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Community-Based Yoga and Lifestyle Intervention for Prevention and Management of Type 2 Diabetes Mellitus in an Urban-Periurban Indian Population: Study Protocol for a Prospective Single-Arm Cohort with Long-Term Follow-Up

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Abstract: *Background: Type 2 diabetes mellitus (T2DM) is a leading non-communicable disease in India, with an estimated 101 million adults affected and a further 136 million at the prediabetes stage. Pharmacological management addresses hyperglycaemia but does not modify the lifestyle drivers of the disease. Yoga-based lifestyle interventions have shown efficacy on glycaemic and lipid endpoints in trial settings, but their feasibility and durability in real-world urban-periurban community settings, particularly with intensive residential camps followed by extended community follow-up, remain inadequately characterised.*

Aim: To describe a prospective single-arm cohort protocol that combines a 10-day intensive yoga-based lifestyle camp with quarterly community follow-up for a total of 24 months, designed to evaluate feasibility, glycaemic outcomes, medication trajectories, and quality of life in adults with prediabetes or T2DM in the Mumbai-Kalyan region of Maharashtra, India.

Methods: This is a prospective, single-arm, pre-post observational cohort with long-term follow-up. Adults aged ≥20 years with either an Indian Diabetes Risk Score (IDRS) ≥60 or a confirmed diagnosis of T2DM (per WHO criteria, ≥1 year duration, on stable pharmacotherapy) will be invited to participate. The intervention comprises a 10-day intensive residential camp (two daily sessions of asana, pranayama, meditation, and supervised low-carbohydrate diet) followed by quarterly half-day reinforcement sessions for 24 months. Primary outcomes are fasting blood glucose (FBG), postprandial blood glucose (PPBG), and glycated haemoglobin (HbA1c). Secondary outcomes include lipid profile, anthropometry, blood pressure, oral hypoglycaemic medication score, IDRS, and quality of life (WHOQOL-BREF). The protocol is aligned with the SPIRIT 2013 recommendations for clinical trial protocols.

Discussion: This protocol contributes to the evidence base for community-based yoga interventions in two ways. First, by combining an intensive camp model with prolonged follow-up, it addresses the dose-response and durability gap in the existing literature. Second, by recruiting from a periurban setting and including prediabetic individuals, it tests the feasibility of yoga as a prevention strategy and not solely a management strategy. Methodological limitations of the single-arm design and the absence of a randomised control are explicitly acknowledged, and recommendations for follow-on randomised trials are outlined.

Trial registration: To be prospectively registered with the Clinical Trials Registry-India (CTRI) prior to participant enrolment; registration number will be inserted in the final manuscript.

Keywords: type 2 diabetes mellitus; prediabetes; yoga; pranayama; community-based intervention; study protocol; India; SPIRIT

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I. INTRODUCTION

India has emerged as one of the global epicentres of the type 2 diabetes mellitus (T2DM) epidemic. The 2023 ICMR-INDIAB-17 cross-sectional national study estimated the prevalence of diabetes at 11.4% of adults aged 20 years or older and of prediabetes at 15.3%, corresponding to approximately 101 million people with diabetes and 136 million with prediabetes [1]. Maharashtra ranks among the high-prevalence states, with both urban and periurban populations showing rising rates as lifestyle transitions accompany economic development [2]. The Asian-Indian phenotype, characterised by early central adiposity, lower BMI thresholds for insulin resistance, and a strong family history component, contributes to early onset and rapid progression [3].

Pharmacological management with oral hypoglycaemics and insulin remains the standard of care, but is constrained by long-term cost, adverse effects, and adherence challenges, particularly in lower-income periurban communities [4]. Lifestyle modification, including dietary change and physical activity, is recommended at every stage of the disease, but uptake and sustainability of conventional lifestyle programmes are limited.

Yoga-based interventions, drawn from the Indian Knowledge Systems tradition, offer an alternative lifestyle framework that is culturally familiar, low-cost, and adaptable to community settings. Meta-analyses by Cui and colleagues [5] and by Thind and colleagues [6] of randomised controlled trials in T2DM have shown statistically significant improvements in FBG (pooled weighted mean difference −23.72 mg/dL [5]), HbA1c, lipid profile, and quality of life, with effect sizes in the small-to-moderate range. The Innes and Selfe systematic review of controlled trials likewise concluded that yoga is associated with improvement in multiple glycaemic and metabolic endpoints [7].

Despite this evidence base, three gaps remain. First, most published trials use short intervention periods (8–12 weeks) and have limited follow-up beyond the intervention period, leaving the question of durability unanswered [6,7]. Second, most studies recruit from hospital outpatient populations rather than community settings, limiting external validity to the population where the disease burden is highest [8]. Third, intensive residential camp models, which are common in Indian yoga practice, have rarely been combined with extended structured follow-up in research designs.

The current protocol addresses these three gaps simultaneously. It describes a prospective, single-arm cohort design that begins with a 10-day intensive residential camp and continues with quarterly half-day reinforcement sessions for a total of 24 months. Recruitment is community-based from the Mumbai-Kalyan periurban region of Maharashtra, and inclusion criteria are broadened to include both adults with established T2DM and adults with high diabetes risk (Indian Diabetes Risk Score ≥60), enabling examination of both prevention and management endpoints. We use the term "intervention" throughout this protocol to refer to the combined yoga, breathing, meditation, and dietary modification package.

II. METHODS

2.1 Study design

Prospective, single-arm, pre-post observational cohort study with long-term follow-up over 24 months. The study is reported in accordance with the SPIRIT 2013 statement for clinical trial protocols [9] and, on completion, will be reported in accordance with the TREND statement for non-randomised behavioural intervention trials [10]. The choice of a single-arm design reflects the pragmatic, real-world implementation context; methodological limitations and rationale for this choice are explicitly discussed in Section 5.

2.2 Setting and recruitment

Participants will be recruited from periurban communities of the Mumbai-Kalyan region of Maharashtra, India, through community health camps, panchayat-level announcements, and partnerships with local primary health centres. Recruitment will follow purposive sampling with an emphasis on socio-economic representativeness across slum, periurban, and urban-poor populations.

2.3 Eligibility criteria

2.3.1 Inclusion criteria

- Adults aged 20 years or older, of any gender.

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- Either (a) confirmed diagnosis of T2DM per World Health Organization criteria (FBG ≥126 mg/dL on two occasions, or 2-h plasma glucose ≥200 mg/dL after a 75 g oral glucose tolerance test, or HbA1c ≥6.5%, or use of oral hypoglycaemic medication) for ≥1 year, or (b) Indian Diabetes Risk Score ≥60 indicating high risk for incident T2DM [11].
- Willing to attend a 10-day intensive residential camp and quarterly follow-up sessions for 24 months.
- Stable medication regimen for the previous 3 months (for participants with established T2DM).
- Written informed consent.

2.3.2 Exclusion criteria

- Type 1 diabetes mellitus or other secondary forms of diabetes.
- Regular yoga practice (≥3 sessions per week) for the previous 3 months.
- Severe psychiatric or neurological disorder limiting participation.
- Pregnancy or planned pregnancy within the study period.
- Severe musculoskeletal disorder limiting yoga practice.
- Acute cardiac event or unstable cardiovascular disease in the past 6 months.
- Active malignancy or end-stage organ disease.

2.4 Sample size justification

Sample size is calculated for the primary outcome of change in HbA1c from baseline to 12 months. Based on the Thind et al. meta-analysis pooled standardised mean difference of 0.36 for HbA1c [6], assuming a within-participant correlation of 0.6 between baseline and follow-up measurements, two-sided alpha of 0.05, and 80% power, a minimum of 80 evaluable participants is required. Accounting for an estimated 25% loss to follow-up over 24 months in a periurban Indian community-based study, the target enrolment is 100 participants.

2.5 Intervention

2.5.1 Intensive residential camp (Days 1–10)

All participants will attend a 10-day residential camp delivered by certified yoga instructors trained in therapeutic yoga for chronic disease. The daily schedule consists of two structured sessions:

Morning session (07:00–09:00): 30 minutes of brisk walking; 45 minutes of asanas (standing, sitting, supine, and prone postures appropriate for diabetes management, including Tadasana, Trikonasana, Padahastasana, Vakrasana, Ardha Matsyendrasana, Bhujangasana, Dhanurasana, Pavanmuktasana, and Shavasana); 20 minutes of pranayama (Nadi Shodhana, Bhramari, Anuloma Viloma); 10 minutes of laughter yoga; and 10 minutes of dhyana (meditation).

Evening session (16:00–18:00): repetition of asanas and pranayama with deeper relaxation focus; Yoga Nidra of 30 minutes' duration.

Twice during the 10-day camp (Day 3 and Day 7), participants will undergo Shankha Prakshalana (gastrointestinal cleansing) under medical supervision, following the standard protocol described in classical hatha-yogic texts.

Dietary intervention during the camp consists of a structured low-carbohydrate, high-protein, high-fibre meal plan (approximately 1600–1800 kcal/day, with carbohydrate content of 40–45% of total energy, protein 25–30%, and fat 25–30%), prepared on-site.

2.5.2 Community follow-up phase (Months 1–24)

After the residential camp, participants attend quarterly half-day reinforcement sessions at a community centre near their residence. Each session includes 90 minutes of supervised yoga practice, 30 minutes of dietary counselling, and 30 minutes of clinical assessment. Between sessions, participants are expected to perform a structured 45-minute daily home practice consisting of asana, pranayama, and meditation. Adherence is monitored through self-reported practice diaries and quarterly attendance logs.

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2.6 Outcome measures

2.6.1 Primary outcomes

- Change from baseline in HbA1c at 12 and 24 months.
- Change from baseline in fasting blood glucose (FBG) at each quarterly assessment.
- Change from baseline in postprandial blood glucose (PPBG, measured 2 hours after a standardised breakfast) at each quarterly assessment.

2.6.2 Secondary outcomes

- Lipid profile (total cholesterol, triglycerides, HDL-C, LDL-C) at baseline, 12, and 24 months.
- Anthropometric measures (weight, BMI, waist circumference, hip circumference, waist-hip ratio) at each quarterly assessment.
- Systolic and diastolic blood pressure at each quarterly assessment.
- Oral hypoglycaemic medication score, calculated based on number, dose, and class of medications, with downward titration following standard endocrinology protocols when clinically indicated [12].
- Indian Diabetes Risk Score, for prediabetes subgroup participants.
- Quality of life, assessed with the WHOQOL-BREF Indian version, at baseline, 12, and 24 months [13].
- Perceived stress, assessed with the Perceived Stress Scale-10 [14].
- Adherence, assessed through practice diaries and attendance logs.
- Adverse events, recorded continuously.

2.7 Schedule of assessments

The schedule of enrolment, interventions, and assessments is summarised in Table 1, following the SPIRIT recommendations.

Table 1. SPIRIT Schedule of Enrolment, Interventions, and Assessments

Time point	Screen	Baseline / Day 0	Camp Day 10	Mo 3, 6, 9	Mo 12	Mo 24
Eligibility / consent	X					
Demographics / history		X				
IDRS	X	X		X	X	X
FBG / PPBG		X	X	X	X	X
HbA1c		X			X	X
Lipid profile		X			X	X
Anthropometry / BP		X	X	X	X	X
Medication review		X	X	X	X	X
WHOQOL-BREF / PSS-10		X			X	X
Yoga intervention			X	X	X	X
Adverse event monitoring		X	X	X	X	X

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2.8 Statistical analysis plan

All analyses will follow the intention-to-treat principle, with sensitivity analyses restricted to participants completing ≥80% of scheduled sessions. Baseline characteristics will be summarised using means with standard deviations or medians with interquartile ranges for continuous variables, and frequencies with percentages for categorical variables.

Primary analysis of glycaemic outcomes will use linear mixed-effects models with a random intercept per participant to account for repeated measurements, with time (visit) as a continuous predictor and adjustment for age, sex, baseline value, and baseline medication category. The choice of mixed-effects modelling reflects the longitudinal structure of the data and the expectation of differential missingness over the 24-month follow-up [15]. Paired comparisons between baseline and 12-month and between baseline and 24-month timepoints will use paired t-tests with Bonferroni correction or, where distributional assumptions are not met, Wilcoxon signed-rank tests. Effect sizes will be reported as Cohen's d for paired comparisons.

Subgroup analyses will be specified a priori and limited to: (i) prediabetes versus T2DM at baseline, (ii) male versus female, (iii) age <50 versus ≥50 years, (iv) baseline BMI <25 versus ≥25 kg/m². Interaction terms will be tested in the mixed-effects models. Missing data will be addressed using multiple imputation under the missing-at-random assumption, with sensitivity analyses under more conservative missing-not-at-random assumptions.

Adverse events will be tabulated by category and severity, with rates per 1000 participant-months. Adherence will be summarised as percentage of scheduled sessions attended and percentage of days with self-reported home practice. All analyses will be performed in R version 4 or later. The analysis plan will be finalised and uploaded to the trial registry before unblinding of the dataset.

2.9 Ethics and dissemination

The protocol has been [will be] reviewed and approved by the Institutional Ethics Committee of [institution name, registration number, and date to be inserted] in accordance with the Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017. The trial will be prospectively registered with the Clinical Trials Registry-India (CTRI) before participant enrolment. Written informed consent will be obtained from every participant. Confidentiality and data protection will follow the Information Technology Act 2000 and Indian Council of Medical Research data sharing guidelines.

All participants will receive their clinical reports at each quarterly assessment, and any clinically significant abnormalities will be communicated to their treating physician with the participant's consent. Findings will be disseminated through peer-reviewed publications, conference presentations, and community feedback sessions in the catchment area. The full dataset, after de-identification, will be made available on reasonable request to qualified researchers.

III. RATIONALE AND EXPECTED CONTRIBUTION

This protocol contributes to the evidence base for yoga-based interventions in T2DM in four ways. First, the combination of an intensive 10-day camp with quarterly community follow-up over 24 months tests whether sustained behaviour change can be achieved through a structured high-intensity initiation followed by reinforcement, addressing the durability question that limits inference from short-duration trials [6,7]. Second, recruitment from a periurban community setting rather than a tertiary-care outpatient population improves external validity to the population where the disease burden is greatest. Third, inclusion of prediabetic participants alongside those with established T2DM enables examination of yoga as both a prevention and a management strategy, which is not possible in trials restricted to one clinical category. Fourth, the structured schedule of quarterly assessments enables description of glycaemic trajectories rather than just two-timepoint comparisons, which is informative for the design of subsequent randomised trials.

The expected primary outcome, based on the meta-analytic literature, is a reduction in HbA1c of approximately 0.4 percentage points and in FBG of approximately 15–20 mg/dL at 12 months, with potential further improvement at 24 months in adherent participants. We also expect modest reductions in medication burden, lipid markers, and perceived stress.

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IV. METHODOLOGICAL LIMITATIONS AND MITIGATION

Several methodological limitations of this protocol are worth stating explicitly, since they will constrain the inferential strength of the results.

First, the single-arm pre-post design does not include a randomised control group. Improvements observed cannot be attributed to the yoga intervention alone, since regression to the mean, secular trends in clinical care, increased attention from study staff, and improved overall health behaviour after enrolment all contribute to apparent improvement [16]. To mitigate this, we explicitly frame the study as a feasibility and effectiveness evaluation rather than an efficacy trial, and we recommend that a randomised controlled trial be designed to follow this work if feasibility is demonstrated.

Second, the intervention is multi-component (asana, pranayama, meditation, diet, group support), and the design does not allow isolation of the individual contributions. Future factorial trials should address this.

Third, the periurban recruitment context may differ from rural and urban populations in important ways, including baseline disease burden, medication adherence, and dietary patterns. Generalisability to other Indian settings should be tested in multi-centre follow-on work.

Fourth, self-reported home practice diaries are prone to overreporting. Where possible, we will use brief in-session demonstrations as a partial check on practice quality.

V. CONCLUSION

This protocol describes a community-based, prospective, single-arm cohort study designed to evaluate the feasibility and clinical effects of a combined intensive-residential and quarterly-reinforcement yoga and lifestyle intervention in adults with prediabetes or T2DM in periurban Maharashtra. The design addresses three gaps in the existing literature: insufficient follow-up duration, limited community-based recruitment, and the absence of structured intensive-initiation models in research designs. While the single-arm structure limits causal inference, the study will provide essential feasibility, adherence, and trajectory data to inform the design of subsequent randomised controlled trials. Successful completion of this protocol would strengthen the evidence base for community-scale implementation of yoga as a complementary strategy in the national response to the diabetes epidemic in India.

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DECLARATIONS

Funding: None declared. Source of support for the proposed study will be acknowledged when finalised.

Conflicts of interest: None declared.

Ethics approval: To be obtained from the Institutional Ethics Committee of the host institution prior to recruitment. Trial registration will be completed prospectively.

Author contributions: SSG conceived the protocol, drafted the manuscript, and will lead implementation. AKJ supervised the design, contributed to the analytical plan, and revised the manuscript. Both authors approved the final version.

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