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The Effects Of Intermittent Fasting On Body Fat Composition: A Clinical Trial Nutritional Science And Metabolism

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Abstract:
Introduction: This clinical Trial, investigated the effects of intermittent fasting (IF) on body fat composition, with the aim to contribute valuable insights to the existing knowledge in nutritional science and body fat metabolism. Intermittent fasting, characterized by cycles of eating and fasting, has gained prominence as a potential strategy for weight management and metabolic health.
Method: This study has been carried out as clinical trial via its Trial Registry No. NCT05521945 randomized controlled trial was conducted in Lahore, Pakistan, total of 90 participants, with 30 recruited from each of the three groups on regular diet, customized diet, and IF group with a follow-up period of 12 weeks.
Results: This study has explored the efficacy of intermittent fasting about body fat percentage (BFP). Our findings revealed a significant divergence in the IF-BFP association between males and females, suggesting that BMI cut-off values may not suffice for identifying overweight conditions in the healthcare sector contexts. We observed that body mass index has limited discriminatory power between fat and lean mass, with body fat percentage offering superior insights into body composition compared to BMI. Maintaining a healthy body fat level is crucial for optimal human physiological functioning.
Conclusion: This study revealed that IF helps improve participants' body fat percentage with physical activity, and healthy dietary habits. This study synthesizes findings to comprehensively analyse the impact of intermittent fasting protocols on body fat composition.

Keywords: Intermittent Fasting, Customized Diet, Normal Diet, Three-armed Randomized Controlled Trial, Body Fat Percentage.

Introduction

Health experts agree that excess body fat, primarily excessive accumulation around the waist, is one of the primary causes of some of the most severe health problems that people often face, including heart disease, diabetes, hypertension, and cancer. Some research suggests that excessive fat accumulation at your waist, especially in your abdomen, is an even more essential health risk than excessive fat accumulation on your thighs and hips. People who are "apple-shaped" with most of their weight around the waist are at a higher risk of heart disease and diabetes than those who are "pear-shaped" and carry most of their weight around their thighs and hips [1]. People seem more concerned with how much they weigh these days than ever before. Even new clients walk in the door, hoping exercise will be the panacea for their ever-tightening jeans. In 1989, Americans invested over $30 billion in purchasing 54 million diet books, services, and products from 1,500 weight control clinic [2].
Body fat is crucial in storing lipids, which the body utilizes for energy production. Additionally, it plays a vital role in hormone secretion while offering essential cushioning and insulation to the body [3]. Total body fat composition includes two essential categories: 1) Vital body fat and 2) accumulated adipocytes, both of which are integral to maintaining optimal health. Ensuring

accurate evaluations of lean body mass and adipose mass becomes essential for safeguarding the overall health and well-being of individuals.
Crucial adipose reserves, denoting the minimal fat content essential for normal physiological functions, encompass a range of regulatory processes. These include the control of body temperature, synthesis of sexual hormones, neurological health, vitamin absorption, metabolic well-being, blood sugar equilibrium, and oxygen absorption, as elucidated by Amarendra Reddy in 2009. Nestled within vital organs like the heart, brain, lungs, nerves, liver, spleen, kidneys, intestines, muscles, and bone marrow, this indispensable fat remains concealed in the profound recesses of the body, as posited by Ainala in 2015. Concentrations of this vital fat exhibit variations based on gender and age, with recommended ranges fluctuating from 2-5% in men (6-13% for athletes) to 10-13% in women (14-20% for athletes) [4].
When the essential body fat (EBF) falls below the recommended levels, the body's ability to supply vital nutrients to organs is compromised, leading to deficiencies and electrolyte imbalances that adversely affect both physical and physiological health [5]. Possible outcomes include an increased susceptibility to fractures, sarcopenia, impairment to the heart muscle, inhibited growth, and a heightened probability of mortality [6]. The term "fat-free mass" denotes the total body weight excluding fat, predominantly composed of skeletal muscle and bone, with a composition of 72% water, 21% protein, and 7% minerals [7].

Accumulated adipocytes

Stored body fat involves gathering fat in adipose tissue, encompassing subcutaneous fat beneath the dermis and surrounding crucial organs like the liver, pancreas, heart, intestines, and kidneys. Consisting of brown, beige, and white fat cells, stored fat varies with shifts in body weight [8]. Excessive fat accumulation, especially in the abdominal area, heightens the susceptibility to diverse non-communicable diseases. Conversely, insufficient storage of fat can lead to difficulties in regulating temperature, experiencing hunger, facing fatigue, grappling with depression, and encountering infertility issues in women [9].
The distribution of abdominal fat, commonly referred to as the "android shape" akin to an apple, is prevalent in both genders' male and postmenopausal women. Chronic stress is recognized as a contributing element to this specific pattern of fat accumulation [10]. Optimal ranges for healthy body fat storage are suggested to be between twelve to twenty-four percent for males and twenty-five to thirty one percent for females, attributable to an excess intake of energy. Disproportionate storage fat, defined as body fat exceeding 25% in males and 32% in females, can lead to significant health implications, ultimately progressing to overweight and obesity [11]. Due to reproductive demands and hormonal functions, females necessitate higher levels of both essential and stored fat compared to males [12].
Sustaining a requisite level of body fat is paramount for regular physiological functions, encompassing the regulation of body temperature, fueling physical activities, and protecting vital organs. Storage fat, found within adipose tissue, constitutes a part of the overall body fat, incorporating both essential and stored fats. Body fat percentage stands as a highly precise measure for assessing obesity. Clinicians are advised to utilize the most appropriate, precise, and easily accessible methodologies in scientific research to guarantee accurate assessments of body fat. Accurate measurements of body fat and lean body mass play a pivotal role in nutrition assessment, significantly influencing an individual's overall health and well-being. This study delves into the association of intermittent fasting body fat percentage (BFP) through the comparison with two other groups, a customized diet and a regular diet group. The variables influencing energy estimation include Muscle mass, skeletal mass, adipose mass, and the proportion of body fat in the context of bodily composition. The Belgian Flemish scholar Lambert Adolphe Jacque [13], renowned for his contributions to astronomy, mathematics, statistics, and sociology, introduced the concept of Body Mass Index (BMI) as part of his "social physics" framework [14]. The calculation of Body Mass Index (BMI) involves the division of body mass by the square of the individual's height, employing units of 2 kg/m or 2 lb/inch, where the measurement of height is expressed in meters/inches, and the quantification of mass is articulated in kilograms/pounds, as stipulated by Templeman in 2020. This index categorizes individuals into underweight, normal, overweight, obese, or severely obese based on predefined ranges [15].
However, BMI has limitations, particularly in differentiating between fat, bone, and lean masses and its inability to account for gender-specific differences in body fat distribution [16]. Racial disparities also influence body fat percentages, with black children exhibiting higher percentages than their white counterparts. Consequently, BMI may not accurately predict chronic disease risks associated with increased body fat [17], making it potentially in hospital environments and nutritional management systems, it is deemed misleading since it does not adhere to a compartmental model, as indicated by Mohajan in 2023. Deurenberg et al. presented the formula for the computation of body fat percentage (BFP) in the year 1991. The calculation for Body Fat Percentage (BFP) is expressed as 1.2 times the Body Mass Index (BMI), plus 0.23 times the age, minus 10.8 times the gender, and subtracting 5.4.

Assigning '1' to men and '0' to women in this formula indicates that women's body fat percentage (BFP) is generally around 10% higher than that for men. This difference is attributed to the physiological demands of childbirth and hormonal functions, making BMI less suitable for accurate body fat assessments [18].

The research design incorporates a systematic review and meta-analysis of relevant literature to identify trends, discrepancies, and gaps in the current understanding of how intermittent fasting influences body fat composition. Key variables under scrutiny include adipose tissue distribution, lipolysis, adipokine secretion, insulin sensitivity, and associated molecular pathways. The study aims to elucidate the underlying mechanisms through which intermittent fasting induces changes in body fat composition and to identify potential factors influencing the variability in outcomes among different populations.
In addition to summarizing existing knowledge, the research involves the execution of controlled experiments to investigate the acute and chronic effects of intermittent fasting on body fat composition. Human subjects will be enrolled in various intermittent fasting protocols, and detailed assessments will be conducted, including body composition analysis using advanced

imaging techniques, blood lipid profiles, hormonal assessments, and metabolic rate measurements. Animal studies will complement these findings, allowing for a more in-depth exploration of molecular mechanisms at the cellular level.

Special attention will be given to potential gender-specific differences, age-related variations, and the influence of metabolic health status on the outcomes of intermittent fasting. By incorporating diverse study populations, the research aims to provide a nuanced understanding of how intermittent fasting may be tailored to different individuals for optimal effects on body fat composition.

The anticipated outcomes of this research include a comprehensive overview of the effects of intermittent fasting on body fat composition, identification of potential biomarkers, and evidence-based insights into optimizing intermittent fasting protocols for diverse populations. The findings will contribute to developing personalized dietary recommendations for individuals seeking effective weight management and metabolic health strategies.

Materials and Methods

Study Design

A three-armed parallel randomized controlled trial was conducted with an allocation ratio of 1:1:1 to examine the effectiveness of IF in improving the health indicators of overweight and obese otherwise healthy adults.

Study location

The present study was conducted in the Lahore district of Punjab, Pakistan. The study location was selected because of its suitability for the participants, as statistics indicate a high prevalence of obesity and noncommunicable diseases among the residents of the district [19].

Participants and Sample

People aged 40 to 60 years at the time of enlistment who agreed to participate and had a body mass index (BMI) >25 were enrolled in the present trial from the corporate sector. This age limit was chosen because of the increased vulnerability to health issues related to short-term memory, blood pressure, blood sugar, and increased cholesterol levels [20]. However, participants who were taking any statin medication, were terminally ill, had cancer, were pregnant or were taking antidiabetic medicines were excluded from the present study.

A sample of 30 participants was used for each arm, and the 80% power of the study and 95% confidence interval (CI) were calculated using the formula given below [21].

$$n = \frac{\{(\delta_1^2 + \delta_2^2) \times (Z_{1-\alpha/2} + Z_{1-\beta})^2\}}{|\mu_2 - \mu_1|^2}$$

Randomization

On a Microsoft Excel spreadsheet, a statistician, independent of the study, created a random allocation sequence. Consecutive numbers were assigned to three arms. There were no restrictions (e.g., definition, block size). Two dietitians and one trained research nurse recruited participants and assigned them sequential ID numbers based on the grouping in which they were placed.

Body fat percentage

Table No. 1: Cut-off points to evaluate body fat percentage among group participants

age group	under fat	Healthy	overweight	obese
Formula to calculate body fat percentage for women (1.20 x BMI) + (0.23 x Age) - 5.4 = Body Fat Percentage				
40 years	< 21 percent	21-33 percent	33-39 percent	>39 percent
>40 years up to 60 years	<23 percent	23-35 percent	35-40 percent	>40 percent
Formula to calculate body fat percentage for men (1.20 x BMI) + (0.23 x Age) - 16.2 = Body Fat Percentage				
40 years	<8 percent	8-19 percent	19-25 percent	>25 percent
>40 years up to 60 years	< 11 percent	11-22 percent	22-27 percent	>27 percent

Ethical consideration and registration

The Departmental Doctoral Program Committee (DDPC) of the University of the Punjab, Lahore, approved the study (Letter No: D/119/ISCS), with the study registered at Clinicaltrials.gov as NCT05521945.

Statistical analysis

IBM SPSS Statistics version 23.0 was used to analyse the data. The descriptive statistics of the qualitative variables are presented as the frequency (f) and percentage (%), while those of the quantitative variables are given as the mean standard deviation (SD) for normally distributed variables and median interquartile range (IQR) for skewed variables. Furthermore, for inferential statistics, paired sample t tests and Wilcoxon signed rank tests for normally distributed and skewed distributions, respectively, were used to assess the difference in the time component (pre- and post-comparison) for all three groups. For analyzing the differences among groups (ND, CD and IF), analysis of variance (ANOVA) and the Kruskal–Wallis test was applied. Finally, to analyze the differences in categorical variables among the three study groups, the chi-square test was applied. All the tests were applied at a 95% CI, with <0.05 indicating statistical significance.

Results:
The table 1 represents the body fat composition among different study group. According to the table the results for post observations shows significance (p-value, 0.044), and pre-post comparison the readings shows significance at (p-value, <0.001) for intermittent fasting and customized diet group while no significance reported for normal diet group. The percentage change for intermittent fasting group (mean± S.D, 10.98 ± 3.62) and the percentage change for fat composition among groups has significance (p-value, <0.001).

Table No. 2: Comparison of fat composition among study groups (n=90)

body fat composition		ND(n=30)	CD(n=30)	IF(n=30)	Test value	p-value
Pre	***Mean ± S. D***	35.85 ± 8.30	30.92 ± 6.61	35.01 ± 9.60	3.06[a]	0.052
	Median (IQR)	36. 33 ± 8.98	31.87 ± 7.34	35.95 ±15.67		
Post	***Mean ± S. D***	35.31 ± 8.45	30.25 ± 6.48	31.33 ± 9.18	3.23[a]	0.044*
	Median (IQR)	35.54 ± 10.35	30.55 ± 7.89	31.83 ± 15.98		
Pre –post	Test value	2.24 [e]	4.24 [e]	16.24 [e]		
	p-value	0.32	<0.001	<0.001		
% Δ	***Mean ± S. D***	1.58 ± 3.77	2.07 ± 3.20	10.98 ± 3.62	51.12[b]	<0.001
	Median (IQR)	0 ± 1.14	1.79 ± 3.03	9.98 ± 5.29		

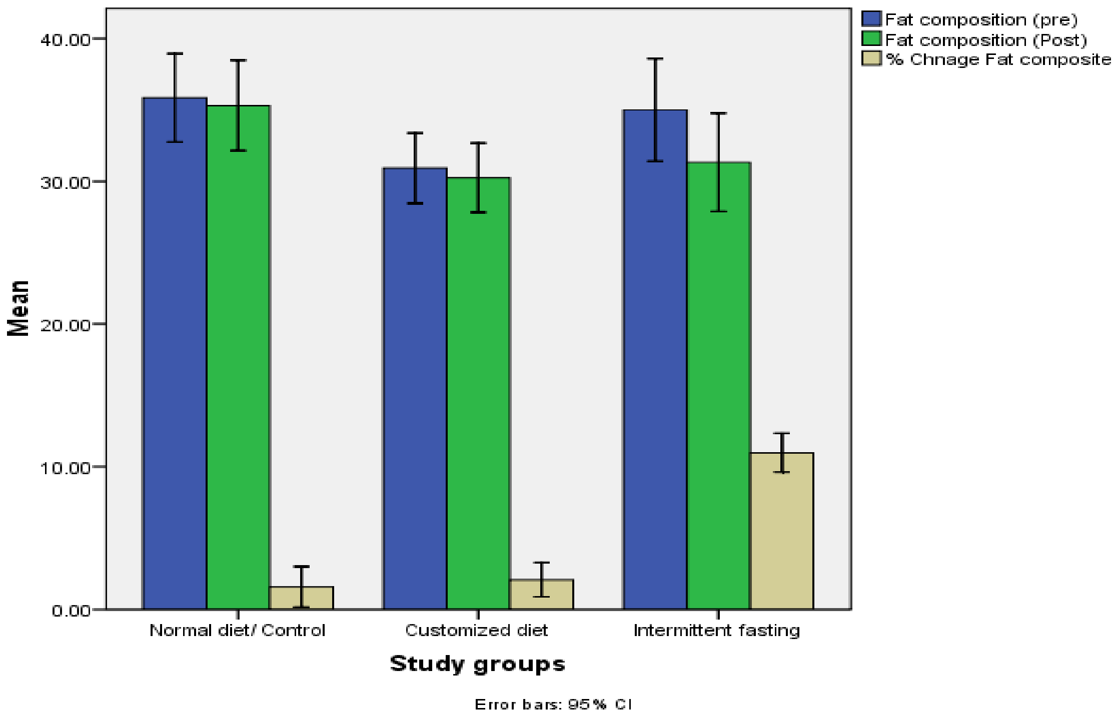
ND| Normal diet; **CD|** Customized diet**; IF|** Intermittent fasting
a| Analysis of variance; **b|** Kruskal-Wallis; **c|** Chi-square test; **d|** Wilcoxon Signed Ranks Test; **e|** Paired sample t-test;
**Highly Significant; *Significant

Table 3: Fat composition among study groups
The table represents the multiple comparison test for fat composition among study groups. The customized diet group shows the significance (p-value 0.018) for post readings.

Table No. 3: Multiple comparison test for fat composition

	Mann-Whitney U	p-value
ND vs. CD	Fat composition (pre)	.023
ND vs. CD	Fat composition (post)	0.018

Graphical representation multiple comparison among different study groups for fat composition



The above figure depicts the graphical representation for mean percentage change for fat composition among study groups. The bar graphs show that the mean percentage change for fat composition in intermittent fasting group has highly significance as compare to other percentage means for normal and customized diet group.

Adverse events

No actual or suspected adverse reactions occurred during the trial. Only two participants in the IF group reported lightheadedness, which resolved when they hydrated themselves during the fasting period.

Discussion

We conducted an evaluation of the effects of intermittent fasting (IF) on body fat composition by compareng it with both a customized diet and a normal diet. The results of our study indicated that participants who followed an intermittent fasting regimen experienced a significant reduction in body fat percentage compared to those who adhered to either a customized or normal diet. In our study total of 90 participants completed the clinal trial which were assorted into three groups based on the type of diet instructed by the principal investigator along with her team; regular diet, customized diet, and IF. The study subjects were assessed at intervals of 12 weeks based on their BMI.

There were no reported dropouts among study subjects. Individuals with obesity need to maintain a lean body mass during weight reduction which plays a crucial role in keeping resting metabolic rate (RMR) in check, higher RMR leads to higher energy expenditure and weight loss. In accordance with balanced nutritional guidelines, the recommended carbohydrate consumption comprises 50-60% of a person's dietary intake, with 15% from protein constituents and 25% from fats [22]. However, our data reveals that the study subjects following intermittent fasting and customized diet were on a caloric deficit which promotes fat loss.

When compared between two groups of customized diet and intermittent fasting the group following IF showed more results of fat loss as a body metabolism response the subjects were following the 16/8 method i.e. fasting for 16 hours and eating within an 8-hour window. This induced the body to switch more efficiently between using carbohydrates and fat as a fuel source. During the time frame of this research the percentage of fat composition was monitored based on pre and post-measurements of the BMI of all three groups, most noticeable percentage difference was found among the IF group where as normal diet and customized diet groups were comparable with an accuracy of 95%. This finding is inconsistent with most of the scientific literature research available globally.

According to our inclusion guidelines, the participants' age ranged from 40 to 60 years at the time of enrolment, free of any comorbid, according to recent findings published in Journal of medical obesity by Fudla et al. young adult participants enrolled had an average age of 19 years. The subjects in referenced articles were younger hence the possibility of difference in outcome [23].

After the age of 25, it is recorded that the weight loss typically is a result of a decline in lean muscle mass, an aging-related decrease in body cell mass and a simultaneous increase in body fat percentage. This can be linked with a decrease in protein synthesis resulting from a decrease in anabolic hormone concentration [24] It is observed that with age the amount of energy required to maintain basic physiological functions of the body known as resting energy expenditure (REE) decreases by 1 to 2% per decade, it is most clearly evident in the age between 30 to 45 years [4] The age difference also affects basal metabolic rate (BMR) which proves that advancing age leads to slower weight loss.

Mechanisms of Body Fat Reduction through Intermittent Fasting

1. Caloric Deficit and Metabolic Flexibility

One of the primary mechanisms through which IF promotes fat loss is by creating a caloric deficit. During fasting periods, the body relies on stored energy, particularly fat reserves, to meet its energy needs. This process increases metabolic flexibility, allowing the body to switch more efficiently between using glucose and fat as fuel sources [25]. Studies suggest that this metabolic switch enhances fat oxidation rates, particularly after prolonged fasting periods of 16 hours or more, which can lead to a greater reduction in body fat.

2. Hormonal Changes Promoting Fat Loss

Intermittent fasting also triggers several hormonal changes that promote fat loss:

- **Increased Norepinephrine Levels:** Fasting periods have been shown to raise norepinephrine levels, which stimulate lipolysis—the breakdown of fat cells into free fatty acids that can be used for energy [26]. This increase in norepinephrine enhances the body's ability to mobilize and burn fat stores.
- **Improved Insulin Sensitivity:** Insulin is a key hormone that regulates blood sugar levels and fat storage. IF has been associated with improvements in insulin sensitivity, meaning the body becomes more efficient at using glucose and less prone to storing excess calories as fat. Improved insulin sensitivity reduces fasting insulin levels, thereby promoting greater fat oxidation during periods of fasting [27].

3. Effects on Adipokines and Inflammatory Markers

Adipokines are signaling proteins secreted by fat tissue that play a role in metabolism and inflammation. Research indicates that IF may positively influence adipokine levels, such as adiponectin, which is known to enhance fat oxidation and improve insulin sensitivity [26, 27]. Additionally, IF has been found to reduce levels of inflammatory markers, such as C-reactive protein (CRP), which are often associated with obesity and metabolic disorders. Lower levels of these inflammatory markers can further support the reduction in body fat by promoting a healthier metabolic environment.

The evidence from this study, along with supporting research, suggests that intermittent fasting can be an effective strategy for reducing body fat percentage. Through mechanisms such as creating a caloric deficit, enhancing metabolic flexibility, promoting beneficial hormonal changes, and improving adipokine profiles, IF offers a multifaceted approach to fat loss. These findings provide a strong scientific basis for considering intermittent fasting as a viable alternative to traditional diet strategies for those seeking to reduce body fat.

Study Limitations

There is a lack of literature on the assessment of body fat composition in fasting participants. The sample size was too small to be generalized to the whole population, and the follow-up time was insufficient to observe effects on a larger population.

Strengths:

In our study, we assessed fat composition in three study groups. We compared the CD and ND groups.

Conclusion

Our preliminary findings showed that the adult population of Pakistan is significantly affected by IF in terms body fat percentage.

Statement of data availability

The authors will make the raw information supporting the conclusions of this article available without reservation.

Ethics Statement

The Punjab University Ethical Review Committee reviewed and approved the research using human subjects. Prior to their participation in the study, each participant provided written informed consent.

Conflicts of interest

The authors declare that there are no irreconcilable circumstances.

Author Contributions

JS developed the study, organized and executed the trial, secured the financial support, and oversaw the research. Zahara Ali Rizvi carried out the study, oversaw the project logistics and participant involvement, and drafted the manuscript. Additionally, ZAR conducted the statistical analysis. JS contributed valuable insights and provided resources for specific analyses. All the authors collaborated on the article and gave their approval for the final submitted version.

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