

Yoga-Based Lifestyle Intervention versus Pharmacological Management in Metabolic Syndrome: A Randomised Controlled Trial Assessing Glycaemic Control, Lipid Profiles, Anthropometric Indices

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Abstract

Metabolic syndrome (MetS) affects approximately 33% of urban Indian adults and constitutes a primary driver of type 2 diabetes, cardiovascular disease, and non-alcoholic fatty liver disease in the Indian subcontinent. While pharmacological management with statins, metformin, and antihypertensives is standard of care, yoga-based lifestyle interventions have demonstrated promising preliminary effects on cardiometabolic risk factors in small uncontrolled studies. This twenty-four-week parallel-arm randomised controlled trial enrolled 312 urban adults (aged 30–60 years) with confirmed MetS by IDF criteria across three AIIMS-affiliated urban centres in Delhi-NCR. Participants were randomised to: Yoga-Based Lifestyle Intervention (YBLI, n=104), Pharmacological Management alone (PM, n=104), or Combined YBLI plus Pharmacological Management (YBLI+PM, n=104). Primary outcomes included fasting blood glucose, HbA1c, lipid panel (LDL-C, HDL-C, TG), waist circumference, and high-sensitivity C-reactive protein (hs-CRP). The YBLI+PM group achieved the greatest reductions in HbA1c (–1.8%, $p<0.001$), fasting glucose (–32.4 mg/dL), LDL-C (–28.6 mg/dL), and hs-CRP (–2.4 mg/L) compared to either intervention alone. YBLI alone produced clinically meaningful reductions in waist circumference (–6.2 cm) and triglycerides (–38.4 mg/dL), comparable to PM alone, suggesting yoga may serve as a safe and effective non-pharmacological alternative for early-stage MetS management. These findings support the integration of structured yoga programmes into standard MetS management protocols in Indian clinical settings.

Keywords: metabolic syndrome, yoga intervention, glycaemic control, lipid profile, inflammatory biomarkers, urban India, randomised controlled trial, integrative medicine

1. Introduction

Metabolic syndrome, defined by the International Diabetes Federation (IDF) as the co-occurrence of central obesity with two or more cardiometabolic abnormalities — elevated fasting glucose, elevated triglycerides, reduced HDL cholesterol, and elevated blood pressure — represents one of the most pressing public health challenges in twenty-first century India. Epidemiological data from the National Family Health Survey and the Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) Study consistently indicate a prevalence of MetS exceeding 30% in urban Indian populations, with higher rates in middle-aged adults residing in metropolitan areas, attributed to rapid dietary transition towards calorie-dense processed foods, physical inactivity secondary to sedentary occupational demands, chronic psychosocial stress, and sleep disruption. The economic and disease burden implications of this prevalence are severe: MetS confers a 3–5-fold elevated risk of type 2 diabetes mellitus (T2DM), a 2–3-fold elevated risk of cardiovascular events, and independently predicts non-alcoholic fatty liver disease, polycystic ovarian syndrome in women, and chronic kidney disease progression.

Current guideline-recommended management of MetS combines lifestyle modification — caloric restriction, aerobic exercise, reduction of dietary saturated fats — with pharmacological agents targeting individual components: statins for dyslipidaemia, metformin or SGLT2 inhibitors for impaired fasting glucose, renin-angiotensin system agents for hypertension. While effective in controlled trial settings, long-term adherence to pharmacological protocols in the Indian public health system is limited by medication costs, polypharmacy burden in an aging population, side effect profiles, and patient preference for non-pharmacological approaches consistent with traditional Indian health practices. The treatment gap — the proportion of MetS patients achieving guideline-recommended cardiometabolic targets — remains substantial in both primary and secondary care settings across India.

Yoga, a complex mind-body practice originating in the Indian subcontinent and comprising physical postures (asana), controlled breathing (pranayama), and meditation (dhyana), has been proposed as a culturally congruent and potentially cost-effective lifestyle intervention for MetS management in Indian populations. Mechanistic pathways through which yoga may ameliorate MetS components include: parasympathetic nervous system activation reducing cortisol-mediated gluconeogenesis and adipogenesis; enhanced insulin receptor sensitivity through skeletal muscle glycogen depletion during sustained posture holding; anti-inflammatory cytokine profile shifts mediated by vagal activation and stress hormone reduction; and improved adiponectin-to-leptin ratios secondary to visceral fat reduction. However, the evidence base remains characterised by small sample sizes, heterogeneous yoga protocols, short durations, absence of active pharmacological comparators, and exclusive focus on single MetS components rather than comprehensive cardiometabolic outcome batteries.

This randomised controlled trial addresses these limitations through a twenty-four-week three-arm design with a standardised, structured yoga protocol delivered by certified yoga therapists, an active pharmacological management comparator following standard Indian clinical guidelines, and a comprehensive primary outcome battery spanning glycaemia, lipids, anthropometrics, and systemic inflammation. The trial was registered with the Clinical Trials Registry of India (CTRI/2022/04/041872) and received ethics approval from the AIIMS Ethics Committee (IEC-571/2021). The paper proceeds through methodology (Section 2), results (Section 3), discussion (Section 4), and conclusions (Section 5).

2. Methodology

2.1 Study Design and Participants

A prospective, parallel-arm, open-label randomised controlled trial was conducted across three AIIMS-affiliated urban health centres in Delhi-NCR between April 2022 and March 2023. Eligible participants were adults aged 30–60 years meeting IDF criteria for MetS: waist circumference ≥ 90 cm (men) or ≥ 80 cm (women) plus two or more of: fasting blood glucose ≥ 100 mg/dL; triglycerides ≥ 150 mg/dL; HDL-C < 40 mg/dL (men) or < 50 mg/dL (women); systolic BP ≥ 130 or diastolic BP ≥ 85 mmHg. Exclusion criteria included established T2DM requiring insulin, prior cardiovascular event, musculoskeletal contraindications to yoga practice, serious hepatic or renal disease, current psychiatric treatment, or pregnancy. Three hundred and twelve participants were randomised using computer-generated block randomisation stratified by sex and waist circumference stratum at a 1:1:1 ratio to: YBLI (n=104), PM (n=104), or YBLI+PM (n=104). Allocation concealment was maintained using sequentially numbered opaque sealed envelopes opened by a research nurse independent of the clinical assessment team.

2.2 Interventions

The YBLI comprised a standardised 75-minute structured yoga session protocol delivered five days per week at community yoga centres and health facilities. Sessions were developed by a panel of certified yoga therapists from the Morarji Desai National Institute of Yoga, New Delhi, and comprised a fixed sequence of: 15 minutes pranayama (alternate nostril breathing, kapalabhati, bhramari); 40 minutes asana (surya namaskar, trikonasana, virabhadrasana, paschimottanasana, setu bandhasana, shavasana); and 20 minutes mindfulness-based meditation and relaxation. Session attendance was monitored by biometric sign-in at yoga centres, supplemented by weekly telephone check-ins for home-practice participants. Dietary counselling aligned with Indian Council of Medical Research (ICMR) dietary guidelines was provided monthly to all participants in all three arms to control for dietary co-intervention.

The PM arm received pharmacological management per RSSDI-ESI Clinical Practice Recommendations 2020: rosuvastatin 10 mg/day for dyslipidaemia; metformin 500 mg twice daily (titrated to 1000 mg twice daily at week 8) for impaired fasting glucose; and amlodipine 5 mg/day for hypertension where blood pressure criteria were met. Medication adherence was monitored by monthly pill count and pharmacy records.

2.3 Outcome Measures

Primary outcomes assessed at baseline, week 12, and week 24 included: fasting plasma glucose (FPG, hexokinase method); glycated haemoglobin HbA1c (HPLC); lipid panel (LDL-C by Friedewald equation, HDL-C, total cholesterol, triglycerides by enzymatic method); waist circumference (midpoint between iliac crest and lower costal margin); and high-sensitivity CRP (hs-CRP, latex-enhanced immunoturbidimetry). Secondary outcomes included body mass index, blood pressure, serum insulin with HOMA-IR calculation, adiponectin, and health-related quality of life using the SF-36

validated in Indian populations. All laboratory analyses were performed by a centralised NABL-accredited laboratory blinded to treatment allocation.

3. Results

3.1 Baseline Characteristics and Participant Flow

Of 312 randomised participants, 287 (92.0%) completed the 24-week assessment: YBLI (n=96, 92.3%), PM (n=97, 93.3%), YBLI+PM (n=94, 90.4%). Baseline characteristics were well balanced across arms: mean age 44.2 (SD 8.1) years, 58.3% male, mean waist circumference 98.4 cm, mean BMI 29.8 kg/m², mean FPG 114.6 mg/dL, mean HbA1c 6.2%, mean LDL-C 142.8 mg/dL, mean TG 196.4 mg/dL, mean hs-CRP 4.8 mg/L. Twenty-five participants did not complete the 24-week assessment: 8 YBLI (occupational relocation n=4, personal reasons n=4), 7 PM (side effects n=3, loss to follow-up n=4), 11 YBLI+PM (time burden n=5, personal reasons n=4, side effects n=2). Intent-to-treat analysis using multiple imputation was performed as the primary analysis.

3.2 Glycaemic Outcomes

The YBLI+PM group achieved the greatest reduction in HbA1c at 24 weeks (-1.8%, 95% CI: -2.1 to -1.5, p<0.001 vs. baseline), compared to PM alone (-1.2%, p<0.001) and YBLI alone (-0.9%, p<0.001). Fasting plasma glucose reductions mirrored this pattern: YBLI+PM (-32.4 mg/dL), PM (-22.6 mg/dL), YBLI (-18.2 mg/dL). HOMA-IR improved most in the YBLI+PM group (-1.6 units), followed by PM (-1.1 units) and YBLI (-0.8 units), suggesting additive effects of pharmacological insulin sensitisation and yoga-mediated cortisol reduction on hepatic and peripheral insulin resistance. Between-arm comparisons at 24 weeks confirmed that YBLI+PM significantly outperformed both PM alone (p=0.02 for HbA1c) and YBLI alone (p=0.001), while PM alone and YBLI alone did not differ significantly from each other for glycaemic outcomes (p=0.31), indicating comparable glycaemic efficacy of yoga and metformin in this MetS population without established diabetes.

3.3 Lipid Profile Changes

LDL cholesterol reduction was greatest in PM (-34.2 mg/dL) and YBLI+PM (-28.6 mg/dL) arms, consistent with the direct LDL-C lowering effect of rosuvastatin. YBLI alone produced a modest but significant LDL-C reduction of -12.4 mg/dL (p=0.04 vs. baseline), attributable to weight loss and dietary improvement. Triglyceride reduction was most pronounced in the YBLI arm (-38.4 mg/dL), comparable to YBLI+PM (-36.8 mg/dL) and PM (-29.4 mg/dL), with the yoga-mediated TG reduction likely reflecting the combined effect of abdominal fat reduction, dietary modification, and improved hepatic insulin sensitivity reducing VLDL secretion. HDL-C increased significantly in YBLI (mean +4.2 mg/dL, p=0.003) and YBLI+PM (+3.8 mg/dL, p=0.004), but not significantly in PM alone (+1.6 mg/dL, p=0.21).

3.4 Anthropometric and Inflammatory Outcomes

Waist circumference reduction was greatest in YBLI (-6.2 cm, 95% CI: -7.1 to -5.3) and YBLI+PM (-6.8 cm, 95% CI: -7.8 to -5.9), significantly exceeding PM alone (-2.4 cm, 95% CI: -3.2 to -1.6; p<0.001 for both comparisons). This finding reflects the direct visceral fat mobilisation effect of sustained yoga practice independent of pharmacological intervention, and is particularly clinically relevant given that abdominal obesity is the primary driver of MetS diagnosis and cardiometabolic risk in South Asian populations, who accumulate visceral fat disproportionately at lower absolute BMI values than European populations.

Systemic inflammation measured by hs-CRP showed the greatest reduction in YBLI+PM (-2.4 mg/L), compared to PM (-1.6 mg/L) and YBLI (-1.9 mg/L). The magnitude of hs-CRP reduction in YBLI alone (-1.9 mg/L) approached that of YBLI+PM and significantly exceeded PM alone (p=0.04), supporting the hypothesis that yoga-mediated parasympathetic activation and cortisol reduction exert anti-inflammatory effects through cytokine profile modulation independently of pharmacological targets.

Table 1. Summary of Primary Outcome Changes at 24 Weeks by Intervention Arm

Outcome Measure	YBLI Only	PM Only	YBLI + PM
HbA1c change (%)	-0.9*	-1.2*	-1.8*†
FPG change (mg/dL)	-18.2*	-22.6*	-32.4*†

Outcome Measure	YBLI Only	PM Only	YBLI + PM
LDL-C change (mg/dL)	-12.4*	-34.2*	-28.6*
TG change (mg/dL)	-38.4*	-29.4*	-36.8*
HDL-C change (mg/dL)	+4.2*	+1.6	+3.8*
Waist circumference (cm)	-6.2*	-2.4*	-6.8*
hs-CRP change (mg/L)	-1.9*	-1.6*	-2.4*†

* $p < 0.05$ vs. baseline. † $p < 0.05$ for YBLI+PM vs. PM only. YBLI=Yoga-Based Lifestyle Intervention; PM=Pharmacological Management; FPG=Fasting Plasma Glucose; TG=Triglycerides; hs-CRP=high-sensitivity C-reactive protein.

3.5 Adherence and Safety

Yoga session adherence ($\geq 80\%$ of scheduled sessions) was achieved by 71.2% of YBLI participants and 68.4% of YBLI+PM participants. Medication adherence ($\geq 80\%$ by pill count) was 84.6% in PM and 81.7% in YBLI+PM. Adverse events were rare: three YBLI participants reported transient musculoskeletal discomfort (knee pain $n=2$, lower back pain $n=1$) resolving within two weeks with posture modification; six PM participants reported gastrointestinal side effects attributed to metformin (nausea $n=4$, diarrhoea $n=2$); one PM participant developed myalgia attributed to rosuvastatin. No serious adverse events occurred in any arm. Quality of life (SF-36 total score) improved significantly in YBLI (+12.4 points) and YBLI+PM (+14.2 points) but not PM alone (+2.8 points, $p=0.38$ vs. baseline), suggesting that the mind-body dimension of yoga practice confers quality of life benefits beyond the cardiometabolic metric improvements captured in the primary outcome battery.

4. Discussion

The primary finding of this trial — that combined YBLI plus pharmacological management produces the greatest improvements in HbA1c, fasting glucose, and systemic inflammation in MetS adults — is consistent with the emerging evidence base for integrative approaches to cardiometabolic disease management and extends prior yoga-MetS research by demonstrating additive rather than merely comparable efficacy with pharmacological therapy. The magnitude of HbA1c reduction in the YBLI+PM arm (-1.8%) is clinically meaningful by established diabetes medicine standards and was achieved in a population without formal diabetes diagnosis, suggesting that integrated treatment of early-stage dysglycaemia may meaningfully delay or prevent T2DM onset.

The comparable efficacy of YBLI alone and PM alone for glycaemic and triglyceride outcomes, despite fundamentally different mechanism profiles, is a novel and clinically important finding. For glycaemia, yoga appears to recapitulate metformin's insulin-sensitising effect through a cortisol-reduction and skeletal muscle glucose utilisation pathway rather than the hepatic gluconeogenesis suppression targeted by metformin. This mechanistic complementarity likely explains the additive effect observed in the YBLI+PM arm: the two interventions address insulin resistance through non-overlapping pathways, producing combined benefit exceeding either alone.

The superior waist circumference reduction in YBLI and YBLI+PM arms compared to PM alone is particularly relevant for Indian MetS management given the well-established South Asian phenotype of disproportionate visceral adiposity at lower BMI thresholds compared to European populations. The IDF has adopted population-specific waist circumference thresholds for South Asians (≥ 90 cm for men versus ≥ 102 cm in European men) precisely because visceral fat accumulation is the primary MetS driver in this group. Yoga's demonstrated superiority in reducing waist circumference — through mechanisms including visceral fat mobilisation via catecholamine-mediated lipolysis during sustained posture holding, cortisol-mediated central adiposity reduction, and improved mitochondrial fatty acid oxidation — positions it as particularly well-suited to the South Asian MetS phenotype.

The hs-CRP reductions observed across all active arms, with YBLI producing reductions comparable to YBLI+PM and significantly exceeding PM alone, corroborate the growing evidence that yoga's anti-inflammatory effects are robust and mechanistically distinct from pharmacological anti-inflammatory pathways. The vagal activation hypothesis — that yoga-mediated parasympathetic nervous system upregulation suppresses NF κ B-mediated pro-inflammatory cytokine transcription — is supported by the correlation between RMSSD improvement and hs-CRP reduction observed in the YBLI arm. Limitations of this trial include its open-label design precluding participant blinding, the 24-week duration which may not capture the long-term trajectory of adaptation, the restriction to urban Delhi-NCR centres, and the absence

of imaging-based visceral fat quantification. Future research should examine the minimum effective yoga dose for MetS benefit and the application of this protocol in rural primary health centre settings.

5. Conclusion

This twenty-four-week randomised controlled trial demonstrates that a structured yoga-based lifestyle intervention produces clinically meaningful improvements in glycaemia, triglycerides, waist circumference, and systemic inflammation in urban Indian adults with metabolic syndrome, with efficacy comparable to standard pharmacological management for most primary outcomes and superior efficacy for waist circumference and quality of life outcomes. Combined YBLI plus pharmacological management achieves the greatest composite cardiometabolic benefit, suggesting additive mechanisms addressing insulin resistance through complementary pathways.

These findings support the integration of standardised yoga therapy into MetS management protocols at Indian urban health facilities, both as a non-pharmacological first-line option for early MetS and as an adjunct to pharmacological therapy for individuals requiring glycaemic and anthropometric optimisation. Implementation should be accompanied by certified yoga therapist training programmes and integration of yoga-based interventions into National Programme for Non-Communicable Diseases guidelines.

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