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Effect of Lifestyle Modifications in Overweight and Obese Subjects with Metabolic Syndrome: Study Protocol for A Randomized Clinical Trial.

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KEYWORDS

Metabolic Syndrome, Overweight, Obesity, Lifestyle modifications, Indian Population

ABSTRACT:

The increasing global burden of overweight/obesity and metabolic syndrome (MetS), driven by unhealthy lifestyles, elevates the risk of type 2 diabetes and cardiovascular disease. This randomized, parallel-group study will assess the impact of lifestyle modification (diet and/or exercise) on metabolic syndrome (MetS) in 120 overweight/obese adults (BMI 25-34.9 kg/m², aged 20-70) with at least three MetS components. Participants will be randomized to either treatment as usual (TAU), or TAU + exercise, or TAU + controlled diet, or TAU + exercise + diet. The primary outcome is body weight change after 12 weeks. Secondary outcomes include changes in metabolic parameters (HOMA-IR, BMI, waist/hip circumference, glucose, lipids, blood pressure, AIP, TyG index), perceived stress, sleep quality, and quality of life, assessed over four visits. Statistical analysis will determine the effectiveness of these lifestyle interventions in managing weight and metabolic health in this population. This study aims to provide evidence for effective strategies to combat the growing impact of MetS and also addresses the elevated treatment costs for metabolic syndrome.

1. Introduction

Following unhealthy dietary patterns and sedentary lifestyles has led to a notable increase in the prevalence of overweight and obesity worldwide. Metabolic syndrome (MetS) is a clinical condition characterized by a clustering of metabolic risk factors, which is defined by the simultaneous occurrence of at least three of the following components: central obesity, dyslipidemia, impaired glucose metabolism, elevated blood pressure (BP), and low levels of high-density lipoprotein cholesterol (HDL-c) [1]. Thus, MetS increases the risk of type 2 diabetes mellitus (T2DM), cardiovascular disease (CVD) and economic burden [2].

A vegetarian diet, being rich in vegetables and fruits, and typically including a low glycemic index foods such as beans, legumes, and nuts, which reduces oxidative stress, chronic inflammation, and thus MetS and its components. A study conducted by Lakshmipriya, Nagarajan, et al., showed how the type of vegetable oils used in cooking is correlated with risk of developing metabolic syndrome in Asian Indians [3]. A study conducted by Jaspinder Kaur et al. showed that vegetarian dietary habits play a protective role against MetS as compared to Non-MetS [4].

Exercise training increases phosphorylation of glucose and stimulates muscle glycogen synthesis and insulin sensitivity [5]. In general, at least 30 min of exercise is recommended. Johnson et al. found that moderate intensity exercise is more effective than high intensity exercise in improving exercise capacity. They also found that moderate intensity exercise improved insulin sensitivity and triglyceride response [6].

Rajvir Bhalwar et.al., explained in their article how a 'thrifty genotype' which had originally developed to save energy and store it for use in times of need, continues to store energy when there is food abundance, resulting in obesity, particularly central obesity. The global prevalence of MetS is estimated to be 20%–25% of the adult population, with a high prevalence in India, affecting about one-quarter of the adult population, with higher risk in older individuals and females. Intake of high levels of saturated fats and trans-fatty acids continues to be an important risk factor for CVD and many of the foods which are high in cholesterol are also rich in saturated fatty acids, with the exception of shrimps and whole eggs, which contain very low amounts of saturated fats. [7]

Multiple organizations (WHO, ATP III, IDF, AHA/NHLBI) proposed varying definitions for metabolic syndrome (MetS). A harmonized definition was later developed by a joint task force (IDF, NHLB, AHA, WHF, IAS, IASO) to standardize diagnosis. This definition requires the presence of any three out of five risk factors (Elevated values of Waist circumference, triglycerides, blood pressure, and fasting glucose and reduced HDL-C) [1]

2. Review of Literature

The A rural community-based study by Misra, Puneet, et al.[8] utilizing the five-component NCEP ATP II criteria in women revealed that while the majority of participants presented with at least one component of MetS, none exhibited all five. This highlights the varying degrees of metabolic abnormalities within the population.

Shifting focus to urban populations, Tharkar et al.[9] investigated the impact of obesity on cardiovascular risk factors and employed a modified NCEP ATP III criteria (adapted for South Asians) to diagnose MetS in urban South Indians. Their findings indicated a MetS prevalence of approximately 32%, with a strong association between cardiovascular risk factors (including increasing age, overweight and obesity, hypercholesterolemia, and family history of hypertension) and the syndrome. Notably, obese individuals exhibited a 25% higher risk of MetS compared to their non-obese counterparts.

Further evidence of high MetS prevalence in urban settings comes from a multisite study by Prakash C. et al.[10], who also utilized modified ATP-III criteria. Their research underscored the urgent need to address obesity to mitigate the escalating rates of diabetes and coronary heart disease in India.

Considering specific demographic groups, Vembu Radha et al. [11] examined infertile women and identified body mass index (BMI) as an independent risk factor for MetS in both women with and without polycystic ovary syndrome (PCOS). Similarly, Dimple Jamkhandi et al. [12] found pre-menopausal women to be at high risk of developing metabolic syndrome. Nirmalya Sinha et al.'s [13] cross-sectional study among the elderly also demonstrated a high prevalence rate of MetS in this age group. Moreover, Dinaker Manjunath et al.'s [14] research indicated a high prevalence of metabolic syndrome among urban young adults in India, with a direct correlation to BMI.

Interestingly, studies have also highlighted the presence of MetS in rural populations. Anamitra Barik et al.'s [15] study among Indian adults revealed a high prevalence of MetS even in rural areas, particularly among women. The authors suggested that low physical activity and overweight could be contributing risk factors in these communities.

Beyond individual factors, lifestyle elements such as dietary habits have also been implicated. Nagarajan Lakshmipriya et al.'s [16] study demonstrated that the types of vegetable oils used in Indian households can be a risk factor for MetS. Their findings indicated that sunflower oil users were more susceptible to developing MetS, a risk that was further amplified by the consumption of refined cereals.

A comprehensive overview is provided by the systematic review conducted by Yuvaraj Krishnamoorthy et al. [17], which concluded that overweight and obese adults have a significantly higher likelihood of having metabolic syndrome compared to adults with normal or low BMI.

Several studies have investigated various anthropometric measurements and potential interventions in the context of metabolic syndrome

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(MetS). For instance, a study by Yi-Hsin Lin et al. [18] showed that lifestyle modifications led to improvements in anthropometric parameters and a reduction in insulin resistance among adults with metabolic syndrome (MetS). Another study by Esther Ngozi et al. [19] found that waist circumference (WC) was the best predictor of metabolic syndrome (MetS) in both men and women. The findings by Khosravian et al. [20] indicated that waist-to-height ratio exhibited the highest diagnostic value, followed by BMI, abdominal volume index (AVI), waist-to-hip ratio, and neck circumference. However, the authors noted the need for further research across different age groups to validate these observations.

The results by Hanieh Roshan et al. [21] showed that the coffee bean extract used in the trial may lead to reductions in systolic blood pressure, fasting blood glucose, HOMA-IR, waist circumference, and appetite compared to a placebo. These findings suggests that green coffee extract supplementation could be a promising strategy for managing key features and major underlying causes of MetS, such as insulin resistance and abdominal obesity.

Further emphasizing the importance of abdominal adiposity in MetS, a study by Ramírez et al.[22] focused on the relationship between individual MetS components and insulin resistance. The study showed that among the various components of MetS, waist circumference emerged as the strongest indicator of insulin resistance. Consequently, the International Diabetes Federation (IDF) definition of MetS, which mandates a high waist circumference for diagnosis, demonstrates the strongest association with insulin resistance. This highlights waist circumference as a critical factor in detecting insulin resistance and facilitating the early identification of metabolic syndrome.

A meta-analysis by Kazue Yamaoka et al. [23] found that lifestyle modification interventions were effective in resolving MetS and reducing the severity of related abnormalities, including fasting blood glucose, waist circumference, systolic and diastolic blood pressure (SBP and DBP), and triglyceride levels in individuals with MetS.

Collectively, these studies paint a picture of the widespread prevalence of metabolic syndrome across various segments of the Indian population, highlighting the significant roles of obesity, age, lifestyle factors, and even dietary choices in its development. The consistent use and adaptation of NCEP ATP criteria across these studies allow for comparisons and a broader understanding of the evolving landscape of metabolic health in India.

3. Methods

Study Design

This is a randomized, parallel group study to evaluate the effect of lifestyle modification in overweight and obese subjects with metabolic syndrome. The overall scheme of study design is given in **Figure 1** and **Table 1** presents an overview of the schedule for enrolment, the intervention and the assessments. The study consists of four visits. Visit 1 - Week 0-Screening and randomization (Baseline), Visit 2 - Week 4 (±3 days), Visit 3 - Week 8 (±3 days) and Visit 4 - Week 12 (±3 days).

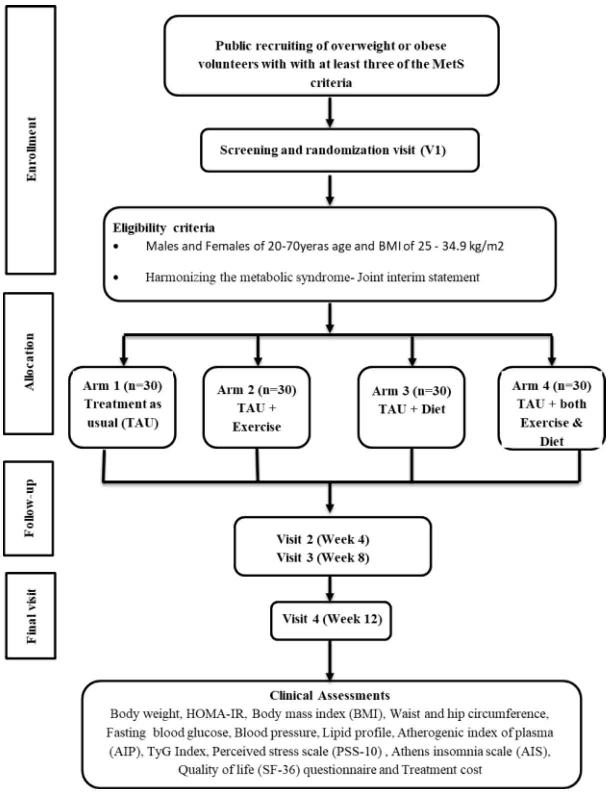

Figure 1: Scheme of Study Design

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Eligibility criteria

Inclusion Criteria

Overweight or obese (BMI 25-34.9 kg/m²) male and female subjects, aged 20-70 years with at least three of the following MetS criteria (harmonized definition): waist circumference (males ≥ 90 cm, females ≥ 80 cm), triglycerides ≥ 150 mg/dL, HDL-C (males < 40 mg/dL, females < 50 mg/dL), SBP ≥ 130 mmHg and/or DBP ≥ 85 mmHg, or fasting glucose ≥ 100 mg/dL or on treatment for any of the above mentioned conditions will be included in the study **Table 2**. Subjects who are willing to adhere to the study procedures (including lifestyle modifications and tracking), are generally healthy, able to attend the scheduled visits, able to understand the risks/benefits of the protocol and provide informed consent will be included.

Exclusion Criteria

Participants will be excluded if have physical or mental disabilities that would hinder study participation; have a history of psychiatric disorders, congestive heart failure or other cardiovascular conditions, sexually transmitted diseases, have received COVID-19 treatment or tested positive within the 3 months prior to screening or during the study; have evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, hepatic, or neurologic diseases, malignancies, or hypothyroidism; with excessive alcohol consumption (>5 drinks/week), smoking (>5 cigarettes/day), or recreational drug use; females who are pregnant, breastfeeding, or planning pregnancy; have any other condition deemed by the investigator to negatively impact study completion or measures; or are participating in another clinical trial within 30 days prior to screening.

This study adhered to the tenets of the Declaration of Helsinki. The protocol also adhered to the guidelines of the International Conference on Harmonization on Good Clinical Practices (ICH-GCP). Before enrolment, written informed consent will be obtained from all subjects after a full explanation of the nature and potential adverse events (AEs) of the study.

Table 1: Schedule of events

Activity	Week 0 (V1)	Week 4 (V2)	Week 8 (V3)	Week 12 (V4)
Socioeconomic status, physical inactivity and education status.	√	-	-	-
Height & ECG	√	-	-	-
Blood sampling for hematology, bio-chemistry, HOMA-IR and urinalysis	√	-	-	√
UPT	√	√	√	√
Body weight & BMI	√	√	√	√
	√	-	-	√
Waist and hip circumference	√	√	√	√
Fasting blood glucose	√	√	√	√
Blood pressure	√	√	√	√
Lipid profile	√	√	√	√
AIP	√	√	√	√
TyG Index	√	√	√	√
PSS-10	√	√	√	√
AIS	√	√	√	√
SF-36	√	√	√	√
Treatment Cost	√	-	-	√

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Outcome measures:

Age, gender, socioeconomic status (as measured by the composite score of modified Kuppuswamy socioeconomic scale, which includes the education and occupation of the family head along with family's monthly income, yielding a score of 3–29), marital status, and level of education, medical, surgical and personal history will be collected at baseline. Anthropometric measurements, biometric measurements and all the other measures will be performed at baseline and Weeks 4, 8 & 12.

Primary outcome measure is Change from baseline to the end of the study period in Body weight. Body weight will be measured, to the nearest 0.5 kg with bare feet, using a calibrated digital weighing machine (Omron™ HN289).

Secondary outcome measures are Change from baseline to the end of the study period in the HOMA-IR, Body mass index (BMI), Waist and hip circumference, Fasting blood glucose, Blood pressure, Lipid profile, Atherogenic index of plasma (AIP), TyG Index, Perceived stress scale (PSS-10), Athens insomnia scale (AIS), Quality of life (SF-36) questionnaire and Treatment cost.

Height will be measured to the nearest 0.5 cm, using calibrated stadiometer. Then the body mass index (BMI) will be calculated by dividing the body weight (kg) by square of the height (in meters).

HOMA-IR is used to calculate Insulin Resistance (IR) using the formula: Insulin resistance = Fasting Insulin (mU/L) × Fasting Glucose (mg/dl) /405.

Waist circumference and Hip circumference will be measured to the nearest 0.5 cm. Combination of the both represent the central obesity

Blood pressure will be measured with a calibrated sphygmomanometer. The mean value of three measurements, made at intervals of 5 minutes, will be used for analysis.

The Atherogenic index of Plasma (AIP) was calculated by logarithmic transformation of the ratio of serum concentrations of triglyceride (TG) and high-density lipoprotein cholesterol (HDL-C). AIP, as a robust biomarker of dyslipidemia and atherosclerosis, has been used to quantify comprehensive lipid levels.

The triglyceride-glucose (TyG) index is the logarithmized product of fasting triglycerides and fasting glucose and has been proposed as the alternative indicator of IR due to its relevance to lipotoxicity and glucotoxicity.

The perceived stress scale (PSS-10) is the most widely used psychological questionnaire containing ten questions for measuring the perception of stress. Higher PSS scores are associated with higher levels of stress and increased susceptibility to stress-induced illness.

Athens insomnia scale (AIS) is an eight-item questionnaire evaluates sleep onset, night and early-morning waking, sleep time, sleep quality, frequency and duration of complaints, distress caused by the experience of insomnia, and interference with daily functioning. Subjects will be asked to check the items (by circling the appropriate number) to indicate the estimate of any sleep related difficulty, provided that it occurred at least three times per week during the last month. Each item is rated on a 4-point numerical rating scale (where 0 estimates no problem and 3 estimates an intense problem with sleep). Higher scores indicate severe insomnia symptoms.

The Short Form 36 (SF-36) is standardized as a self-report measure of functional health and well-being. It consists of 36 questions under the eight domains: physical functioning (10 items), role-physical (4 items), bodily pain (2 items), and general health (5 items). The mental health measure is composed of vitality (4 items), social functioning (2 items), role-emotional (3 items), and mental health (5 items). Each domain is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. A score of zero is equivalent to maximum disability, and a score of 100 is equivalent to no disability.

Treatment cost is calculated by adding the costs derived from the medication and the use of health services and clinical tests. Elevated treatment costs for metabolic syndrome stem from factors such as the necessity for multiple medications, a greater incidence of hospital admissions, and the increased consumption of healthcare services.

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Table 2: Criteria for Clinical Diagnosis of the Metabolic Syndrome

Measure	Categorical Cut Points
Elevated **waist circumference**	Population- and country-specific definitions. For Asian men: ≥90 cm For Asian women: ≥80 cm
Elevated **triglycerides** (drug treatment for elevated triglycerides is an alternate indicator)	≥150 mg/dL (1.7 mmol/L)
Reduced HDL-C (drug treatment for reduced HDL-C is an alternate indicator)	< 40 mg/dL (1.0 mmol/L) in males < 50 mg/dL (1.3 mmol/L) in females
Elevated blood pressure (antihypertensive drug treatment in a patient with a history of hypertension is an alternate indicator)	Systolic ≥130 and/or diastolic ≥85 mmHg
Elevated fasting glucose (drug treatment of elevated glucose is an alternate indicator)	≥100 mg/dl

4. Statistical methods and planned analysis

Sample size

The sample size is calculated using a two-sided t-test of size 5% (α = 0.05). Furthermore, the minimum mean difference in the primary endpoint of change from baseline body weight is assumed to be 5.0 with a common standard deviation (SD) of 5.5. The difference in mean and common SD of change from baseline body weight arrived based on informations publised by Ross R. et al [24]. Considering the drop-out rate of 10% among subjects (~ 3 subjects per group), approximately 30 subjects per group will be randomised in order to obtain a power of 90% of meeting the primary objective to perform. Therefore, the total sample size is 120 subjects (30 subjects per treatment group in 1:1:1:1 ratio to be randomized).

Intervention Regimen

The diet counseling will be provided by a certified dietician using the gender specific diet chart with calculated calories to the subjects randomized to diet specific groups as per randomization code.

The exercise will be prescribed by certified physical trainer based on age, gender, and individual physical status to the subjects randomized to exercise-specific groups as per randomization code.

Subjects are advised to follow the lifestyle intervention (diet, exercise or both) as per the assigned group. The Diet and Exercise regimen that will be advised to the subjects are given in **APPENDIX – A** and **APPENDIX – B** respectively.

Randomization and Blinding

Randomization codes will be generated via computer using a permuted block design. The randomization code list will be centrally maintained by principal investigator and will be distributed to the sub investigator.

Approximately 150 healthy subjects will be screened to select 120 randomized subjects. Once the subject is deemed eligible, he/she will be randomized at 1:1:1:1 ratio to either one of the four study groups (TAU, TAU+ exercise, TAU + controlled diet and TAU + both exercise & controlled diet), based on randomization codes, assigning 30 subjects per arm. Dropout subjects will not be replaced.

Data Collection and Management

The investigator should ensure that the data is correctly, completely, clearly, and timely entered into the case report form based on the original observations of the subject. The auditor shall monitor whether the research is conducted in accordance with the research plan and confirm that whether all case report forms are completed correctly and consistent with the original data. If errors and omissions are made, the researcher shall be promptly corrected. The case report form after the inspection by the auditor needs to be transmitted to

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the data administrator of the clinical research in time. The data administrator should compile the data entry-program for data management. In order to ensure the accuracy of the data, two data entry personnel should independently perform double entry and proofreading. For questions in the case report form, the data administrator will generate a question-answer form and send an inquiry to the researcher through the clinical monitor. The researcher should answer the question as soon as possible, and the data administrator will modify the data according to the researcher's answer. If necessary, a question answer form can be issued again.

5. Discussion

The prevalence of MetS is influenced by various factors, including diagnostic criteria, ethnicity, and age. Global estimates indicate that age-adjusted MetS prevalence is around 24-25% in US adults, approximately 23% in European countries, and 20-25% among South Asians [25]. There has been established research on metabolic syndrome in Indian population [26-30]. The increasing prevalence of metabolic syndrome (MetS) in India poses a significant public health and economic challenge. MetS elevates the risk of developing serious chronic conditions such as heart disease and type 2 diabetes, and its associated health issues contribute to a substantial economic burden on healthcare systems while diminishing individual work productivity.

Studies reveal variations in urban prevalence depending on the diagnostic criteria used, with more recent criteria often yielding different results compared to earlier findings [31-37]. Generally, rural areas in India have shown a lower prevalence of MetS, particularly in South India, although some deviations from this pattern have been observed. [38-43]

The prevalence of MetS in adult Indians is approximately 30%, with notable regional disparities. Madhya Pradesh has reported the highest prevalence at 50%, while Jammu & Kashmir has the lowest at 15%. Furthermore, MetS prevalence increases significantly with age, ranging from 13% in the 18-29 age group to 50% in the 50-59 age group. There is also a gender difference, with a higher prevalence in females (35%) compared to males (26%). Urban populations (32%) exhibit a higher prevalence of MetS compared to rural populations (22%) [44]. The age-related increase in prevalence of MetS may be attributed to factors such as the development of insulin resistance, hormonal changes, and an increase in visceral adipose tissue with advancing age. [45]

Lifestyle modifications, including calorie restriction, exercise, and behavioral changes, are the cornerstone of MetS management for overweight and obese individuals [46]. Even a modest weight loss of can lead to significant improvements in triglycerides (TGs), fasting blood glucose, insulin, and HbA1c levels, as well as an increase in HDL cholesterol [47]. Moreover, individuals with existing hypertension or at risk of developing it can experience a meaningful reduction in blood pressure with moderate weight loss. Importantly, adopting dietary and exercise changes can enhance insulin sensitivity, even in the absence of significant weight loss [48]. Regular exercise during weight maintenance is crucial for abdominal fat loss and preventing weight regain. Health organizations recommend at least 30 minutes of moderate-intensity physical activity on most days of the week for the general population, based on documented fitness improvements. [49, 50]

At a cellular level, insulin resistance, a key feature of MetS, triggers pro-inflammatory processes in blood vessels and immune cells, thereby promoting the development and instability of atherosclerotic plaques [51, 52]. The Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) is a commonly used tool to estimate insulin resistance. Studies indicate that elevated HOMA-IR values are frequently observed in individuals with MetS and are strongly associated with an increased risk of cardiovascular diseases and type 2 diabetes. Thus, HOMA-IR has a greater propensity for MetS and hyperglycemia, highlighting its utility in early detection and intervention [53].

High BMI signals general obesity, but central obesity (excess belly fat) is a much better predictor of MetS. Central obesity is measured by waist circumference or waist-hip ratio [54]. The Atherogenic Index of Plasma (AIP), the ratio of triglycerides to good cholesterol (HDL), is another key marker for heart risk in MetS patients. High AIP indicates increased risk of clogged arteries and heart problems due to the unhealthy fat levels seen in MetS [55].

Research has increasingly shown a strong connection

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between higher TyG index values and various cardio metabolic issues, meaning problems affecting both the heart and metabolism [56-59]. Psychological stress may also increase the risk of MetS, suggesting that traditional lifestyle recommendations may need to be complemented with stress management strategies [60]. Shorter sleep duration has been associated with a higher risk of developing hypertension and diabetes [61]. Sedentary behavior and insomnia have been identified as significant predictors of MetS in older men, independent of physical activity and individual MetS components. In older women, however, exercise/balance capacity and sedentary time were independent predictors. Interventions targeting increased physical activity, reduced sitting time, and improved sleep quality may be crucial for MetS prevention in older adults [62, 63].

The impact of MetS extends beyond physical health, affecting Health-Related Quality of Life (HRQOL), often measured using tools like the SF-36. The increasing morbidity and reduced life expectancy associated with MetS have led to greater attention on understanding its impact on HRQOL [64-66]. The long-term effects of MetS can also negatively impact overall economic output and strain healthcare resources. Effective management of MetS has the potential to reduce treatment costs by preventing complications and improving overall health [67]. Future research should further investigate the economic consequences of MetS in India, encompassing direct medical expenses, indirect costs like lost productivity, and intangible costs such as reduced quality of life [68]. Merely acknowledging the trend in increasing obesity is inadequate; proactive, targeted interventions are needed [69]. For managing MetS in overweight and obese individuals, lifestyle changes, particularly physical activity, and dietary changes are paramount.

6. Dissemination

The findings of this trial will be published in peer-reviewed journals, irrespective of the direction or magnitude of the results, and will also be presented at national and international scientific meetings. If permitted by journal policies, the results will be made available online wherever possible.

7. Source(s) of support

The trial is a self-funded project as a part of academic research.

8. Author Contribution

The study conception and design were by Prason Kumar J, A.Elphine Prabhahar, K.Lakshmi and the literature data were acquired by Prason Kumar J and Pradeepa P.

The drafting of the manuscript was done by Prason Kumar J and Pradeepa P and critical revisions were made by A.Elphine Prabhahar and K.Lakshmi.

Prason Kumar J, A.Elphine Prabhahar and K.Lakshmi contributed to overseeing the design of the protocol, suitable population and outcomes.

9. Conflict of Interest:

Authors declare that they have no competing interests.

10. Ethical Consideration

Before the study starts, the study protocol, Informed Consent Form (ICF), and any other appropriate documents will be submitted to the Institutional Ethics Committee with a cover letter or with a form outlining the documents submitted, their dates of issue, and the site (or region or area of jurisdiction, as applicable) for which approval is sought. This trial was approved by PCRI Ethics Committee on 03 Jul 2025. EC registration number is ECR/1851/Inst/AP/2023.

Before the patient is enrolled in the study, he/she will be explained about the study protocol and all the corresponding activities and ICF will be provide to the subject for his/her volunteer approval.

11. Trial Registration

This study was registered in Clinical trials registration of India (CTRI) and was allotted the registration number of CTRI/2024/09/073376.

12. Trial status

Patient recruitment was started and the study was ongoing.

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