SYSTEMATIC REVIEW OR META-ANALYSIS

Structured diabetes self-management education and glycaemic control in low- and middle-income countries: A systematic review

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Abstract

Aim: To determine the association between structured diabetes self-management education (DSME) and glycaemic control in persons living with diabetes (PLD) in low- and middle-income countries (LMICs).

Methods: PubMed, Embase and Cochrane databases were searched up to June 2020 for intervention studies on the effect of structured DSME on glycaemic control in PLD in LMICs (PROSPERO registration CRD42020164857). The primary outcome was reduction in glycated haemoglobin. Included studies were assessed for risk of bias (RoB) with the Cochrane RoB tool for randomised trials. Findings were summarized in a narrative synthesis.

Results: Out of 154 abstracts retrieved and screened for eligibility, nine studies with a total of 1389 participants were included in the review. The structured DSME interventions were culturally tailored and were delivered in-person. They were associated with reductions in glycated haemoglobin in all studies: mean/median reduction ranged between 0.5% and 2.6% relative to baseline.

Conclusions: There is a dearth of literature on the association between structured DSME and glycaemic control among PLD in LMICs. The evidence available suggests that in LMICs, particularly in sub-Saharan Africa, structured DSME is associated with reduction in glycated haemoglobin. We recommend further intervention studies on the effects of structured DSME in LMICs.

Keywords
diabetes, DSME, HbA1c, interventions, LMIC, SSA
1 | INTRODUCTION

Diabetes mellitus is a global epidemic and more than half a billion adults are currently living with it. If the current trends persist, it is estimated that by 2045, this number will increase to 784 million. Diabetes is characterized by hyperglycaemia. Chronically high blood glucose levels result in endothelial dysfunction and life-changing complications such as permanent blindness. Moreover, hyperglycaemia is associated with increased diabetes-related mortality, and all-cause mortality. The consequences of the rising prevalence of diabetes are far reaching and alarming; especially in low- and middle-income countries (LMICs), where health systems are already burdened by high rates of infectious diseases. The current COVID-19 pandemic compounds the difficulties of delivering care to a growing number of persons with communicable and non-communicable conditions. To cope with the current and future burden of disease, a sustainable approach adapted to local resources is required.

Good glycaemic control in the early phase of diabetes can delay the development of complications and is associated with favourable long-term outcomes. Previous studies from high-income countries have shown that diabetes self-management education (DSME) is effective in improving glycaemic control, but quality of life measures are inconclusive. Moreover, DSME can positively alter diabetes-specific knowledge and lifestyle. DSME equips people with skills for effective disease management. DSME is associated with reductions in all-cause mortality in high-income countries.

Self-management education is a key component of the chronic care model, a cost-effective model, which has been shown to improve interdisciplinary care, and outcomes of chronic conditions like diabetes. Although DSME is such an important tool for optimising diabetes care, studies on DSME in Africa are limited. Unstructured information is frequently provided on an ad hoc basis by healthcare professionals. Often personnel delivering DSME in sub-Saharan Africa (SSA) have had no formal training in DSME or in the delivery of DSME. Offering structured DSME, following a predefined curriculum, allows DSME to be more scalable. Compared with ad hoc sessions, structured DSME is less dependent on the availability expertise, and it can be delegated to more abundant health care professionals such as auxiliary nurses.

Although DSME has been well studied, there is a dearth of evidence on the effectiveness of structured DSME, particularly in low-income settings. The aim of this systematic review was to evaluate the association between structured DSME and glycaemic control among people living with diabetes (PLD) in LMICs.

What’s new?

- Majority of persons living with diabetes reside in low- and middle-income countries (LMICs) with the largest rise in prevalence predicted to occur in sub-Saharan Africa (SSA) by 2030.
- Previous systematic reviews on the effects of diabetes self-management education (DSME) on glycaemic control in Africa have been inconclusive. Furthermore, in LMICs, studies on structured diabetes education programs are limited.
- In high income countries, structured DSME is associated with better glycaemic control. Structured education allows standardisation and is scalable.
- In LMICs, structured DSME, which is linguistically adapted and delivered in-person, is associated with HbA1c reductions. Structured DSME may, therefore, improve care outcomes in LMICs especially in SSA.

2 | METHODS

We conducted a systematic review on the association between structured DSME and glycaemic control in LMICs in June 2020. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines was used to guide the reporting, and the protocol was registered with the International Prospective Register of Systematic Reviews (registration number CRD42020164857). PubMed, Embase and Cochrane Library electronic databases were searched using the following keywords: ‘diabetes mellitus’, ‘structured diabetes self-management education’, ‘developing countr*’, ‘glycaemic control’ and ‘low- and middle-income country’. The detailed search strategy is attached as Table S1.

Available titles and abstracts of articles were systematically screened by the first authors for relevance. Conflicts during the screening process were resolved by referring the matter to a third co-author whose decision was final. Duplicates were removed and papers meeting the predefined eligibility criteria were identified. Full texts of eligible publications were retrieved for review and final selection. All intervention studies, published in English, evaluating the effect of structured DSME on glycaemic control in PLD in LMICs were included. These included (un-)blinded randomised controlled trials (RCT), non-RCT and quasi-experimental pre-test post-test study designs. Articles that did not focus on structured DSME
and/or did not follow a curriculum, were excluded. Observational studies, studies including children or adolescents (under 18 years of age), and studies not assessing HbA1c as an outcome, were also excluded. Furthermore, qualitative research, biomolecular studies, case reports and studies not published in a peer reviewed journal were excluded. Following failure of a single attempt to contact the corresponding author, three studies were excluded for unavailability of full texts.

The following data were extracted: general information (author, journal, year, country); study characteristics (study design, objectives, inclusion and exclusion criteria, sampling strategy and sample size, demographic details, and duration of follow-up); information on the DSME program (number of sessions, duration, mode of delivery, provider of intervention, level of intervention, location of intervention, intervention content/areas of focus and care provided to the control group); outcome data (loss to follow-up, outcome measures). The primary outcome was reduction in HbA1c. No secondary outcomes were evaluated.

The revised Cochrane Risk-of-Bias tool for randomised trials (RoB 2) was used to assess the RCT studies (n = 5) and judge internal validity. The following domains were assessed for risk of bias (RoB): (1) selection process (random sequence generation and allocation concealment); (2) deviations from the intended intervention (influences of not masking participants and personnel). Blinding is not possible for DSME interventions; (3) incomplete outcome data (withdrawals and lost to follow-up); (4) appropriateness of the outcome measurement and (5) selection of reported results. Studies were then assigned to one of the three categories: low risk, some concerns or high risk.

3 | RESULTS

3.1 | Description of study characteristics

A total of 154 titles/abstracts were screened for eligibility by two reviewers after removal of duplicates. Fifteen publications were selected for full-text analysis. Subsequently, six articles were excluded for one or more of the following reasons: inappropriateness of the intervention, ineligible study outcome, full-text unavailability or not published in peer reviewed literature. Nine studies met the eligibility criteria and were included in this systematic review. The literature selection process is illustrated in Figure 1.

Table 1 summarizes the study characteristics of the included studies. A total of 1389 participants were included in this systematic review. The sample size of individual studies included ranged from 90 to 300 participants.

Majority of the included studies were conducted in SSA; two in South-Africa and one in each of the following countries: Kenya, Rwanda, Mali and Nigeria. The remaining studies were conducted in Guatemala and the Philippines.

Four out of the nine studies were unblinded RCTs, one was a cluster randomised controlled trial, and four used a pre-test post-test design. Most of the studies focused on primary care facilities. Other study interventions were implemented in secondary or tertiary centres. Four reviews specifically studied the impact of DSME in rural agricultural settings. Five studies evaluated the benefits of DSME specifically on participants with type 2 diabetes. Three of these five exclusively enrolled existing, sub-optimally controlled participants (defined by an HbA1c ≥8%). but Flood et al., included participants regardless of their HbA1c if they were newly diagnosed. Two studies enrolled both people with either type 1 diabetes mellitus or type 2 diabetes mellitus (T2DM). One of the two studies was designed for people with significant hyperglycaemia (HbA1c >8.5%). About 70% of the study population were women (n = 972).

Follow-up of participants ranged between 3 and 48 months with majority of studies (n = 8) reporting a follow up duration between 3 and 12 months. Price et al., focused on long-term glycaemic outcomes and collected data at 6, 18, 24 and 48 months post-intervention. Analysis was restricted to baseline and end-line data when HbA1c was assessed multiple times.

Although glycated haemoglobin (HbA1c, %) was the primary outcome in all studies, changes in this clinical outcome were expressed differently. Secondary outcomes in the included studies comprised a wide array of anthropometric, biochemical and health behaviour and knowledge indicators. Several studies also reported medication use and adherence and health care consultation.

Considering the heterogeneity among included studies in terms of study population, duration of follow-up, outcome measures and outcome assessment methods, a meta-analysis was not feasible. The study results were, therefore, summarised narratively.

3.2 | Quality assessment

A summary of the RoB assessment for all studies is shown in Table 1. The RoB was judged as low in the RCTs conducted by Amendezo et al., Debussche et al. and Essien et al. The RoB was considered high in the studies by Gathu et al. and Paz-Pacheco et al. Only a few of the randomised trials explicitly explained the process for random sequence generation and the allocation.
sequence concealment. Blinding of participants and personnel was impossible due to the nature of the intervention. Two\textsuperscript{14,23} of the publications lacked detailed information about deviations from the intended intervention, resulting in an increased RoB. In 80\% of the RCTs, concerns arose because of the number of missing outcome data, and information on the pattern of loss to follow-up. The RoB assessment is shown in Table 1 and summarised in Figure S1.

### 3.3 | Intervention characteristics

Seven studies\textsuperscript{14,19,20,21,22,23,26} focused solely on the impact of a structured DSME program. DSME was only part of the intervention in the two remaining papers.\textsuperscript{24,25} In general, the DSME interventions included interactive teaching sessions following a previously developed curriculum and focused on multiple aspects of diabetes self-management. The areas of focus of each DSME program are listed.
in Table 1. Although the main DSME content was similar across studies, the intervention characteristics varied considerably in the number and duration of sessions, the frequency of the intervention, the DSME provider and the location where the intervention was delivered. Van Zyl et al.25 used a single-group pre-test post-test design. The intervention was a physician education programme combined with a structured consultation.25 In this study, two similar dedicated diabetes clinics were audited before and after implementation of the intervention. Participants in the intervention arm attended quarterly clinics where they received education on several topics.

Generally, the DSME interventions included sessions on exercise, nutrition, medication use and adherence, glucose monitoring, routine medical reviews and complications of diabetes. Other main subject areas were foot care, smoking cessation and cardiovascular risk management. Overall, minor differences in the content of the interventions were observed across the included studies (Table 1).

Price et al.24 evaluated the long-term glycaemic outcome of a structured nurse-led care. Empowerment-based diabetes education and drug titration with a clinical algorithm were the key elements of this intervention. A diabetes-trained nurse conducted monthly visiting at local primary health clinics within a specified region. During each visit, group-based diabetes education was offered followed by individual consultations. Participant’s medications were titrated by the diabetes nurse.24

In all studies, the intervention was linguistically adapted to suit the population. Flood et al.20 and Deussche et al.26 aimed to implement a culturally tailored DSME program. In 44%19,21,23,28 of the studies, the DSME program was delivered to groups, whereas 22%24,25 of the studies combined a group-based approach with individualised education. In 33%14,20,25 of the studies individual DSME was provided following a previously developed curriculum. All DSME sessions were delivered in-person. The total number of educational sessions ranged between 3 and 12. Each session lasted 85 min on average and ranged between 45 and 120 min. Structured DSME was provided by varied health care professionals, including physicians, nurses, nutritionists, psychologists and (certified) diabetes educators. Community health workers contributed in two studies.22,24 In Deussche et al.26 and Paz-Pacheco et al.23 the DSME programs were offered by trained peer educators.

3.4 The effect of structured DSME on glycaemic control

All included studies used HbA1c as an outcome measure of the effect of structured DSME on glycaemic control. For all included studies, a decrease in HbA1c after implementation of structured DSME was observed: mean/median reduction in HbA1c ranged between 0.5% and 2.6% relative to baseline values.

Different statistical analyses were used in the studies. Six trials (67%)14,19,21,23,25,26 performed a statistical test of difference between-group comparison of mean HbA1c levels at study end. Statistically significant differences in mean HbA1c improvements between the intervention arm and the control arm, were evident in four (67%)19,21,23,26 of these studies. Three studies (33%)19,23,25 expressed the effect of DSME, by presenting the change in HbA1c after the DSME program was implemented; all three studies reported a significant improvement in HbA1c levels (Table 1) from baseline. Three studies19,23,25 analysed the proportion of participants achieving good glycaemic control post-intervention. They uniformly reported an increase in the proportion of study participants achieving recommended HbA1c levels. Van Zyl et al.25 defined good glycaemic control as HbA1c <7.5% and described a non-significant rise in the number of participants achieving target in both the intervention group (from 33% to 40%, p = 0.17) and in the control group (from 25% to 38%, p = 0.060). Amendezo et al.19 observed an increase from 16% to 39% in the proportion of participants achieving an HbA1c target of ≤7%. At 12 months, they noted that significantly more participants met the HbA1c target in the intervention group, compared with the control group (49% vs. 29%, p = 0.003). Similarly Paz-Pacheco et al.23 reported a significantly greater proportion of participants reaching an HbA1c goal of ≤7% after receiving structured DSME, compared with controls (60% vs. 39%, p = 0.019).

4 DISCUSSION

This systematic review aimed at evaluating the impact of structured DSME on glycaemic control in LMICs. We identified and summarised the available evidence from nine studies conducted in LMICs that focused on the effect of structured DSME on HbA1c. Structured DSME was found to be associated with improved glycaemic control. After implementation of the structured DSME intervention, all included studies reported a decrease in HbA1c. Additionally, some studies showed an increase in the proportion of participants achieving glycaemic targets. Most studies (n = 7) described a decrease in mean HbA1c levels of >1.0%. This is clinically significant: the United Kingdom Prospective Diabetes Study UKPDS showed that every 1% reduction in HbA1c is associated with significant reductions in diabetes related morbidity and mortality occur.2 Medications reduce HbA1c between 0.60% and 1.48%.27 Compared with pharmacological therapies, DSME has been shown to be cost-effective.28
| Author (year), country       | Study design                         | Duration of structured DSME intervention | Enrolled participants                                                                 | Sample size, mean age (±SD), distribution of sexes women/men | Follow-up period (months) |
|-----------------------------|--------------------------------------|------------------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------------|
| Amendezo et al. (2017), Rwanda | Unblinded randomised controlled trial | 45–60 min sessions monthly; time frame of intervention unspecified | Adults (21+ years old), diagnosed with T1DM or T2DM at least 3 months prior to enrolment into the study | 251 participants, mean age 50.9 (±10.9) years, F 69.3%/M 30.7% | 12                       |
| Debussche et al. (2018), Mali | Unblinded randomised controlled trial | 1.5–2 h-sessions 3-monthly for 1 year    | People with T2DM, aged between 30 and 80 years, which were poorly controlled (HbA1c ≥8%) | 151 participants, mean age 52.5 (±9.8) years, F 76.2%/M 23.8% | 12                       |
| Essien et al. (2017), Nigeria | Unblinded randomised controlled trial | 2-h sessions 2-weekly for 6 months      | Participants aged 18+ years with either T1DM or T2DM, with HbA1c levels ≥8%, who were able to engage in moderate exercise without issue, and were free of any eye disease that would otherwise limit their ability to read printed materials | 118 participants, mean age 52.7 (±10.5) years, F 60.2%/M 39.8% | 6                        |
| Gathu et al., (2018), Kenya | Unblinded randomised controlled trial | 1-h sessions 6-weeks; total of 3 sessions | Sub-optimally controlled T2DM (defined as HbA1c levels ≥8%), aged between 48 years and 65 years | 140 participants, mean age 48.6 (±9.8) years, F 44.3%/M 55.7% | 6                        |
| Paz-Pacheco et al. (2017), Philippines | Cluster randomised controlled trial | 1-h sessions weekly for 4 weeks | T2DM                                                                                    | 155 participants, mean age 57.1 (±11.5) years, F 70%/M 30%     | 6                        |
| Flood et al. (2017), Guatemala | Uncontrolled pre-test post-test design | Series of six home visits; weekly visits in first month then monthly in month 5/6; duration per session unspecified | Existing T2DM with either an HbA1c level >8.0% or diabetic complications, or newly diagnosed T2DM | 90 participants, mean age 53.8 (±12.3) years, F 82%/M 18% | 12                       |
| Micikas et al. (2015), Guatemala | Uncontrolled pre-test post-test design | Weekly diabetes club meetings, weekly home visits and pre-consultation visits in clinic; duration of meetings and time frame of intervention unspecified | Adult with T2DM (18+ years) who consulted the ODM clinic in the past year | 104 participants, F 91%/M 9% | 4                        |
| Price et al. (2011), South Africa | Uncontrolled pre-test post-test design | Monthly; duration per session and time frame of intervention unspecified | People with T2DM                                                                          | 80 participants, mean age 56 (±11) years, F 70%/M 30%         | 48                       |
| Outcome measure(s) | Mean/median HbA1c at baseline | Mean/median HbA1c at study end | Decrease in mean/median HbA1c | Statistically significant between-group difference in change in HbA1c (p-value) | Risk of bias^* |
|---------------------|-------------------------------|-------------------------------|-------------------------------|--------------------------------------------------------------------------|----------------|
| HbA1c, SBP and DBP, BMI, FBG | Baseline median HbA1c (95% CI): 9.1% (8.7–9.6) | 12-month median HbA1c (95% CI): 7.49% (7.22–7.76) | Intervention group: –1.7% (p < 0.001); Control group: 0.52% (p = 0.015) | Yes (p < 0.001) | Low risk |
| HbA1c, body weight, BMI, WC, SBP and DBP, antidiabetic and anti-hypertensive treatment, diabetes knowledge, and dietary practices | Mean baseline HbA1c (SD): Intervention group: 10.6% (SD = 1.8); Control group: 10.8% (SD = 1.9) | 6-month median HbA1c (95% CI): 8.3% (7.8–8.7); Control group: 10.1% (9.5–10.7) | Intervention group: –2.6%; Control group: –0.4% | Yes (p < 0.0001) | Low risk |
| HbA1c, SBP and DBP, and BMI | Mean baseline HbA1c (SD): Intervention group: 9.8% (SD = 1.78); Control group: 9.9% (SD = 1.45) | 6-month median HbA1c (SD): Intervention group: 8.1% (SD = 1.89); Control group: 9.3% (SD = 1.75) | Intervention group: –0.98% (SD = 2.29); Control group: –0.6% (SD = 1.54) | Statistically not significant difference of 0.37 (SD = 0.41) (p = 0.37) | High risk |
| HbA1c, BMI, WC, SBP and DBP, FBG, total cholesterol, LDL, HDL, triglycerides, health behaviour measures, medication use data | Median baseline HbA1c (IQR): Intervention group: 6.35 (3.95); Control group: 7.25 (3.7) | 6-month median HbA1c (IQR): Intervention group: 6.45 (2.7); Control group: 7.6 (3.1) | Absolute change from baseline HbA1c (IQR): Intervention group: median HbA1c reduction of –0.5% (1.35); Control group: median HbA1c increase of 0.25 (1.10) | Yes (p = 0.01) | Moderate risk |
| HbA1c, SBP and DBP, diabetes knowledge and diabetes self-care measures | Mean HbA1c at baseline: 9.9% (9.5–10.3%) | Mean HbA1c at 12 months: 8.4% (8.0–8.8%) | Mean HbA1c decreased significantly, with an estimated absolute mean change of –1.5%; 95% CI: –1.9 to –1.0 (p < 0.001) | Yes (p < 0.001) | Low risk |
| HbA1c, blood pressure, BMI, health behaviour and diabetes knowledge | Mean HbA1c at baseline: 10.1% | Mean HbA1c at 4 months: 8.9% | A statistically significant decrease of 1.2% (p = 0.001) | Yes (p = 0.001) | Low risk |
| HbA1c and BMI | HbA1c at baseline: 10.8 (±4.0) | HbA1c at 48 months: 9.7 (±4.0) | Mean HbA1c significantly decreased with −1.1% (p = 0.015) | Yes (p = 0.015) | High risk |
To the best of our knowledge, this is the first systematic review assessing the effect of structured DSME on glycaemic control in LMICs. Our results regarding improvements in HbA1c are consistent with previous systematic review and meta-analysis results conducted in high-income settings, but contrary to results from a previous systematic review and meta-analysis conducted in Africa. This difference may be to the fact that we focused only on interventions that were structured. Our findings echo the statement that DSME can improve HbA1c in T2DM by about 1%. Self-management education also reduces the rate of complications and improves mortality.

In this review, we examined the effect of structured DSME on glycaemic control as assessed in RCTs, and quasi-experimental pre-test post-test study designs. Due to the nature of the intervention, blinding of participants and providers was impossible. This could potentially increase the risk of performance bias and exaggeration of the intervention effect. The sample size of most of the included studies was small, and this could limit the validity of the studies. The evidence on structured DSME intervention studies from LMICs illustrates the need for further research especially in SSA, preferably with larger study populations.

In a recently published multi-centre trial, a single 90-min structured DSME session demonstrated significant improvement in fasting and postprandial glucose at 6 months in comparison with usual care. Reduction in HbA1c however did not reach statistical significance ($p = 0.06$). They documented a significant fall in HbA1c at 6 months and at 18 months but at 4 years post-intervention, the HbA1c had risen. We postulate that the lack of long-term studies may point to the challenges of funding research in the low resource settings.

Furthermore, Prince et al.’s results raises questions about the durability and underlying mechanisms of improvements in glycaemic control following structured diabetes education programs. The loss of durability of glycaemic control after a structured education intervention may be explained by difficulty in maintaining lifestyle changes over a longer period of time. The Hawthorne effect where people modify their behaviour because they are aware they are being observed (in a study) is well documented.

The extensive search strategy and manual screening of reference lists for additional articles make it unlikely that we have missed any structured DSME intervention studies. We, however, cannot exclude publication bias stemming from unpublished data and grey literature. Heterogeneity of study designs, populations, overall methodology and strategy, prevented us from performing a meta-analysis. This should be considered when generalizing our findings. Additionally, our search was limited to publications in English. Duration of follow-up was less than a year for all but one study; therefore, further studies on the durability of the improvement in glycaemic control following structured DSME are warranted.

### 5 | Conclusion

This systematic review summarises the results of nine intervention studies which assessed the association between glycaemic control and structured DSME in LMICs. The results suggest that structured DSME positively impacts...
on glycaemic control and may and, therefore, ultimately contribute to improved outcomes in PLD in LMICs. The available evidence is limited. We, therefore, highly recommend larger clinical trials to assess the association between glycaemic control and structured DSME in LMICs. The findings will be invaluable in assessing the suitability of structured DSME as a vehicle for improving diabetes outcomes in LMICs.

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CONFLICT OF INTEREST
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| Outcome measure(s) | Mean/median HbA1c at baseline | Mean/median HbA1c at study end | Decrease in mean/median HbA1c (p-value) | Risk of bias |
|---------------------|------------------------------|-------------------------------|----------------------------------------|-------------|
| HbA1c, number of clinic visits, and consultation time | Mean baseline HbA1c (SD): Intervention group: 9.77% (SD = 3.36) Control group: 10.27% (SD = 3.60) | After intervention mean HbA1c (SD): Intervention group: 8.481% (SD = 2.60) Control group: 9.153% (SD = 3.28) | Intervention group: −1.29% Control group: −1.12% | No (p = 0.14) High-risk |

Effect of intervention on HbA1c levels

| TABLE 1 (Continued) |
|---------------------|
| Author (year), country | Study design |
| South Africa | post-test design |
| Four sessions held quarterly: DSME intervention |
| Enrolled participants | Duration of structured unspecified duration per session |
| People with diabetes visiting diabetes clinics one of the tertiary care |
| 300 participants, mean women/men distribution of sexes mean age (SD), ± Sample size, arm, F 63.7%/M 54.72 (±14.46) age in control and 56.38 age in intervention period Follow-up |

HbA1c, number of clinic visits, and consultation time on glycaemic control and may and, therefore, ultimately contribute to improved outcomes in PLD in LMICs. The available evidence is limited. We, therefore, highly recommend larger clinical trials to assess the association between glycaemic control and structured DSME in LMICs. The findings will be invaluable in assessing the suitability of structured DSME as a vehicle for improving diabetes outcomes in LMICs.

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