cent level while the F-value for other lipid fractions were not significant. The interaction effect testing whether the group differences exist on all the periods (0day, 30^{th} day and 60^{th} day) for TC, HDL-c and LDL-c is 30.875, 14.030, 100.746 respectively which is found to be significant at 1 per cent level. Triglycerides level for females on all the three periods was found to be significant at 5 per level.

For females the inulin induced effect had positive effect over the three periods (0day, 30^{th} day and 60^{th} day) for TC, TGL, HDL-c and LDL-c and was found to be significant. No significant changes on the interaction effect on the groups and periods was observed for VLDL-c levels

A systematic review by Wu T. *et al.,* 2010 also indicates a significantly decrease in the total cholesterol and triacylglycerol of subjects with hyperlipidemia through dietary inulin-type fructans, whereas the effects were absent in normal subjects.

Blood lipids of subjects with hyperlipidemia could be decreased significantly by foods enriched with 17 g of inulin-type fructans per day. Another finding by Saberi M. and Harighi A. 2016 on the effect of prebiotics on Hyperlipidemia showed Serum triglycerides, total cholesterol and LDL significantly decreased and HDL increased. Levels of triglycerides, total cholesterol and LDL-C ($p<0.001$) after 56 days of consumption of certain prebiotic significantly reduced and HDL-c ($P<0.05$) increased However in this study although other lipid fractions reduced to certain extent HDL-c levels did not increase at significant level.