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Scaling up structured lifestyle interventions to improve the management of cardiometabolic diseases in low-income and middle-income countries: a systematic review of strategies, methods and outcomes

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ABSTRACT

Introduction Cardiometabolic diseases (CMDs), the leading causes of death in low-income and middle-income countries (LMICs), are proven to be mitigated through structured lifestyle interventions (SLIs—dietary changes, physical activity, tobacco cessation and alcohol intake), but the challenge lies in scaling them up in LMICs. Therefore, we undertook a systematic review to identify the strategies, methods and outcomes used in scaling up SLI programmes to improve cardiometabolic outcomes in LMICs.

Methods We searched studies implementing scale-up strategies (delivery approaches enhancing an intervention's adoption, implementation and sustainability), methods (theories, models and frameworks) and present outcomes (feasibility, fidelity, etc) following the Proctor E framework. We searched six databases to identify studies published in English with no time restriction, guided by the Setting, Perspective, Intervention, Comparison and Evaluation framework. Quality assessment was performed using the Cochrane risk-of-bias, National Institutes of Health and Joanna Briggs Institute tools. Given the heterogeneity of the outcome measures, we conducted a narrative synthesis of the extracted information.

Results Out of the 26 studies included, 18 (69%) adapted SLI interventions to suit local contexts. Strategies such as system integration, strengthening facility services and training led to up to 100% attendance of participants. Notably, only four studies (15%) used theories, models and frameworks for the full scale-up process, which is crucial for large-scale implementation in resource-limited settings. 15 (58%) studies reported the feasibility of scale-up, whereas 7 (27%) reported no significant differences in lifestyle behaviours or CMD biomarkers.

Conclusions Early community and local stakeholders' engagement is crucial for codeveloping strategies for the scale-up of SLIs. Conducting readiness assessments and system integration are all essential considerations for improving scale-up outcomes. Additionally, we strongly recommend using suitable frameworks to guide the scale-up of SLIs to maximise the benefit for the population.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Cardiometabolic diseases (CMDs) are the major causes of death worldwide, especially in low-income and middle-income countries (LMICs).
⇒ Structured lifestyle interventions (dietary changes, physical activity, tobacco cessation, alcohol intake and so on) have been proven effective at preventing and managing CMDs.
⇒ There is a gap in what strategies work and how they can be assessed using different available methods for the better outcome of the scale-up implementation study in LMICs.

WHAT THIS STUDY ADDS

⇒ The implementation of structured lifestyle interventions using different strategies such as engaging family and community at the beginning of the study to cocreate adaptations and early resource assessment led to improved outcomes of scale-up implementation.
⇒ Only 15% of the 26 included studies used frameworks for understanding the scale-up process in LMICs, which is crucial for policy-makers and implementers.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Findings from this study will guide researchers, policy-makers and implementers to plan and document strategies and methods to improve the scale-up implementation of structured lifestyle intervention programmes.

INTRODUCTION

In low-income and middle-income countries (LMICs), there is an increase in cases of non-communicable diseases (NCDs).[1] An estimated 17 million premature deaths worldwide occurred before the age of 70, 86% of which were from LMICs.[1] The predominant cause of NCD-related death is cardiometabolic diseases (CMDs), a preventable group of NCDs that include cardiovascular disease (17.9 million deaths annually), diabetes (2 million deaths per annum), stroke and non-alcoholic fatty liver disease.[2–5]

To effectively combat CMD-related deaths, a cost-effective approach, such as reducing tobacco use, addressing harmful alcohol consumption and promoting a healthy diet and physical activity (healthy lifestyle approach), is essential.[5] A healthy lifestyle approach can be implemented by building the capacity of individuals and populations to choose healthier lifestyles and empowering them; the United Nations General Assembly also recommends this approach for the prevention and control of CMDs.[6] In addition, policy-makers and implementers now focus on empowering individuals through capacity building, which has led to increased investment in developing and implementing systemic solutions, such as structured lifestyle interventions (SLIs) to prevent and control CMDs across diverse settings.[7] We adapted the definition of WHO on lifestyle intervention and defined SLIs as planned or scheduled interventions (education and/or skill building) with a focus on weight loss, increased dietary fibre intake, reduced alcohol and saturated fat intake, tobacco cessation and increased physical activity.[8]

The WHO recommended that SLIs include group-based, patient-centred education sessions that support individuals, family members and caregivers in developing disease-related attitudes, beliefs, knowledge and skills. Such interventions should also have a foundation in relevant learning and health behaviour theories and ensure quality assurance through trained educators and evidence-based resources.[8 9] The SLI initiative has succeeded globally; for example, the Diabetes Prevention Program (USA), the Good Aging in Lahti Region, the Greater Green Triangle (Australia), the Da Qing (China) and the Kerala Diabetes Prevention Program (India) have facilitated effective lifestyle changes that have improved biomarkers for the prevention and management of CMDs.[10–18] These results have garnered interest among policy-makers and funders, prompting consideration for scale-up through adoption and implementation.[19 20] However, studies assessing the transition from research settings to the practical implementation of SLIs in LMICs are rare, particularly those examining scaling up.[19]

In this review, we adopted the definition of scaling up from the WHO ExpandNet network: 'deliberate efforts to increase the impact of successfully tested health innovations to benefit more people and to foster policy and programme development on a lasting basis'.[21 22] The key elements of scale-up include innovation, system resource teams, user organisation, scale-up strategies and the environment.[22] While different theories, frameworks and models exist to assess scale-up in various stages of the process as explained by Barker *et al* and others,[23–25] there is a lack of comprehensive explanation for the pathways of scale-up and successful strategies employed.[26] The challenge lies in establishing proof of principle and designing innovations suitable for scale-up, highlighting the need for guidance from the innovation stage to the outcomes of large scale-up for policy-makers and implementers.[27 28]

The existing literature predominantly focuses on individual intervention components and their effectiveness, with limited attention given to the intricacies of scaling up such programmes within LMICs.[29 30] Most reviews compared the efficacy of an intervention established through randomised controlled trials (RCTs) with a large population from a high-income country.[31–33] Similarly, a 2012 review targeting global lifestyle interventions that included findings from Europe and the USA identified gaps in reporting external validity components of intervention translations and recommended more detailed reporting for future institutionalisation.[34] However, it remains unclear from these reviews what and how these strategies work for SLIs; therefore, this review intends to address the gap in the knowledge on how to improve the implementation of proven programmes in communities on a large scale in LMICs.[35] This gap is significant because understanding the strategies and methods used for scaling up SLIs, along with documented outcomes, is crucial for guiding public health policies and healthcare practices in LMICs. We aimed to examine the strategies, methods and outcomes related to scaling up the implementation of SLIs for the prevention and control of CMDs in LMICs, to provide a consolidated understanding of current best practices, and to identify areas for improving the development of public health strategies.

MATERIALS AND METHODS

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (online supplemental file 1 and 2).[36] This review is registered in PROSPERO (ID: CRD42023416974) and is available online.

The Setting, Perspective, Intervention, Comparison, Evaluation framework[37] (online supplemental file 3) was used to guide the key concept, the search strategy was developed in consultation with the librarian, and preliminary searches by AS and GDD were conducted to refine the criteria and the search strategy. The detailed search strategy is available in online supplemental file 4). We searched OVID MEDLINE (1946 to 13 April 2023), Embase (1947 to 2023 April 21), PsycINFO (1806 to April Week 3, 2023), CABI (1910 to 2023 Week 16), CINAHL (1954 to April 22, 2023), and the Cochrane Library from inception to April 22, 2023.

Study selection

We included peer-reviewed studies assessing the use of SLIs for the prevention and control of CMDs in LMICs in the English language, without restriction of the publication timeline. The following study designs with original studies were included: RCTs and quasi-experimental, comparative, observational, longitudinal and mixed-method studies (qualitative and quantitative).

We excluded case studies, commentaries, letters, perspectives, viewpoints, editorials, review papers and systematic reviews. Studies reporting on approaches without conducting actual assessments were also excluded.

Data collection process and data items

All identified studies were imported to Covidence software by AS, and duplicates were removed.[38] The titles and abstracts of the studies were independently assessed by researchers (AS, LY, GDD and RD) against the inclusion and exclusion criteria. The reviewer discussed any discrepancies, and three senior reviewers (BK, BO and TH) were consulted. Agreement between the reviewers was assessed using Cohen's kappa coefficient in Covidence software, which indicated 64% agreement in the full-text screening.

(A) Implementation scale-up strategies were defined as delivery approaches enhancing an intervention's adoption, implementation and sustainability.[39 40] (B) Methods refer to various implementation scale-up theories, models and frameworks (TMFs) guiding the process of translating research into practice, considering factors influencing implementation scale-up adapted from Nilsen *et al* which categorises the TMF into (a) a guiding process that includes the process model, (b) understanding the mechanism including determinant frameworks, classic theories and implementation theories and finally (c) evaluation of implementation that includes the evaluation frameworks.[39 41] (C) As per Proctor *et al*'s taxonomy, the outcomes included implementation outcomes related to feasibility, fidelity, penetration and sustainability including integration out of eight implementation outcomes; success determinants and challenges during programme implementation are included.[42] The primary effectiveness outcomes are included, but more emphasis is given to implementation outcomes. Feasibility is the extent to which SLIs can be successfully applied within a given setting as stated in the studies; fidelity is the degree to which SLIs are implemented as intended by developers (original protocol) and assessed through five dimensions (adherence, delivery quality, programme component, intervention exposure and involvement or response of participants); and the integration of SLIs within service settings and subsystems in terms of service providers (number of providers delivering the service divided by the total number of providers trained or expected to deliver) and service users (number of eligible persons using the service divided by the total eligible persons).[42] To understand the focus of the study, we present the type of effectiveness-implementation studies as hybrid type 1 (primary aim to determine the intervention effectiveness and secondary to understand the implementation context), type 2 (coprimary aim to determine the intervention effectiveness and implementation context) and type 3 (primary aim to determine the utility of implementation and secondary to assess the effectiveness) as explained by Curran *et al*.[43] We searched grey literature such as conference reports, government documents and the references of the relevant systematic review but did not identify any relevant to this topic. Additionally, we sought supplementary publications from the included studies to gain insights into the implementation processes and outcomes.

Data extraction strategy

The template for data extraction was prepared in Covidence by AS and verified by TH. Studies for extraction were randomly assigned to two independent individuals who entered the data into the template in Covidence software. A third independent reviewer verified the results. Any discrepancies were resolved through discussions among the reviewers. The data extraction template comprised the study design, study type, participant details with intervention and comparison groups, implementation strategy, intervention effectiveness outcomes, scale-up strategy, adaptation of implementation strategy following the Adaptome model,[44] mode of delivery, including delivery channel and cultural adaptations, implementation outcomes based on a minimum dataset of implementation outcomes and determinants,[39] outcome of scale-up and assessments that included effectiveness, feasibility, fidelity, sustainability with integration, and points of success and challenges of scale-up. All the data were downloaded from Covidence into Excel for further synthesis.

Study quality

Two reviewers independently assessed the risk of bias in the included studies. Any conflicts were resolved by consensus, a third researcher reviewed the data if they were unresolved, and the risk of bias was finalised based on the score provided by each tool used. A study was considered at high risk of bias if at least one of the domains was at 'high risk' or if there was 'some concern' in multiple domains. We used the Revised Cochrane risk-of-bias tool for RCTs (RoB 2.0) and presented the results using the Robvis tool.[45 46] The National Institutes of Health quality assessment tool[47] assessed the cohort, cross-sectional and pre–post study data. Any study rated poor had a significant risk of bias; those with a fair rating were susceptible to some bias, and studies with a good rating had the least risk of bias. We considered the overall study rate poor if the total 'yes' score was ≤6, fair if the total 'yes' score was 7–9 and good if the total 'yes' score was ≥10[48] for 14 item questions from the NIH tool used for cohort and cross-sectional studies. The Joanna Briggs

Institute (JBI) critical appraisal checklist was used to assess quasi-experimental and qualitative studies.[49 50]

Certainty of evidence

We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to summarise the quality of the retrieved studies.[51] The GRADE assessment was performed to downgrade five factors: risk of bias, inconsistency, indirectness, imprecision and publication bias for both RCT and observational studies. For RCTs, the downgrade started from high quality (++++), whereas for the observational studies, the downgrade started from a level of low quality (++). For serious concerns, the value was downgraded by one score and by two scores for very serious concerns. For the observational studies, three additional factors were considered for potential upgrading: effect size, plausible confounding and dose-response gradient. The grade was assessed for the studies using GRADEPro software.[52]

Data synthesis and presentation

Given the wide nature of the studies, the heterogeneity in the target population and the outcome measures, we conducted a narrative synthesis of the studies, and no attempt was made for meta-analysis. The study characteristics and key findings of the scale-up studies are described with their attributes in the tables. The findings were classified based on the objectives of identifying strategies, methods used by the studies and outcomes. We have mentioned unclear or not clear when the information provided in the studies is not clear or unavailable.

RESULTS

Study selection

A detailed PRISMA flow chart is attached (figure 1). The initial literature search returned 1712 studies. After removing duplicates, 1433 studies were screened. Of the 1433 studies screened, 131 were assessed for eligibility.

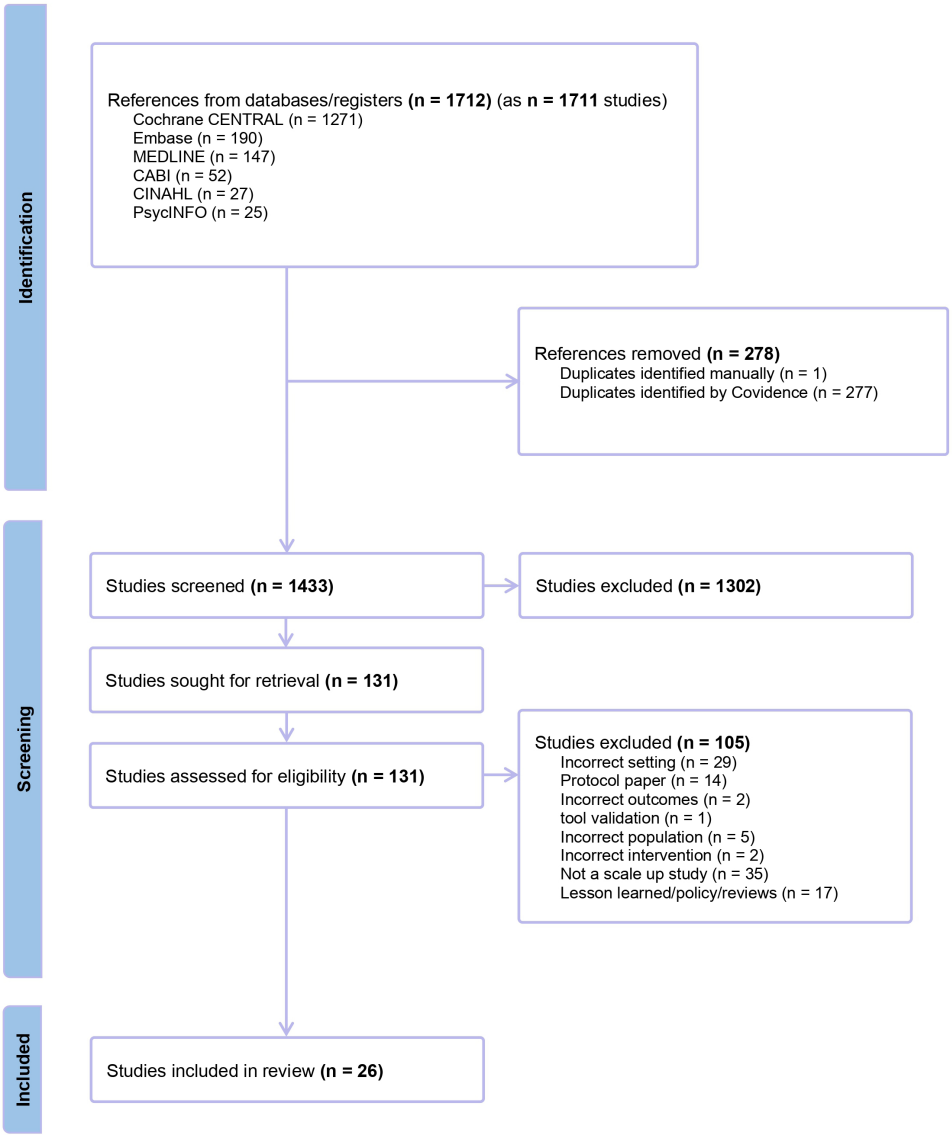

Figure 1 PRISMA flow chart of studies included in the review. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Table 1 Baseline characteristics (n=26)

Author year	Country	Study design	Setting
Disease management			
Kolawole *et al* 2008[53]	Nigeria	Cross-sectional comparative	Community
Mwakalinga *et al* 2021[54]	Malawi	Cross-sectional	Community
Fairall *et al* 2016[55]	South Africa	cRCT	Primary healthcare centres
Jafar *et al* 2010[56]	Pakistan	cRCT	Home
Sharifirad *et al* 2009[57]	Iran	Quasi experimental	Diabetes associations
Ogedegbe *et al* 2018[58]	Ghana	cRCT	Community health centre
Sun *et al* 2022[59]	China	cRCT	Community
Valdés González *et al* 2020[60]	Cuba	Pre–post	Primary healthcare centres
Tschida *et al* 2021[61]	Guatemala	Pre–post (mixed methods)	Community
Liu *et al* 2012[62]	China	RCT	Community
Debussche *et al* 2018[63]	Mali	RCT	Diabetes association, community
Utz *et al* 2018[64]	Morocco	cRCT	Health centre
Agbaria *et al* 2020[65]	Palestine	Quasi experimental study followed by pre–post	Community
Brady *et al* 2021[66]	Mozambique and Malawi	Pre–post (mixed methods)	Primary healthcare centres
Rotheram-Borus, *et al* 2012[67]	South Africa	Pre–post	Primary health centres
van Olmen *et al* 2016[68]	Cambodia	Qualitative	Community
Disease prevention			
Ravindranath *et al* 2020[69]	India	Pre–post	Community
Sranacharoenpong *et al* 2018[70]	Thailand	RCT	Primary healthcare centres
Ramachandran *et al* 2013[71]	India	RCT	Worksite
Choi *et al* 2015[72]	Korea	Pre–post	Community
Weber *et al* 2016[73]	India	RCT	Community
van de Vijver *et al* 2016[74]	Kenya	Comparative cross-sectional survey	Community
Alvear Durán *et al* 2021[75]	Ecuador	Pre–post	Worksite
Disease prevention and management			
Ibrahim *et al* 2016[76]	Malaysia	Quasi experimental	Community
Oli *et al* 2019[77]	Nepal	cRCT	Community
van Olmen *et al* 2022[78]	Uganda, South Africa and Sweden	Quasi experimental	Primary healthcare centres

cRCT, cluster RCT; RCT, randomised controlled trial.

A total of 26 studies were included in the review. The characteristics of the included studies are presented in table 1 and online supplemental file 5. The studies were published between 2008 and 2021. Out of 26 studies, 16 focused on disease management, 7 focused on disease prevention and 3 focused on both.

Study characteristics

Of the 26 studies, 16 (61.5%) involved disease management, which included diet (such as the Mediterranean diet, food exchange education, carbohydrate portions, sugary drinks, strategies to eat well at parties, dietary planning), physical activity (benefits of exercise, activity, types of physical activity), blood sugar and pressure monitoring, family support and goal setting[53–68]; 7 (26.9%) involved disease prevention, with food labelling, kitchen gardening, physical activity (yoga sessions, supervised training), peer support groups and goal setting[69–75]; and 3 (11.5%) involved disease management and prevention, focusing on diet (education and practical meal planning, healthy meal contest), physical activity (outdoor activity, 10 000 steps, group walking), peer support groups and care companion.[76–78]

A total of 12 (46%) studies focused on the effectiveness of implementation,[53–57 62 64–66 75 76 78] 6 (23%) were hybrid type 1 studies focused on the effectiveness with some implementation[58 59 63 67 71 77] and 1 (3.8%) study was a hybrid type 2 study that focused on both effectiveness and implementation[69] and 3 (12.5%) hybrid type 3 studies focused on some effectiveness and implementation of the intervention.[68 70 78] There were 7 pre–post studies, 3 observational/cross-sectional studies, 4 quasi-experimental studies, 1 qualitative study and

Table 2 Summary of strategies, methods and outcomes of the implementation scale-up (n=26)

Strategies	Methods: Theories, models and frameworks	Outcomes
► Adaptation – Modified language – Health literacy – Considered the background of trainers – Food and culture ► Delivery – Local NGO – National/province/state government – Mothers and neighbours – Association and civil society – Social welfare – other community structures ► Others: – Training and deploying peer leaders, volunteers and other lay health workers. – Free for members – Glucometer and BP machine – Prescription by nurse – Free medications – Kitchen garden, Yoga, walking groups – Mobile messaging – Door to door screening – Providing lunch – Involving all family members	► Guiding process – Chronic care model – Health for your heart model – Cooperative healthcare clinic model ► T5 instructional design modelUnderstanding mechanism – Educational outreach model – Health belief model – Group model – Participatory model – 'Learning nests' approach – Transtheoretical model – Diffusion of innovation – Social cognitive theories, dual process theory ► Evaluation – RE-AIM framework – MRC guideline and taxonomy of implementation outcome – Detsky and Naglie cost-effectiveness analysis – World Hypertension League monitoring and evaluation framework	► Feasibility – Application through large scale using the available human resource – Group-based interventions are efficient – Use of technology adds value ► Fidelity recruitment, retention rate was high among the studies implemented with state/health system ► Sustainability (Integration) and penetration: – State/health system owned interventions – The trained providers implemented high retention rate 63%–100% ► Success: – System integrated – Association, NGOs engagement – Adapted by local activities – Relevant language and culture-based information ► Challenges – Shortage of providers – Resources-out of stock – Low enrolment of male participants

BP, blood pressure; MRC, Medical Research Council; NGO, non-government organisation; RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance.

11 experimental controlled studies. The studies were conducted in various settings, including primary healthcare, non-governmental organisations (NGOs), local health clinics, community public health systems and other community settings. The duration of the study ranged between 6 months and 36 months.

Quality of the studies

The risk of bias assessment (online supplemental file 6) revealed that most of the RCTs included were at high risk, followed by one with some concerns[56] and one with low risk.[64] The National Institutes of Health quality assessment on cohort, cross-sectional and pre–post studies revealed one study as good,[69] six studies as fair[60 61 66 72 74 75] and three as poor on risk scoring.[53 54 67] The JBI checklist for quasi-experimental study risk assessment had an overall good risk score in three studies,[57 65 76] and one study scored this risk assessment as fair.[78] One scored fairly on the qualitative study assessment.[68]

Strategies used for scale-up

Table 2 summarises the strategies (n=16) used for scale-up implementation (online supplemental file 7). We found that 22 studies mentioned adoption by the proportion and representativeness of providers or the team involved in the intervention (delivery of intervention strategy), such as being provided by community health workers and nurses.[53–56 58–70 73 74 76–78] The adaptation was also based on the criterion that training should support the person in developing beliefs, knowledge, skills and attitudes.[66] The cultural adaptation of the materials involved the association of patients during the adaptation process. 18 (69%) of the 26 studies adopted the intervention based on language, health literacy and the background of the trainers including the learning nest approach.[56 59–67 69–71 73–76 78] One study explained how the process goes beyond changes based on language, food and images provided for local relevance.[65] Four studies reported collecting feedback from stakeholders on traditional recipes, family opposition, cultural norms, hospitality and socially acceptable settings for physical activities, appraising socioreligious, income and logistic barriers for successful adaptation.[65 70 72 78] Six reported that information sharing and codesigning also need to occur during the intervention development phase.[60 66 68 69 76 78] The studies reported the use of different delivery modalities to enhance implementation at a large scale; slightly more than 50% (n=14) of the studies implemented intervention through local NGOs, the national/state government, mothers' groups/neighbours or civil societies.[53 57 60–63 65–67 69 72 76–78] The strategies for implementing the programme were largely contextual and heavily dependent on the available resources, such as skilled human resources, health information resources and community organisations. For example, one study mentioned that the peer support group with 30 members shared 1 glucometer and limited test strips for self-monitoring blood glucose.[54] Four studies used strategies such as establishing community organisations,

establishing new structures, strengthening and linking services to facility-based care, contracting with local pharmacies, authorising nurses to prescribe medication, providing access to medicine and tests, and managing patients through mobile devices, such as sending text messages during the scale-up process.[58 68 71 78] Community centres, churches, mosques and other public spaces were included in these studies, and brochures and radio media were used to reach large populations in five included studies.[61 65 73 74 76]

According to 14 studies, the community health workers available for education can include nurses, midwives working in the community,[54 55 58 60 62 64 66 70] non-physician/village doctors or community and outreach health workers[56 59 63 68 70 78] in addition to peer educators and lay health workers. Four studies have incentivised peers (performance-based 15% additional annual income plus 3% incentive, from US$3 to US$40) for successful implementation,[59 68 74 77] while others (n=2) mentioned that they did not provide any incentives.[55 61] The training of peer educators and the roles and responsibilities of the actors engaging in implementation at the system level are emphasised by five studies, as is the case for peer educators in the community.[58 62 68 69 74] Two studies reported that strategies for widening the scope of availability of affordable medicines were equally important for engaging participants in the intervention.[60 68]

Methods applied for scale-up implementation

The methods are the different TMFs used by the studies to assess the implementation scale-up presented and adapted from Nilsen.[41] A total of 14 studies presented the TMFs. The studies (figure 2) used TMFs for guiding processes such as the chronic care model, cooperative healthcare clinic model and the T5 instructional model. They also used different learning and behavioural theories, such as dual process theory, social learning theory, the health belief model and the transtheoretical model for behavioural change. However, very few studies (n=4, 15%) have reported the framework they used for the assessment of the scale-up process.[60 61 69 78 79] The scale-up studies were assessed using components of the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework, the Medical Research Council guidelines, the taxonomy of implementation outcomes and applied Self-Determination Theory. In contrast, one study used Detsky and Naglie for cost-effectiveness analysis. Studies that used a chronic care model to implement the programme were assessed using the World Hypertension League monitoring and evaluation framework.[60] One of the studies reported using the diffusion of innovation theory, but the process and outcome of the study are unclear.[77] None of the studies we included presented the full scale-up process using tools.

Outcomes of the scale-up implementation

The implementation outcomes of the study (n=26) included primary effectiveness outcome, feasibility, fidelity, penetration and sustainability (integration) as per the taxonomy of outcomes by Proctor *et al*. This also included determinants of success and challenges during programme implementation (table 2 and online supplemental file 8).

Effectiveness

All the included studies (n=26) presented the effectiveness of the intervention. While most of those studies presented significant changes in knowledge, self-care, blood glucose control and blood pressure (systolic blood pressure and diastolic blood pressure) levels, seven scale-up studies (27%) mentioned no significant differences in treatment intensification rates,[55] lifestyle behaviours[58] or cardiometabolic biomarkers.[67 69–71 74]

Feasibility

We assessed feasibility at two levels: the studies that mentioned the feasibility of implementation after pilot tests and the studies that mentioned the feasibility of scaled up implementation. Table 2 and online supplemental file 8 show that most of the studies in our analysis (n=24, 92%) revealed that their implementation was feasible, which is based on the studies mentioning their feasibility findings, and 15 (58%) studies reported the feasibility of scale-up implementation.[53–56 58–73 75–78] One study indicated that these interventions were implemented on a large scale and included 15 000 peer-trained individuals and 375 000 educated individuals. Similarly, the other studies included sustained intervention among 15 000 participants, and the services were scaled to other contexts (state, country, etc). These studies integrated interventions into the health system, engaged multiple stakeholders, such as the government, academia and civil society and involved local community health workers and peer supporters.[56 59 60 69 74]

Fidelity

Fidelity was assessed at the provider level using the guidelines where the number of topics/sessions covered was assessed, and the participants who adhered to the intervention were provided (table 2 and online supplemental file8). Four studies reported that training the providers before the delivery of the intervention is an important strategy for ensuring fidelity and ensuring the quality of implementation.[58 59 69 78] In two studies, participants were likely to complete curriculum elements such as phone, text messages or mobile-based applications if they received their preferred medium and were closely followed up.[61 65] In contrast, one study mentioned low clinic attendance during the follow-up period; the reason for this difference remains unclear.[55] The studies reported that the coverage of SLI sessions decreased with increasing number of sessions; they reported that session coverage ranged from 33% to 74% for all 12 sessions, 80%

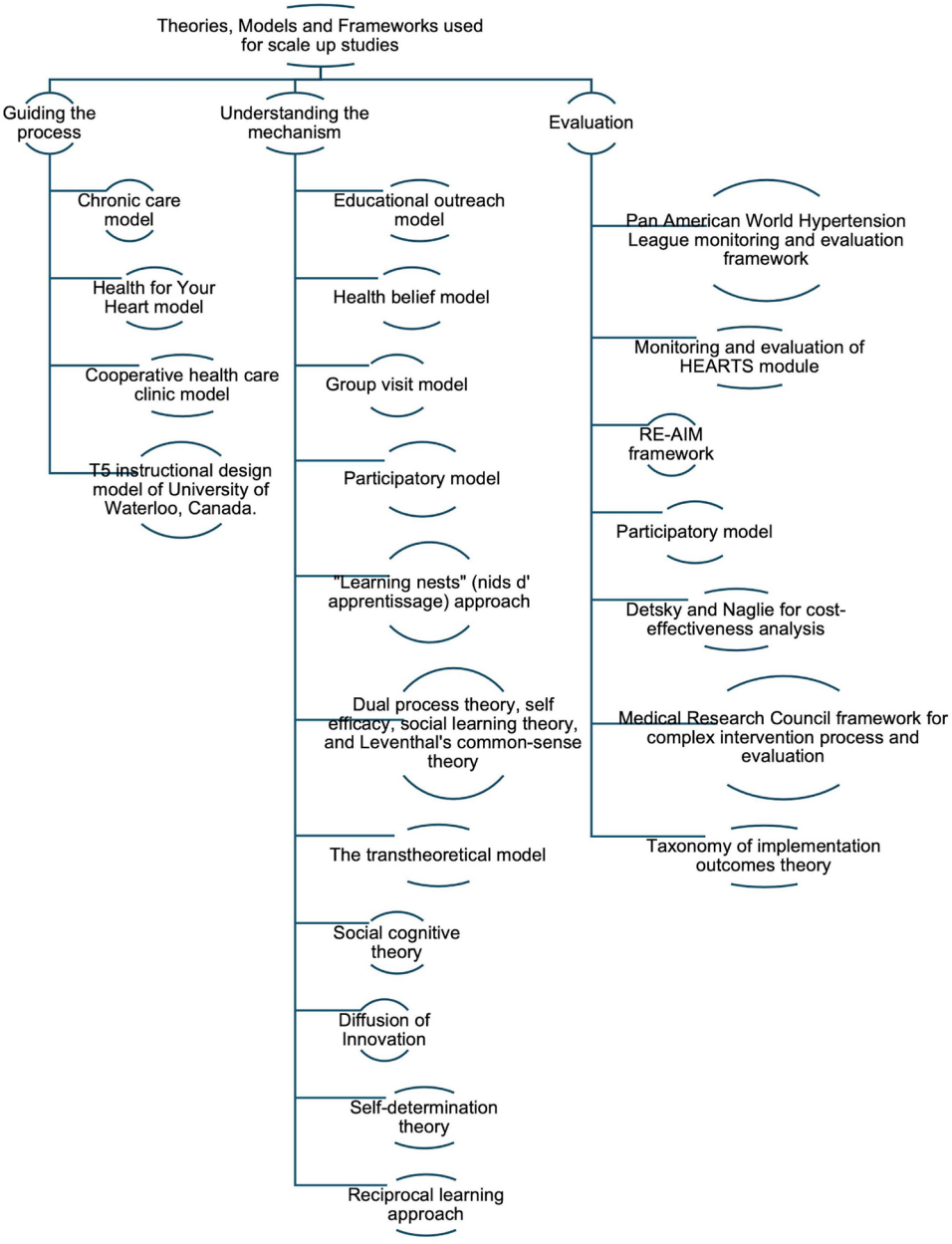

Figure 2 Methods used for scale-up implementation (n=14). CVD, cardiovascular disease; HEARTS, Healthy-lifestyle counselling, Evidence-based protocols, Access to essential medicines and technology, Risk-based CVD management, Team-based care and Systems for monitoring; RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance.

to 88% for 6 sessions and 98% for at least one session. The staff were not able to attend all the sessions[55 69 76]; however, session participation ranged from 94% to 100% when conducted at their worksite.[75]

Penetration

The penetration of the intervention ranged from 63% to as high as 100% when owned by the health system.[55 66 75]

Sustainability (integration)

Almost all studies revealed that strengthening facility services and improving access to medication led to the retention of participants. On the other hand, two studies have reported on holding services at worksites; providing lunch facilities and incentives was an alternative strategy that retained 94% of the participants at each meeting and 100% of those participants attended over 6 months.[71 75] The studies reported the reason for declining participation as a lack of time.

Some studies have also reported the integration of service within the existing setting and its subsystems (table 2 and online supplemental file 8). Two of the studies revealed successful outcomes with greater implementation of lifestyle interventions when integrated into an existing health system; they integrated the interventions into social welfare programmes and active steering committees at the state level to govern and guide the implementation process and embedded these interventions into a state-level mission.[69 75] Two reported that

integrating interventions in primary care, a nurse-led outreach service within the existing health system[55 58] and the polyclinic catchment area can be good strategies for implementing these interventions. The public–private partnership approach for implementing the programme within a public system as mentioned by Tschida *et al* is effective for scale-up.[61]

Success and challenges

The success factor for implementation and scaling up is when the implementation is system-integrated, adapted by local activities and relevant to the language.[54–56 60 63 69 71 74 76] The studies also outlined cultural challenges, including a shortage of providers, resources being out of stock and low enrolment of male participants.[54 61 66 67 70 78]

Certainty of evidence

The GRADE certainty of evidence (online supplemental file6) showed that all studies included in the outcome analysis had a very low certainty of evidence. No upgrades were made for any of the observational studies.

DISCUSSION

This study aimed to identify the strategies, methods and outcomes related to scaling up the implementation of SLIs for the prevention and control of CMDs in LMICs. This systematic review identified 26 studies that reported on the strategies and methods used to scale up SLIs for the prevention and control of CMDs applied in the community setting of LMICs. This review complements our recent study on challenges and enablers to the scale-up implementation in different Global Alliance for Chronic Diseases projects by Ramani-Chander *et al*.[80] This also complements the recent reviews by McCrabb *et al*[31] that evaluated pre-scale-up and post-scale-up interventions for obesity and the study by McKay *et al*,[39] which described different frameworks used for the scaling up of interventions in physical activity, including implementation outcome indicators and delivery of implementation strategies through Delphi methods.

Few studies have assessed the implementation process and outcomes using frameworks. The failure to adequately assess the scale-up implementation could be due to a lack of funding[80]; studies also mentioned that the delivery of large-scale interventions was limited by a lack of models.[55 70] In contrast, some studies recommend that future studies explain the process of scaling up and sustainability that can guide the implementation of large-scale studies.[68 69 78 81]

Our review highlights several important findings. (A) Strategies: First, studies have adapted and implemented different strategies to suit the context and improve the lifestyle of participants. Adopting lifestyle interventions modified according to contextual needs has the potential to scale up, as Milat *et al*[19] noted. The adaptation of a programme with a focus on the involvement of the community or family enhances the likelihood of successful implementation. However, this approach did not ensure the participation of men in the programme, as presented in previous studies.[61 69] Cultural adaptation according to context is important; in addition to adaptation owing to language and food, it is important to modify interventions according to the local availability of food and traditional recipes.

Second, local stakeholder engagement in the process of adaptation and implementation is important for meeting the community's needs, as shown in the above strategies. A study by Ramani-Chander *et al* confirms that stakeholder engagement and building trust are integral parts of early scale-up implementation strategies.[80] As stated by the large-scale trials in this review, it is equally important that these interventions be delivered early on a larger scale to achieve effective outcomes.[60 69 78] As mentioned by Nguyen *et al* and Ramani-Chander *et al*,[80 82] early identification of needs and readiness at the system and community level to scale up and an assessment of the integration of these interventions into the public health system, as mentioned by Atun *et al*,[83] is critical for scaling up the programme.

(B) Methods: Third, while the use of guiding theory, models or frameworks to understand the implementation process and its outcomes, as well as understanding the barriers and facilitators, can enhance implementation, we found few related studies. Using frameworks or theories, only 15% of the 26 studies included in our analysis mentioned and measured their interventions and implementation. This finding is consistent with the findings of Strifler *et al*, who reported the least use of TMFs for dissemination, sustainability and scale-up studies.[84] It has been reported that implementation scale-up and sustainability are likely to occur when studies are based on theories and are also of interest to the government, as mentioned in a study by Koorts *et al*.[85] A study that used the RE-AIM framework to evaluate implementation outcomes revealed recruitment barriers among male participants, the importance of patient-centred care, the clarity of the role of healthcare worker involvement, and participants' time and budget. Assessment of resources is imperative for integrating projects into public health systems.[86]

(C) Outcomes: Fourth, we found that studies involving training the providers and community volunteers and performing formative studies to integrate interventions into a system ensured the fidelity of the interventions. Participation retention can be motivated by bringing the intervention close to their doorstep or the worksite, facilities for lunch or incentives. Integrating services within the existing health service and ownership of the programme by the public health system can ensure the retention of the participation and delivery of the programme. In addition, it was found that the failure to present the effectiveness of the study did not change in scaling up of the intervention by decision-makers, due to high demand from the healthcare providers and health system on the intervention or when the interventions were not readily available, which overcomes the 'silo' approach, an

approach where the diseases such as NCDs and mental health can be overlooked due to single preference to other diseases such as communicable diseases.[55 86] However, having procurement and supply of medicines different from public procurement can pose challenges to the integration and sustainability of the programme.[68 55 86]

Limitations

To our knowledge, this is the first systematic review to identify the strategies, methods and outcomes of scale-up studies on SLIs for the prevention and control of CMDs in LMICs. This review is limited by a lack of meta-analyses. Due to the varied nature of the studies, we could not conduct a meta-analysis. Given that this review focused on work in LMICs, limiting the studies to only the English language may have led to the omission of some crucial studies published in other languages. This might have caused overestimation or underestimation of the results. We could not evaluate all the studies using the taxonomy of Proctor E, as the studies did not use the framework for evaluation. Most of the outcomes related to feasibility, fidelity, penetration and sustainability including integration were either not mentioned or not assessed. We recommend that scale-up studies report the use of TMFs; the strategies implemented during the scale-up process; and the outcome of the study using the framework so that it is clear for the policy maker or the implementors to scale up the component or the whole intervention to the other contexts (state, country, etc).

CONCLUSIONS

We found that the intervention and implementation strategies should be adapted to the local context. There should be strong stakeholder engagement, codesigning of the scale-up process with key stakeholders, intervening through community structures, integration of the intervention into the health system, strengthening the capacity of community health workers to implement the SLIs at the community level, and training and deploying the peer leaders, volunteers, and other lay health workers. Engaging the participants through mobile texts or other media, strengthening facility services and access to medicine leads to the retention of participants. Readiness assessment should be used as a strategy, and interventions should be integrated early into the existing system for improved implementation outcomes. Engaging family and community at the beginning of the study to cocreate adaptations in culture, language and traditional recipes improves the fidelity and effectiveness of the intervention.

A gap remains in using methods to assess scale-up implementation to guide the process for future implementers and policymakers. We recommend the early recognition of a suitable framework for developing a scale-up study on SLIs in LMICs for effective policy-making.

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