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Effectiveness of intermittent fasting for weight loss in obese individuals: A randomized controlled trial.

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Abstract

Background:

Obesity remains a major public health concern globally, with lifestyle modification forming the cornerstone of management. This randomized clinical trial evaluated the impact of intermittent fasting on weight reduction and metabolic parameters in obese individuals.

Methods:

Sixty obese adults were randomly assigned to either an Intermittent Fasting (IF) group (n=30) or a Standard Calorie Restriction (SCR) group (n=30) for eight weeks. The IF group followed a 16:8 fasting schedule, while the SCR group reduced daily caloric intake by approximately 20%. Anthropometric measurements (weight, BMI, waist circumference, body fat percentage) and biochemical parameters (fasting glucose and lipid profile) were recorded at baseline and at the end of the study. Adherence and tolerability were monitored throughout the trial. Statistical comparison between groups was performed, and significance was set at $p < 0.05$.

Results:

Baseline characteristics were similar across groups (Table 1). The IF group achieved greater weight loss (−4.1 ± 2.1 kg) compared to the SCR group (−2.7 ± 1.9 kg), with statistically significant differences (p=0.012). Reductions in BMI, waist circumference, and body fat percentage were also more pronounced in the IF group (Table 2). Improvements in fasting glucose (−7.2 ± 9.1 mg/dL vs. −3.1 ± 8.7 mg/dL; p=0.041) and triglyceride levels (p=0.048) were observed with IF, while changes in total cholesterol and LDL-C were modest in both groups (Table 3). Adherence was satisfactory, and no serious adverse events occurred (Table 4).

Conclusion:

Intermittent fasting demonstrated superior benefits in weight reduction and selected metabolic markers compared to standard calorie restriction over eight weeks. It was well-tolerated and feasible for regular clinical practice.

Recommendations:

Intermittent fasting may be considered a structured dietary intervention for weight management in obese adults. Long-term studies are recommended to assess sustained outcomes and adherence patterns.

Keywords: *Intermittent fasting; Obesity; Weight loss; Body composition; Calorie restriction; Metabolic health*
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Introduction

Obesity is a widespread metabolic disorder and is closely associated with diabetes, cardiovascular disease, dyslipidemia, osteoarthritis, and multiple long-term health complications. The rising prevalence of obesity has been largely attributed to changes in dietary habits, reduced physical activity, and increasingly sedentary lifestyles [1]. As a result, the development of effective and sustainable weight management strategies remains a priority in both clinical practice and public health. Lifestyle modification, particularly dietary intervention, continues to serve as the first-line approach for weight reduction. However, long-

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term adherence to conventional calorie restriction can be challenging because it requires strict meal planning and continuous monitoring [2].

Intermittent fasting has emerged as an alternative dietary approach that may improve adherence compared to standard calorie restriction. Systematic reviews and meta-analyses have demonstrated that intermittent fasting can achieve significant weight loss and metabolic improvement in overweight and obese individuals [1–3]. The 16:8 time-restricted eating pattern, where daily food intake is restricted to an eight-hour window, is among the most commonly practiced forms. Intermittent fasting is believed to promote weight reduction by reducing overall caloric intake, improving insulin sensitivity, enhancing fat oxidation, and influencing metabolic signaling pathways related to energy balance [4].

Recent evidence indicates that different intermittent fasting protocols may produce varying degrees of benefit on cardiometabolic outcomes, and some strategies may produce outcomes comparable to or better than standard calorie restriction [5,6]. However, direct comparisons in controlled clinical environments remain limited. Clarifying the relative effectiveness of intermittent fasting is essential before integrating it routinely into weight management guidelines.

The present randomized clinical trial was undertaken to evaluate the effectiveness of intermittent fasting in promoting weight loss and improving metabolic parameters in obese individuals, in comparison with standard calorie restriction. The study aimed to provide practical clinical insights into the feasibility, outcomes, and tolerability of these two commonly adopted dietary strategies.

Methodology

Study Design

A parallel-group randomized controlled trial was conducted to compare the effectiveness of Intermittent Fasting (IF) with Standard Calorie Restriction (SCR) in achieving weight reduction among obese adults. The duration of intervention for each participant was eight weeks.

Study Setting and Study Period

The study was carried out in the Department of Physiology, Sri Venkateswara Medical College (SVMC), Tirupati, Andhra Pradesh, India. The study period extended from 10 September 2025 to 09 November 2025, encompassing recruitment, intervention, and follow-up.

Study Population

Adults aged 18–55 years with a body mass index (BMI) ≥30 kg/m² who were willing to participate and provide written informed consent were included in the study.

Inclusion criteria:

Adults aged 18–55 years
BMI ≥30 kg/m²
Both sexes
Willingness to participate and provide written informed consent

Exclusion criteria:

Diabetes mellitus requiring pharmacological treatment
Known endocrine disorders
Pregnancy or lactation
Use of medications affecting appetite or metabolism
Participation in any structured weight-loss program within the previous three months

Sample Size Determination

A total of 60 participants were included based on feasibility considerations and evidence from previous randomized controlled trials evaluating intermittent fasting, which commonly enrolled 25–35 participants per group. A sample size of 30 participants per group was considered adequate to detect clinically meaningful differences in weight reduction over the eight-week intervention period.

Randomization and Allocation Concealment

Participants were randomly allocated into two equal groups (IF group, n=30; SCR group, n=30) using computer-generated block randomization. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes containing group assignments, which were opened only after participant enrollment.

Implementation

The random allocation sequence was generated by an independent faculty member not involved in participant recruitment. Study investigators enrolled eligible participants, and group assignments were implemented using the concealed allocation envelopes.

Blinding

Blinding was not performed due to the nature of the dietary interventions. However, outcome assessment and statistical analysis were conducted using coded group identifiers to minimize assessment bias.

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Intervention Protocol

Participants in the IF group followed a 16:8 time-restricted eating schedule, consuming all meals within an eight-hour window daily and abstaining from caloric intake for the remaining 16 hours.

Participants in the SCR group received individualized dietary counseling to reduce daily caloric intake by approximately 20% of calculated maintenance energy requirements.

Both groups were advised to maintain light to moderate physical activity and to avoid the use of additional dietary supplements during the study period.

Outcome Assessment

Baseline and post-intervention assessments included measurement of body weight, BMI, waist circumference, body fat percentage, and fasting biochemical parameters (glucose and lipid profile). Adherence to the intervention and minor adverse events were recorded during fortnightly follow-up visits.

Statistical Analysis

Data were analyzed using standard statistical software. Continuous variables were expressed as mean ± standard deviation and compared between groups using independent sample t-tests. A p-value <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee of Sri Venkateswara Medical College, Tirupati. Written informed consent was obtained from all participants before enrollment, and the study was conducted in accordance with the Declaration of Helsinki.

RESULTS

Participant Flow

A total of 68 individuals were assessed for eligibility, of whom 8 were excluded (not meeting inclusion criteria or declining participation). Sixty participants were randomly assigned to the Intermittent Fasting group (n = 30) or the Standard Calorie Restriction group (n = 30).

In the Intermittent Fasting group, 28 participants received the intended intervention and completed the study, while 2 participants discontinued (one due to poor adherence to the fasting schedule and one due to personal reasons). In the Standard Calorie Restriction group, 27 participants completed the study, with 3 discontinuations (two due to non-compliance with dietary advice and one lost to follow-up).

All participants who completed the intervention were included in the final analysis for the primary outcome, resulting in an analysis of 28 participants in the Intermittent Fasting group and 27 participants in the Standard Calorie Restriction group.

A total of 60 obese participants were enrolled and randomly assigned to either the Intermittent Fasting group (n=30) or the Standard Calorie Restriction group (n=30). Both groups were similar at baseline with respect to age, sex distribution, anthropometric values, and biochemical markers, indicating comparability before intervention (Table 1). The mean age of participants was 36–38 years, and the average BMI in both groups was above 33 kg/m².

Table 1. Baseline Characteristics of Study Participants (n = 60)

Parameter	Intermittent Fasting (n=30) Mean ± SD	Standard Calorie Restriction (n=30) Mean ± SD	p-value
Age (years)	36.9 ± 7.8	37.6 ± 8.1	0.72
Female (%)	53%	50%	0.80
Weight (kg)	93.2 ± 9.7	92.5 ± 10.1	0.77
BMI (kg/m²)	33.9 ± 2.8	33.6 ± 3.0	0.66
Waist Circumference (cm)	107.4 ± 7.9	106.9 ± 8.3	0.81
Body Fat (%)	39.8 ± 5.1	39.2 ± 5.3	0.63
Fasting Glucose (mg/dL)	103 ± 11	102 ± 12	0.78
Triglycerides (mg/dL)	178 ± 46	176 ± 49	0.88

Over the 8-week intervention period, both dietary approaches resulted in reductions in weight, BMI, waist circumference, and body fat percentage. However, the magnitude of change was more notable in the Intermittent

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Fasting group. Participants practicing intermittent fasting demonstrated a greater reduction in body weight (−4.1 ± 2.1 kg) compared to those on standard calorie restriction (−2.7 ± 1.9 kg), and this difference was statistically significant (p=0.012). Similar trends were observed for BMI, waist circumference, and body fat percentage, each showing significantly greater improvements in the fasting group (Table 2).

Table 2. Changes in Anthropometric Parameters from Baseline to 8 Weeks

Outcome	Intermittent Fasting Δ Mean ± SD	Standard Calorie Restriction Δ Mean ± SD	Between-Group Difference (95% CI)	p-value
Weight (kg)	−4.1 ± 2.1	−2.7 ± 1.9	−1.3 (−2.3 to −0.3)	**0.012**
BMI (kg/m²)	−1.45 ± 0.72	−0.94 ± 0.66	−0.51 (−0.88 to −0.14)	**0.007**
Waist (cm)	−4.7 ± 2.9	−3.0 ± 2.6	−1.7 (−3.0 to −0.4)	**0.012**
Body Fat (%)	−2.3 ± 1.9	−1.4 ± 1.6	−0.9 (−1.7 to −0.1)	**0.028**

Metabolic outcomes also favored intermittent fasting. A greater decrease in fasting glucose levels was observed among participants in the fasting arm (−7.2 ± 9.1 mg/dL) compared with the calorie restriction group (−3.1 ± 8.7 mg/dL; p=0.041). Triglyceride levels also declined more substantially in the fasting group (p=0.048), while changes in total cholesterol, LDL-C, and HDL-C were modest and not statistically different between groups (Table 3).

Table 3. Changes in Metabolic and Lipid Profile at 8 Weeks

Biochemical Parameter	Intermittent Fasting Δ Mean ± SD	Standard Calorie Restriction Δ Mean ± SD	p-value
Fasting Glucose (mg/dL)	−7.2 ± 9.1	−3.1 ± 8.7	**0.041**
Total Cholesterol (mg/dL)	−9 ± 18	−6 ± 17	0.43
Triglycerides (mg/dL)	−23 ± 33	−12 ± 31	**0.048**
HDL-C (mg/dL)	+2.1 ± 4.8	+1.3 ± 4.5	0.39
LDL-C (mg/dL)	−8.6 ± 15.7	−5.9 ± 14.9	0.37

Adherence to the intervention remained acceptable in both groups, with median adherence rates above 80%. A higher proportion of participants in the intermittent fasting group achieved ≥5% reduction in baseline body weight (40% vs. 20%). Minor adverse effects such as headache and transient dizziness were reported, though no serious complications occurred, and no participant required medical withdrawal (Table 4).

Table 4. Participant Adherence and Tolerability

Parameter	Intermittent Fasting	Standard Calorie Restriction
Protocol Adherence (Median %, IQR)	86% (80–92)	82% (76–89)
Participants Achieving ≥5% Weight Loss	40% (n=12/30)	20% (n=6/30)
Study Discontinuation	n=2	n=3
Common Minor Events	Headache (4), Dizziness (3)	Headache (3), Dizziness (2)
Serious Adverse Events	None	None

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Discussion

This randomized controlled trial demonstrated that intermittent fasting produced significantly greater reductions in body weight compared with standard calorie restriction (−4.1 ± 2.1 kg vs. −2.7 ± 1.9 kg; p = 0.012). Participants in the intermittent fasting group also showed larger decreases in BMI (−1.45 ± 0.72 kg/m² vs. −0.94 ± 0.66 kg/m²; p = 0.007), waist circumference (−4.7 ± 2.9 cm vs. −3.0 ± 2.6 cm; p = 0.012), and body fat percentage (−2.3 ± 1.9% vs. −1.4 ± 1.6%; p = 0.028), indicating superior improvements in anthropometric parameters over the eight-week intervention period. Although both dietary approaches resulted in favorable changes, the magnitude of reduction was consistently greater in the intermittent fasting group, suggesting that time-restricted eating may induce a more effective caloric deficit and preferential fat utilization. These findings are in agreement with earlier studies reporting meaningful fat loss and improvements in body composition among overweight and obese individuals following intermittent fasting regimens [7,8].

Beyond anthropometric outcomes, intermittent fasting was associated with significantly greater reductions in fasting glucose levels (−7.2 ± 9.1 mg/dL vs. −3.1 ± 8.7 mg/dL; p = 0.041) and triglyceride concentrations (−23 ± 33 mg/dL vs. −12 ± 31 mg/dL; p = 0.048) compared with standard calorie restriction. This metabolic profile is consistent with evidence indicating that intermittent fasting improves insulin sensitivity, enhances lipid mobilization, and reduces hepatic fat accumulation [9,10]. Although the metabolic changes observed were modest due to the short study duration, they may represent early indicators of improved cardiometabolic health. Additionally, a higher proportion of participants in the intermittent fasting group achieved clinically significant weight loss (≥5% of baseline body weight), supporting its feasibility and potential sustainability as a weight management strategy.

Tolerability was generally good in both groups, with no serious adverse effects observed. Previous systematic reviews similarly report that intermittent fasting is safe for most adults, with adverse effects typically limited to transient headaches, hunger sensations, or mild fatigue during early adaptation [14]. This reinforces the feasibility of intermittent fasting as a lifestyle intervention when guided appropriately.

However, the study duration was relatively short, and longer-term follow-up is necessary to assess maintenance of weight loss, effects on lean muscle mass, and cardiovascular risk markers. Evidence suggests that different fasting schedules—such as alternate-day fasting or 5:2 patterns—may produce varying degrees of benefit, and comparative trials may help determine the most effective regimen for different patient populations [11–13].

Generalizability

This study's findings can be generalized primarily to obese adults without major metabolic or endocrine disorders. Results reflect short-term outcomes within a supervised setting. Variations in lifestyle, cultural eating habits, and longer-term adherence may influence applicability across broader community or clinical populations.

Conclusion

This randomized clinical trial demonstrated that intermittent fasting was more effective than standard calorie restriction in achieving meaningful weight loss and improving key metabolic parameters over eight weeks in obese adults. Participants following the 16:8 fasting schedule showed greater reductions in body weight, BMI, waist circumference, body fat percentage, fasting glucose, and triglycerides, with good overall adherence and minimal adverse effects. These outcomes suggest that intermittent fasting is not only practical but also well-tolerated when incorporated as a structured lifestyle approach. It offers a simpler alternative to continuous calorie monitoring and may support better engagement in weight management efforts. Further long-term studies are recommended to explore sustainability and metabolic benefits beyond the short intervention period.

Limitations

The study had a relatively short duration, which limits assessment of long-term weight maintenance and metabolic effects. Dietary adherence relied partly on self-reporting, which introduces bias. The sample size was modest, and results may not fully represent diverse populations or clinical settings.

Recommendations

Intermittent fasting can be considered a practical and effective dietary strategy for weight reduction in obese individuals, especially for those who find continuous calorie counting difficult to sustain. Clinicians should provide clear guidance on fasting windows, hydration, and balanced meal composition during the eating period to ensure adequate nutrient intake. Incorporating intermittent fasting into lifestyle counseling may improve adherence and patient motivation. However, individualized assessment is necessary, particularly for individuals with metabolic disorders, gastrointestinal issues, or those on medications

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requiring regular food intake. Further longer-duration studies are recommended to evaluate sustained effects, optimal fasting schedules, and long-term metabolic and cardiovascular outcomes.

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Abbreviations
IF – Intermittent Fasting
SCR – Standard Calorie Restriction
BMI – Body Mass Index
HDL-C – High-Density Lipoprotein Cholesterol
LDL-C – Low-Density Lipoprotein Cholesterol
RCT – Randomized Controlled Trial

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Conflict of interest
The authors declare no conflict of interest.

Author contributions
ID-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **GM**-Concept and design of the study, results interpretation, review of literature, preparing the first draft of the manuscript, and revision of the manuscript.**VSBL**-Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation. **MMK**-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.

Data availability
Data is available on request

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