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Effectiveness of Community-Based Lifestyle Interventions in the Prevention and Management of Type 2 Diabetes Mellitus: A Systematic Review Protocol.

Mrs.Kala Suneetha¹, Dr.Sumathy P², Dr.Bhima Uma Maheswari P³, Halaswamy⁴

¹Ph.D. Scholar, Sri Balaji Vidyapeeth University, Puducherry, Suneemsc2009@gmail.com, <https://0000-0003-0346-695X>

²Msc(N) PhD, Professor & Vice Principal, Kasturba Gandhi Nursing College Sri Balaji Vidyapeeth (Deemed University) Puducherry sumathyp@kgnc.ac.in <https://0000-0002-0006-5280>.

³Msc(N) PhD, Principal Padmashree Institute of Nursing Bangalore umamaheswari4567@gmail.com

⁴K.M.G. (M.Sc. Nursing), Ph.D. Scholar, Sri Balaji Vidyapeeth University. halaswamykmg@gmail.com

ABSTRACT: Type 2 diabetes mellitus (T2DM) affects hundreds of millions of adults worldwide and imposes an escalating clinical and economic burden, particularly in low- and middle-income countries. While landmark trials have shown that structured lifestyle interventions can substantially reduce T2DM incidence, translating these findings into scalable, community-embedded programmes remains challenging, and existing systematic reviews have inadequately addressed multicomponent designs, LMIC contexts, implementation outcomes, and cost-effectiveness. This protocol describes a systematic review and meta-analysis, conducted per PRISMA-P and PRISMA 2020 standards and guided by the Cochrane Handbook, that will evaluate the effectiveness of community-based lifestyle interventions (CBLIs) for both T2DM prevention in high-risk adults and management in adults with established disease. Eight major databases plus trial registries and grey literature will be searched from 2000 onward, with two reviewers independently screening records, extracting data, and assessing risk of bias using RoB 2 and ROBINS-I. Primary outcomes include HbA1c, fasting plasma glucose, and T2DM incidence; secondary outcomes span cardiometabolic markers, quality of life, behavioural change, cost-effectiveness, and implementation metrics (reach, fidelity, equity). Where data permit, random-effects meta-analysis will be performed, with heterogeneity explored through pre-specified subgroup and sensitivity analyses; otherwise, narrative synthesis following SWiM guidelines will be used. Certainty of evidence will be graded using GRADE. By synthesising effectiveness, implementation, and economic evidence across diverse community settings, this review is expected to clarify which CBIL models work best, for whom, and in what contexts—informing policy and practice decisions for scaling diabetes prevention and management programmes globally.

1. INTRODUCTION

Type 2 diabetes mellitus (T2DM) represents one of the most pressing global public health challenges of the 21st century. According to the International Diabetes Federation, approximately 537 million adults (20–79 years) were living with diabetes

in 2021, a figure projected to rise to 783 million by 2045 if current trends persist. The vast majority (>90%) of these cases are T2DM, a chronic metabolic disorder characterised by relative insulin deficiency, peripheral insulin resistance, and progressive pancreatic beta-cell dysfunction.

The global burden of T2DM extends far beyond hyperglycaemia alone. It encompasses a spectrum of microvascular complications (nephropathy, retinopathy, neuropathy) and macrovascular sequelae (cardiovascular disease, stroke, peripheral arterial disease), contributing substantially to premature mortality and disability-adjusted life years (DALYs). The economic costs are equally staggering, with direct medical costs exceeding USD 966 billion globally in 2021. In low- and middle-income countries (LMICs), where the burden is rapidly increasing, healthcare systems face particular strain due to limited resources for long-term pharmacological management.

T2DM is, to a large degree, a condition driven by modifiable behavioural and environmental risk factors. Physical inactivity, unhealthy dietary patterns, overweight and obesity, psychosocial stress, and tobacco and alcohol use are well-established contributors to disease onset and progression. This recognition has spurred significant interest in lifestyle-based approaches that address upstream determinants of metabolic health. Landmark trials such as the Diabetes Prevention Program (DPP) in the United States, the Finnish Diabetes Prevention Study (FDPS), and the Da Qing study in China demonstrated that structured lifestyle interventions could reduce the incidence of T2DM by 28–58% in high-risk populations over follow-up periods of 3–6 years.

Despite this strong evidence from controlled trial settings, implementing effective lifestyle interventions at population scale remains a challenge. Traditional clinic-based programmes are resource-intensive, often inaccessible to marginalised populations, and fail to account for the social, cultural, and environmental contexts in which health behaviours are embedded. Community-based lifestyle interventions (CBLIs) have emerged as a promising alternative paradigm. By situating programmes within everyday social environments — including community centres, workplaces, religious institutions, schools, and primary care settings — CBLIs aim to leverage social networks, community resources, and culturally appropriate delivery to enhance reach, uptake, and sustainability.

2.2 Community-Based Interventions: Conceptual Framework

A community-based intervention, as defined by the World Health Organization (WHO), is one that is implemented within and by the community, rather than delivered to a passive recipient population. The defining features of CBLIs include: geographic or social community setting; involvement of community members and organisations in design, delivery, and evaluation; multi-level targeting (individual, interpersonal, community, and policy levels); and emphasis on equity and social determinants of health.

CBLIs for T2DM prevention and management may incorporate diverse components: structured dietary education and counselling; supervised or prescribed physical activity programmes; behaviour change support using techniques drawn from cognitive-behavioural therapy, motivational interviewing, and self-determination theory; peer support and group-based formats; digital health tools; and linkage to community resources. The relative effectiveness of different components, their optimal combinations, duration, intensity, delivery modalities, and contextual adaptations remain areas of active investigation.

2.3 Existing Evidence and Knowledge Gaps

Multiple systematic reviews have examined lifestyle interventions for T2DM, but significant gaps persist. Existing reviews frequently: (1) pool clinic-based and community-based studies without subgroup analyses; (2) focus narrowly on a single component (e.g., diet-only or exercise-only) rather than multicomponent programmes; (3) exclude LMICs where the burden and context differ markedly; (4) report only surrogate glycaemic endpoints (e.g., HbA1c) without assessing broader quality-of-life or behavioural outcomes; (5) inadequately assess intervention fidelity, implementation outcomes, and contextual moderators; and (6) fail to synthesise evidence on cost-effectiveness, which is critical for policy decisions.

Furthermore, a growing body of work using digital technologies, community health workers (CHWs), and lay health educators has emerged since the last major reviews, warranting updated synthesis. There is also increasing recognition that intervention effectiveness may be moderated by sociodemographic characteristics (age, sex, ethnicity, socioeconomic status), cultural context, and baseline glycaemic risk, yet few reviews have conducted sufficiently granular subgroup analyses.

Objectives:

This systematic review and meta-analysis aims to:

Assess the effectiveness of community-based lifestyle interventions in preventing T2DM in adults at high risk (pre-diabetes or metabolic syndrome).

Evaluate the effectiveness of CBLIs in improving glycaemic control, cardiometabolic risk factors, and quality of life in adults with established T2DM.

Examine the effectiveness of specific intervention components, delivery formats, and intensity levels and investigate the moderating effects of participant characteristics (age, sex, ethnicity, SES), setting (LMICs vs. HICs), and programme features on outcomes and synthesise evidence on the cost-effectiveness of CBLIs for T2DM.

Map implementation outcomes including reach, adoption, implementation fidelity, maintenance, and equity considerations.

2. MATERIALS AND METHODS

2.1 Study Design

This review will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P 2015) and will be conducted and reported in accordance with the PRISMA 2020 statement. The Cochrane Handbook for Systematic Reviews of Interventions (version 6.3) will provide methodological guidance. A quantitative synthesis (meta-analysis) will be conducted where studies are sufficiently homogeneous; otherwise, a narrative synthesis following the Synthesis Without Meta-Analysis (SWiM) guidelines will be employed.

2.2 Eligibility Criteria (PICOS Framework)

2.2.1 Population

Studies will be included if they enrol adult participants (aged ≥ 18 years) who are:

Adults with confirmed T2DM diagnosis (defined by any validated clinical or research criteria, including WHO, ADA, or national guideline criteria in the study country); OR

Adults at high risk for T2DM, including those with impaired fasting glucose (IFG), impaired glucose tolerance (IGT), prediabetes, metabolic syndrome, gestational diabetes history, or a validated high risk score (e.g., FINDRISC score ≥ 12).

There are no restrictions on sex, ethnicity, body mass index, comorbidity profile, or geographic location. Studies exclusively recruiting children or adolescents (<18 years), pregnant women, or individuals with Type 1 diabetes will be excluded.

2.2.2 Interventions

Eligible interventions must meet all three criteria:

Community-based setting: Delivered fully or primarily in a non-clinical community setting (including but not limited to community centres, workplaces, religious institutions, primary care community sites, participants' homes or neighbourhoods, digital/remote platforms targeting community populations, or schools for adult learners).

Lifestyle focus: Must include at least one structured lifestyle component targeting diet, physical activity, or behavioural self-management. Pharmacological-only interventions will be excluded.

Intentional programme: The intervention must be a structured, intentional programme rather than a passive information provision or single educational session.

Included intervention types:

Dietary interventions (structured dietary education, medical nutrition therapy, culturally adapted dietary counselling)

Physical activity interventions (supervised exercise, physical activity promotion, sedentary behaviour reduction)

Combined diet and physical activity programmes

Multicomponent behavioural programmes incorporating cognitive-behavioural techniques, motivational interviewing, self-monitoring

Peer support, group-based, or community health worker-delivered programmes

Digital health (mHealth, telehealth, e-health) delivered within community settings

2.2.3 Comparators

Studies must include at least one of the following comparators:

Usual care / standard medical care

Waiting list or no intervention control

Minimal intervention (e.g., single educational leaflet)

Active control (alternative intervention) — included for component comparisons

2.2.4 Outcomes

Primary Outcomes:

Glycated haemoglobin (HbA1c) — continuous (%) or proportion achieving target (e.g., <7.0%)

Fasting plasma glucose (FPG) (mmol/L or mg/dL)

Incidence of T2DM (for prevention studies in high-risk populations)

Secondary Outcomes:

Body weight, body mass index (BMI), and waist circumference

Blood pressure (systolic and diastolic)

Lipid profile (total cholesterol, LDL-C, HDL-C, triglycerides)

Physical activity levels (MET-minutes/week, steps/day)

Dietary quality measures (dietary scores, macronutrient intake)

Health-related quality of life (HRQoL) using validated instruments (e.g., SF-36, EQ-5D, PAID, DDS)

Diabetes self-efficacy and self-management behaviours

Medication adherence

Cardiovascular events (MACE), hospitalisations, mortality

Intervention cost-effectiveness (incremental cost-effectiveness ratio, cost per QALY)

Implementation outcomes: reach, adoption, fidelity, sustainability, equity

2.2.5 Study Designs

Eligible study designs include: randomised controlled trials (RCTs), including cluster-RCTs and stepped-wedge designs; quasi-experimental designs (controlled before-after, interrupted time series with control); and, for implementation and economic outcomes, observational cohort studies with concurrent control groups. Cross-sectional studies, case series, and qualitative studies will be excluded from primary quantitative synthesis but may be used to inform narrative synthesis or implementation mapping.

2.2.6 Time, Language, and Publication Restrictions

Studies published from January 2000 onwards will be included, capturing the post-DPP/FDPS evidence era. No language restriction will be applied; non-English studies will be translated using institutional resources or Google Translate with reviewer

verification. Both published peer-reviewed articles and grey literature (clinical trial registries, government reports, conference proceedings) will be included.

2.3 Information Sources and Search Strategy

2.3.1 Electronic Databases

Searches will be conducted in the following databases:

MEDLINE (via PubMed) — from 2000 to present

EMBASE (via Elsevier) — from 2000 to present

Cochrane Central Register of Controlled Trials (CENTRAL)

CINAHL (Cumulative Index to Nursing and Allied Health Literature)

PsycINFO — for behavioural and psychological outcomes

Global Health (EBSCO)

WHO Global Index Medicus (including LILACS, AIM, IMSEAR, WPRIM, EMRO)

ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP)

2.3.2 Supplementary Search Methods

Hand-searching reference lists of all included studies and relevant systematic reviews

Forward citation tracking of all included studies using Web of Science and Scopus

Contacting authors of included studies for unpublished data or ongoing trials

Searching grey literature: OpenGrey, ProQuest Dissertations, national diabetes programme websites (e.g., CDC NDPP, NHS DPP, WHO DPAS), and relevant organisational websites

Review of bibliographies of included systematic reviews (LiBiCri approach)

2.3.3 Sample Search String (MEDLINE/PubMed)

The following illustrates the core search logic for PubMed. Full syntax will be developed with an information specialist and adapted for each database:

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((("diabetes mellitus, type 2"[MeSH] OR "type 2 diabetes"[tiab] OR "T2DM"[tiab] OR "prediabetes"[tiab] OR "impaired glucose tolerance"[tiab] OR "impaired fasting glucose"[tiab] OR "diabetes prevention"[tiab]) AND ("community-based"[tiab] OR "community based"[tiab] OR "community health"[MeSH] OR "community intervention"[tiab] OR "community program*"[tiab] OR "peer support"[tiab] OR "community health worker*"[tiab] OR "lay health*"[tiab] OR "workplace"[tiab] OR "church"[tiab] OR "faith-based"[tiab]) AND ("lifestyle intervention"[tiab] OR "lifestyle modification"[tiab] OR "diet*"[tiab] OR "physical activity"[tiab] OR "exercise"[tiab] OR "behaviour change"[tiab] OR "behavioral intervention"[tiab] OR "self-management"[tiab] OR "weight loss"[tiab]) AND ("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR "quasi-experimental"[tiab] OR "cluster randomized"[tiab]))
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2.4 Study Selection Process

2.4.1 Screening Workflow

All search results will be imported into Covidence systematic review software (Veritas Health Innovation) for deduplication and screening management. The selection process will proceed in two stages:

Stage 1 — Title and Abstract Screening: Two reviewers (from the core team) will independently screen all deduplicated titles and abstracts against a priori inclusion/exclusion criteria using a standardised screening form. Disagreements will be resolved by discussion or referral to a third reviewer. The kappa statistic will be calculated to assess inter-rater reliability; a minimum kappa of 0.70 will be considered acceptable.

Stage 2 — Full-Text Review: Two reviewers will independently assess the full texts of all records passing Stage 1 screening. Reasons for exclusion will be recorded and reported in a PRISMA 2020 flow diagram. Corresponding authors will be contacted for clarification where eligibility is uncertain.

2.5 Data Extraction

2.5.1 Data Extraction Form

A standardised data extraction form will be developed in Microsoft Excel and piloted on five randomly selected included studies before finalisation. Two reviewers will independently extract data from each included study; discrepancies will be resolved by consensus or third-party adjudication. Authors will be contacted to provide missing data.

2.5.2 Data Items

The following data will be extracted from each included study:

Domain	Specific Items
Study Identification	First author, year, journal, DOI, country, study design, registration number
Participants	Sample size, age, sex distribution, ethnicity, BMI, HbA1c at baseline, T2DM diagnosis criteria, risk category, comorbidities, socioeconomic characteristics
Setting	Country, urban/rural, setting type, community partner organisations, healthcare system context, LMIC/HIC classification
Intervention	Name, theoretical basis, components, delivery format (group/individual/digital), provider type, duration, frequency, intensity (total contact hours), fidelity measures, cultural adaptation features
Comparator	Type, description, contact time
Outcomes	All primary and secondary outcomes measured, instruments used, time points (post-intervention, follow-up ≥ 6 months), units
Results	n per arm at each time point, means and SDs (or other effect statistics), event rates, adjusted vs. unadjusted estimates, p-values, 95% CIs
Adverse Events	Harms reported, type, severity, attribution
Economics	Cost data, perspective, time horizon, ICER, QALY data if available
Funding & CoI	Funding source, author conflicts of interest

2.6 Risk of Bias Assessment

2.6.1 Tools

Risk of bias will be assessed independently by two reviewers using validated, design-appropriate tools:

Randomised Controlled Trials: Cochrane Risk of Bias tool version 2 (RoB 2), assessing domains of randomisation, allocation concealment, blinding of participants/personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias sources.

Cluster-RCTs: RoB 2 with the cluster extension (addressing recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability of analysis).

Quasi-experimental and non-randomised studies: ROBINS-I (Risk Of Bias In Non-randomised Studies of Interventions), assessing confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of reported results.

Discrepancies will be resolved by discussion or third-party adjudication. Overall risk of bias judgements will be: Low, Some Concerns, or High for RCTs; and Low, Moderate, Serious, or Critical for ROBINS-I.

2.6.2 Reporting Bias

Publication bias will be assessed through visual inspection of funnel plots (where ≥ 10 studies contribute to a meta-analysis) and formal statistical testing using Egger's test for continuous outcomes and the Begg-Mazumdar test for binary outcomes. Where asymmetry is detected, the trim-and-fill method will be applied to estimate the potential impact of missing studies.

2.7 Statistical Analysis

Data Synthesis and Statistical Analysis

2.7.1 Meta-Analysis

Where two or more studies report the same outcome using sufficiently similar populations, interventions, comparators, and time points, data will be pooled using random-effects meta-analysis with the DerSimonian-Laird (DSL) estimator as the primary method (with REML as sensitivity analysis). This approach is chosen to account for expected between-study heterogeneity.

For continuous outcomes (HbA1c, FPG, BMI, blood pressure), the standardised mean difference (SMD) or mean difference (MD) will be used, depending on whether outcomes are measured on the same scale. For binary outcomes (T2DM incidence), relative risk (RR), risk difference (RD), and number needed to treat (NNT) will be calculated. For time-to-event outcomes (T2DM incidence with variable follow-up), hazard ratios will be pooled using log-transformed HRs and their standard errors.

2.7.2 Heterogeneity Assessment

Statistical heterogeneity will be quantified using the I^2 statistic (with 95% uncertainty intervals), the T^2 (tau-squared) between-study variance, and the H statistic. Interpretation of I^2 will follow Cochrane guidance: 0–40% may not be important; 30–60% represents moderate heterogeneity; 50–90% substantial; and 75–100% considerable. χ^2 test for heterogeneity (Q-statistic) will be reported. Where considerable heterogeneity is present, meta-analysis will be supplemented by narrative synthesis and subgroup analyses rather than pooling.

2.7.3 Subgroup and Sensitivity Analyses

Pre-specified subgroup analyses:

Prevention vs. management populations (high-risk vs. established T2DM)

Intervention component: diet-only, physical activity-only, combined, multicomponent

Delivery format: group-based, individual, digital, hybrid

Delivery agent: trained professionals vs. CHW/lay workers

Programme intensity: low (<12 contact hours), moderate (12–24 hours), high (>24 hours)

Setting: LMIC vs. HIC (World Bank classification)

Follow-up duration: ≤ 12 months vs. >12 months

Cultural adaptation: adapted vs. non-adapted programmes

Participant characteristics: age group, sex, baseline HbA1c, BMI category, ethnicity

Sensitivity analyses:

Restricted to RCTs only (excluding quasi-experimental studies)

Restricted to low risk of bias studies

Impact of unpublished / grey literature

Alternative statistical model: fixed-effects for comparison

Handling of missing data: complete case analysis vs. imputation scenarios

2.7.4 Certainty of Evidence

The certainty (quality) of evidence for each outcome will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. Evidence will be rated across five domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Evidence from RCTs begins at High certainty and can be downgraded (or upgraded in special circumstances for observational evidence). Final certainty ratings: High, Moderate, Low, or Very Low. Summary of Findings (SoF) tables will be generated using GRADEpro GDT software.

2.7.5 Narrative Synthesis

Where quantitative pooling is inappropriate due to heterogeneity, insufficient data, or diverse outcome measurement, a narrative synthesis will be conducted following the SWiM guidelines. This will include tabular presentation of study characteristics and results, thematic grouping by intervention type and population, direction-of-effect summaries, and vote-counting by direction of effect as a last resort.

2.7.6 Implementation and Economic Evidence

Implementation outcomes will be mapped using the Consolidated Framework for Implementation Research (CFIR) and the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework. Economic data will be extracted and presented in narrative form; where data allow, a decision-analytic model may be populated to estimate cost per QALY in a standardised population.

2.7.7 Software

All statistical analyses will be conducted in R (version 4.3 or later) using the meta and metafor packages. Funnel plots, forest plots, and Baujat plots will be generated for each primary pooled analysis. GRADE assessments will be managed in GRADEpro GDT.

3. REPORTING

3.1 PRISMA 2020 Flow Diagram

A PRISMA 2020-compliant flow diagram will document the number of records identified, screened, assessed for eligibility, included, and excluded (with reasons) at each stage. Both database searches and other sources will be reported separately.

3.2 Dissemination

Results will be disseminated through:

Peer-reviewed publication in an open-access journal (target: The Lancet Diabetes & Endocrinology, Diabetes Care, or BMC Medicine)

Presentation at international conferences (International Diabetes Federation Congress, European Association for the Study of Diabetes)

Summary reports for policymakers and public health bodies (WHO, national diabetes programmes)

Plain-language summaries and patient-facing materials

3.3 Health Equity

This review will explicitly consider equity dimensions using the PROGRESS-Plus framework (Place of residence, Race/ethnicity/culture, Occupation, Gender/sex, Religion, Education, Socioeconomic status, Social capital, Plus: age,

disability, sexual orientation, migration status). Where data permit, equity-stratified subgroup analyses will be performed, and equity implications of findings will be discussed using an equity lens.

3.4 Ethical Considerations

As a synthesis of published research, this review does not require ethical approval. All included primary studies should have received institutional ethical approval; documentation of ethics approvals in primary studies will be extracted and reported.

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8.2 Author Contributions

Kala Suneetha (Principal Investigator) — conceptualisation, methodology, supervision, funding acquisition, writing (review and editing); Dr. Sumathy P (Co-Investigator) — methodology, investigation, formal analysis, writing (original draft); Dr. Bhima Uma Maheswari (Co-Investigator) — formal analysis, software, validation, writing (review and editing); Information Specialist — methodology (search strategy design), investigation, data curation; Patient/Public Representative — validation, writing (review and editing). Mr. Halaswamy Co-Investigator formal analysis and review. All authors will approve the final protocol, any subsequent amendments, and the resulting publication, and will take public responsibility for its content. Ethics Statement

This protocol describes a systematic review and meta-analysis of previously published, publicly available data and does not involve the collection of new data from human participants; as such, it does not require approval from an institutional review board or research ethics committee (see also Section 5.2). Ethical approvals and participant consent procedures reported by primary studies will be extracted and summarised in accordance with the data items listed in Section 3.5.2. Should the scope of this review be amended to include the collection of primary data (for example, structured interviews with study authors or stakeholders), ethical approval will be sought from [Institution Name] Research Ethics Committee prior to commencement, and this statement will be updated accordingly.

Conflict Of Interest:

None

Data Availability Statement

No new data were generated for this protocol. Upon completion of the review, the full dataset extracted from included studies, the completed risk-of-bias assessments, the statistical analysis code (R scripts), and the PRISMA 2020 flow diagram data will be deposited in a public repository (e.g., the Open Science Framework) at the time of manuscript submission, consistent with open science principles. The data extraction form template (Appendix B) and complete, date-stamped search strategies for all databases (Appendix A) will be made available as supplementary files. Any restrictions on the sharing of extracted data (for example, where authors of primary studies request that unpublished data not be redistributed) will be documented and justified at that time.

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