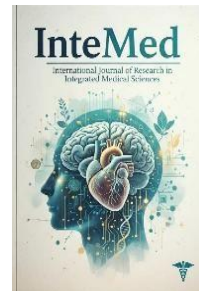




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Review Article

Combined Yogic Practices and Ayurvedic Dinacharya in Adults With Perceived Stress Poor Sleep and Metabolic Risk Study Protocol for a Three Arm Randomized Controlled Trial

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Abstract:

Background: Perceived stress, poor sleep, physical inactivity and metabolic risk commonly occur together. Yoga may improve stress and sleep, while Ayurvedic *Dinacharya* provides a structured framework for waking, hygiene, physical activity, meal timing and sleep. Existing studies do not establish whether adding a standardized *Dinacharya* programme provides benefit beyond Yoga alone.

Objective: To determine whether a 12-week programme of standardized Yoga plus Ayurvedic *Dinacharya* reduces perceived stress more than standard lifestyle advice and whether *Dinacharya* adds benefit beyond the same Yoga programme alone.

Methods: This assessor-blinded, three-arm, parallel randomized controlled trial will enrol 228 adults aged 18 to 60 years with an operationally defined elevated Perceived Stress Scale score, poor sleep quality and at least one metabolic risk indicator. Participants will be allocated

equally to standard lifestyle advice, standardized Yoga, or the same Yoga programme plus standardized *Dinacharya*. The intervention will last 12 weeks, with follow-up at week 24. The primary outcome is change in the 10-item Perceived Stress Scale score from baseline to week 12 for Yoga plus *Dinacharya* versus standard advice. Secondary outcomes include sleep quality, anthropometry, blood pressure, fasting glucose, lipid profile, adherence and adverse events. The primary analysis will follow the intention-to-treat principle.

Ethics and registration: Institutional ethics approval and prospective Clinical Trials Registry India registration will be obtained before the first participant is enrolled. Written informed consent will be required. Trial findings will be reported regardless of direction or statistical significance.

Trial status: Recruitment has not started. The planned recruitment period is 12 months after ethics approval and prospective registration.

Keywords: Yoga, *Dinacharya*, perceived stress, sleep quality, metabolic risk, randomized controlled trial, Ayurveda

Introduction

Psychological stress, inadequate sleep and metabolic abnormalities frequently share behavioural determinants. Irregular work and sleep schedules, limited physical activity, late meals and sustained psychological arousal may influence perceived stress, sleep continuity, body weight, glucose regulation, blood pressure and lipid levels. An intervention that changes daily behaviour may therefore affect more than one of these outcomes.

Ayurveda describes *Dinacharya* as an organized daily regimen that includes waking, personal hygiene, elimination, *Abhyanga*, *Vyayama*, food related discipline and sleep.^{1,2} These practices must be converted into explicit, measurable behaviours before they can be evaluated clinically. Classical concepts will not be treated as direct equivalents of hormones, metabolism or circadian physiology.

Yoga combines physical postures, regulated breathing, focused attention and relaxation. A recent systematic review found low-certainty evidence that Yoga reduces perceived stress compared with passive controls, while evidence against active comparators remained less clear.³ Trials in insomnia, type 2 diabetes and metabolic syndrome have also reported changes in sleep, anthropometric measures, glycaemic indices and lipid parameters, although Yoga styles and co-interventions differed substantially.⁴⁻⁷

Direct evidence for integrated Yoga and Ayurveda is limited. A recent pilot combined brief Yoga with an Ayurvedic herbal intervention in psychotropic-associated metabolic syndrome, but the single-arm design, high attrition and multiple intervention components prevented causal attribution.⁸ No controlled trial identified in the preparatory review isolated the incremental effect of adding a standardized *Dinacharya* programme to the same Yoga module.

The present protocol therefore uses three parallel groups: standard lifestyle advice, Yoga alone, and Yoga plus *Dinacharya*. This design estimates the overall effect of the combined programme and the additional effect of *Dinacharya* beyond Yoga. The protocol follows SPIRIT 2025 principles and uses the TIDieR framework to describe each intervention in reproducible detail.^{9,10}

Aim

To evaluate the effect of a standardized 12-week Yoga and Ayurvedic *Dinacharya* programme on perceived stress, sleep quality and selected metabolic risk measures in adults.

Objectives

Primary Objective

To compare the change in the 10-item Perceived Stress Scale score from baseline to week 12 between the Yoga plus *Dinacharya* group and the standard lifestyle advice group.

Secondary Objectives

- To compare perceived stress in the Yoga plus *Dinacharya* group with the Yoga alone group at week 12.
- To compare sleep quality, anthropometry, blood pressure, fasting glucose and lipid parameters across the three groups.
- To determine whether changes observed at week 12 are maintained at week 24 for outcomes that do not require fasting laboratory testing.
- To assess recruitment, retention, intervention adherence, protocol fidelity and adverse events.

Hypotheses

The primary hypothesis is that Yoga plus *Dinacharya* will produce a greater reduction in perceived stress at week 12 than standard lifestyle advice. The key secondary hypothesis is that Yoga plus *Dinacharya* will produce a greater reduction than Yoga alone, indicating an additional effect of the daily regimen. Secondary hypotheses concern improvement in sleep quality and selected metabolic risk measures.

Materials and Methods

Study Design

This is a prospective, single-centre, assessor-blinded, three-arm, parallel randomized controlled trial with 1:1:1 allocation. The active intervention will last 12 weeks. Participants will be followed for a further 12 weeks without supervised sessions to assess maintenance. The primary endpoint is week 12.

Table 1 Trial design and comparison groups

Group	Intervention	Schedule	Purpose
A	Standard lifestyle advice and usual medical care	One structured counselling session, written guidance and neutral fortnightly contact for 12 weeks	Pragmatic comparison for the full combined programme
B	Standardized Yoga plus usual medical care	50 minute sessions on 5 days each week for 12 weeks	Estimates the effect of Yoga without prescribed <i>Dinacharya</i>
C	The same standardized Yoga plus Ayurvedic <i>Dinacharya</i> and usual medical care	Yoga on 5 days each week plus daily regimen targets for 12 weeks	Estimates the combined effect and the incremental contribution of <i>Dinacharya</i>

individuals will receive written study information before consent. Screening will include medical history, medication review, physical examination, the study questionnaires, blood pressure, anthropometry and fasting laboratory tests.

Eligibility Criteria

Inclusion Criteria

- Age 18 to 60 years, irrespective of sex.
- A 10-item Perceived Stress Scale score of at least 14 at screening. This is an operational recruitment threshold and not a psychiatric diagnosis.
- A Pittsburgh Sleep Quality Index global score greater than 5.
- At least one metabolic risk indicator: body mass index from 23.0 to 34.9 kg per square metre; waist circumference at least 90 cm in men or 80 cm in women; resting blood pressure at least 130 over 85 mmHg but below 160 over 100 mmHg; fasting plasma glucose from 100 to 125 mg per dL; triglycerides at least 150 mg per dL; or HDL cholesterol below 40 mg per dL in men or 50 mg per dL in women.¹¹
- Ability to participate safely in modified low to moderate intensity Yoga after clinical screening.
- Willingness to maintain usual prescribed medication and report every medication or treatment change.
- Written informed consent.

Exclusion Criteria

- Confirmed diabetes requiring glucose lowering medication, fasting plasma glucose at least 126 mg per dL on repeat testing, or another metabolic condition requiring immediate treatment modification.
- Resting blood pressure at least 160 over 100 mmHg, unstable cardiovascular disease, recent myocardial infarction or stroke, uncontrolled arrhythmia, or another condition that makes exercise unsafe.
- Severe renal, hepatic, neurological, musculoskeletal or systemic illness likely to prevent adherence or affect the outcome measures.
- Current psychosis, bipolar mania, active substance dependence, severe major depression with suicide risk, or

Study Setting and Duration

The trial is planned at a tertiary Ayurveda teaching hospital and its affiliated community outreach services in Pune, Maharashtra, India. Recruitment will begin only after ethics approval and prospective registration. The anticipated study period is 18 months, comprising up to 12 months of recruitment and completion of the 24-week follow-up for the final participant.

Study Population

Adults with perceived stress, poor sleep and at least one metabolic risk indicator will be recruited from outpatient services, staff and student health referrals, community screening activities and approved public notices. Interested

another psychiatric condition requiring urgent specialist care.

- Diagnosed or clinically suspected untreated moderate to severe obstructive sleep apnoea, restless legs syndrome, parasomnia or another primary sleep disorder requiring specialist assessment.
- Night shift work during the intervention or expected major travel across time zones.
- Pregnancy, lactation, planned pregnancy during the trial, or major surgery within the preceding three months.
- Structured Yoga practice more than twice weekly during the preceding three months or current participation in another lifestyle intervention trial.
- Known allergy to sesame oil or a positive patch test before prescribed *Abhyanga*.

Consent and Enrolment

A trained investigator will explain the purpose, procedures, foreseeable discomforts, possible benefits, alternatives, confidentiality protections and voluntary nature of participation. Candidates will receive adequate time to ask questions. Written informed consent will be obtained before any trial-specific procedure. Individuals with screening findings that require clinical evaluation will be informed and referred; enrolment will not delay necessary care.

Randomization and Allocation Concealment

An independent statistician who is not involved in recruitment will create a computer-generated allocation sequence using randomly varied block sizes of six and nine. Randomization will be stratified by sex and baseline perceived stress category, defined as a score below 27 or at least 27. Group assignments will be placed in sequentially numbered, opaque, sealed envelopes or implemented through a password-protected allocation system. The next assignment will be released only after eligibility, consent and baseline assessment are complete. Recruiters will not have access to the sequence or block sizes.

Blinding

Participants and intervention instructors cannot be blinded to behavioural treatment. Outcome assessors, laboratory staff and the statistician conducting the primary coded analysis will remain unaware of allocation. Participants will be reminded not to disclose their group during

assessments. Any unblinding and its reason will be documented.

Interventions

Intervention Preparation

A detailed intervention manual will define the sequence, duration, frequency, permitted modifications, contraindications, home practice instructions and adherence records. Yoga instructors and lifestyle counsellors will complete protocol training before recruitment. The same Yoga module will be used in Groups B and C. Major dietary prescriptions, weight loss targets and medication changes will not form part of the experimental intervention, because they would prevent attribution of effects to Yoga and *Dinacharya*.

Group A Standard Lifestyle Advice

Participants will receive one individual 30 minute session covering general recommendations on physical activity, balanced meals, sleep opportunity, tobacco and alcohol avoidance, and continuation of prescribed medical care. Written guidance will not contain Yoga instruction, individualized meal timing, *Abhyanga* or a structured *Dinacharya* checklist. Neutral fortnightly contacts will record health changes and adverse events without providing the active protocol. After the week 24 assessment, participants may receive the Yoga manual if they request it.

Group B Standardized Yoga

Participants will perform a 50-minute Yoga module on five days each week for 12 weeks. Three weekly sessions will be supervised in person or by an approved live remote format, and two will be guided home sessions. The first two supervised sessions will emphasize safe technique and individualized modifications. Breath holding, forceful breathing and competitive performance will not be used.

Table 2 Standardized Yoga module for Groups B and C

Component	Content	Duration	Safety and progression
Arrival and breath awareness	Comfortable sitting or supported posture with diaphragmatic breathing	3 minutes	No breath retention
Loosening practices	Gentle neck, shoulder, wrist, hip, knee and ankle movements with slow marching	7 minutes	Range adapted to pain and balance
Asana	<i>Tadasana</i> , <i>Ardha Kati Chakrasana</i> , supported <i>Trikonasana</i> , <i>Vakrasana</i> , <i>Bhujangasana</i> , <i>Setu Bandhasana</i> and modified <i>Pavanamuktasana</i>	20 minutes	Chair or wall support and reduced range permitted
Pranayama	Slow diaphragmatic breathing, <i>Nadi Shodhana</i> without retention and <i>Bhramari</i>	10 minutes	Stop for dizziness, distress or breathlessness
Meditation	Breath focused attention with nonjudgmental redirection	5 minutes	Eyes may remain open if preferred
Relaxation	Supported <i>Shavasana</i> or seated guided relaxation	5 minutes	Position modified for comfort

Group C Yoga Plus Dinacharya

Participants will receive the identical Yoga module and supervision used in Group B. They will also follow a standardized daily regimen based on selected practical elements of *Dinacharya*. Each behaviour is defined in measurable terms. The programme does not claim that these behaviours are biologically equivalent to specific modern physiological pathways.

Table 3 Standardized Dinacharya protocol for Group C

Component	Operational prescription	Adherence record	Precautions
Regular waking	Choose a feasible daily wake time and remain within 30 minutes on at least 6 days each week	Daily time entry	Adjusted for unavoidable caregiving or medical needs
Morning hygiene	Oral hygiene and gentle tongue cleansing after waking	Daily yes or no entry	Stop tongue cleansing for pain, bleeding or oral lesions
Bowel routine	Allow an unhurried morning opportunity after hydration without force or suppression of natural urge	Daily yes or no entry	No straining, laxative initiation or delay of indicated care
Abhyanga	After a negative patch test, apply approximately 20 mL plain sesame oil to limbs and trunk for 10 minutes before bathing on 3 mornings each week	Date and skin response	Avoid broken skin, active dermatitis, fever and slippery surfaces

Component	Operational prescription	Adherence record	Precautions
Meal timing	Use individually selected meal windows with no more than 60 minutes day-to-day variation; finish the evening meal at least 2.5 hours before planned bedtime	Meal and bedtime diary	No calorie restriction is prescribed; medically required meal timing takes priority
Regular sleep	Choose a feasible bedtime and remain within 30 minutes on at least 6 nights each week while allowing adequate sleep opportunity	Daily bedtime and wake time	Persistent insomnia or excessive sleepiness triggers clinical review
Reduced presleep stimulation	Avoid work, emotionally activating media and bright handheld screens during the final 60 minutes before bedtime	Daily yes or no entry	Recorded as a contemporary behavioral adaptation rather than a classical procedure

Adherence and Intervention Fidelity

Yoga adherence will equal completed sessions divided by the 60 prescribed sessions, expressed as a percentage. Supervised attendance will be recorded by the instructor; home practice will be documented in a diary and reviewed weekly. *Dinacharya* adherence will equal achieved component days divided by prescribed component days. Adherence of at least 80 percent will define the per-protocol population but will not determine inclusion in the primary intention-to-treat analysis.

All instructors will use the same manual and session checklist. A trained supervisor will observe a random 10 percent of sessions and score sequence, duration, prohibited practices and permitted modifications. Corrective training will be documented. Group B contacts will match the brief weekly review time given to Group C, but will address attendance and safety only and will not prescribe *Dinacharya*.

Concomitant Care

Routine medical care will continue in every group. Investigators will not stop or reduce prescribed medication. Participants will be asked not to begin another structured Yoga, meditation, sleep or weight reduction programme during the 12-week intervention. Every medication change, acute illness, major dietary change and new co-intervention will be recorded and considered in sensitivity analyses.

Outcome Measures

Primary Outcome

The primary outcome is the between-group difference in change in the 10-item Perceived Stress Scale score from baseline to week 12 for Group C versus Group A. The PSS-10 asks about perceived stress during the preceding month and yields a total score from 0 to 40, with higher values indicating greater perceived stress.^{12,13} An approved language version suitable for each participant will be used consistently. The Hindi version has demonstrated acceptable reliability and validity in an Indian community sample.¹⁴ Any additional translation required by the study population will undergo permission, forward and backward translation, cognitive testing and psychometric evaluation before recruitment.

Secondary Outcomes

Sleep quality will be measured with the Pittsburgh Sleep Quality Index, which assesses sleep quality and disturbance over the preceding month and yields a global score from 0

to 21. Higher scores indicate poorer sleep, and a score above 5 identifies poor sleepers in the original validation study.¹⁵ Required permission and approved language versions will be obtained before use.

Body weight will be measured on a calibrated digital scale in light clothing without footwear. Height will be measured once with a wall mounted stadiometer. Body mass index will be calculated as weight in kilograms divided by height in metres squared. Waist circumference will be measured at the midpoint between the lowest rib and the iliac crest at the end of normal expiration. Two measurements within 0.5 cm will be averaged; a third will be taken when they differ by more than 0.5 cm.

Resting blood pressure will be measured with a validated automated device after at least five minutes of seated rest, with an appropriate cuff and no exercise, caffeine or tobacco during the preceding 30 minutes. Two readings one minute apart will be averaged. A third reading will be obtained when the first two differ by more than 10 mmHg systolic or 6 mmHg diastolic.

Fasting plasma glucose, total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol will be measured after an 8 to 12 hour overnight fast at baseline and week 12 in an accredited laboratory using the same methods at both visits. Clinically important abnormal findings will be communicated and referred for medical evaluation.

Table 4 Outcomes and prespecified interpretation

Domain	Measure	Primary time point	Planned interpretation
Perceived stress	PSS-10 total score	Week 12	Primary comparison Group C versus Group A; key secondary comparison Group C versus Group B
Sleep	PSQI global score	Week 12	Between group difference in change and proportion with score no greater than 5

Domain	Measure	Primary time point	Planned interpretation
Anthropometry	Weight, body mass index and waist circumference	Week 12	Adjusted mean differences with 95 percent confidence intervals
Cardiovascular	Systolic and diastolic blood pressure	Week 12	Adjusted mean differences with 95 percent confidence intervals
Biochemical	Fasting glucose, total cholesterol, triglycerides, LDL and HDL cholesterol	Week 12	Adjusted mean differences; log transformation considered for skewed triglycerides
Maintenance	PSS-10, PSQI, weight, waist circumference and blood pressure	Week 24	Exploratory persistence after supervised intervention ends

Domain	Measure	Primary time point	Planned interpretation
Feasibility and safety	Recruitment, retention, adherence, protocol fidelity and adverse events	Throughout	Counts, proportions and event rates by group

Assessment Schedule

Table 5 Schedule of enrolment interventions and assessments

Procedure	Screening	Baseline	Week 6	Week 12	Week 24
Information and consent	X				
Eligibility and medical review	X				
Randomization		X			
PSS-10 and PSQI	X	X	X	X	X
Weight and waist circumference	X	X	X	X	X

Procedure	Screening	Baseline	Week 6	Week 12	Week 24
Blood pressure	X	X	X	X	X
Fasting glucose and lipid profile	X	X		X	
Intervention delivery		X	X	X	
Adherence and co-interventions		X	X	X	X
Adverse events	X	X	X	X	X

Sample Size

The calculation is based on the single primary comparison of Group C with Group A for change in PSS-10 at week 12. In the absence of a directly applicable pilot estimate, the protocol assumes a standardized between-group difference of 0.50, a two-sided alpha of 0.05 and 80 percent power. This requires approximately 64 evaluable participants in each compared group. Allowing 15 percent attrition requires 76 participants per group. Equal allocation across three groups therefore gives a total recruitment target of 228 participants. This calculation is conservative because the primary model will use repeated observations and baseline adjustment.

Data Collection and Quality Control

Each participant will receive a unique trial code. Source records and case report forms will be completed in ink or in a validated electronic system with an audit trail. Range checks will be built into data entry. A second trained person will verify all primary outcome values, eligibility fields, randomization codes and serious adverse events, together with a random 10 percent sample of remaining fields.

Corrections will preserve the original entry, date and reason.

Questionnaire assessors will receive standardized instructions and will not coach responses. Scales will be scored only after all items have been reviewed for completeness. Equipment calibration, cuff size, fasting status and measurement time will be recorded. Laboratory reports will be imported or entered independently and checked against source documents.

Statistical Analysis

A detailed statistical analysis plan will be finalized and dated before group codes are released for the primary analysis. The primary analysis will follow the intention-to-treat principle and include all randomized participants in their assigned groups. Baseline characteristics will be summarized without significance testing. Continuous variables will be described with mean and standard deviation or median and interquartile range according to distribution; categorical variables will be described with counts and percentages.

The primary outcome will be analysed using a linear mixed-effects model containing group, time, the group-by-time interaction, baseline stress stratum and sex as fixed effects, with a participant-specific random intercept. The prespecified primary contrast is the adjusted difference between Group C and Group A at week 12. The result will be reported as an adjusted mean difference with a 95 percent confidence interval and two-sided P value. Statistical significance for the primary comparison will use an alpha of 0.05.

The Group C versus Group B contrast is the key secondary comparison for the incremental effect of *Dinacharya*. Group B versus Group A and all sleep, anthropometric, blood pressure and biochemical comparisons are secondary. Secondary outcomes will use an appropriate generalized or linear mixed model with baseline adjustment. Holm correction will be applied within related families of secondary comparisons. Effect estimates and confidence intervals will be emphasized rather than isolated P values.

Model assumptions will be examined with residual plots. Skewed laboratory outcomes may be log-transformed; when a suitable model cannot be obtained, a rank-based or robust analysis will be used. Binary outcomes will be

analysed with log-binomial or Poisson regression with robust variance. No interim efficacy analysis is planned.

Mixed models provide valid estimates under a missing-at-random assumption when the model is correctly specified. The amount and reasons for missing data will be reported by group. Sensitivity analyses will include multiple imputation using baseline predictors and observed follow-up values, a complete-case analysis, and a per-protocol analysis restricted to participants with at least 80 percent adherence. No last-observation-carried-forward procedure will be used. Exploratory mediation and subgroup analyses will be clearly labelled and interpreted without confirmatory claims.

Safety Monitoring

Expected risks include transient muscle soreness, joint discomfort, dizziness, loss of balance, presyncope, anxiety during breath-focused practice, skin irritation from sesame oil and falls on an oily surface. Instructors will review symptoms before each supervised session. Practices will be modified or stopped for pain, chest discomfort, unusual breathlessness, marked dizziness, syncope, palpitations, acute illness or a participant request.

Adverse events will be recorded from consent through week 24 and classified by severity, seriousness, expectedness and relatedness. Serious adverse events will be communicated promptly to the principal investigator and reported to the ethics committee according to institutional timelines. An independent physician not involved in intervention delivery will review serious or unexpected events. A formal data safety monitoring board is not planned for this low-risk behavioural trial unless required by the ethics committee.

The intervention may be discontinued for an individual after a serious related event, repeated clinically important symptoms, newly identified contraindication, pregnancy, medical advice, inability to follow safety instructions or participant request. Discontinuation of the intervention will not automatically withdraw permission for follow-up unless the participant requests complete withdrawal.

Ethical Considerations

The study will begin only after approval by a registered Institutional Ethics Committee. Conduct will follow the 2024 Declaration of Helsinki and the Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human

Participants.^{16,17} The protocol, participant information sheet, consent forms, recruitment materials, questionnaires and amendments will receive ethics review before use.

The trial will be registered prospectively with the Clinical Trials Registry India before the first participant is enrolled, consistent with CTRI requirements for lifestyle and AYUSH related interventional research.¹⁸ The registration record will state the final site, investigators, sample size, outcomes, allocation method, intervention details, recruitment dates, funding, competing interests and data sharing plan.

Participation is voluntary. Refusal or withdrawal will not affect usual care. Identifiable information will be stored separately from research data and accessed only by authorized staff. Publications will use aggregate results. Medical management and compensation for research related injury will follow applicable national and institutional requirements.

Protocol Amendments

Any substantive change to eligibility, interventions, primary outcome, sample size, analysis or safety procedures will be dated, justified and approved before implementation, except when an immediate change is required to protect participants. Approved changes will be updated in the registry, intervention manual, participant documents and subsequent publications.

Dissemination

The final randomized trial will be reported in accordance with CONSORT 2025 and the intervention descriptions will be updated using TIDieR.^{19,10} Results will be submitted for peer reviewed publication regardless of magnitude, direction or statistical significance. The registry will be updated after study completion. Participants who request it will receive a plain language summary.

After publication of the primary report, the deidentified participant data underlying the published results, a data dictionary and statistical code will be available from the corresponding investigator for approved scientific proposals, subject to ethics approval, participant consent and a signed data-use agreement. The planned access period is from six months until five years after publication.

Discussion

This protocol addresses a specific gap in the evidence. Studies of Yoga frequently compare a complex programme

with no treatment or combine Yoga with dietary counselling, making component effects difficult to interpret. The proposed three group design keeps the Yoga module identical in Groups B and C and defines each *Dinacharya* behaviour, allowing a direct estimate of its additional contribution.

The study selects one primary outcome and one primary comparison. Sleep and metabolic measures remain clinically important secondary outcomes, but they will not be used to redefine the trial after data are available. The week 24 follow-up will show whether behavioural changes persist after supervised treatment. Adherence and fidelity measures will help distinguish failure of the intervention from failure to deliver or follow it.

Several limitations will remain. Participants and instructors cannot be blinded, and self-reported stress, sleep and adherence are susceptible to expectation and reporting effects. The standard advice group will receive less intervention contact than the active groups, so the primary comparison estimates a pragmatic package effect rather than a purely specific treatment effect. The single-centre setting may limit generalizability. Requiring stress, poor sleep and metabolic risk creates a clinically relevant sample but will not represent all adults who practise Yoga or *Dinacharya*.

The protocol deliberately avoids unsupported one-to-one translations of Ayurvedic concepts into modern biological mechanisms. Its scientific question is behavioural and clinical: whether a reproducibly defined daily regimen improves prespecified outcomes when added to the same Yoga programme.

Conclusion

This protocol provides a complete and testable method for evaluating combined Yoga and Ayurvedic *Dinacharya* without assuming an effect before data are collected. Prospective registration, concealed randomization, assessor blinding, standardized interventions, one primary outcome, intention-to-treat analysis and explicit safety monitoring are intended to produce findings that can be interpreted and reproduced.

Declarations

Ethics approval: Approval will be obtained from a registered Institutional Ethics Committee before recruitment.

Trial registration: Prospective CTRI registration will be completed before enrolment of the first participant.

Consent: Written informed consent will be obtained from every participant before trial-specific procedures.

Data availability: No participant dataset exists because recruitment has not started. The planned sharing procedure is described in the Dissemination section.

References

1. Agnivesha. Charaka Samhita, revised by Charaka and Dridhabala, with Ayurveda Dipika commentary of Chakrapanidatta. Acharya YT, editor. Sutrasthana, Chapter 5, Matrashitiya Adhyaya. Varanasi: Chaukhambha Surbharati Prakashan; 2017.
2. Vagbhata. Ashtanga Hridaya, with Sarvangasundara commentary of Arunadatta and Ayurveda Rasayana commentary of Hemadri. Paradakara HS, editor. Sutrasthana, Chapter 2, Dinacharya Adhyaya. Varanasi: Chaukhambha Surbharati Prakashan; 2018.
3. Schleinker A, Moosburner A, Anheyer D, Burgahn L, Cramer H. Effects of yoga on stress in stressed adults: a systematic review and meta-analysis. *Front Psychiatry*. 2024;15:1437902. doi:10.3389/fpsy.2024.1437902.
4. Verma K, Singh D, Srivastava A. Comparative impact of yoga and ayurveda practice in insomnia: a randomized controlled trial. *J Educ Health Promot*. 2023;12:160. doi:10.4103/jehp.jehp_1489_22.
5. Viswanathan V, Sivakumar S, Prathiba AS, Devarajan A, George L, Kumpatla S. Effect of yoga intervention on biochemical, oxidative stress markers, inflammatory markers and sleep quality among subjects with type 2 diabetes in South India: results from the SATYAM project. *Diabetes Res Clin Pract*. 2021;172:108644. doi:10.1016/j.diabres.2020.108644.
6. Yadav R, Yadav RK, Khadgawat R, Pandey RM, Upadhyay AD, Mehta N. Randomized controlled trial of a 12-week yoga-based lifestyle versus dietary intervention on cardiometabolic risk factors and continuous risk score in Indian adults with metabolic syndrome. *Behav Med*. 2020;46(1):9-20. doi:10.1080/08964289.2018.1538098.
7. Sorout J, Kacker S, Saboo N, Kumar M. Stress attenuation effect of combined approach of yoga and diet intervention among metabolic syndrome patients. *Niger Med J*. 2024;65(5):761-774. doi:10.60787/nmj.v65i5.525.
8. Santhosh C, Hemant B, Shivarama V, Chikkanna U, Jasti N, Suresh MA, et al. Safety and potential utility of integrated Yoga and Ayurveda intervention for psychotropic-associated metabolic syndrome in patients with severe mental disorders: a prospective single-arm pre-post pilot study. *J Ayurveda Integr Med*. 2025;16(5):101198. doi:10.1016/j.jaim.2025.101198.
9. Chan AW, Boutron I, Hopewell S, Moher D, Schulz KF, Collins GS, et al. SPIRIT 2025 statement: updated guideline for protocols of randomised trials. *BMJ*. 2025;389:e081477. doi:10.1136/bmj-2024-081477.
10. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication checklist and guide. *BMJ*. 2014;348:g1687. doi:10.1136/bmj.g1687.
11. Alberti KGMM, Zimmet P, Shaw J. Metabolic syndrome a new worldwide definition. A consensus statement from the International Diabetes Federation. *Diabet Med*. 2006;23(5):469-480. doi:10.1111/j.1464-5491.2006.01858.x.
12. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385-396.
13. Cohen S, Williamson GM. Perceived stress in a probability sample of the United States. In: Spacapan S, Oskamp S, editors. *The Social Psychology of Health*. Newbury Park: Sage; 1988. p. 31-67.
14. Pangtey R, Basu S, Meena GS, Banerjee B. Perceived stress and its epidemiological and behavioral correlates in an urban area of Delhi, India: a community based cross sectional study. *Indian J Psychol Med*. 2020;42(1):80-86. doi:10.4103/IJPSYM.IJPSYM_528_18.
15. Buysse DJ, Reynolds CF III, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res*. 1989;28(2):193-213. doi:10.1016/0165-1781(89)90047-4.
16. World Medical Association. WMA Declaration of Helsinki ethical principles for medical research involving human participants. Ferney Voltaire: World Medical Association; 2024.
17. Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving

Human Participants. New Delhi: Indian Council of Medical Research; 2017.

18. Clinical Trials Registry India. Declaration of responsibility and compliance with prospective CTRI registration. New Delhi: ICMR National Institute for

Research in Digital Health; 2026. Available from: <https://ctri.nic.in/> Accessed 22 September 2026.

19. Hopewell S, Chan AW, Collins GS, Hrobjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 statement: updated guideline for reporting randomised trials. *BMJ*. 2025;388:e081123. doi:10.1136/bmj-2024-081123.

