RESULTS & DISCUSSION

The results and discussion of the current study entitled "**Precision Nutrition Approach For Prevention and Management of Obesity** " is presented as follows:

4.1.1 Characteristics of study participants

4.1.1.1 Gender of the participants in the study

4.1.1.2 Age Categories of the participants of the study

4.1.1.3 Educational Qualification of the study participants

4.1.1.4 Occupation of the study participants

4.1.2 Participant's medical history and current medical conditions

4.1.3 Perceived advantages and disadvantages of nutrigenetic testing

4.1.4 Confidence level of consumers

4.1.5 Motivation factors to adopt personalised nutrition advice

4.1.6 Perceptions about genetic information providers

4.1.7. Perceived utilities of personalised nutrition genetic testing

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4.3.2.1 Weight and BMI loss in the study groups

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4.4 Improvements in dietary intakes at baseline, 30days, 60 days and 90 days of follow up

4.5 Changes in the diet composition and dietary intake of the study participants

4.6 Changes in the gut microbiome composition from base line to 90 days

4.7 Post Interventional Changes in Gut Microbiota Profiles

4.1.1 Characteristics of study participants

Characteristics of individuals who participated in the interview session have been discussed in the following section:

4.1.1.1 Gender of the participants in the study (N=500)

Almost 48% of the participants were males and 52% were females. The same has been presented in the Figure.1.

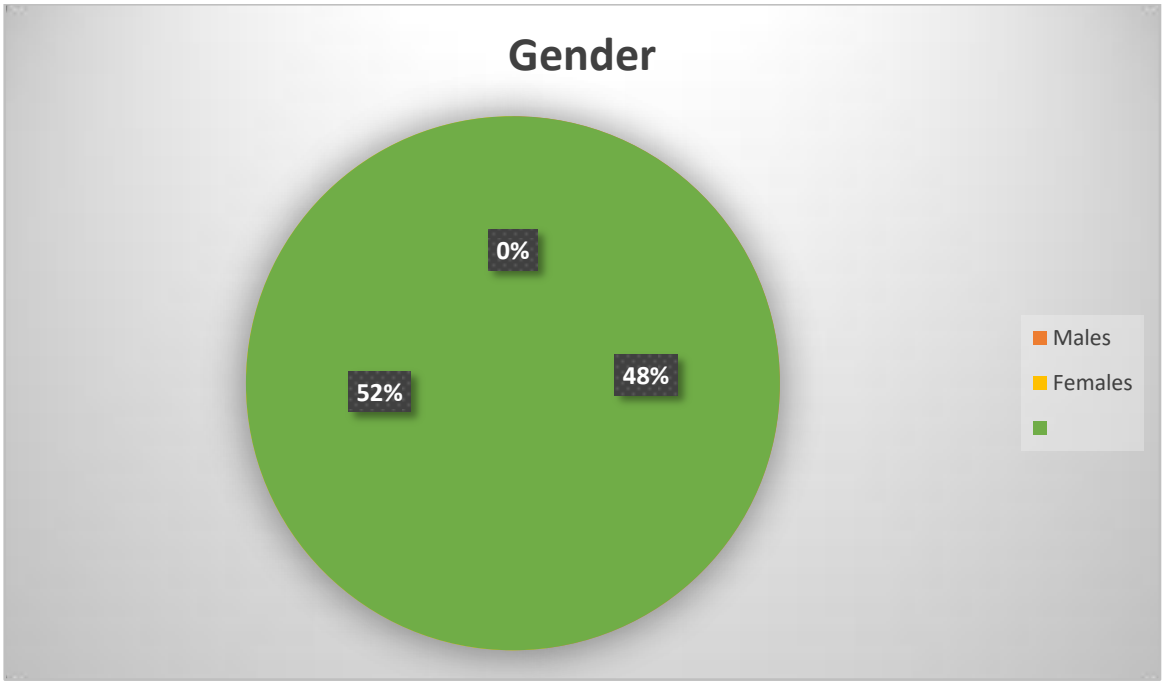


Figure. 22Gender of the participants in the study

4.1.1.2 Age Categories of the participants of the study (N = 500)

The mean age of the participants was 38.3 ± 14.9 years. Majority of the participants were from the age group between 40- 49 yearsand is presented in Table. IX.

Table.IXAge categories of the participants of the study

Age	Sample distribution	%
18-29 years	84	16.8
30-39 years	110	22
40-49 years	123	24.6
50-59 years	76	15.2
60-69 years	52	10.4
Above 70 years	55	11

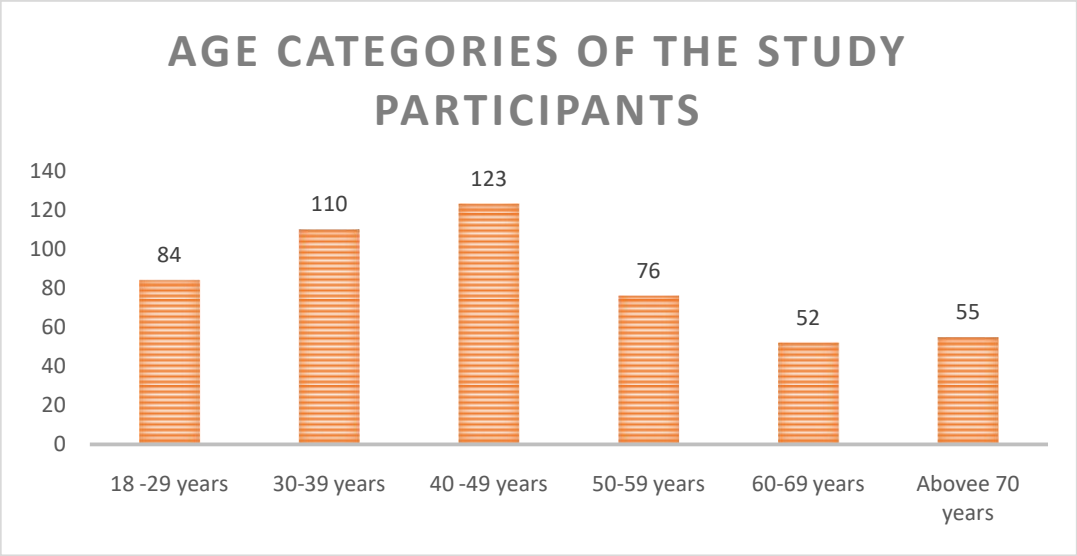


Figure.23 Age Categories of the participants in the study

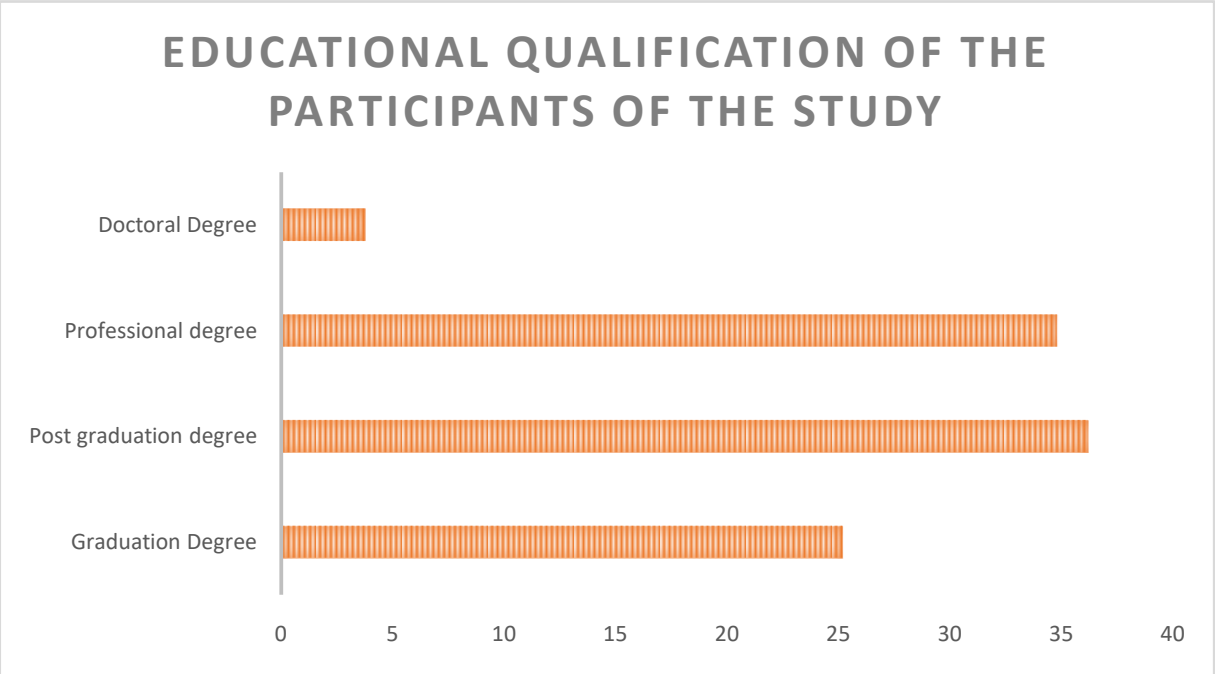
4.1.1.3 Educational Qualification of the study participants

The educational qualifications of the study participants have been represented in Table X andthe percentage distribution is presented in Figure 24. Majority of the participants held a post graduate degree (n=181, 36.2%) and professional degree (n= 174, 34.8 %).

Table X . Educational Qualification of the study participants

Characteristics	Sample Distribution	Percentage
Graduation Degree	126	25.2
Post- graduation Degree	181	36.2
Professional Degree	174	34.8
Doctoral Degree	19	3.8

Figure 24. Educational Qualifications of the study participants



4.1.1.4 Occupation of the study participants

The occupation of the study participants are represented in Table XI and the percentage distribution is presented in Figure 25. Nearly 36% of the study participants had a university post- graduation degree and 34.8% had professional degree. Most of the participants had business as their occupation (33.4%) and 25.2% were working in private sectors.

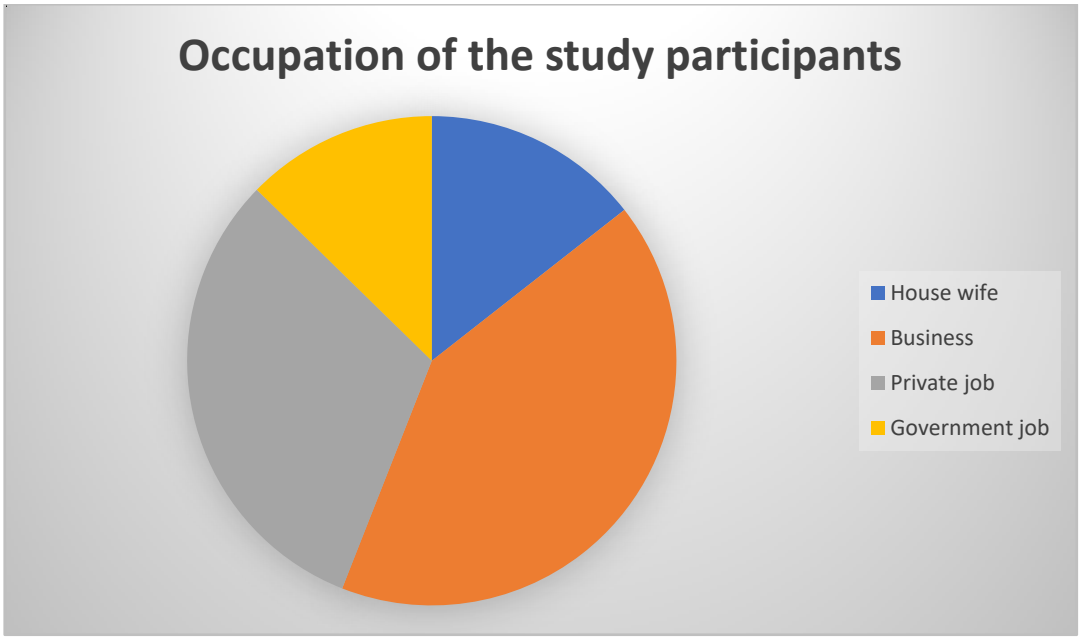


Figure 25. Occupation of the study participants

Table XI. Occupation of the study participants

Occupation	Sample Population	Percentage
House wife	58	11.6
Business	167	33.4
Private Job	126	25.2
Government Job	51	10.2

The characteristics of individuals who participated in the baseline survey is thus summarised in Table. XII. Percentage distribution of these samples are also provided.

Table XII. Characteristics of the study participants

Characteristics	**Sample Distribution (N = 500)**	**%**	***p*** [1]
Gender			
Male	241	48.2	0.0001
Female	259	51.8	
Age			
18-29 years	84	16.8	0.0001
30-39 years	110	22	
40-49 years	123	24.6	
50-59 years	76	15.2	
60-69 years	52	10.4	
Above 70 years	55	11	
Educational Qualifications			
Graduation Degree	126	25.2	0.04
Post- graduation Degree	181	36.2	
Professional Degree	174	34.8	
Doctoral Degree	19	3.8	
Occupation			
House wife	58	11.6	0.0001
Business	167	33.4	
Private Job	126	25.2	
Government Job	51	10.2	

[1] Chi-square test was used to assess differences between subgroups

4.1.2 Participant's medical history and current medical conditions

Associations with personal and/or familial medical history and the willingness to follow the personalised dietary recommendations were observed . People were more inclined to follow a personalised diet based on their genetic makeup if they had diagnosed hypertension ($p = 0.02$), diagnosed type 2 diabetes ($p = 0.03$), and obesity ($p = 0.04$) and if they had diagnosed heart ailments ($p = 0.01$). In this study, the vast majority of participants reported to be willing to adopt a personalised diet that is based on genetic testing. Moreover, more than 85% of participants who were diagnosed with type 2 diabetes reported to be willing to follow the dietary recommendations based on their genetic makeup. This suggested that individuals identified having a medical condition may be more motivated to comply with a personalised dietary intervention.

Multinomial logistic regression analysis

Multinomial logistic regression analysis was conducted to determine the degree to which the current medical condition of the participants predicted willingness to undergo genetic testing and/or follow a personalised diet. The participants who had any medical history or having any current medical condition were compared with those who did not have any medical history. Those who were willing to undergo a genetic test for a personalised diet were 1.34 times more likely to report obesity, 1.25 times more likely to report high blood pressure. Males were more likely to report their willingness to take the test done to follow a personalised diet.

Table XIII. Multinomial Logistic Regression Analysis: Current medical conditions and their willingness to undergo genetic testing for personalisednutrition

	'Willing to take the genetic test for personalised nutrition'			**'Not willing to take the genetic test for personalised nutrition'**		
	B	**SE**	**Exp (B)**	**B**	**SE**	**Exp (B)**
Gender	-0.024	0.068	0.974	- 0.166	0.072	0.847*
Diabetes	0.108	0.240	1.271*	- 0.160	0.131	0.852
Blood pressure	0.040	0.104	1.041	0.106	0.117	1.112
High blood cholesterol	0.300	0.087	1.350**	0.292	0.178	1.339
obesity	0.204	0.703	1.226**	-0.451	0.086	0.637

***** $P < 0{\cdot}05$, **$P < 0{\cdot}01$

4.1.3 Perceived advantages and disadvantages of nutrigenetic testing

The advantages and disadvantages perceived by the consumers about receiving personalized dietary advice based on genetic makeup are presented in Table XIV. When asked about the perceived advantages of receiving DNA based dietary advice, ease of understanding and specificity of the diet advice was the most frequently reported theme (57.5%), followed by more personalised and enjoyable (22.4%) and reduced costs due to disease prevention (20.1%).

Table.XIV Advantages and Disadvantages of Nutrigenetic Testing

Advantages	**%**	**Disadvantages**	**%**
Personalised nutrition is easier to understand and specific than general diet advice.	57.5	Personalized nutrition is much more time-consuming.	34.3
Genotype-based personalized nutrition advice is much Personalized & more enjoyable.	22.4	Personalised nutrition can add cost by advising to consume specific food.	45.7
Costs of diseases can be prevented by personalized nutrition.	20.1	Personalised nutrition advice is not feasible because it is difficult to prepare different foods for different family members.	20

Additionally, 23.5% of the study participants perceived no disadvantage to receiving DNA based dietary advice. And about the disadvantages, "adds cost by advising to consume specific foods (45.7)% was the most frequently mentioned disadvantage followed by "personalised nutrition is much more time consuming" (34.3%) and non- feasibility and difficulty to prepare different foods for different family members (20%).

4.1.4 Confidence level of consumers

As shown in Table XV, 31.2% of respondents feels confident that genetic test-based personalized nutrition helps them to have full control of their health and see it as an attractive option, while nearly 27.6% feels genetic based personalised nutrition has lot of risks. Nearly 28.2% of them believes that it could help them prevent diseases.

Table. XV Confidence Level of Consumers

I feel that genetic- based personalized nutrition	**N**	**Percent**
Has a lot of risks.	138	27.6
Has a lot of uncertainty around it.	65	13
Helps me to have full control of my health.	156	31.2
Could help me to prevent diseases.	141	28.2

4.1.5 Motivation factors to adopt personalised nutrition advice

In the survey used in the study, participants were asked to indicate the factors that motivated them to opt for personalised nutrition advice and the response options for this question listed with participants being instructed to select all that applied.

Table. XVI Motivation to adopt personalised nutrition advice

	Motivation factor of consumers	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	Mean response ± SD
	Numerical Value	1	2	3	4	5	
1.	Personalized nutrition makes me able to live longer in good health.	9	7	45	260	179	4.43 ± 0.79
2.	Personalized nutrition can help disease prevention.	5	18	6	186	285	4.17 ± 1.05
3.	If I weigh up the benefits and drawbacks of genetic-based personalized nutrition, I can see more benefits.	4	8	42	164	282	3.98 ± 1.05

Three statements were included in the survey to assess motivations to adopt personalised nutrition advice based on genetic testing in order to determine their perceptions of these statements to understand the underlying motivation factors. The most commonly selected response among the 500 participants was ‘personalised nutrition could help disease prevention’ (57%), followed by ‘can see more of benefits over drawbacks of genetic based personalised nutrition” (56.4%) and ‘personalised nutrition makes me able to live longer in good health’ (52%).The response options used in the questionnaire, ‘personalised nutrition makes me able to live longer in good health’ (Mean response ± SD, 4.17 ± 1.05), ‘personalised nutrition can help disease prevention’ (Mean response ± SD, 4.43 ± 0.79) and ‘If I weigh up the benefits and drawbacks of genetic based personalised nutrition, I can see more of benefits (Mean response ± SD, 3.98 ± 1.05). Trends in increases toward the positiveend of the scale were observed for the statements.

4.1.6 Perceptions about genetic information providers

Table.XVII Perceptions about genetic information providers

	Individual's perceptions about sources and genetic information provider	**Strongly disagree**	**disagree**	**Neither agree or disagree**	**agree**	**Strongly agree**	**Mean response ± SD**
	Numerical Value	**1**	**2**	**3**	**4**	**5**	
1.	The service provider was very capable of providing personalised nutrition advice.	**1(0.2%)**	**2(0.4%)**	**10(2%)**	**87(17.4%)**	**400 (80%)**	4.43 ± 0.79
2.	The service provider had much knowledge and skills about personalised nutrition advice.	**2 (0.4%)**	**3(0.6%)**	**25(5%)**	**150(30%)**	**321(64.2%)**	4.17 ± 1.05
3.	The complex scientific results were simplified and presented through positively framed simple messages.	**3 (0.6%)**	**10(2%)**	**87(17.4%)**	**150(30%)**	**385(77%)**	3.98 ± 1.05
4.	There is little easily available and easy to understand information in the personalised nutrition report.	**3(0.6%)**	**12(2.4%)**	**52(10.4%)**	**83(16.6%)**	**350(70%)**	2.93 ± 0.79
5.	Health care provider lacked adequate education and enough time.	**1(0.2%)**	**5 (1%)**	**10(2%)**	**201(40.2%)**	**283(56.6%)**	3.67 ± 1.05
6.	Lack of agreement among, and accountability of service providers.	3(**0.6%)**	5(**1%)**	8 (**1.6%)**	110(**22%)**	374(74.8%)	4.23 ± 1.28

In terms of the service provider's capability to offer personalized nutrition advice, 80% strongly agreed that they were very capable of providing personalised nutrition advice.Participants assessed the service provider's knowledge and skills about personalized nutrition advice, with 0.4% strongly disagreeing, 0.6% disagreeing, 5% neither agreeing nor disagreeing, 30% agreeing, and 64.2% strongly agreeing.The presentation of complex scientific results through positively framed simple messages was evaluated, resulting in 0.6% strongly disagreeing, 2% disagreeing, 17.4% neither agreeing nor disagreeing, 30% agreeing, and 77% strongly agreeing.Participants indicated opinions on the availability of easily understandable information in the personalized nutrition report, with 0.6% strongly disagreeing, 2.4% disagreeing, 10.4% neither agreeing nor disagreeing, 16.6% agreeing, and 70% strongly agreeing.Concerning the health care provider's education and time, 0.2% strongly disagreed, 1% disagreed, 2% neither agreed nor disagreed, 40.2% agreed, and 56.6% strongly agreed that there was a lack of adequate education and time.Participants expressed opinions on the agreement and accountability of service providers, resulting in 0.6% strongly disagreeingand 74.8% strongly agreeing.

4.1.7. Perceived utilities of personalised nutrition genetic testing

Table.XVIIIPerceived utilities of personalised nutrition genetic testing

	Utility of DNA test	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	Mean response ± SD
	Numerical Value	1	2	3	4	5	
1.	I benefited by using personalised nutrition advice in my daily life	2 (0.4%)	2 (0.4%)	30(6%)	56(11.2)	410(82%)	4.28 ± 0.79
2.	My family benefited by using personalised nutrition advice	1(0.2%)	3 (0.6%)	17(3.4%)	92 (18.4%)	387 (77.4%)	4.17 ± 1.02
3.	This gene-based dietary advice has helped me to prevent the disease	2 (0.4%)	1(0.2%)	21 (4.8%)	44 (8.8%)	432 (86.4%)	3.98 ± 1.05
4.	I still follow my previous diet habits to the greatest degree possible, and only have to complement my diet with some personalized foods and food supplements	5 (1%)	30 (6%)	11 (2.2%)	68 (13.6%)	386 (77.2%)	2.93 ± 0.79
5.	Knowing about my own personalised nutrition test results caused some anxiety	28 (5.6%)	32 (6.4%)	56(11.2%)	102 (20.4%)	282 (56.4%)	3.67 ± 1.05
6.	Personalised nutrition puts restriction on cultural dietary habits	354(70.8%)	96(19.2%)	38 (7.6%)	6 (1.2%)	6 (1.2%)	4.23 ± 1.28

A substantial 82% of the respondents strongly agree that they benefit from personalized nutrition advice in daily life, showcasing a significant positive response.Similarly, 77.4% strongly agree that their families also benefit from personalized nutrition advice, indicating a high level of perceived utility among participants.Notably, 86.4% of them strongly agree that gene-based dietary advice has helped them prevent diseases, highlighting the potential health impact of such personalized approaches.A noteworthy 77.2% strongly agree that they still follow their previous diet habits to the greatest possible degree, complementing it with personalized food and supplements, underscoring the integration of personalized recommendations into existing dietary practices.Regarding the emotional aspect, 56.4% strongly agree that knowing about their personalized nutrition test results caused some anxiety, emphasizing the need for thoughtful communication and support in delivering such information.Significantly, a vast majority (70.8%) strongly disagree that personalized nutrition puts restrictions on cultural dietary habits, indicating a general acceptance and adaptability to these recommendations within cultural contexts.

4.1.8. Source of health care providers to disseminate information relatedtogenetic information and personalized nutritionreports

Participants were asked to indicate which health care providerdisseminated the information related to genetic test and personalised nutrition recommendations. The response options were ‘registered dietitian’, ‘physician’, ‘genetic counsellor’, ‘other’, and participants were asked to choose the source of information provider. The selected responses were ‘registered dietitian’ (56%), followed by ‘physician’ (27%), ‘genetic counsellor’ (14%) and ‘other’ (3%).

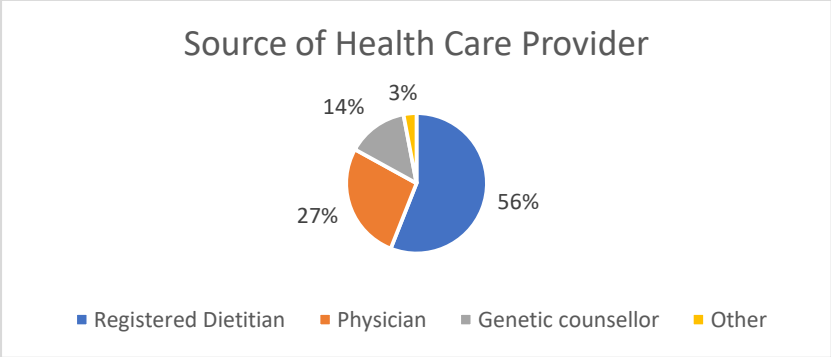


Figure 26. Source of health care providers to disseminate information relatedtogenetic information and personalized nutritionreports

4.1.9. Willingness to adopt personalised nutrition recommendations

More than a third of respondents, n=186 (37.2 %) had the intention to adopt personalised nutrition recommendations in their daily life. While 28.4 % (n = 142) of them responded that they will definitely adopt personalised nutrition recommendations. Nearly 20.8% (n= 104) of the respondents reported that they are benefited by personalised nutrition recommendations, whereas 13.6% (n= 68) considered adopting personalised nutrition recommendations in the near future.

Table XIX.Participants' responses to the statements on their willingness to adopt personalised nutrition recommendations

Statements	N =500	%
I intend to adopt personalised nutrition recommendations in my daily life	186	37.2%
I am considering to adopting personalised nutrition in the near future	68	13.6%
I will definitely adopt personalised nutrition recommendations	142	28.4%
I am benefited by personalised nutrition recommendations	104	20.8%

4.2 Development and Design of Algorithm for formulating a gene and gut microbiome based dietary advice

4.2.1 Descriptive characteristics of the study participants

The two study groups selected were very similar in their characteristics, as there were no significant differences in age, sex, weight, BMI and waist circumference (Table.XX).There were fifty two participants in the standard diet group and 54 participants in the personalised nutrition group were at the baseline. The participants were classified as obese (≥ 25 -30 kg/ m^2), with an average BMI of approximately 32 kg/m2 in both groups with no other co- morbidities.

Table. XX. Descriptive Characteristics of the Study Participants

	Standard Diet Group (Mean ± SD)	**Personalised Nutrition Group (Mean ± SD)**
Sample size	52	54
Gender % female	72.09	72
Age (yrs)	31.9 ± 9.4	33.5 ± 10.2
% obese	72	69.8
BMI (kg/m^2)	32.3 ± 6	28.2 ± 6
Weight (kgs)	80.3 ± 28.7	78.4 ± 24.2
Height (cms)	98.9 ± 11.9	97.9 ± 13.4
Waist circumference (cms)	97.9 ± 13.4	97 ± 18.2

4.2.2 SNP based dietary recommendations given to the personalised nutrition group

The proportion of participants in the personalised group given dietary advice according to the genetic variations (SNPs) and the rationale for such advice are shown (Table. XXI).

Table. XXI Personalized nutrition recommendations given to the personalised nutrition group in addition to base line diet

Nutrigenetic recommendations provided to the personalised nutrition group (Group 2)	**% Receiving Modified Advice**
Variation in PPARGC1A (rs 8192678)	
Rationale: Involved in the regulation of mitochondrial biogenesis and regulation of genes involved in energy metabolism.	
Recommendations: 1. Limit your carbohydrates to 50% of your total calories. 2. Reservatrol containing foods such as grapes, red grapes, peanuts, blueberries helps to improve the mitochondrial biogenesis.	76.1
Variation in ACE (rs 699)	
Rationale: Involved in adipocyte growth and differentiation	
Recommendations: 1. Pomegranate contains natural ACE inhibitors that helps to regulate the blood pressure. 2. Potassium rich foods such as guava, banana, raddish, cherries, pista and pepper. 3. Spices and herbs can be added to enhance the flavour of the food instead of salt.	80.6
Variation in FTO (rs9939609)	
Rationale: Associated with body mass index, obesity risk and type 2 diabetes	
Recommendations: 1. High fibre diet will help to lose weight. Daily inclusion of fibre rich foods is recommended. 2. 30 g of dietary fibre is recommended, equivalent to 2 medium sized fruits and 3 servings of vegetables. 3. Consume a maximum of 50% of daily through complex carbohydrates 4. Monounsaturated fats help in improving insulin sensitivity. 5. Cinnamon helps to improve your insulin secretion. Adding a tsp of cinnamon powder every day will help. 6. Arginine containing foods such as peanuts, walnuts, chick peas, green grass helps to enhance insulin secretion.	98.6
Variation in LIPC (rs 1800588)	

Rationale: Involved in the regulation of plasma LDL concentrations and in conversion of LDL to IDL and VLDL	
Recommendations: 1. Protein and fibre rich snacks will help to enhance the satiety value. 2. Timely spaced meals will help to maintain satiety.	48.6
Variation in MC4R (rs 17782313)	
Rationale: Associated with increased food intake and decreased energy expenditure	
Recommendations: 1. Mindful eating, slow paced eating, protein and fibre rich snacks are recommended to improve satiety.	89.4
Variation in CD36 (rs1527479)	
Rationale: Involved in regulation and transport of fatty acids	
Recommendations: 1. Limit the amount of high calorie snacks. Substitute it with protein and fibre based snacks.	72.4
Variation in ADIPOQ (rs 17300539)	
Rationale: Involved in metabolic and hormonal process	
Recommendations: 1. Spinach, pumpkin seeds, avocadoes, sesame seeds, olives, olive oils, fish oils (foods rich in MUFA) helps to improve adiponectin levels.	65.6
Variation in PPARG (rs 1801282)	
Rationale: Involved in the regulation of adipocyte differentiation	
Recommendations: 1. Low carbohydrate diet is recommended. (50- 55% of daily calories). 2. Pine nuts improves insulin sensitivity. Include ½ tsp of pine nuts in the daily diet.	82.3
Variation in MTHFR (rs 1801133)	
Rationale: Catalyzes the conversion of 5,10- methylenetetrahydrofolate to 5-methyltetrahydrofolate, a co-substrate for homocysteine remethylation to methionine.	94.3
Recommendations: Vitamin B9, B12, Vitamin B2, betaine, choline rich foods to be included in the daily diet.	
Variation in APOA5 (rs 662799)	
Rationale: It regulates the plasma triglyceride levels	
Recommendations: 1. Ideal ratio of omega 6 to omega 3 is 2:1. 2. Daily recommended intake of cooking oil is 20 gms.	43.5

All the participants received nutrigenetic based advice in at least one of the recommendation categories, withthe majority (83%) receiving advice in 6 of the 10 recommendation categories listed in the above table.

4.2.3 Nutrition-related genetic variation among participants in the personalised nutrition group

The genetic results of participants in the personalised nutrition group are summarised in Table. XXII

Table XXII. Nutrition Related Genetic Variation among participants

S.No	Nutrient, Gene &rs number	Genotype Distribution (%)	Associated Risk/ Response
1.	Energy, PPARGC1A (rs 8192678)	AA (62.9%) AG (62.7%) GG (15.6%)	Regulation of adipocyte differentiation
2.	Sodium, ACE (rs 699)	AA (36.4%) TA (21.2%) TT (42.4%)	Adipocyte Growth
3.	Dietary Fibre, FTO (rs 9939609)	AA (35.4%) TA (45.2%) TT (19.4%)	BMI, obesity, & type 2 diabetes risk
4.	Lipids, LIPC (rs 1800588)	TT (24.3%) TC (61.2%) CC (14.5%0	Regulation of LDL
5.	Protein &Fibre, MC4R (rs 17782313)	AA (38.4%) TA (21.8%) TT (39.8%)	Increased food intake and energy expenditure
6.	Lipids, CD36 (rs 1527479)	AA (13.6%) AG (64.5%) GG (78.1%)	Regulation and Transport of Fatty acids
7.	MUFA, ADIPOQ (rs 17300539)	AA (22.1%) TA (36.2%) TT (41.7%)	Involved in metabolic and hormonal process
8.	MUFA, PPARG (rs 1801282)	TT (22.2%) TC (61.5%) CC (16.3%)	Regulation of adipocyte differentiation
9.	Folate, MTHFR (rs 1801133)	AA (74.2%) AG (13.1%) GG (12.7%)	Folate and Vitamin B metabolism
10.	Omega 3 fats, APOA5 (rs 662799)	AA (81.2%) AG (13.1%) GG (12.7%)	Regulates plasma triglycerides level

4.2.4Base line descriptive characteristics of the study participants of the all the study groups

The study groups selected were very similar in their characteristics in terms of age, sex, weight, BMI and waist circumference (Table .XXIII).There were 50 participants in the precision nutrition group at the baseline. The participants were classified as obese (≥ 25 -30 kg/ m^2), with an average BMI of approximately 32 kg/m2 in all the three groups with no other co- morbidities.

Table. XXIII. Descriptive Characteristics of the Study Participants

	Standard Diet Group (Mean ± SD)	**Personalised Nutrition Group (Mean ± SD)**	**Precision Nutrition Group (Mean± SD)**
Sample size	52	54	50
Gender % female	72.09	72	70
Age (yrs)	31.9 ± 9.4	33.5 ± 10.2	32.1 ± 6.5
% obese	72	69.8	72.3
BMI (kg/m^2)	32.3 ± 6	28.2 ± 6	30.5 ± 4.3
Weight (kgs)	80.3 ± 28.7	78.4 ± 24.2	82.3 ± 21.8
Height (cms)	98.9 ± 11.9	97.9 ± 13.4	98.3 ± 9.8
Waist circumference (cms)	97.9 ± 13.4	97 ± 18.2	97.4 ± 11.2

Three parameters namely gut microbiome composition, relative abundance and diversity was used to determine the gut microbiome profile of the study participants. Information related to each of the determinants are presented as follows.

4.2.5. Analysis of the baseline characteristics of the study participants

The baseline characteristics of the study participants in standard diet group, personalised nutrition group and the precision nutrition group is presented in the table. XXIV.

Table XXIV. Analysis of the base line characteristics of the study participants

Variables	**Standard diet group N = 54**	**Personalised Nutrition group N= 52**	**Precision Nutrition group Diet N=50**	**P-Value[a]**
Body Measurements, Median (IQR)				
Weight (kg)	63.0 (54.0-67.l0)	81.0 (72.0-90.5)	84.0 (73.5-79.5)	<0.001
BMI(Kg/m2)	22.5 (22.0-23.3)	29.0 (27.7-33.0)	29 (27.4-31.2)	<0.001
Body Fat %	25.0 (19.6-28.4)	35.7 (30,6-40.6)	31.4 (25.5-37.3)	<0.001
Fat Mass (kg)	14.6 (13.1-16.3)	27.0 (23.9-34.7)	25.3 (21.1-31.9)	<0.001
Lean mass (kg)	46.4 (39.7-54.6)	52.4(46.3-61.8)	61.0 (44.8-69.1)	0.015
Activity Levels*				
Sedentary Lifestyle	14 (0.0%)	18(17.4%)	15 (18.5%)	0.032[b]
Slightly Active	11 (61.1%)	25 (65.2%)	27 (63.0%)	
Moderately Active	18 (38.9%)	4(4.3%)	3 (11.1%)	
Very active	0 (0.0%)	3(13.0%)	5(7.4%)	

[a]p- value derived from Friedman Test; [b]p-value derived from chi-squared test

*Physical Activity Level (PAL): Sedentary: 1.2 (little to no exercise), Lightly active: 1.375 (light exercise or sports 1–3 days a week), Moderately active: 1.55 (moderate exercise or sports 3–5, Very active: 1.725 (hard exercise or sports 6-7 days a week), Super active: 1.9 (very hard exercise or daily physical labor)] (ICMR guidelines)

The study participants in precision nutrition group (n=50), personalised nutrition group (n= 52), standard diet group (n= 54) respectively, with a median age of 36. 3 years. In terms of sex, there were 22 females and 28 males in precision nutrition group and 23 females and 29 males and 20 females and 34 males in the personalised nutrition group. Regarding the dietary intake, especially related to macronutrient intake, the mean percentage was 63.4% for carbohydrates, 15.3% for protein and 21.3 % for fats.

4.2.7 Criteria used for the assessment of the gut microbiome markers

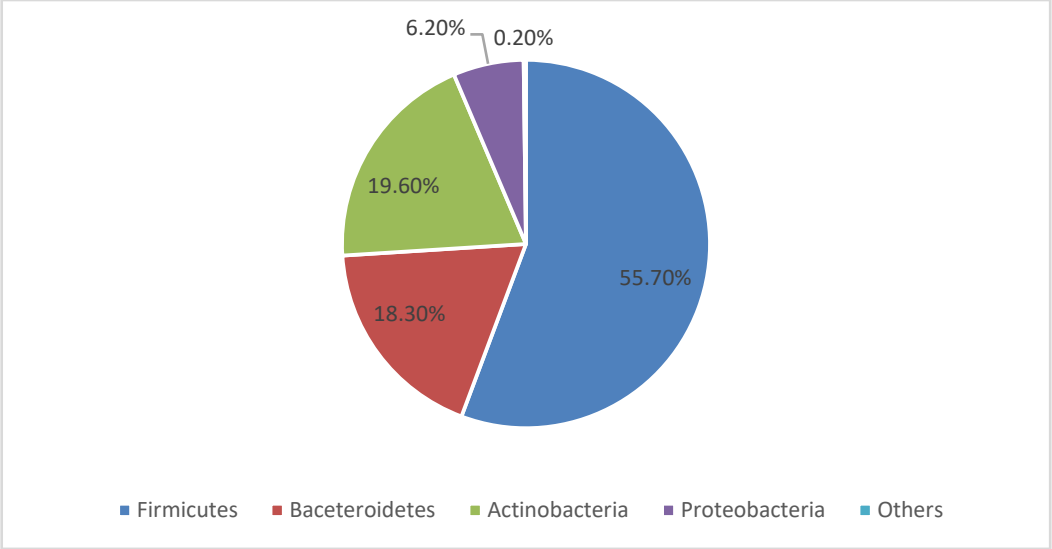
Three parameters namely gut microbiome composition, relative abundance and diversity was used to determine the gut microbiome profile of the study participants. Information related to each of the determinants are presented as follows.

4.2.7.1 Gut Microbiome composition of the study participants

Four bacterial sub-groups namely actinobacteria, bacteroidetes, firmicutes, proteobacterial were chosen in this study to determine the gut composition of the study participants. In the majority of the study participants, obese individuals in the precision nutrition group (N =50), the firmicutes phyla constituted the highest proportion of the bacterial population, with the relative abundance of 55.7% firmicutes respectively.

The phylogenetic characterization of all the samples of the study participants in the precision nutrition group uncovered four main bacterial phyla in the following proportions: Firmicutes (55.7%), Bacteriodetes (18.30%), actinobacteria (19.6%), proteobacteria (6.20%) and other less abundant bacterial phyla (<0.2%) were fusobacteria, verrucomicrobia were also present. Across all taxa, 115 genera and 9480 OTUs, with an average of 687 observed OTUs per sample were identified. The gut microbiome profile of the study participants is presented in Figure. 27.

Figure. 27. Gut Microbiome Composition of the obese individuals of the precision nutrition group

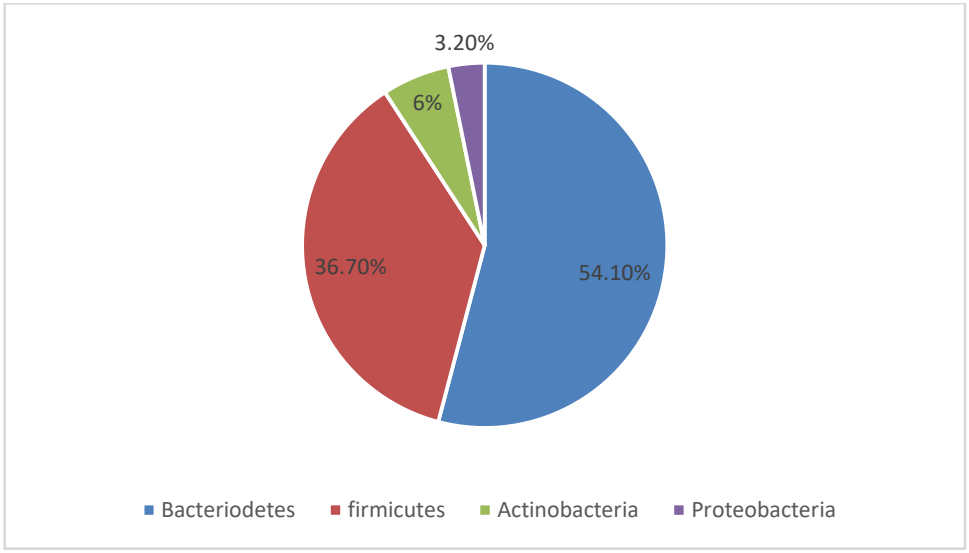


4.2.7.2 Gut bacterial diversity of the study participants

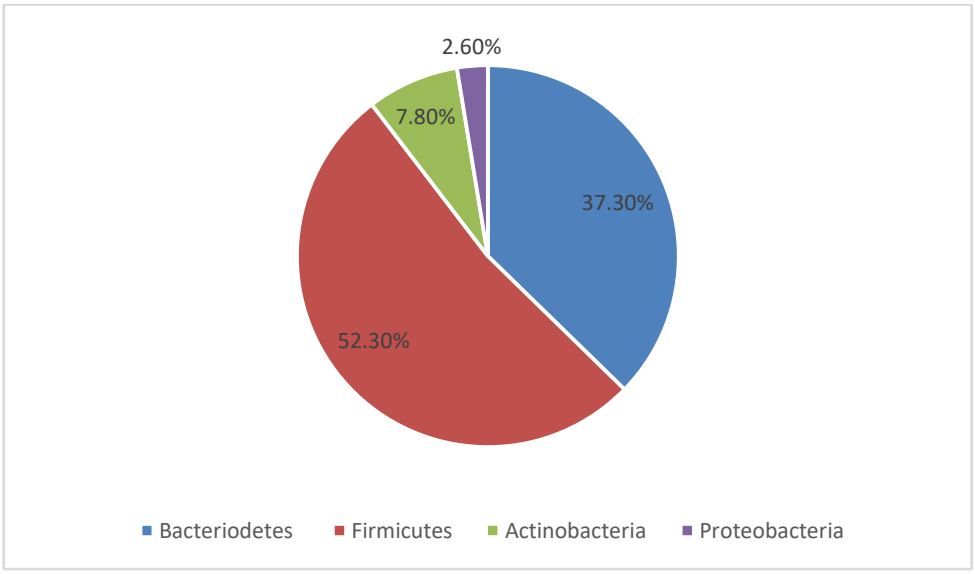
The phylum level distribution of the bacterial species found in the gut of the study participants of the precision nutrition group are presented in the below figure.28. The four major bacterial phyla namely firmicutes, bacteroidetes, actinobacteria and proteobacteria were included for this study. The female participants had significantly lower firmicutes to bacteroidetes ratio (F/B) in comparison to the male participants of the study ($p = 0.040$) respectively. The phylum level distribution of the bacterial relative abundance in the gut of the male and female study participants are given in Figure.28.

Figure 28. Phylum level distribution of bacterial relative abundance (%) in the gut of male or female participants.

28.a Female study participants



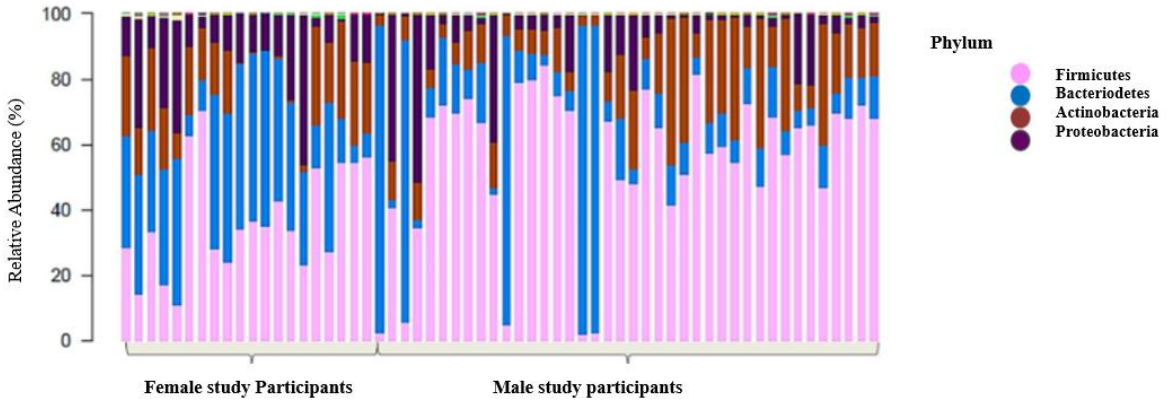
28.b. Male study participants



4.2.7.3 Relative abundance of gut bacteria present in the study participants

The relative abundance of the gut bacterial species present in the gut of the study participants of the precision nutrition group at the family and genus level are represented in the histogram as in figure 29. This shows the relative abundance of ≥1% among the study subjects.

Figure. 29. Relative abundance of gut bacteria present in the study participants



Five species namely Akkermansiamuciniphila, Bifidobacterium, Eubacterium, Roseburia and Faecalibacteriumprausnitzii were selected for the study of which bifidobacterium showed significant differences in their abundance across the population (≤ 0.05 Kruskal-Wallis H test).

4.2.7. Gut Microbiome Based Dietary Advice recommended to the precision nutrition group

The dietary advice based on the gut microbiome profiling was developed with the main objectives of improving the gut microbiome composition, increasing the diversity and abundance of species. According to several studies, these bacterial genus and species havebeen associated with beneficial health marker, has an importantfunctional role and have been negatively associated with various diseases including obesity.

The proportion of participants in the precision nutrition group given dietary advice according to the gut microbiome profiling and the rationale for such advice are shown (Table.XXVI). All the participants received gut microbiome-based advice in at least one of the recommendation categories, withthe majority (76%) receiving advice in 3 of the 5 recommendation categories listed in Table.XXV.

Table. XXV. Percentage of the study participants receiving the gut Microbiome Based Dietary Recommendations

Species	Functional Role	Dietary Recommendations	Percentage receiving this advice
Akkermansiamuciniphiliasp	Rationale: symbiotic relationship with the host and helps in butyrate production		
.	Modulates basal metabolism, reduces endotoxemia and prevents atherosclerosis, enhances SCFA production, prevents hyperlipidemia by clearing lipid intermediates, restores epithelial tight junction proteins, and prevents liver disorders.	Include prebiotics (bananas, whole grains), and fructooligosaccharides; following a FODMAP diet may increase the abundance of *A. muciniphilia* (foods to limit: wheat, rye, cashew, pistachios, onion, garlic, cabbage, prunes, apple, pear, watermelon, coconut water); polyphenols like grapes may also increase their abundance.	64%
Faecalibacteriumprausnitzii sp.	One of the important butyrate producers		
	Anti-inflammatory potential in IBD, restores gut barrier in diabetic conditions, enhances butyrate production, reduces microbial translocation.	High-fiber diet with less meat, inclusion of prebiotics, inulin-type fructans (banana, garlic, onions, wheat bran), and fructo-oligosaccharides.	53%
Roseburiasp	Helps in energy production for the butyrate producers.		
.	Prevents intestinal inflammation and maintains energy homeostasis by producing metabolites, regulates barrier homeostasis, and cytokine	Food sources to include: coconut palm, tomato, legumes.	52.6%

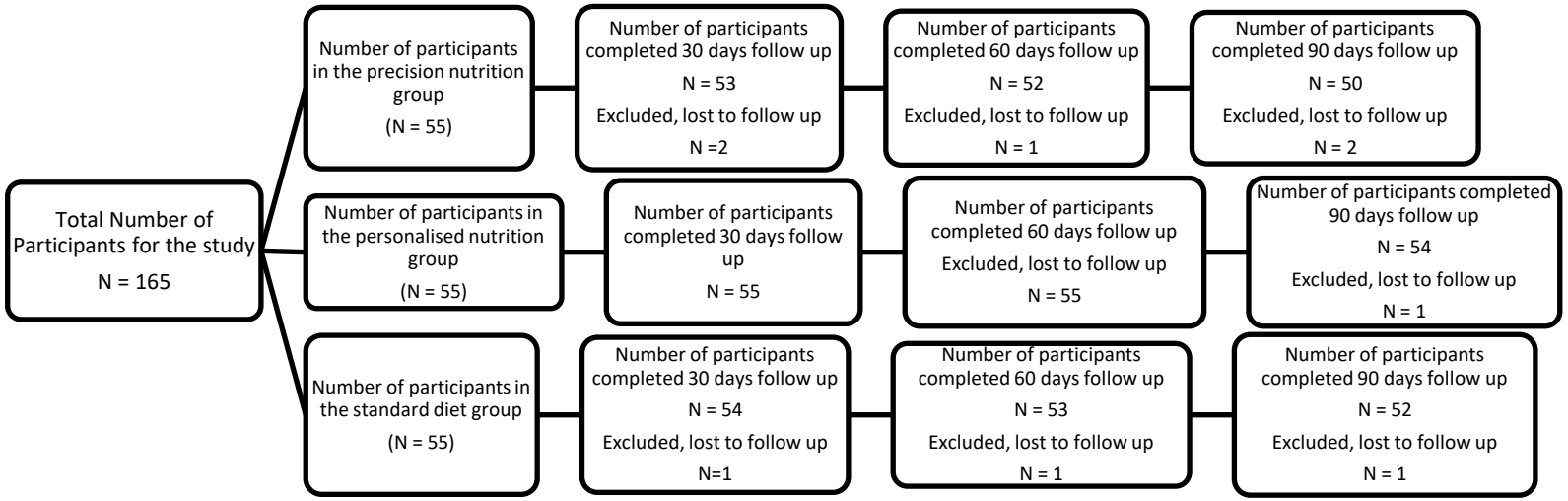
	release through its metabolite butyrate. Its role has been implicated against disorders of the nervous, digestive, respiratory, circulatory system, and metabolic, autoimmune diseases.		
Eubacterium sp	Involved in the production of SCFAs, vitamin B and fatty acids.		
.	Enhances butyrate formation, maintains intestinal metabolic balance, modulates gut inflammation, facilitates metabolic improvement in insulin-resistant individuals, and mediates anti-cancer effects through butyrate.	Include sources of polyphenols, cocoa flavanols, and cranberry.	56.4%
Bifidobacterium sp.	Rationale: Forms beneficial phenolic acids.		
	Has anti-mutagenic activities against colorectal cancer, acts against diarrhoea, reduces symptoms of IBD, produces health-promoting metabolites – conjugated linoleic acid and bacteriocins.	Include fermented dairy products (curd, buttermilk, cheese), prebiotics, and non-digestible oligosaccharides (galactooligosaccharides – dairy products, beans, root vegetables; fructooligosaccharides).	76%

Phase III: Comparative analysis of precision nutrition, personalised nutrition and generic nutrition based dietary advice on long term weight management

4.3.1. Flow diagram of study participants from baseline to 30 days, 60 days and 90 days

A total of 165 participants were enrolled in the study as outlined in figure. 30 . Fifty participants completed the 90 days follow up in the precision nutrition group, 54 participants completed the three months in the personalised nutrition group and 52 in the standard diet group, corresponding to the number of participants excluded or lost to follow up, 5 participants in the precision nutrition group, one participant in the personalised nutrition group and 3 participants in the standard diet group.

Figure. 30 . Flow diagram of participants from baseline, 30 days, 60 days and 90 days of the study period



The retention rates were higher among the participants in the personalised nutrition group followed by the lowest in the precision nutrition group. The demographic information of the study participants indicated that study group consisted majorly of middle-aged female and male subjects who were positive towards changing their diet for better health.

4.3.2 Changes in the anthropometric measurements at baseline, 30 days, 60 days and 90 days

The three study groups selected were similar in terms of age, sex, BMI and no significant differences observed at the beginning of the study.

TABLE XXVI: Anthropometric measurements at baseline, 30 days, 60 days and 90 days

	Baseline (mean ± SD, 95% CI)	**30 days (mean ± SD, 95% CI)**	**60 days (mean ± SD, 95% CI)**	**90 days (mean ± SD, 95% CI)**
Standard Diet Group				
Body fat (%)	48.18 ± 6.6, 45.6 to 50.7	47.16 ± 7.18[a], 44.5 to 49.9	45.91 ± 6.97[b], 43.3 to 48.9	44.7 ± 7.02, 42.1 to 47.4
Weight (kg)	89.83 ± 49.71, 206.1 to 233.5	86.97 ± 49.36, 199.4 to 226.6	82.72 ± 51.41, 197.7 to 225.8	81.51 ± 51.64, 199.2 to 227.8
BMI (kg/m^2)	37.82 ± 7.7, 35.6 to 40.1	36.65 ± 7.91, 34.3 to 39	36.38 ± 8.12, 34.0 to 38.7	36.68 ± 8.07, 34.2 to 39.1
Waist circumference (cms)	108.43 ± 7.3, 102.6 to 110.36	106.4 ± 7.7, 101.34 to 107.12	103 ± 7.7, 100.37 to 104.56	102.34 ± 2.3 , 101.4 to 105.65
Personalised Nutrition Group				
Body fat (%)	44.93 ± 7.95, 42.5 to 47.4	42.77 ± 8.29[a], 40.2 to 45.4	41.55 ± 8.24[b], 39.0 to 44.1	42.32 ± 8.15, 39.7 to 44.9

Weight (lb)	93.34 ± 32.29, 189.8 to 216.9	90.56 ± 32.10, 181.1 to 208.0	87.48 ± 32.60, 178.6 to 206.4	86.85 ± 34.16, 182.7 to 211.0
BMI (kg/m^2)	35.22 ± 6.06, 33.0 to 37.5	33.72 ± 6.13, 31.4 to 36.0	33.36 ± 6.20, 31.0 to 35.7	34.11 ± 6.46, 31.8 to 36.5
Waist circumference (cms)	110.41±4.3, 104.3 to 111.2	109.43 ±4.5, 108.21 to 110.3	108.31±3.8, 106.32 to 109.1	106.54 ±4.8 105.32 to 107.86
Precision Nutrition Group				
Body fat (%)	45.18 ± 5.6, 45.4 to 51.3	46.26 ± 6.18[c], 44.5 to 49.9	42.91 ± 4.97[b], 42.2 to 47.9	43.7 to 7.02, 41.1 to 45.4
Weight (lb)	92.83 ± 49.71, 203.1 to 240.5	90.97 ± 49.36, 179.4 to 226.6	87.72 ± 51.41, 197.7 to 225.8	86.51 ± 51.64, 197.2 to 220.4
BMI (kg/m^2)	34.82 ± 7.7, 34.6 to 36.1	34.5 ± 5.91, 34.3 to 32	32.38 ± 8.12, 31.0 to 36.7	30.68 ± 8.07, 32.2 to 39.1
Waist circumference (cms)	111.78 ±4.5, 108.12 to 114.32	109.84 ±6.2, 102.34 to 110.12	107.43± 2.6, 106.43 to 108.92	105.43 ±8.7, 103.2 to 106.23

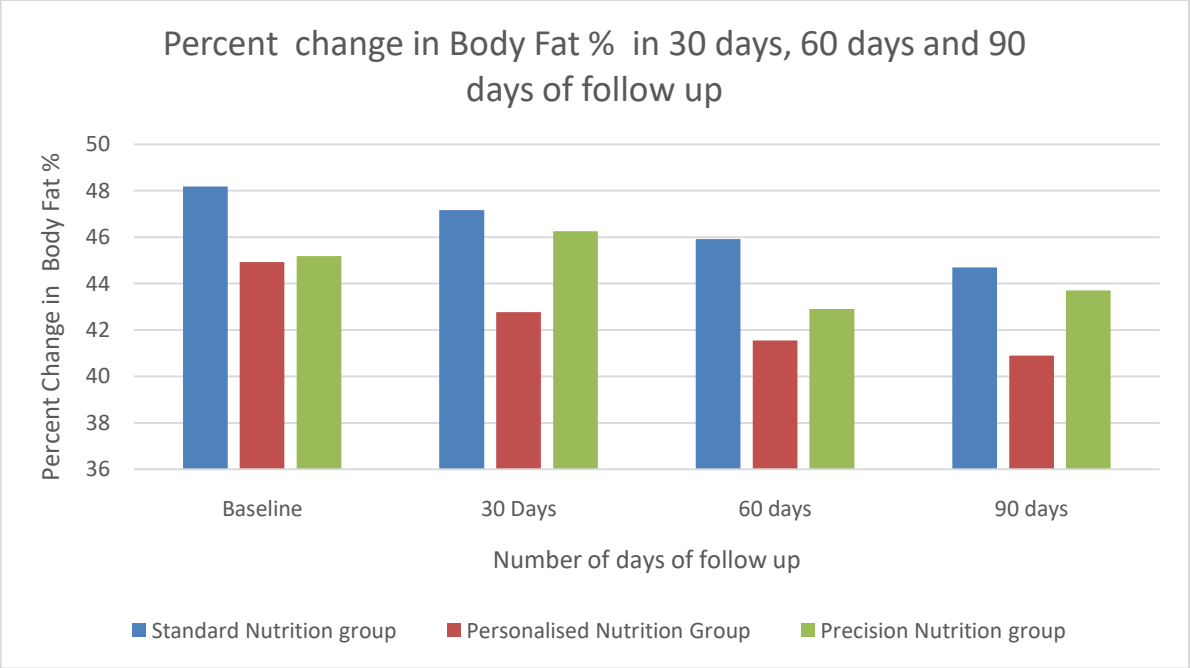
[a]*P* = 0.023. *P* interaction for body fat (%) = 0.002, effect size = 0.087.

[b]*P* = 0.022. *P* interaction for body fat (%) = 0.002, effect size = 0.087.

During the period from baseline to 90 days, the data in the records demonstrated that all the three groups were very similar. All the three groups showed a similar average weight loss and 85% of the study participants were able to maintain the weight loss (82% in the standard group, 86.5% in the personalised nutrition group and 87.5% in the precision nutrition group). The results were significantly better in the precision nutrition group ($p < 0.021$) than theother two groups.

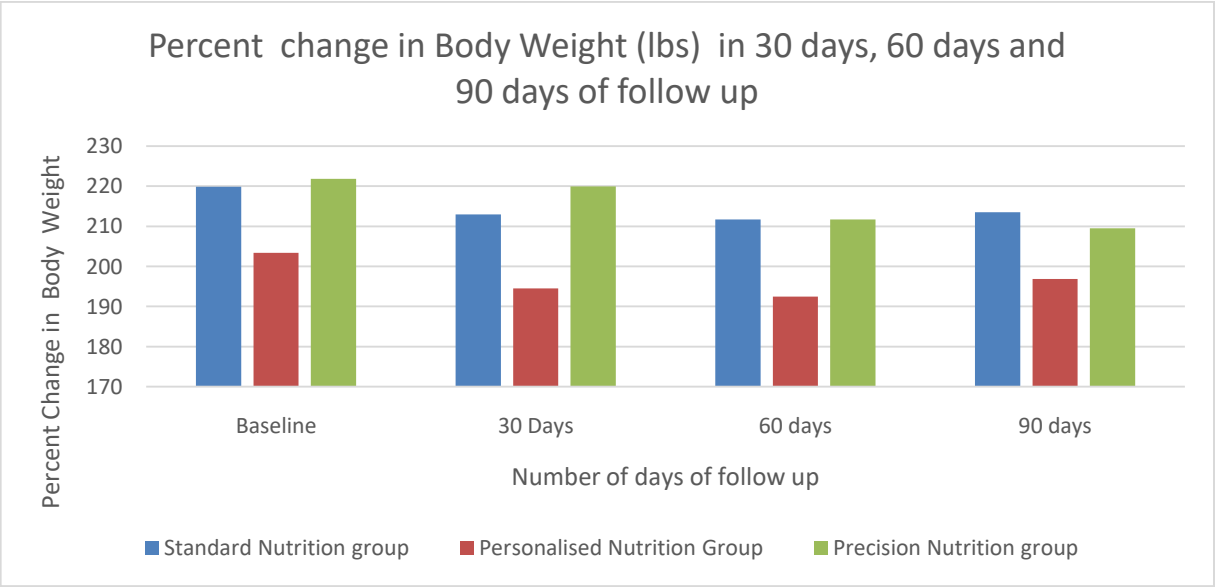
The difference in the body fat percentage among three study groups are presented in pr Figure. 31.

Figure. 31 Percent change in body Fat % in 30 days, 60 days and 90 days follow-up



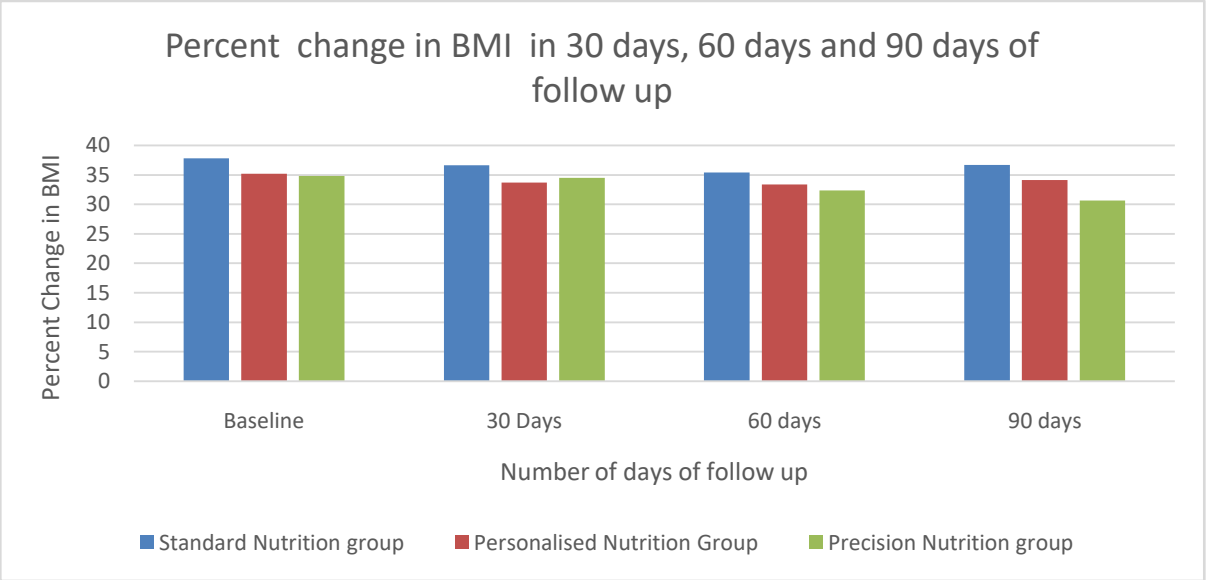
The percentage change in body weight among three study groups in 30, 60 and 90 days follow- up are represented in figure.32.

Figure 32. Percent change in Body Weight (lbs) in 30 days, 60 days and 90 days of follow up



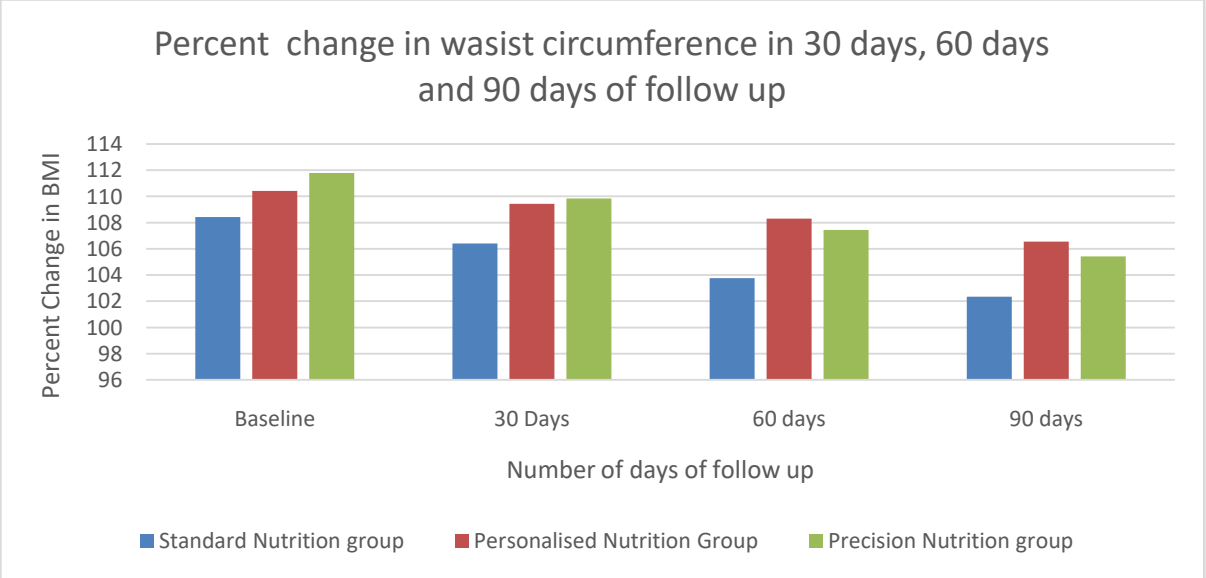
The percentage change in BMI among the three study groups in different time periods of follow- up are represented in figure.33.

Figure. 33 Percentage change in BMI in 30 days, 60 days and 90 days of follow-up



The percentage change in Waist circumference in different time periods of follow- up are presented in figure. 34.

Figure 34. Percentage change in waist circumference in 30 days, 60 days and 90 days of follow up



4.3.2.1Weight and BMI loss in the study groups

The weight loss and reduction in BMI between the three study groups is presented in Table XXVII. The change in the body weight and BMI between the three study groups can be found below.

Table XXVII Weight and BMI loss in the study groups

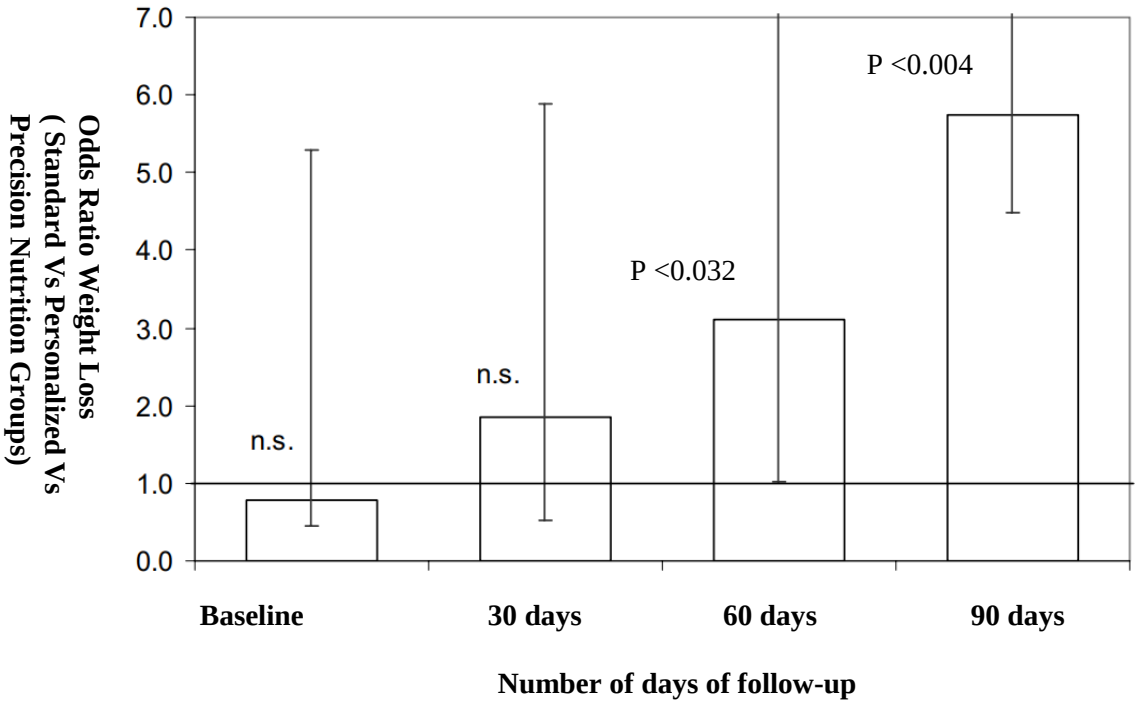
Standard diet group						**Personalized nutrition Group**						**Precision Nutrition Group**			**P < ***
Time point	n	Weight as % of baselines	Delta kg	Delta BMI (Kg/m2)	% lost weight	n	Weight as % of baselines	Delta kg	Delta BMI (Kg/m2)	% Lost weight	n	Weight as % of baselines	Delta kg	Delta BMI (Kg/m2)	% Lost weight
Baseline	55	100.0%				55	100.0%				55	100%			
30th day	53	95.4%	4.77	1.59	94.3%	55	96.3%	3.70	2.10	92.5%	54	97.8%	8.30	1.48	0.50
60th day	52	92.2%	3.65	2.78	86.9%	55	93.4%	6.42	3.51	96.1%	53	96.5%	7.89	8.43	0.64
90th day	50	87.2%	2.98	-0.86	31.8%	54	95.6%	3.61	2.54	73.1%	52	95.4%	4.65	3.21	0.023

* The p value corresponds to the analysis of variance comparing the change in BMI between the three study groups, namely standard diet group, personalised nutrition group and precision nutrition group.

4.3.2.2 Odds Ratio of weight loss between the three study groups

The Odds ratio of weight loss for individuals in three groups namely, standard nutrition Vs Personalised nutrition Vs Precision nutrition group are presented below in Figure.30.

Figure.35. Odds ratio of weight loss between the three study groups



The study participants in the precision nutrition group were able to sustain the weight loss resulting in a gender adjusted odds ratio of 6.83 (95% CI 2.23- 24.5 P< 0.003). The difference in the weight loss was more apparent when it is calculated as percent of BMI weight gain/ weight loss in the precision nutrition group which had a 6.2% loss vs a 3.3 % gain in the non- tested group ($p < 0.001$). Hence the participants in the precision nutrition group were able to sustain weight loss than in other groups.

The difference in the body weight and BMI was more obvious in the precision nutrition group after 60 days. The study participants in the precision nutrition. The study participants in the personalized nutrition group had 7.5% loss vs 7.89 % in the precision nutrition group and 5.98% in the standard nutrition group ($P < 0.003$). The precise nutrition recommendations resulted in better BMI reduction, although the weight loss was very similar till the 30 days of the study, significant improvements and differences among the groups were observed only after 60 days of the study.

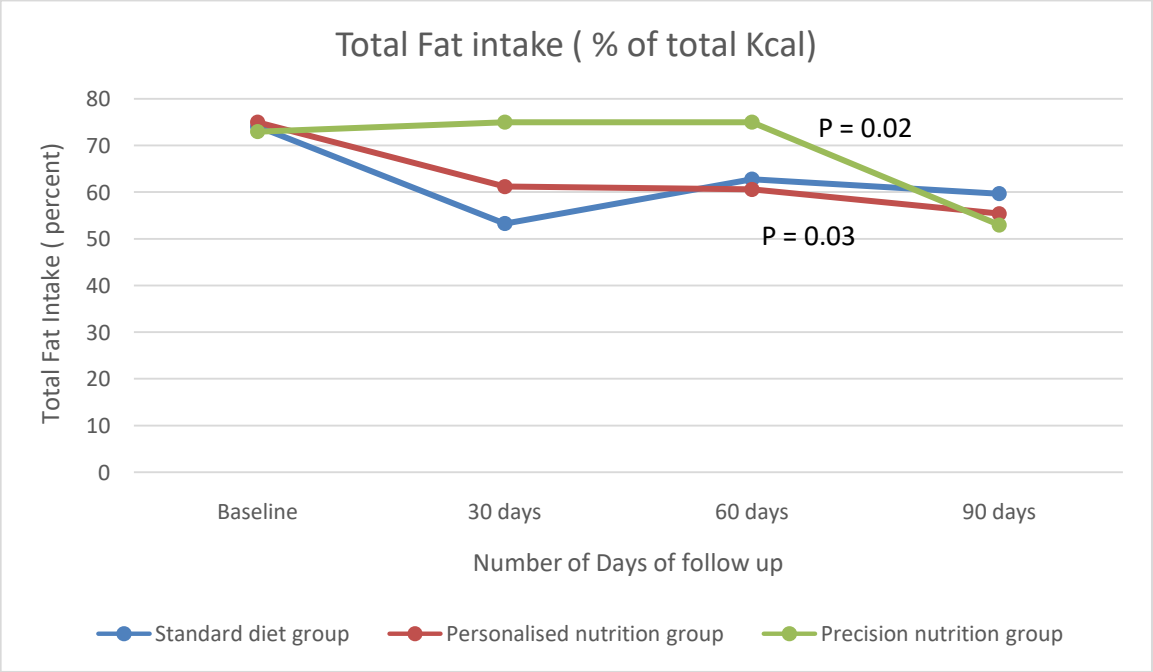
4.3.3 Diet composition and dietary intake of the study participants in 30, 60 and 90 days of follow-up

The diet composition and intake during different time periods namely 30 days, 60 days and 90 days among the three study groups are presented in TableXXVIII.

The dietary intake and diet composition of the study participants were recorded at different time points, at baseline, 30 days, 60 days and 90 days respectively. As evident from the data in the table, the total fat percentage among the study participants in the personalized nutrition significantly reduced from (34.3±4.8 % Kcal to 28.2±4.8% Kcal, P= 0.02). The amount of unsaturated fats consumed also reduced significantly among the precision nutrition group from baseline to 90 days (48.5±17.24 g to 43.6±17.2 g, P = 0.02).

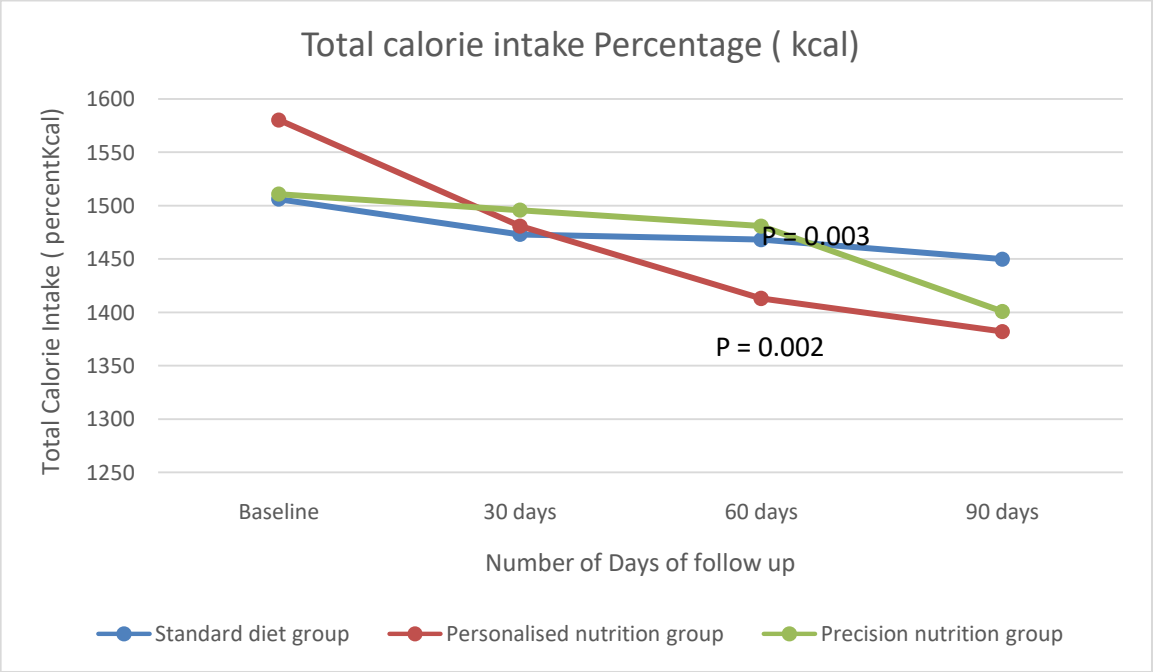
The total fat intake (in percentage of Kcal) of the study participants of the three groups at different time points are presented in Figure. 36.

Figure. 36 Total fat intake of study participants of the three groups



The protein intake of the study participants in the personalized nutrition group increased, (86.6±23.5 g to 88.6±23.5g, P = 0.11), and the protein intake was more than the standard nutrition group participants. The calorie intake of the participants in the three study groups reduced approximately 100 – 120 kcal at the end of the study. The calorie intake of the participants in the personalized nutrition group reduced significantly, (1580.34±528.2% to 1452.1±680.8% kcal, P = 0.003) and the calorie intake of the participants in the precision nutrition group significantly reduced, (1510.9±528.2% to 1400.9±543.4 % Kcal, P= 0.002), presented in Figure. 37.

Figure.37. Total calorie intake of participants in three study groups at different time points



The diet composition of the study participants in the three groups which were analysed showed that the addition of nutrigenetically tailored advice and adding gut microbiome-based information showed significant changes in the diet composition and dietary intake of the study participants in the three groups.

Table XXVIII Diet composition and dietary intake in 30, 60 and 90 days of follow up

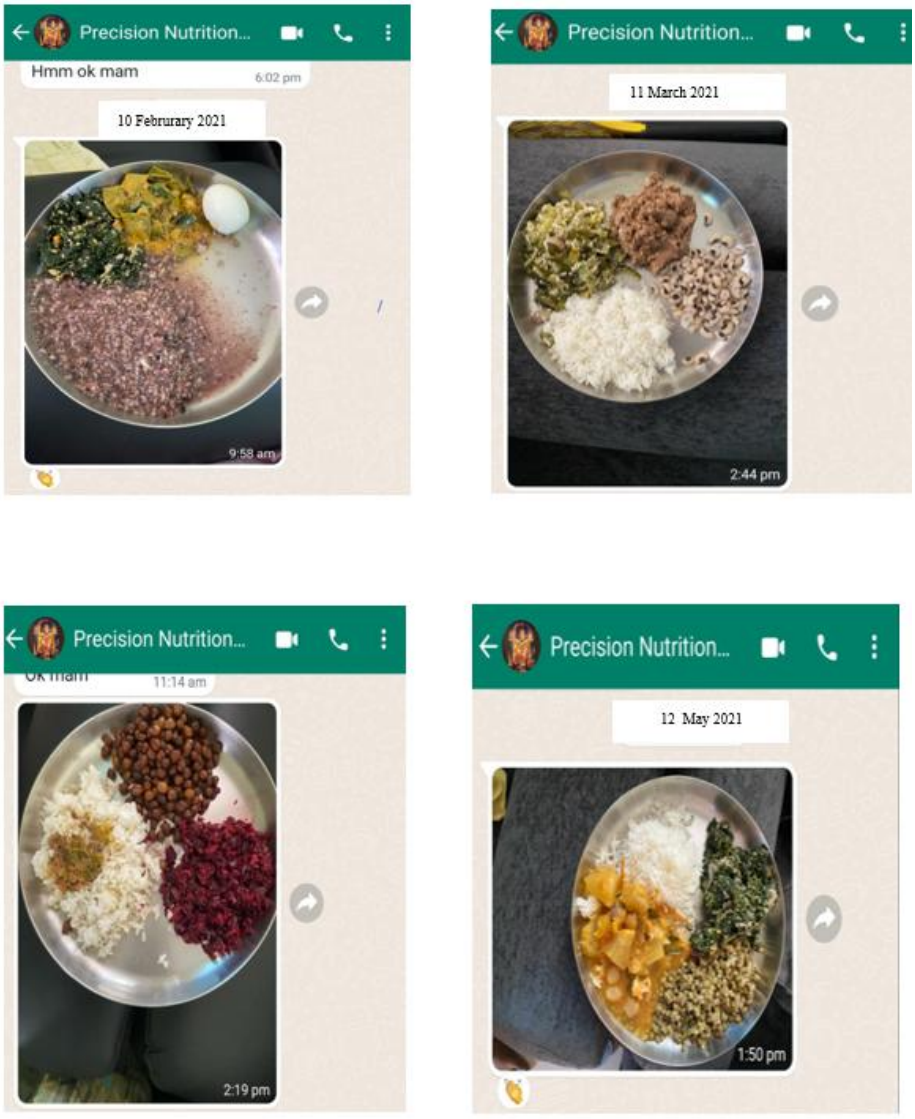
	Baseline			**30 days**			**60 days**			**90 days**						
Nutrient intake	**Standard diet**	**Personalised diet**	**Precision Nutrition Diet**	**Standard diet**	**Personalised diet**	**Precision Nutrition Diet**	**Standard diet**	**Personalised diet**	**Precision Nutrition Diet**	**Standard diet**	**Personalised diet**	**Precision Nutrition Diet**	**RM ANOVA P Value:** Standard diet	**RM ANOVA P Value: Personalised nutrition diet**	**RM ANOVA P Value: Precision Nutrition Diet**	**Split-Plot ANOVA P interaction**
Calories (Kcal+-SD)	1506.2±502.9	1580.34±528.2	1510.9±528.2	1473.2±358.5	1480.9±543.4	1495.9±543.2	1566.2±394.1	1713.2±602.6	1480.9±543.4	1473.5±339.6	1452.1±680.8	1400.9±543.4	0.17	**0.003**	**0.002**	0.99
Protein (g+-SD)	70.7±23.3	86.6±23.5	84.7±21.6	73.6±26.7	87.1±25.8	70.1±23.5	75.1±28.4	89.6±29.3	86.6±23.5	68.6±29.0	91.2.3±24.2	88.6±23.5	0.63	0.20	0.45	0.44
Protein (%Kcal+-SD)	16.7±2.8	19.1±5.3	19.9.1±3.2	20.3±6.1	19.1±4.8	20.0±5.3	19.2±5.0	19.7±7.1	20.4±3.3	18.6±5.8	22.6±5.8	21.1±5.3	0.11	0.91	0.11	0.35
Total Fat (g+-SD)	74.1±33.6	75.0±22.6	73.0±20.6	53.3±20.8	61.2±28.3	75.0±22.6	62.8±27.9	60.6±28.3	75.0±22.6	59.7±19.1	55.4±29.4	53.0±22.6	0.14	**0.01**[a]	0.32	0.63
Total Fat (%Kcal+-SD)	37.7±8.2	36.0±4.8	34.3±4.8	31.2±8.3	31.9±7.4	29.0±5.8	35.5±10.1	31.4±9.2	28.7.0±4.8	36.2±7.2	30.2±8.7	28.2±4.8	0.12	**0.02**	**0.01**	0.24
SFA (g+-SD)	24.6±12.3	24.4±8.1	24.1±6.1	18.6±9.7	19.7±11.1	19.4±8.1	21.1±8.8	21.3±12.8	19.2±8.1	19.7±6.5	17.6±10.8	19.0±8.2	0.22	0.08	0.06	0.85
SFA (%Kcal+-SD)	12.2±3.1	11.9±3.3	11.1±3.3	10.8±4.4	10.2±3.7	11.5±3.3	11.7±3.9	10.8±4.6	11.9±3.3	11.9±3.1	9.3±3.3	11.9±3.3	0.64	0.13	0.14	0.45
Total UnSFA (g+-SD)	48.7±22.4	49.6±17.2	48.5±17.2	33.7±13.0	40.5±18.7	47.9±17.2	41.1±23.1	38.2±16.4	49.6±17.2	38.6±14.7	36.8±19.2	43.6±17.2	0.17	**0.02**	0.05	0.56
Total UnSFA (%Kcal+-SD)	24.5±6.1	23.3±3.8	22.1±3.8	20.2±5.7	20.8±5.6	20.9±3.8	22.7±8.4	19.7±5.4	19.8±3.8	22.8±5.2	19.7±6.0	19.3±3.8	0.23	0.05	0.45	0.35

4.4 Improvements in dietary intakes at baseline, 30days, 60 days and 90 days of follow up

The dietary intake of the study participants in all the three groups were recorded weekly at different time points, baseline, 30 days, 60 days, 90 days. Whatsapp was used to monitor their dietary intakes via pictures of the meal consumed. The difference in the meal composition and dietary intake also showed the adherence to dietary intake at different points of the study period.

Plate.3

Plate. 3 Improvements in dietary quality and quantity at different time points of the study period in the precision nutrition group



4.5 Changes in the diet composition and dietary intake of the study participants

The changes in the diet composition and dietary intake of the three study groups at different time points, baseline, 30 days, 60 days and 90 days are presented in Table. XXIX.

Table. XXIX Changes in the dietary intake of study participants among the three study groups in different time periods

	Baseline(n %achieving target)			**P value**	**30 days (n, % achieving target)**			**P Value**	**60 days (n, % achieving target)**			**Significance**	**90 days (n, % achieving target)**			**P value**
Nutrient	Standard diet group	Personalised nutriation group	Precision Nutrition group		Standard Diet Group	Personalised Nutrition Group	Precision Nutrition Group	P value	Standard diet group	Personal Nutrition Group	Precision Nutrition group	P value	Standard Nutrition Group	Personalised Nutrition Group	Precision Nutrition Group	
Individualized Calories target	20, 37.7%	26, 44.8%	24, 42.4%	0.45	22, 50.0 %	22, 52.4 %	20, 51.3%	0.86	23, 57.5%	15, 44.1%	24, 48.1	0.25	16, 57.1%	17, 56.7%		0.97
<25% kcal From total fat	6, 11.3%	5, 8.4%	6, 9.2%	0.61	6, 13.6%	7, 16.7%	8, 15.4%	0.87	6, 15.0%	6, 17.6%	7, 12.3%	0.76	0,0.0%	8,25.8%		<0.01
Group – based Total fat target	6, 11.3%	23, 39.0%	26, 40.0%	<0.01	6, 13.6%	27, 64.3%	27, 41.2.%	<0.01	6, 15.0%	19, 55.9%	21, 62.3%	<0.01	0,0.0%	18, 58.1%	22, 63.3%	<0.01
10%-35% Kcal	52, 98.1%	59, 100.0%	57, 99.2%	0.47	43, 97.7%	42, 100.0%	57.8% 93.4%	0.99	40, 100.0%	34, 100.0%	43, 99%	1.00	25, 89.3%	31, 100.0%	43.7% 99.2%	0.10

from protein																
Group-based Protein target	52,	44,	58,	<0.01	43,	31,	42,	0.01	40,	25,	26,	<0.01	27,	22,	24,	0.01
	98.1 %	74.6%	84%		97.7%	70.5%	83.5%		100.0%	73.5%	81.2%		96.4%	71.0%	84.4%	
<10% kcal from Saturated fat	14,	14,	13,	0.74	21,	22,	23,	0.57	15,	15,	16,	0.56	8,	18,	21,	0.02
	26.4%	23.7%	23.5%		47.7%	52.4%	53.4%		37.5%	44.1%	45.7%		28.6%	58.1%	62.4%	

4.6 Changes in the gut microbiome composition from base line to 90 days

The relative abundances of Bacteroidetes at the baseline and at the end of 90 days in the precision nutrition group is represented in Figure 38 as pre and post intervention.

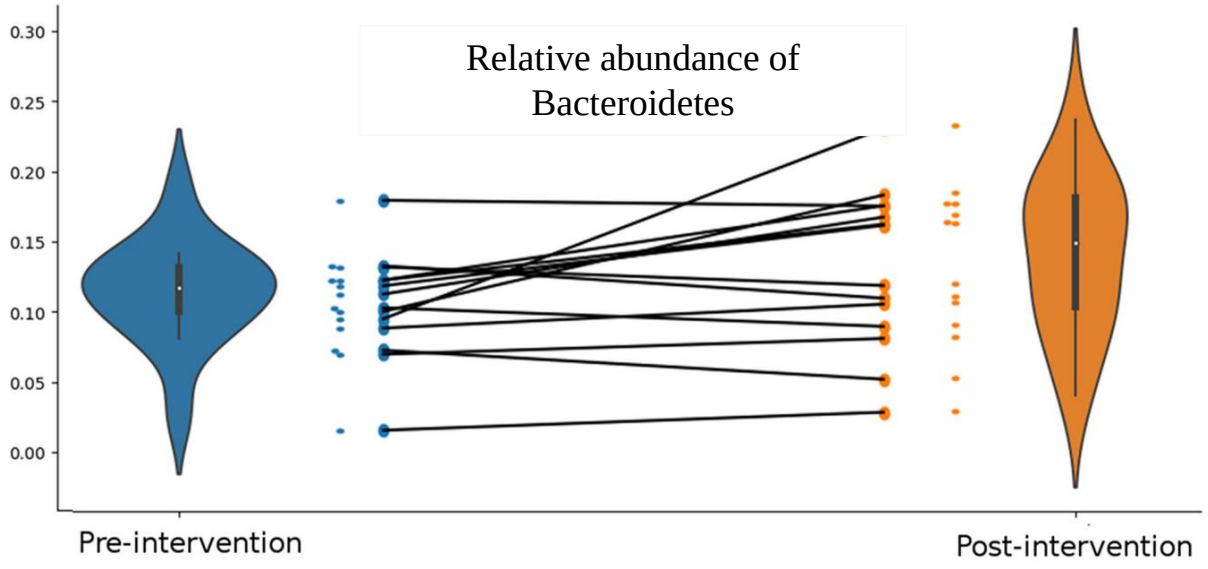


Figure 38. Bacteroidetes relative abundances for the personalized nutrition group pre and post-intervention

4.7 Post Interventional Changes in Gut Microbiota Profiles

After 90 days of intervention, a significant shift in microbiota profiles in terms of alfa- or beta-diversity was observed in both groups. A trend of decrease in the firmicutes family for the personalized nutrition intervention group was observed; and was found to be statistically significant (p= .05, paired t-test). A statistically significant increase in the bacteriodetes genus was observed in the personalized nutrition group (p= .04).

The percentage distribution of gut microbiome profiles with different bacterial groups are presented in Figure.39.

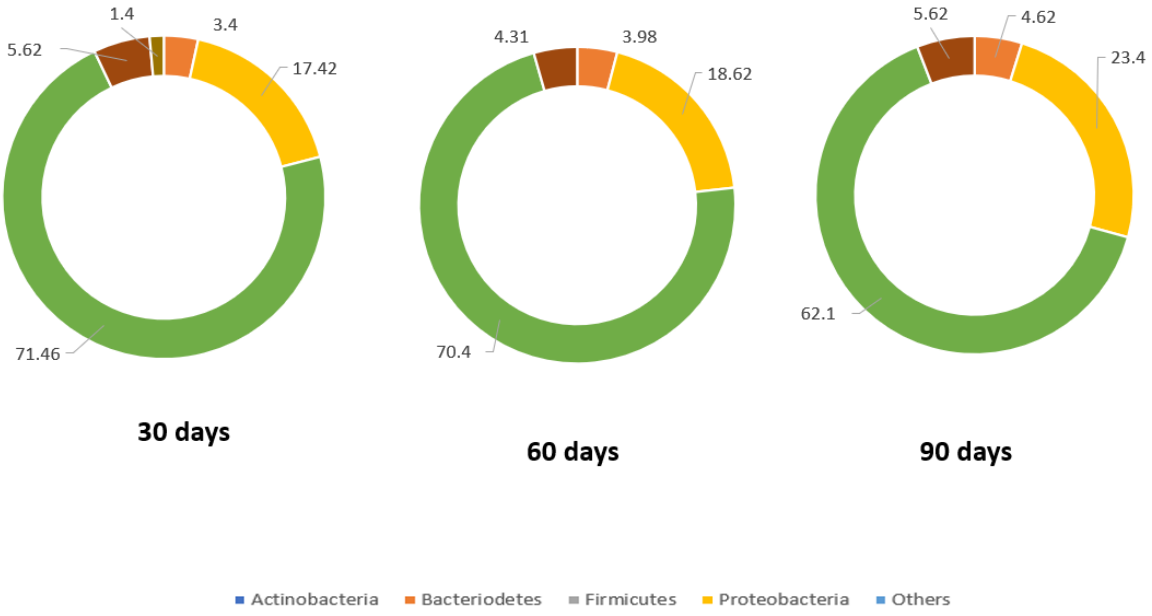


Figure. 39. Post Interventional Changes in gut microbiome profiles