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EFFICACY AND SAFETY OF 'GARSY', A GARCINIA-BASED MULTI-INGREDIENT HERBAL SUPPLEMENT, IN WEIGHT MANAGEMENT AND METABOLIC HEALTH: A RANDOMISED CONTROLLED CLINICAL TRIAL

W.D.S.K. Dharmapala, D.A. Gayanjalee, K.A.R. Keragala, P.T.M. Abeyrathna, *A. Chandrasekara

Department of Nutrition and Dietetics, Faculty of Livestock, Fisheries and Nutrition, Wayamba University of Sri Lanka. Makandura, 60170, Sri Lanka
*Corresponding author: Prof. Ananda Chandrasekara
Email: ananda.ch@wyb.ac.lk, ananda.ch@icloud.com
Telephone No: +94719922664

Abstract:

Visceral fat accumulation, characterised by central obesity, is the primary cause of insulin resistance and significantly increases the risk of associated conditions such as cardiovascular diseases, hypertension, and type 2 diabetes mellitus. This randomised, single-blind, placebo-controlled clinical trial aimed to evaluate the efficacy and safety of "Garsy," a novel multi-ingredient herbal supplement comprising Garcinia cambogia, Cinnamomum zeylanicum, Piper nigrum, curry leaves, and bee honey. Eighty-one overweight and obese adults aged 20–65 years were randomised to receive either "Garsy" or a placebo for 12 weeks. Outcomes measured included anthropometric parameters, body composition, and metabolic markers.

Following intervention, the "Garsy" group exhibited significant reductions in body weight (from 73.16 ± 13.0 kg to 72.6 ± 13.1 kg, $p<0.05$), waist circumference (from 91.0 ± 9.86 cm to 88.1 ± 9.9 cm, $p<0.05$), and total body fat percentage (from 38.6 ± 8.0% to 38.2 ± 8.4%, $p<0.05$). Additionally, significant improvements were observed in metabolic parameters, including triglycerides (from 155.5 ± 85.6 mg/dL to 133.9 ± 73.7 mg/dL, $p<0.05$), fasting blood glucose (from 108.6 ± 29.2 mg/dL to 103.1 ± 17.9 mg/dL, $p<0.05$), and the triglyceride-glucose index indicating reduced insulin resistance (from 8.9 to 8.7, $p<0.05$). No significant changes were found in the placebo group. Only a few mild and occasional gastrointestinal complaints were

reported in both groups, and no significant changes were observed in renal function measurements or C-Reactive Protein, an inflammatory marker, indicating a favourable safety profile.

This study provides robust evidence supporting the therapeutic potential of "Garsy," a multi-ingredient herbal supplement, in weight loss and improving metabolic health among overweight and obese adults, thereby highlighting its clinical utility as a safe adjunctive intervention for the management of obesity and metabolic syndrome.

Keywords: Herbal supplement, Garcinia cambogia, Central obesity, Metabolic syndrome, Insulin resistance

Introduction

The global obesity epidemic represents a significant public health challenge. According to the World Obesity Atlas 2023 report, 38% of the world's population is currently overweight or obese, with projections indicating an increase to 51% by the year 2035.[1] Obesity is closely linked with heightened risks of several chronic diseases, including cancer, cardiovascular diseases (CVDs), metabolic syndrome (MetS), type 2 diabetes mellitus, and elevated all-cause mortality.[2,3] Central or abdominal obesity is a critical component of MetS, which encompasses various metabolic disturbances such as hyperglycemia, hypertension, visceral adiposity, atherogenic dyslipidemia, endothelial dysfunction, and genetic predispositions.[2,3]

Beyond lifestyle interventions, such as diet modification, physical exercise, and behavioural strategies, pharmacological treatments have also been employed effectively in managing obesity.[4] Recently, herbal medicines have gained attention due to their capacity to manage metabolic risk factors such as abdominal obesity, dyslipidemia, hypertension, and insulin resistance.[4,5] Numerous preclinical and clinical studies support the efficacy of herbal bioactive compounds in managing obesity through mechanisms including appetite suppression, enhanced thermogenesis, inhibition of pancreatic lipase activity leading to reduced fat absorption, stimulation of lipolysis, and suppression of lipogenesis.[4–6]

The current study evaluates the therapeutic efficacy and safety of "Garsy," a novel herbal food supplement comprising Garcinia cambogia, Murraya koenigii (curry leaves), Cinnamomum zeylanicum (cinnamon bark), Piper nigrum (black pepper), and bee honey. Although these

ingredients have individually exhibited beneficial effects on weight management and metabolic health,[5–7,12] their synergistic potential as a combined formulation has not yet been thoroughly investigated. Importantly, each ingredient possesses a long-standing history of safe use within Ayurvedic medicine, underpinned by extensive empirical observations.[12]

Methodology

Study design: This was a randomised, single-blind, placebo-controlled, parallel-group clinical trial conducted over 12 weeks to evaluate the anti-obesity efficacy and safety profile of the multi-ingredient herbal supplement “Garsy” in overweight and obese adults. Participants were randomly allocated to either the intervention (herbal supplement) or placebo group, matched for age, gender, and BMI. Both the herbal supplement and the placebo candies were identical in appearance and were produced by Good Manufacturing Practices.

Preparation of Herbal Supplement and Placebo: The herbal supplement "Garsy" was prepared by uniformly mixing Garcinia cambogia extract, ground cinnamon, finely powdered black pepper, minced curry leaves, and bee honey. The mixture was moulded into candy, solidified at room temperature, and dehydrated. The placebo candy was similarly formulated using Mila bark (an inactive fibrous substance containing cellulose) and corn flour to mimic the active supplement in appearance, texture, and flavour but lacked active bioactive constituents.

Participant Recruitment and Eligibility: Participants were recruited via community advertisements and preliminary eligibility screening was conducted through telephone interviews to confirm age (18-60 years), BMI (≥23 kg/m^2), and adiposity (>20% for males, >25% for females). Exclusion criteria included menopausal status, pregnancy or lactation, current treatment for diabetes, cardiovascular or endocrine disorders, chronic kidney disease, acute illness, specific dietary programs, smoking, or heavy alcohol consumption. A total of 102 eligible participants aged between 20 to 65 years underwent detailed evaluations.

Baseline Data Collection: Participants provided written informed consent after receiving comprehensive information about study procedures, objectives, risks, and benefits. Baseline data collection included medical history, lifestyle behaviours, dietary intake via 24-hour dietary recall, and physical activity using the International Physical Activity Questionnaire (short form). Anthropometric parameters (weight, height, waist circumference) and body fat percentage (via

Bioelectrical Impedance Analysis) were measured. Blood samples were collected following a 12-hour overnight fast for biochemical analysis (lipid profile, kidney function tests, liver enzymes, and C-reactive protein [CRP]).

TyG index- The triglyceride-glucose (TyG) index, calculated using fasting triglyceride and glucose levels, has been validated as a simple and reliable surrogate marker for insulin resistance in diverse populations.[9,10] Moreover, studies have demonstrated a strong association between the TyG index and subclinical atherosclerosis and coronary artery calcification, emphasizing its clinical relevance as a metabolic marker in both research and practice.[11]

$$\text{TyG index} = \ln\left(\frac{\text{Fasting Triglycerides (mg/dL)} \times \text{Fasting Glucose (mg/dL)}}{2}\right)$$

Intervention and Follow-Up: Participants in both groups received standardised dietary and physical activity guidelines aligned with Sri Lankan nutritional recommendations. They consumed three daily doses of candy (1,500 mg each, totalling 4,500 mg/day) post-meals for 12 weeks. Follow-up visits occurred at weeks 8 and 12 to reassess anthropometric parameters. Compliance was monitored via weekly telephone calls, and participants were observed for any adverse events, including gastrointestinal issues, allergic reactions, headaches, and other unexpected symptoms. At week 13, fasting blood samples and anthropometric parameters were again evaluated.

Statistical Analysis: Data were analysed using the IBM SPSS 29 (2024). Descriptive statistics summarised demographic and baseline clinical data. Continuous variables were presented as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. Paired t-tests were utilised to compare pre-and post-intervention measurements within and between groups. Statistical significance was set at $p < 0.05$, with data presented as adjusted means or correlation coefficients, along with corresponding 95% confidence intervals (CI) where applicable.

Ethical Considerations: Ethical clearance was obtained from the Ethics Committee of Wayamba University of Sri Lanka (202404H02, dated 25 April 2024). Participant confidentiality was strictly maintained, data anonymised and securely stored.

Results

Table 1. Baseline characteristics in the Intervention (herbal supplement-) group and the placebo group

Characteristics	Total (n=81) Mean ± SD	Intervention (n=35) Mean ± SD	Control (n=46) Mean ± SD
Age (years)	39.8± 7.5	36.8 ± 6.9	42.2± 7.3
Height (cm)	159.6 ± 8.3	158.2 ± 8.9	160.7 ± 7.7
Weight (kg)	71.8 ± 10.8	73.2± 13.0	70.9 ± 8.7
WC (cm)	89.7 ± 8.2	91.0 ± 9.8	88.6 ± 6.7
BMI (kgm^{-2})	28.2 ± 3.9	29.2 ± 4.6	27.5 ± 3.2
Systolic BP (mmHg)	120.8± 16.9	120.8 ± 18.3	120.8± 16.0
Diastolic BP (mmHg)	82.6± 15.7	81.6 ± 11.3	83.3 ± 18.5
Body fat percentage (%)	36.5 ± 8.5	38.6 ± 8.0	34.9 ± 8.6
Body fat mass (kg)	26.5 ± 8.5	28.5 ± 9.3	24.87 ± 7.5
FBG (mg/dL)	108.6 ± 28.3	108.6 ± 29.2	108.7 ± 27.8
Serum TC (mg/dL)	200.5 ± 36.0	207.4 ± 36.8	195.3± 34.9
Serum triglycerides(mg/dL)	148.4 ± 108.0	155.5 ± 85.6	142.9 ± 123.0
Serum HDL (mg/dL)	46.4 ± 11.4	46.1 ± 10.5	46.8 ± 12.2
Serum Creatinine (mg/dL)	0.8 ± 0.2	0.8 ± 0.2	0.8 ±0.2
EFGR (mL/min/1.73 m^2)	80.3 ± 7.7	82.20 ± 6.9	79.4 ±8.2
CRP (mg/L)	3.7 ± 5.6	4.27 ± 7.0	3.3 ± 4.3
ALT (U/L)	36.0 ±31.5	36.5 ± 36.4	35.7 ± 27.6
AST (U/L)	24.8 ± 13.7	25.6 ± 17.8	24.2 ± 9.6
TyG index	8.8 ± 0.6	8.8 ± 0.6	8.9 ± 0.6

WC- Waist Circumference, **BP** – Blood Pressure, FBG- Fasting blood glucose, **TC**- Total Cholesterol, **TG** – Triglyceride, **HDL** – High-density Lipoprotein, **EFGR**- Estimated glomerular filtration rate, **CRP** – C-

reactive Protein, **AST** – Aspartate Aminotransferase, **ALT** – Alanine Aminotransferase, **BMI**- Body mass index, **TyG index**- Triglyceride-Glucose Index

Participants' characteristics

Of the 102 participants initially randomised, 50 were assigned to the intervention group and 52 to the placebo group. During the 12-week intervention period, 21 participants withdrew—15 from the intervention group and 6 from the placebo group—primarily due to personal reasons and difficulty adhering to the daily regimen in conjunction with work-related obligations. A total of 81 participants (35 in the intervention group and 46 in the placebo group) completed the study and were included in the final analysis. While a slight disparity in mean age was observed between the two groups at baseline, statistical analysis indicated no significant differences in other baseline demographic, anthropometric, or biochemical parameters. This supports the validity of the group allocation and ensures comparability of treatment outcomes.

Comparison between the groups at the baseline and 12 weeks of post-intervention

Anthropometric parameters, including body weight, waist circumference, body mass index (BMI), and body composition indicators (body fat percentage and fat mass), were assessed at baseline and after 12 weeks in both the intervention and placebo groups. The results are summarised in **Table 1.** Measurements are presented as mean ± standard deviation (SD), and statistical significance was evaluated using paired t-tests to compare pre- and post-intervention values within each group.

Following the 12-week intervention, participants in the herbal supplement group demonstrated significant reductions in body weight, waist circumference, and body fat mass compared to their baseline values. No statistically significant changes were observed in the placebo group. These findings are consistent with previous randomised controlled trials and clinical research demonstrating the efficacy of multi-ingredient herbal formulations, such as those containing Garcinia cambogia and related compounds, in reducing abdominal fat accumulation and improving metabolic health markers in overweight and obese individuals. [7,8,12]

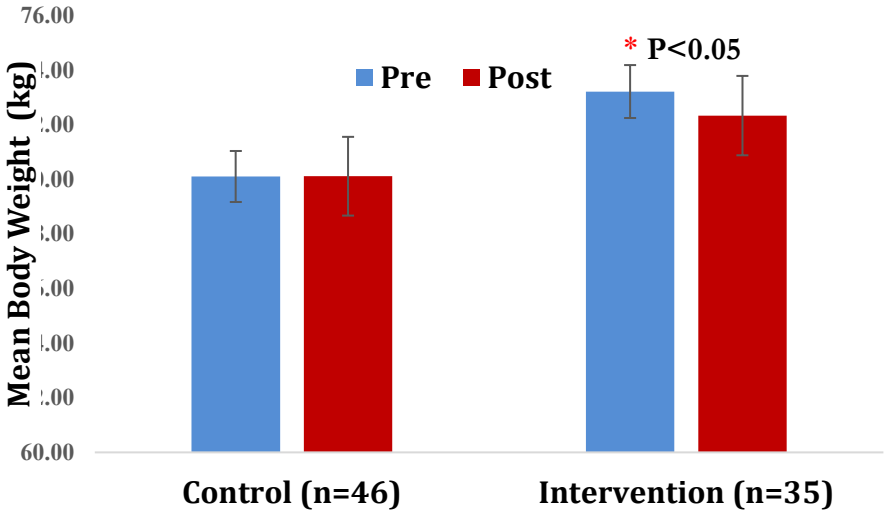

Figure 1: Mean Body weights of the participants during the study period (control =46, intervention =35)

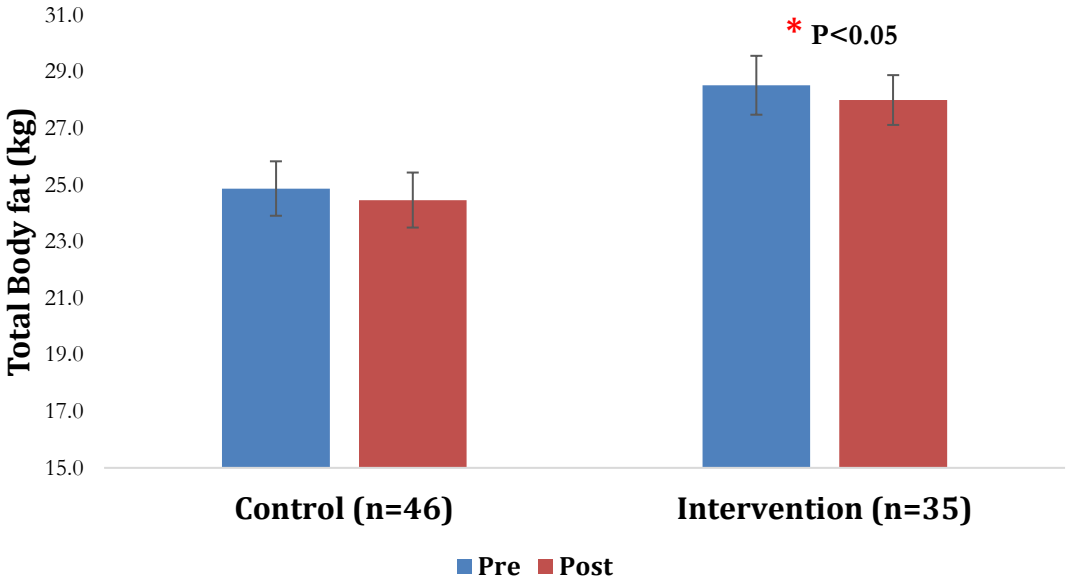

Figure 2: Mean total body fat weights of the participants (control =35, intervention 46)

Figure 1 illustrates the trend in mean body weight across the study period for both groups, while Figure 2 presents the mean total fat weight before and after the intervention.

Table 2. Comparison of mean changes in body weights, waist circumferences and body fat percentages between the treatment and placebo groups at baseline and 12 weeks of post-intervention.

Parameter	Treatment Group (n=35) (M±SD)		Control Group (n=46) (M±SD)	
	Baseline	Post-intervention	Baseline	Post-intervention
Body weight (kg)	73.2±13.0	72.6±13.1*	70.9±8.7	70.4±8.7
WC (cm)	91.0±9.9	88.09±9.9*	88.6±6.7	88.05±7.0
Body fat (%)	38.6±8.0	38.2±8.4*	34.9±8.6	34.5±8.7

The significance of the differences between pre- and post-test results was assessed through paired t-tests conducted before and after. (*$p < 0.05$).

Biochemical Parameters

Table 3. Comparison of mean changes in Biochemical parameters between the treatment and placebo groups at baseline and 12 weeks of post-intervention.

Parameter	Treatment Group (n=35) (M±SD)		Placebo Group (n=46) (M±SD)	
	Baseline	Post-intervention	Baseline	Post-intervention
FBG (mg/dL)	108.6±29.2	103.06±17.9*	108.7±27.8	106.2±24.40
Serum T. C (mg/dL)	207.5±36.8	200.9±34.2	195.3±34.9	189.8±34.1
Serum TG (mg/dL)	155.5±85.6	134.0±73.7*	142.9±123.0	132.5±111.3
Serum HDL (mg/dL)	46.1±10.5	47.9±10.3	46.8±12.25	48.6±11.5
Serum LDL (mg/dL)	130.8±34.7	126.4±32.5	120.5±30.7	115.2±28.8
ALT (U/L)	37.3±37.6	35.2±37.0	37.4±28.3	35.4±24.0
AST (U/L)	25.0±18.5	25.2±17.6	24.9±9.6	25.2±10.0
Serum Creatine mg/dL)	0.80±0.19	0.77±0.19	0.85±0.18	0.83±0.17
Serum Urea (mg/dL)	19.49±4.28	19.88±5.17	20.42±4.80	20.67±5.78
TyG- index	8.9±0.6	8.7±0.6*	8.8±0.6	8.7 ±0.6

A significant reductions of the fasting blood glucose, fasting serum triglycerides and triglyceride-glucose index (TyG-index) (8.9 to 8.7 ($p < 0.05$)) were observed in the treatment group, suggesting improved insulin sensitivity. No significant difference was seen in the control group. The use of the TyG index as a surrogate for insulin resistance is supported by its correlation with gold-standard measurements and its predictive value for metabolic and cardiovascular risk. [9–11]

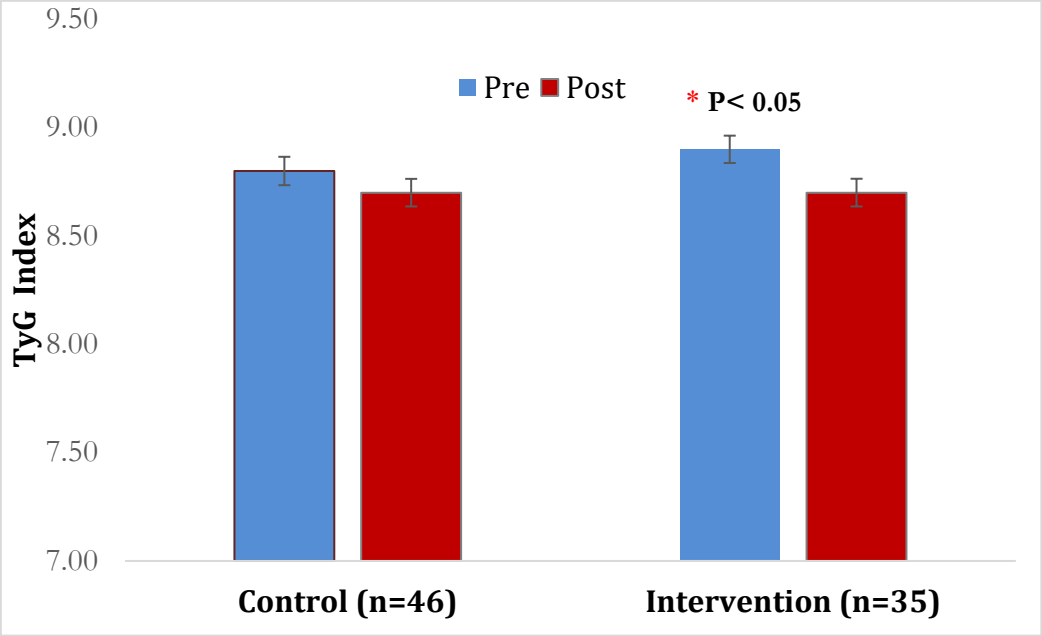

Figure 3: TyG index differences of the participants during the study period (n=81)

Discussion

One of the main findings of this study was the significant improvement in anthropometric and body composition parameters observed among participants who received the multi-ingredient herbal supplement "Garcy" during the intervention period. After three months of supplementation, there was a notable reduction in body weight (73.2 ± 13.0 kg to 72.63 ± 13.1 kg, $p < 0.05$), fat mass (28.5 ± 9.5 kg to 28.0 ± 9.1 kg, $p < 0.05$) and waist circumference (91.01 ± 9.86 cm to 88.1 ± 9.92 cm, $p < 0.05$) a key indicator of central obesity. These findings align with recent systematic reviews and meta-analyses that confirm the beneficial effects of polyherbal and multi-ingredient herbal medicines on body weight, fat mass, and metabolic risk factors among individuals with obesity and metabolic syndrome. [4,12] Interestingly, the improved body composition parameters observed in the intervention group were accompanied by significant changes in biochemical markers such as fasting blood glucose and lipid profiles,

including triglyceride level. A significant improvement in metabolic parameters, including a reduction in triglycerides (155.48 ± 85.65 mg/dL to 133.97 ± 73.69 mg/dL, $p < 0.05$) and fasting blood glucose (108.67 ± 27.88 mg/dL to 103.10 ± 17.96 mg/dL, $p < 0.05$), were observed in the treatment group. Triglyceride Glucose index, which is an indication of insulin resistance, was reduced from 8.9 to 8.7 ($p < 0.05$). These changes were not observed in the control group.

The observed reduction in body weight and body fat mass may be attributed to the synergistic effects of the bioactive compounds in the herbal supplement, including hydroxycitric acid (HCA) from Garcinia cambogia, cinnamaldehyde from Cinnamomum zeylanicum, and piperine from Piper nigrum, acting on multiple metabolic pathways.[5,6,8] HCA, for instance, has been shown to inhibit citrate lyase, thereby reducing de novo fatty acid synthesis and promoting lipid metabolism.[7] Recent clinical trials demonstrate that multi-ingredient supplements containing plant bioactives exert synergistic effects, resulting in significant improvements in weight, fat mass, and metabolic health parameters among overweight and obese adults.[8,12]

Furthermore, the TyG index, as utilized in this study, is not only a validated marker for insulin resistance but is also predictive of future cardiovascular events, subclinical atherosclerosis, and coronary artery calcification.[9–11] This highlights the utility of the TyG index as a valuable tool for metabolic assessment and risk stratification in both clinical and research settings.

The findings of the present study reinforce the value of integrating polyherbal interventions as adjuncts in the management of obesity and metabolic syndrome, as highlighted by comprehensive reviews and experimental studies.[4,8,12] Future research should aim to conduct longitudinal studies with larger sample sizes and longer follow-up periods to validate these findings and further explore the mechanisms underlying the observed benefits of multi-ingredient herbal supplementation.

Liver and kidney function markers, along with CRP values, remained within normal ranges, ensuring the safety of the supplements. Only mild gastric symptoms were observed among few participants in both treatment and control groups during the 12 weeks, and the herbal tablet used in this study was otherwise well tolerated. This highlights the anti-obesity potential of the herbal supplement "**Garsy**", particularly in reducing abdominal fat accumulation, a major contributor to metabolic syndrome and a key risk factor for cardiovascular diseases and insulin resistance.

Conclusion

This study provides important evidence regarding the relationship between weight loss, body fat reduction, and the management of metabolic syndrome in adults. The Garcinia-based multi-ingredient herbal supplement, "**Garsy**", was shown to produce significant reductions in body weight, waist circumference, total body fat, and insulin resistance, while maintaining an excellent safety profile. These findings offer strong support for the efficacy and safety of this herbal supplement in improving body composition and managing central obesity. Furthermore, the results underscore the therapeutic value of combining bioactive compounds with complementary mechanisms of action to address the complex pathophysiology of obesity and metabolic syndrome.

Suggested Recommendation for Future Research

Despite the promising outcomes, this study is subject to limitations, including the relatively short intervention period and modest sample size. Therefore, further extended studies are warranted to assess the long-term efficacy, particularly in diverse populations and across varying degrees of obesity and metabolic syndrome. Additionally, mechanistic studies elucidating the synergistic actions of the supplement's bioactive components will be valuable in optimising polyherbal interventions for obesity and metabolic health.

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