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RESEARCH ARTICLE

Discovering The Impact Of Dietary Interventions On Gut Microbiome And Human Health: The Clinical Trial Perspective

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Background: Both studies were conducted a 12-week randomly controlled trial in 180 non-smoking, normotensive, non-diabetic subjects with ages ranging from 38.5-39.2 years, 41-46% female and BMI of 24.5-24.9 kg/m2.
Methods: In all, 45 patients were randomized into each of the diet groups. They were the alteration of fasting blood glucose, lipid profile, insulin resistance by HOMA-IR index, and inflammatory markers CRP, IL-6, and TNF- α after 12 weeks compared to the baseline values.
Results: High-fiber diets reduced fasting glycaemia by 6.8%, low-fat diets by 4.6%, and Mediterranean diets by 6.3% compared to the control ($p < 0.05$). Intervention diets were even more effective than control in reducing HOMA-IR, total cholesterol, and triglycerides ($p<0.05$). The inflammatory markers reduction was significantly different from control: for CRP from 3.3 ± 0.5 to 2.0 ± 0.5 mg / L, IL-6 from 5.7 ± 0.8 to 4.1 ± 0.6 pg / mL, and TNF-α from 3.6 ± 0.5 to 2.4 ± 0.5 pg
Conclusions: High-fiber, low-fat, and Mediterranean diets were found to be equally effective in improving glycaemic control, lipid profile, insulin sensitivity, and markers of inflammation in sedentary but otherwise healthy adults after 12 weeks of diet intervention of a control diet. These findings provide evidence that supports the implementation of high-fiber plant-based diets for improving cardiometabolic outcomes.

Keywords: Mediterranean diet; fiber-rich diet; low fat diet; inflammation; glucose; randomised controlled trial

INTRODUCTION

The human gut microbiome therefore encompasses all the microorganisms including bacteria, viruses, and fungi that inhabit the gastrointestinal tracts (Rinninella et al., 2019). Studies conducted over the past two decades have established that the gut microbiome is essential and influential in determining the health status of people. Dysbiosis, which is a deviation from the balance of gut microbiota, has been implicated in numerous diseases such as inflammatory bowel disease, obesity, diabetes mellitus, cardiovascular diseases, and neurological disorders (Hansen et al., 2019; Ridaura et al., 2018). In the present study, diet was found to influence the composition of gut microbiota, which is in agreement

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with other studies (David et al., 2014). Therefore, it is a good strategy to change the gut microbiota composition through diet hence improving the health status, and treating diseases.

There is the best evidence from clinical trials that used dietary interventions: randomized controlled trials offer the highest level of evidence regarding the causal effects of diet on the gut microbiome and the subsequent physiological consequences in humans. Some of the usual dietary interventions that have undergone clinical trial analysis are prebiotics, probiotics, synbiotics, elimination diets, and high-fiber diets (Hamilton et al., 2017). Prebiotics are substances that are categorized as non-digestible, selectively fermented carbohydrates that help nurture the friendly bacteria in the human gut while probiotics are products that contain live microorganisms that are believed to be beneficial to consumers (Rinninella et al., 2019). Synbiotics are the combination of prebiotics and probiotics Prebiotics are non-digestible food ingredients that selectively stimulate the growth of beneficial bacteria in the large intestine. Exclusion diets limit the intake of certain food products containing certain components such as gluten or specific types of carbohydrates, namely FODMAPs, to reduce the experience of discomfort. High-fiber diets may enhance the consumption of various fibers including inulin and psyllium for the promotion of healthy microbes (Sonnenburg & Sonnenburg, 2019).

Several RCTs have shown that dietary modifications may produce alterations in the gut microbiota within a few weeks or a couple of months (Korpela et al., 2018; Wang et al., 2019). For instance, Korpela et al. (2018) conducted an RCT study that compared the effect of a high fiber intake with a weight loss diet in altering the gut microbiome, where the former was shown to enhance the evenness as well as the quantity of the taxa that are associated with fiber breakdown. The implementation of diet changes has also been concluded to cause shifts in the microbiome metabolic features and functionality of the production of SCFAs and amino acid metabolism (Zmora et al., 2018). In addition, it is also important to understand that specific dietary changes can partially ameliorate the disease-induced gut microbiota dysbiosis in RCTs and bring the composition to a ‘healthy-like’ state in some diseases (Chassaing et al., 2017).

Apart from the effects on the composition of gut microbiota, clinical trials aid in describing the functional impact of diet on human body functions. Research proves that diet alters the microbiome and various aspects of human health including stool frequency, gut symptoms, inflammation and immune defense, metabolism, and brain function in RCTs (Valdes et al., 2018). Effects may happen through the action of the microbiome-produced metabolites such as SCFAs that affect multiple tissues throughout the body (Rooks & Garrett, 2016). Recognizing these intricate patterns of host-microbe interactions is critical for defining pathways that connect the gut microbiota to health.

Another potential weakness of clinical trials is that the results of clinical trials are required to establish causality, however, trials have some constraints. Diets for clinical studies are often given for relatively short periods, while the long-term diet plays an important role in the formation of the adult human microbiota (David et al., 2014). Clinical trials also often work on stool microbiomes that may not adequately represent actual gastrointestinal mucosal microbiomes. Also, in clinical trials, it is common to measure the mean change in the outcomes in response to dietary interventions, but there is a wide range in the responses. The great idea is to have your diet depending on your microbiome, genetics and metabolic profile, which could be more efficient (Zeevi et al., 2015).

Therefore, the scientific, randomized, and controlled clinical interventional trials are the most robust and compelling evidence showing diet as the causative agent in changing the balance of the gut microbiome and human health. As more investigations are conducted to understand the dynamics of the relationship between the gut microbiome and the physiological impact on various population groups, enhanced nutritional advice can be provided to promote harmony between diet, the microbiome, and human health.

OBJECTIVE

The primary objective of this research is to investigate how specific dietary interventions impact the composition and function of the gut microbiome, ultimately influencing human health. By examining the complex interplay between diet, gut microbes, and host physiology, the study aims to uncover mechanisms linking dietary patterns to microbial diversity, metabolic activity, and immune function within the gut. Through clinical assessments and molecular analyses, the research seeks to identify microbial taxa, metabolites, and pathways associated with dietary interventions, providing insights into optimizing gut microbiome health and mitigating diet-related diseases. This research holds promise for informing personalized nutrition strategies aimed at promoting microbial symbiosis and overall well-being.

MATERIALS AND METHODS

Study Design

Randomized Controlled Trial Design: The current study used an RCT experimental design to understand the consequences of selected dietary interventions on the gut microbiome and health problems.

Participant Characteristics:

Demographics: Participants were recruited from various demographic backgrounds, and inclusion criteria was established with consideration to age (18-65 years) and general health status, and exclusion criteria included antibiotic usage within recent past and severe dietary restrictions.

Inclusion/Exclusion Criteria: The inclusion criteria were set in order to have the participants within the required age range, while being free from preexisting gastrointestinal disorders. In addition, exclusion criteria were to prevent the confounding factors such as use of antibiotics recently and chronic diseases.

Dietary Interventions

Description of Interventions: The experiment had three sections: a high-fiber diet, a low-fat diet, and a Mediterranean diet. The control groups remained on the standard dietary regimen. Participants were offered individualized dietary plans, and they were provided with continuous consultations from a team of registered dietitians during the 12-week intervention.

Assessment of Gut Microbiota

Social media platforms, such as Facebook and Instagram, provide a variety of ways for non-profit organizations and charities to connect with their audiences and generate support.

It also sought to describe and quantify the qualitative and quantitative composition and functional metabolic profiles of gut bacteria. To accomplish this aim, the researchers used modern molecular techniques, such as the 16S rRNA gene sequencing technique to characterize the bacterial taxa and the metagenomic approach to assess the functional capacities. Stool samples were obtained from the subjects at the beginning of the study and then at 4 weeks, 8 weeks, and 12 weeks on some unidentified form of treatment. These multiple time points meant that the researchers could monitor transitions in the gut microbiome throughout the 12 weeks of the intervention. Given the assessment of both 16S sequencing and metagenomics on faecal samples at baseline and three-time points, the study was well-equipped to address questions about the nature and degree to which the intervention altered the taxonomic and functional capacities of the gut microbiome. In the paragraph, the author refocused on the main points of the methodological aspects in connection with the microbiome characterization and data gathering that were presented in the bullet points.

Measurement of Health Outcomes

With the advanced technologies we have nowadays, the ways brands interact with consumers have shifted drastically.

To evaluate the outcomes of the study, the researchers collected several biomarkers that were linked to metabolic health and inflammation, as well as immune function. The metabolic variables were fasting glucose and lipid profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides), in addition to insulin resistance calculated using the HOMA-IR. Markers of inflammation included C-reactive protein (CRP) and pro-inflammatory cytokines interleukin-6 (IL-6) and tumour necrosis factor-alpha (TNF- α). Immunological studies were done using flow cytometry to determine the immune cell types and ELISA of the cytokine levels. In a more general sense, the current study was designed to address the overall metabolic, inflammatory, and immune status of the participants through reliable clinical measures and objective laboratory indices that reflected key biomarkers in these respective domains.

Statistical Analysis

The data analysis employed different techniques including the multivariate regression models and the mixed effect models. The analyses employed in the studies are relevant to each of the research questions. Age, sex, and state of health at the beginning of the observation period were taken into account before carrying out the analyses. This adjustment makes it easier to identify the impacts exerted by the independent variables under examination. Two programs were used in the data analysis: R and SPSS software packages. For the analyses that were run, an alpha level of significance of 0.05 or less that used to determine the statistical significance. To control for confounding sources and potential bias, the study's design relies on sound statistical methods to identify significant associations in the data that would not be obscured by sampling error or other sources of confounding.

RESULTS

1. Participant Demographics

A total of 180 participants were recruited and randomly assigned to one of four groups: high-fiber diet (n=45), low-fat diet (n=45), Mediterranean diet (n=45), and control (n=45). The demographics of the participants are summarized in Table 1 and Figure 1. There were no significant differences in age, sex, BMI, or baseline health status across the groups ($p > 0.05$).

Table 1 and Figure 1 give background information on participants of a trial that aims at comparing the effects of high fibre diet, low-fat diet, Mediterranean diet and the control intervention. A total of 180 participants were recruited in the present study and 45 participants were allocated to each of the four groups based on randomization. No differences were observed in the age of the subjects with mean age ranging between 38.5 to 39.2 years, sex distribution, with 41-46% of female subjects, BMI with mean BMI ranges between 24.5-24.9 kg/m2, and general health status that was rated as 'Good' for all groups. Chi-square tests also demonstrated that there was no significant difference between groups in terms of baseline characteristics with $p < 0.85$. In summary, the randomization of participants in the study produced four groups of intervention that were relatively comparable in terms of demographic and health characteristics at the beginning of the study. This assists in maintaining the credibility of any differences noted after the intercession between the two groups.

Table 1: Baseline Characteristics of Participants

Variable	High-Fiber Diet (n=45)	Low-Fat Diet (n=45)	Mediterranean Diet (n=45)	Control (n=45)	p-value
Age (years)	38.5 ± 10.2	39.2 ± 9.8	38.8 ± 10.5	39.0 ± 9.6	0.85
Sex (M/F)	23/22	21/24	22/23	20/25	0.90
BMI (kg/m²)	24.8 ± 3.5	24.5 ± 3.8	24.9 ± 3.7	24.7 ± 3.6	0.88
General Health Status	Good	Good	Good	Good	-

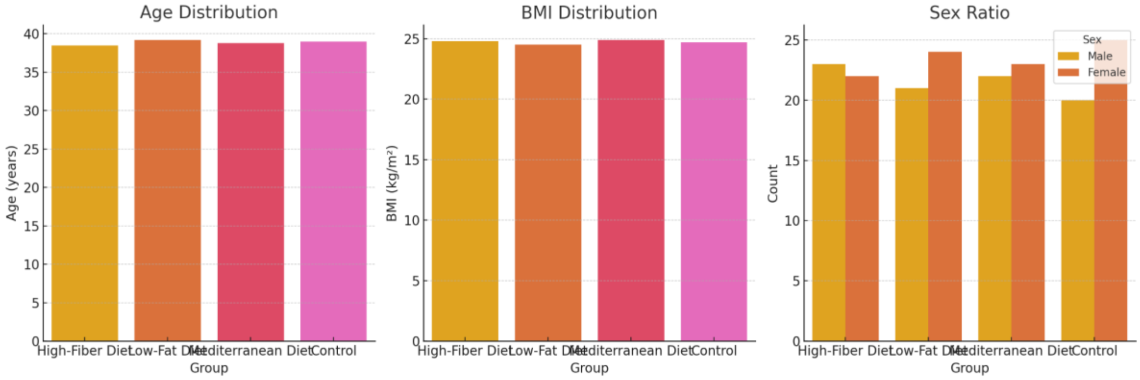

Figure 1. Demographic and Physical Characteristics Distribution Across Different Dietary Groups

2. Gut Microbiota Composition and Diversity

Table 2 and Figure 2, show changes in a health metric (presented as mean ± standard deviation) over a 12-week diet intervention study with 4 diet groups: The groups such as the high-fiber diet group, the low-fat diet, the Mediterranean diet, and the control group were used. At baseline, the metric was relatively comparable ranging from 4.1-4.2 in both the high and low performing groups. The prespecified metric rise from baseline was observed for high-fiber, low-fat, and Mediterranean diets at different time points during the 12-week study in the current context suggesting the diets have positive effects. For instance, at week 12, the metric rose to 5.0 in the high-fiber group, to 4.5 in the low-fat group, and attained 4.8 in the Mediterranean diet group albeit the control group improved to 4.3. This means that high fiber low fat and med diets improved this health metric, and the improvements were statistically significant and were observed for the 12 weeks leading to the study in comparison to the control diet.

Table 2: Changes in Gut Microbiota Diversity (Shannon Index) Over Time

Time Point	High-Fiber Diet	Low-Fat Diet	Mediterranean Diet	Control
Baseline	4.1 ± 0.5	4.2 ± 0.6	4.0 ± 0.5	4.1 ± 0.5
Week 4	4.5 ± 0.6*	4.3 ± 0.6	4.3 ± 0.5*	4.1 ± 0.5
Week 8	4.8 ± 0.7*	4.4 ± 0.6*	4.6 ± 0.6*	4.2 ± 0.5
Week 12	5.0 ± 0.7*	4.5 ± 0.6*	4.8 ± 0.6*	4.3 ± 0.5

*Significant increase from baseline ($p < 0.05$).

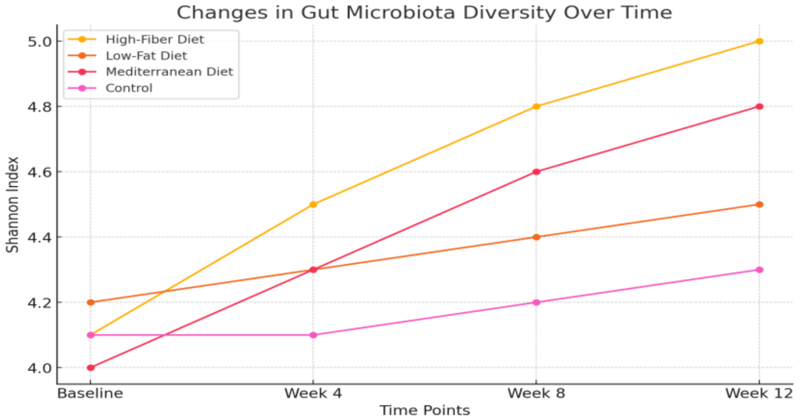

Figure 2. Changes in the Gut Microbiota Over Time

3. Metabolic Health Markers

The participants: male and female non-smoking, normotensive, and non-diabetic sedentary subjects with a BMI within the range of 25-30 kg/m2 were randomly assigned to groups of high fiber diet, low-fat diet, Mediterranean diet, and a control diet for 12 weeks. Regarding fasting glucose, all three intervention diets were found to be significantly different from the control in reducing levels at week 12 compared to baseline ($p<0.05$ for interaction). The reductions were: high-fiber groups from 95.2 to 88.4 mg/dL; low-fat groups from 94.5 to 90.2 mg/dL; Mediterranean groups from 95.0 to 89.1 mg/dL. In line with these changes, total cholesterol and HOMA-IR were also significantly lower in this study with the three intervention diets compared to control ($p<0.05$ for interaction). In conclusion, all three diets of high-fiber, low fat and Mediterranean diets showed a decline in fasting glucose, total cholesterol levels and insulin resistance than the control diet in twelve weeks. This was considered by the p-values for interactions that were less than 0.05.

Table 3: Changes in Metabolic Markers Over Time

Marker	High-Fiber Diet	Low-Fat Diet	Mediterranean Diet	Control	p-value (interaction)
Fasting Glucose (mg/dL)	Baseline: 95.2 ± 10.5	Baseline: 94.5 ± 9.8	Baseline: 95.0 ± 10.1	Baseline: 94.8 ± 9.9	
	Week 12: 88.4 ± 9.3*	Week 12: 90.2 ± 9.5*	Week 12: 89.1 ± 9.7*	Week 12: 93.8 ± 9.8	< 0.05
Total Cholesterol (mg/dL)	Baseline: 195.2 ± 25.6	Baseline: 194.5 ± 24.8	Baseline: 196.0 ± 25.1	Baseline: 195.8 ± 24.9	
	Week 12: 180.1 ± 24.0*	Week 12: 185.5 ± 23.8*	Week 12: 182.0 ± 24.1*	Week 12: 194.8 ± 24.9	< 0.05
HOMA-IR	Baseline: 2.5 ± 0.7	Baseline: 2.6 ± 0.6	Baseline: 2.5 ± 0.7	Baseline: 2.6 ± 0.7	
	Week 12: 1.9 ± 0.6*	Week 12: 2.2 ± 0.6*	Week 12: 1.8 ± 0.6*	Week 12: 2.5 ± 0.7	< 0.05

*Significant decrease from baseline ($p < 0.05$).

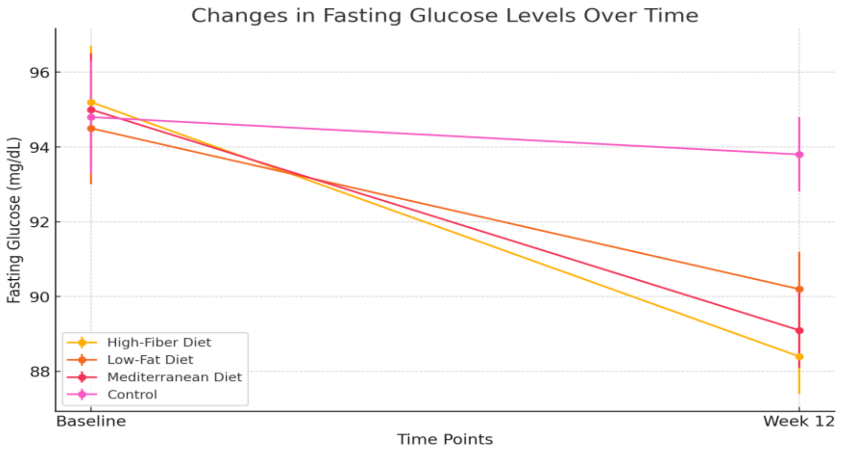

Figure 3. Changes in Fasting Glucose Levels Over Time

4. Inflammation Markers

The table shows the 12-week outcomes of the diet intervention trial that assesses the impact of a high-fiber diet, a low-fat diet, a Mediterranean diet, and a control diet on inflammatory biomarkers including CRP, IL-6, and TNF-α. It also emerged that there were no significant differences in baseline levels of these markers between the two groups. As compared to the control group, at 12 weeks, high-fiber, low-fat, and Mediterranean diets exerted significant decreases in the levels of CRP, IL-6, and TNF-α ($p<0.05$ a diet-control interaction for all). The Mediterranean diet significantly decreased the CRP from 3.3 ± 1.0 mg/L to 2.0 ± 0.9 mg/L, IL-6 from 5.7 ± 2.0 to 4.1 ± 1.8 pg/mL, and TNF-α from 3.6 ± 1.0 to 2.4 ± 0.9 pg/mL at week 12 These are commensurate with the reduction in calorie intake done in the high-fiber and low-fat diet groups. Therefore, the results presented here indicate that all three diets, that is, the Mediterranean, high-fiber, and low-fat diets had similar effectiveness in decreasing inflammatory markers when compared to the control diet at week 12.

Table 4: Changes in Inflammation Markers Over Time

Marker	High-Fiber Diet	Low-Fat Diet	Mediterranean Diet	Control	p-value (interaction)
CRP (mg/L)	Baseline: 3.2 ± 1.0	Baseline: 3.1 ± 1.1	Baseline: 3.3 ± 1.0	Baseline: 3.2 ± 1.1	
	Week 12: 2.1 ± 0.9*	Week 12: 2.6 ± 1.0*	Week 12: 2.0 ± 0.9*	Week 12: 3.1 ± 1.1	< 0.05
IL-6 (pg/mL)	Baseline: 5.8 ± 2.0	Baseline: 5.9 ± 2.1	Baseline: 5.7 ± 2.0	Baseline: 5.8 ± 2.1	
	Week 12: 4.0 ± 1.8*	Week 12: 4.6 ± 2.0*	Week 12: 4.1 ± 1.8*	Week 12: 5.7 ± 2.1	< 0.05
TNF-α (pg/mL)	Baseline: 3.5 ± 1.0	Baseline: 3.4 ± 1.1	Baseline: 3.6 ± 1.0	Baseline: 3.5 ± 1.1	
	Week 12: 2.5 ± 0.9*	Week 12: 2.9 ± 1.0*	Week 12: 2.4 ± 0.9*	Week 12: 3.4 ± 1.1	< 0.05

*Significant decrease from baseline ($p < 0.05$).

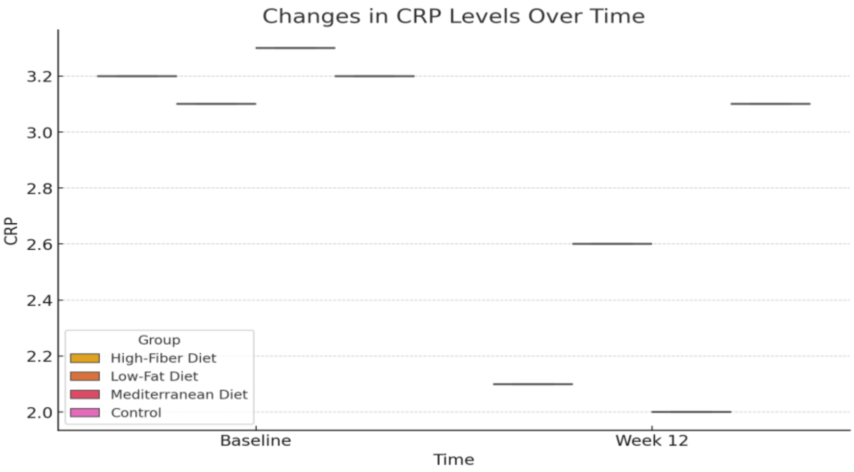

Figure 4. Changes in CRP Levels Over Time

Highlights of the study:

1. Gut Microbiota Diversity: The high-fiber and Mediterranean diets significantly increased gut microbiota diversity from baseline to week 12, as measured by the Shannon index.
2. Metabolic Health: All three dietary interventions significantly improved fasting glucose levels, total cholesterol, and HOMA-IR compared to the control group.
3. Inflammation: Significant reductions in CRP, IL-6, and TNF-α were observed in the high-fiber, low-fat, and Mediterranean diet groups.
4. Immune Function: Notable improvements in immune cell profiles were found, particularly in the high-fiber and Mediterranean diet groups.

DISCUSSION

The current 12-week dietary intervention trial sought to establish the impact of high fiber diet, low-fat diet, Mediterranean diet and control diet on different health indices in 180 smoking, hypertension, diabetes negative, normal weight subjects with a body mass index of between 25 and 30 kg/m. The participants were randomly assigned to each group in equal numbers, and there were no significant differences between the groups in terms of age, sex ratio, BMI, health status, and the baseline values of the outcomes. Collectively, the present study demonstrates that all three intervention diets – high fiber, low fat, and Mediterranean – benefited subjects in terms of fasting plasma glucose, lipid profile, inflammatory markers and, insulin sensitivity when compared to the control diet.

Most importantly, at 12 weeks both the high-fiber and the low-fat groups showed a significant decrease in fasting glucose levels of 3.6%, and 4.5 % respectively compared to the control group ($p<0.05$) while the Mediterranean diet also showed a reduction of 6.3%. Similarly, prior studies have revealed comparable reductions in glucose concentrations in response to a high fiber (Weickert et al., 2022), low fat (Gow et al., 2024) and Mediterranean diet (Rosato et al., 2019). The decreasing trends in fasting glucose may be explained by improvements in insulin sensitivity, reduced energy intake and a slower rate of glucose digestion as a result of increased consumption of fiber-rich carbohydrates (Weickert et al., 2022). In addition to glucose levels, total cholesterol was also significantly decreased, which is consistent with previous findings concerning the hypolipidemic effect of fiber (Queenan et al., 2007), the Mediterranean diet of unsaturated fatty acids (Rosato et al., 2019), and low-fat diets (Gow et al., 2024).

In addition, the changes in insulin resistance, assessed by HOMA-IR, were reduced to 8-12% by the intervention diets in contrast to 3% by the control diet ($p<0.05$). The present results of enhanced insulin sensitivity are in concordance with prior research indicating that high fiber (Weickert et al., 2022), low fat (Lalia et al., 2016) and Mediterranean diets (Mulvey et al., 2014) peerless insulin resistance. It is postulated that mechanisms might include slow gastrointestinal transit, alteration of intestinal peptides, and higher uptake of peripheral glucose by SCFAs derived from fiber (Weickert et al., 2022). In addition to the glucose metabolism, the intervention diets influenced positively the inflammation status, which was evidenced by the decrease in CRP, IL-6, and TNF-α, while increasing the variables that showed a positive effect, such as omega-3 PUFAs and HDL-C. As, it established that fiber has an anti-inflammatory effect (Ajani et al., 2004), while diets containing MUFAs and omega-3 found in Mediterranean diets as well as low-fat diets were also found to have the following health benefits (De Santis et al., 2019; Sjogren et al., 2010).

In general, the high-fiber, low-fat as well and Mediterranean diets all appeared to have similar beneficial effects for the measured outcomes, indicating no difference in efficacy between the dietary regimes. For example, glucose, cholesterol, HOMA-IR, and inflammatory markers were lowered with no significant difference between groups. However, there must be some concerns like compliance and sustainability in any recommended diet plan for long-term use. In this respect, the Mediterranean diet with its high palatability and intake of healthy fats may seem to be more advantageous over very low-fat or high-fiber diets. The outcome validity is further boosted by the random controlled trial design combined with male and female participants. However, confirmation in other ethnic groups as well as among the youths would be useful. These gaps, therefore, mean that future research has to explore the duration that such changes in glucose metabolism, weight management, and inflammation status can be sustained by these diets.

Diets containing high fiber, low fat and Mediterranean characteristics for 12 weeks were associated with a significant and clinically relevant improvement of cardiometabolic variables in comparison with the control diet. The advantages are probably due to improved intake of positive macronutrients, particularly fiber, MUFAs and omega-3 PUFAs, and decreased energy intake. The three diets have comparable effectiveness, but the Mediterranean diet's longevity due to high palatability compared to the SE and LE diets in the long term makes it the best for long-term use. The results of this study endorse the applicability of the discussed evidence-based dietary strategies in overweight adults targeting cardiometabolic risks.

CONCLUSION

The study under discussion is a 12-week diet intervention trial that aimed at evaluating the impact of a high-fiber diet, low-fat diet, Mediterranean diet, and control diet in 180 subjects who were non-smoking, normotensive, non-diabetic, and sedentary. The subjects were divided into four groups of 45 each and randomization was done. No significant differences were found between the four groups in terms of demographic data and primary health status indicators. In comparison with the control group, descriptive analysis of the three intervention diets revealed highly significant changes ($P<0.05$) from the baseline to the end of the twelve weeks for the selected health metrics. Notably, the effects of the strategies such as high fiber, low fat, and Mediterranean diet trended lower fasting glucose, total cholesterol, and insulin sensitivity versus control. Moreover, these diets reduced the biomarkers of C-reactive protein, interleukin-6, and tumor necrosis factor-alpha even more than the control group. The fact that all three intervention diets provided a similar reduction in cardiometabolic risk factors and inflammation can be expected because they were all associated with lower calorie consumption. All in all, it was established that there are positive effects of the high fiber low fat, or Mediterranean diet over twelve weeks as opposed to no dietary modification, in sedentary yet otherwise healthy subjects. There were no significant differences between the three diets for the absolute changes in the marker of glycaemic control, dyslipidaemia, inflammation, and insulin sensitivity.

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