Structured diabetes self-management education and glycaemic control in low-resource urban primary care settings

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Structureerde zelfmanagementeducatie en glykemische controle voor diabetes in stedelijke eerstelijnszorginstellingen met weinig middelen

(met een samenvatting in het Nederlands)

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door

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geboren op 30 december, 1973

te Accra, Ghana

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This book is dedicated to my father, Mr Robert Lamptey who 'nudged' me into medicine; who taught me always to aspire to excellence and to give medicine my all.

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General Introduction

Setting the context

Still waters run deep. Type 2 diabetes, the commonest form of diabetes, is largely an asymptomatic disease. The pathophysiologic defects often continue irrespective of attainment of euglycaemia.[1,2]

Globally diabetes is cascading out of control, fuelled by obesity[3] and sedentary lifestyles[4] and perpetuated by gestational diabetes[5] and epigenetic changes.[6] Currently the number of people living with diabetes has crossed the half a billion mark [7] and if current trends persist, the projections are that, 783 million people will be living with diabetes by 2045.

Alarmingly, for every person who is known to have diabetes, there is another who is undiagnosed. The global prevalence of undiagnosed diabetes among adults aged 20-79 years is 45% (240 million cases of undiagnosed diabetes). Africa has the highest proportion of undiagnosed diabetes with a prevalence of 56%.[8]

The prevalence of diabetes is highest among the elderly aged between 75-79 years.[7] Prevalence rates are higher in high-income countries and range between 8.3 -12%.[7] Prevalence rates are lower in low- and middle-income countries (LMIC)[7] and are lowest in Africa with prevalence rates of 6%.[7] The projected increase in prevalence over the next 25 years is however highest in sub-Saharan Africa. This situation can be likened to a tsunami. If Africa continues on this trajectory, with rapid urbanisation and commercialisation, diabetes will “explode” on the continent.[9] Sub-Saharan Africa especially will experience a 134% rise in prevalence[7] relative to existing rates as depicted in Figure 1 below. These predictions are grim for a continent with limited resources and weak health systems. A continent already battling with a double burden of disease; a continent where the COVID-19 pandemic has caused a worsening in several health indices.[10-12]

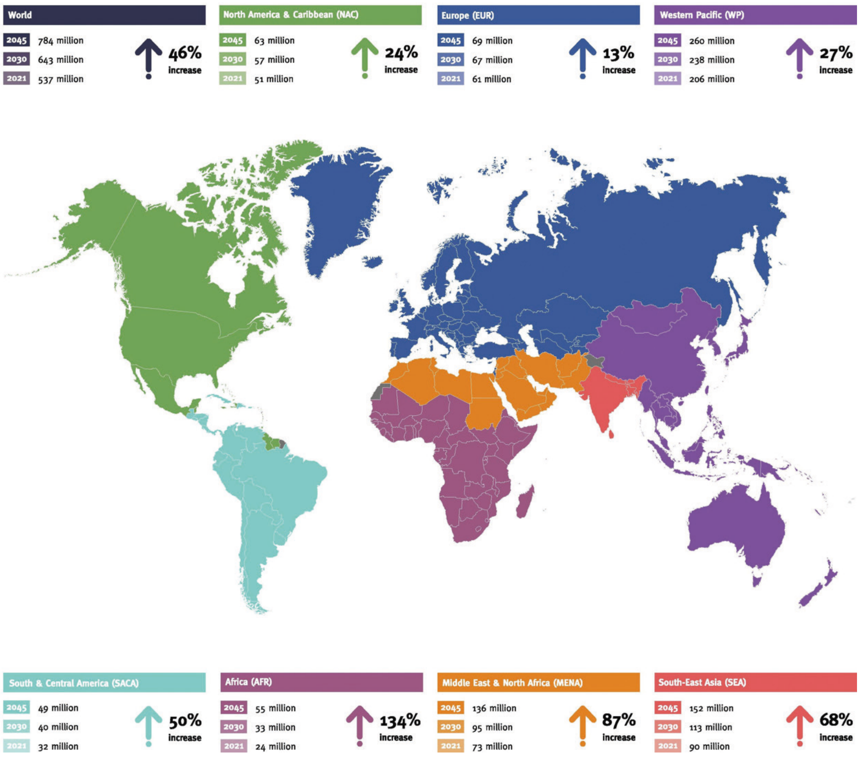
The chronic nature of diabetes, however, presents an opportunity to make gains before complications develop. Aggressive glycaemic control, preferably earlier on in the disease process, prevents and delays both the onset of diabetes[13] and microvascular complications.[14,15] The foundation of diabetes care is lifestyle modification, sustained over a lifetime and this entails healthy food and intense exercise on a regular basis. More comprehensively framed, this entails meal planning and timing, portion control, reading labels, monitoring blood glucose, adjusting medications, keeping routine reviews, managing stress, and keeping fit.

Managing diabetes requires self-management education. To effectively turn the tide and halt the devastating effects of poorly controlled diabetes, diabetes self-management education (DSME) should be accessible to all people living with diabetes and persons at increased risk for diabetes. Technology opens a world of opportunity for disseminating self-management education. Unfortunately, this may not hold true in many low-middle income countries, where 80% of people living with diabetes reside.[7] In resource constrained settings, reaching people with low health literacy and numeracy is particularly challenging.

In high-income countries DSME has been shown to achieve comparable HbA1c reductions to therapeutic agents.[16] For low-income countries and specifically, sub-Saharan Africa the literature on effectiveness of DSME is sparce and conflicting.[17]

Given the gravity of the projections for the African content, with 24 million people living with diabetes residing in Africa, there is the need to urgently find effective ways of delivering DSME in Africa. This entails exploring existing DSME programs and assessing the diabetes self-management knowledge and behaviours of people living with diabetes in low-resource settings, to be able to tailor DSME programs to their culture and literacy levels.

Diabetes around the world | 2021



Contextual framework

Knowledge does not always translate into behavioural change. However, without knowledge there is no opportunity for change. Knowledge and behaviour change are therefore both necessary for achieving better glucose control in people living with diabetes.

Poor glycaemic control is the driver of diabetes complications. Persistent hyperglycaemia and post prandial glucose spikes are particularly damaging to small blood vessels. Over time these result in life-threatening complications such as sight-threatening diabetic retinopathy.

Glycaemic control is intricately linked to routines. Levels of physical activity shape insulin resistance and thus influence the effectiveness of insulin levels in response to meals. Indirectly determining how high blood glucose rises after a meal and how long it remains elevated for. The carbohydrate load ingested at a sitting also directly impacts post meal blood glucose control and insulin spikes.

DSME equips people living with diabetes and those at increased risk for diabetes with appropriate knowledge and skill to self-manage diabetes. Often it requires a modification in behaviour or an attempt to modify lifelong habits. It may require making changes to religious demands, traditional culinary habits, and perceptions of body image. DSME must therefore be culturally tailored to the individual and his community.

It is important to elucidate the mechanisms by which DSME exerts its effectiveness. These may not be transferable between settings. There are several facets of DSME which are important. These include the theoretical underpinnings of the education program, the mode of delivery, the intensity and the duration of the program and the background of the instructors. All these variables and more may have an influence on the effect size of the association between DSME and glycaemic control.[18-20]

Barriers and enablers of effectiveness of diabetes self-management education

Behaviour modification is the desired goal of DSME. However, ability to modify behaviour transcends several layers. Personal, community and government/policy level factors all influence self-management choices. At each level there are enablers and barriers of behaviour change following DSME. At the personal level, resilience will enhance sustenance of lifestyle modifications whilst depression is associated with diabetes related distress and poor self-care behaviours. At the community level stigma and rarefication of being overweight influence perception of body image and is likely to interfere with self-care. Policies on food labelling and a ban on use of trans fat in commercial products for example are likely to enhance attempts at better self-management.

Rationale

More than half of the people living with diabetes (53.6%) in Africa are undiagnosed.[21] The high rate of undiagnosed diabetes in Africa contributes to the high rates of complications.[22] Additionally, poor glycaemic control and limited access to specialist care increase the burden of diabetes in Africa.[21] Poorly controlled diabetes is associated with well documented major complications. Impaired kidney function, retinopathy, dyslipidaemia, and erectile dysfunction are common examples. In sub-Saharan Africa, the T2DM the population attributable fraction for these co-morbidities ranges from 6-64%.[23]This implies that eliminating exposure to diabetes would result in up to 64% reduction in the incidence of these co-morbidities

Given the high disease burden in sub-Saharan Africa[9] coupled with constrained resources, we sought to study structured DSME in urban low-resource settings in Ghana. Our goal was to explore existing DSME programs and to understand the DSME knowledge and practices of patients living. with diabetes. In addition, we sought to investigate the factors associated with the effectiveness of DSME in improving short term glycaemic control.

Thesis objectives

1. The objectives of this thesis were to:
2. Determine the association between structured DSME and glycaemic control in LMIC and to estimate the effect size by conducting a systematic review of the published literature;
3. To explore existing DSME programs and to understand the DSME knowledge and practices of patients living with diabetes in resource constrained urban primary care facilities in sub-Saharan Africa;
4. Culturally adapt an evidence based structured DSME program for people living with diabetes in sub-Saharan Africa context; and
5. Test the effectiveness of an evidence based structured DSME program for people living with diabetes in such settings.

Outline of the thesis

Part 1 – Background on structured DSME

- Chapter 2: describes a systematic review of the literature on structured DSME and glycaemic control in LMIC
- Chapters 3: existing DSME programs and the DSME knowledge and practices of patients living with diabetes in resource constrained urban primary care facilities in Accra, Ghana.

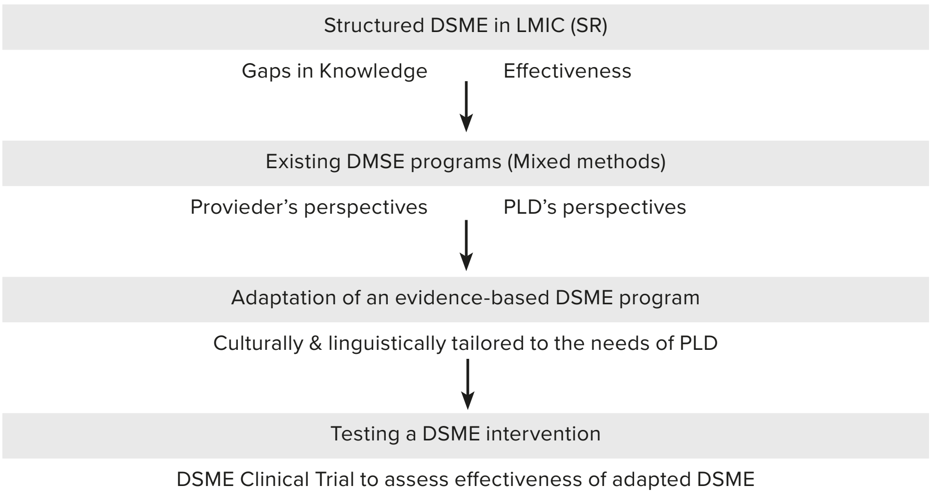
Part 2 - Structured DSME programs and glycaemic control in resource constrained settings

- Chapter 4: describes the cultural and linguistic adaptation of an evidence based structured DSME program
- Chapter 5: describes a randomised controlled trial testing of the adapted Structured DSME program for effectiveness in changing glycaemic control in 2 resource constrained settings in Ghana

Part 3

- Chapter 6 Discussion
- Chapter 7 Summary

Graphic display of thesis outline



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Part 1

Diabetes Self-Management Education

2

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

Roberta Lamptey, Maud P. Robben, Mary Amoakoh-Coleman, Daniel Boateng, Diederick E. Grobbee, Melanie J. Davies, Kerstin Klipstein-Grobusch.

Diabetic Medicine. 2022 Feb 18:e14812.

Abstract

Aim

To determine the association between structured Diabetes self-management education and glycaemic control in persons living with diabetes in low- and middle-income countries.

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 with the Cochrane risk of bias 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 diabetes self-management education 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 percent relative to baseline.

Conclusions

There is a dearth of literature on the association between structured DSME and glycaemic control among PLD in LMIC. The evidence available suggests that in LMIC; particularly in SSA, structured DSME is associated with reduction in glycated haemoglobin. We recommend further intervention studies on the effects of structured DSME in low- and middle-income countries.

Key words

Diabetes, DSME, HbA1c, interventions, LMIC, SSA

Novelty statement

- Majority of persons living with diabetes reside in low- and middle-income countries (LMIC) with the largest rise in prevalence predicted to occur in sub-Saharan Africa (SSA) by 2045. Previous systematic reviews on the effects of diabetes self-management education (DSME) on glycaemic control in Africa have been inconclusive. Furthermore, in LMIC, 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 LMIC, structured DSME which is linguistically adapted and delivered in-person, is associated with HbA1c reduction. Structured DSME may therefore improve care outcomes in LMIC, especially in SSA.

Introduction

Diabetes mellitus is a global epidemic and 536 million adults are currently living with diabetes.[1] If the current trends persist, it is estimated that by 2045, this number will increase to 784 million.[1] 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. [2]

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.[3] 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.[4]

Good glycaemic control in the early phase of diabetes can delay the development of complications and is associated with favourable long-term outcomes.[2,5] Previous studies from high-income countries have shown that diabetes self-management education (DSME) is effective in improving glycaemic control [5,6] but quality of life measures are inconclusive.[7] Moreover, DSME can positively alter diabetes-specific knowledge and lifestyle. DSME equips people with skills for effective disease management. [8,9] DSME is associated with reductions in all-cause mortality in high-income countries. [10]

Self-management education is a key component of the chronic care model, a cost-effective model which has been shown to improve inter-disciplinary 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.[11,12] Unstructured information is frequently provided on an ad hoc basis by healthcare professionals. Often personnel delivering DSME in SSA have had no formal training in DSME or in the delivery of DSME.[13,14] Offering structured DSME, following a predefined curriculum, allows DSME to be more scalable. Compared to ad hoc sessions, structured DSME is less dependent on the availability of 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. [15,16] 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.

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[17] were 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 Supplementary Table 1. Relevant research papers selected from the reference lists of key articles, were searched for additional data.

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 pre-defined 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 LMIC 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)[18] was used to assess the RCT studies (n=5) and judge internal validity. The following domains were assessed for risk of bias: (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.

Results

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 [14,19-26] 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 90-300 participants. Majority of the included studies were conducted in sub-Saharan Africa; two in South-Africa[16,17] and one in each of the following countries: Kenya[14], Rwanda[19], Mali[26], and Nigeria.[21] The remaining studies were conducted in Guatemala[20,22] and the Philippines.[23]

Four out of the nine studies were unblinded RCTs [14,19,21,26], one was a cluster randomised controlled trial[23], and four used a pre-test post-test design.[20,22,24,25] 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.[20,22-24] Five studies [14,20,22,23,26] 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%)[14,20,22] but Flood et al [20], included participants regardless of their HbA1c if they were newly diagnosed. Two studies[19,21] enrolled both people with either type 1 diabetes mellitus (T1DM) or T2DM. One of the two studies was designed for people with significant hyperglycaemia (HbA1c >8.5%).[21] About 70% of the study population were women (n=972).

Follow-up of participants ranged between 3-48 months with majority of studies (n = 8) reporting a follow up duration between 3-12 months. Price et al,[24] 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,[23] and health care consultation.[25]

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.

Quality assessment

A summary of the risk of bias (RoB) assessment for all studies is shown in table 1. The RoB was judged as low in the RCTs conducted by Amendezo et al.[19], Debussche et al[26], and Essien et al.[21] The risk of bias was considered high in the studies by Gathu et al.[14], and Paz-Pacheco et al.[23] 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[14,23] of the publications lacked detailed information about deviations from the intended intervention, resulting in an increased risk of bias. 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 Risk of bias assessment is shown in Table 1 and summarised in supplementary material 4.

Intervention characteristics

Seven studies[14,19-23,26] focused solely on the impact of a structured DSME program. DSME was only part of the intervention in the two remaining papers.[24,25,27] 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. While 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.[27] used a single group pre-test post-test design. The intervention was a physician education program combined with a structured consultation.[27] 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. [24,28]

In all studies, the intervention was linguistically adapted to suit the population. Flood et al.[20], and Debussche et al.[26], aimed to implement a culturally tailored DSME program. In 44% [19,21,23,26] of the studies, the DSME program was delivered to groups, while 22%[24,29] of the studies combined a group-based approach with individualised education. In 33% [14,20 27]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 to 12. Each session lasted 85 minutes on average and ranged between 45 to 120 minutes. 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 Debussche et al.[26] and Paz-Pacheco et al.[23] the DSME programs were offered by trained peer educators.

2

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 an absolute difference of 0.5% and 2.6% relative to baseline values.

Different statistical analyses were employed in the studies. Six trials (67%)[14,19,21,23,26,27] 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%)[19,23,30] 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 studies[19,23,27] 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.[27] defined good glycaemic control as HbA1c $<7.5\%$, and described a non-significant rise in the number of subjects 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 $\leq 7\%$ At 12 months, they noted that significantly more participants met the HbA1c target in the intervention group, compared to 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 to controls (60% versus 39%, p=0.019).

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.[2] Medications reduce HbA1c between 0.60 - 1.48%. [31] Compared to pharmacological therapies, DSME has been shown to be cost-effective.[32]

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[33] but contrary to results from a previous systematic review and metanalysis conducted in Africa.[16] This difference may be due 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%.[34] Self-management education also reduces the rate of complications, and improves mortality. [7,8,10,35,36]

In this review, we examined the effect of structured DSME on glycemic 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 [11,37], preferably with larger study populations.

In a multi- centre trial published outside our search time, a single 90-minute structured DSME session demonstrated significant improvement in fasting and post-prandial glucose at 6 months in comparison to usual care. Reduction in HbA1c however did not reach statistical significance(p=0.06). They documented significant fall in HbA1c at 6months and 18 months but 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 long 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." We postulate that the lack of long-term studies may point to the challenges of funding research in the low-resource settings.

The extensive search strategy, and manual screening of reference lists for additional articles makes 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 [24] therefore, further studies on the durability of the improvement in glycaemic control following structured DSME are warranted.

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 LMIC. 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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Table 1. Study characteristics

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Amendezo et al. (2017)[19], Rwanda	Unblinded randomised controlled trial	45–60minute sessions monthly; time frame of intervention unspecified	Adults (21+ years old), diagnosed with T1DM or T2DM at least three months prior to enrolment into the study	251 participants, mean age 50.9 (±10.9) years, F69.3% / M30.7%	12 months	HbA1c, SBP and DBP, BMI, FBG	Baseline median HbA1c (95%CI): Intervention group: 9.19% (8.7 to 9.6) Control group: 8.74% (8.32 to 9.15)	12-month median (95%CI): Intervention group: 7.49% (7.22 to 7.76) Control group: 8.21% (7.88 to 8.53)	Intervention group: -1.7% (p <0.001) Control group: 0.52% (p = 0.015)	Yes (p <0.001)	Low-risk

Table 1. Continued

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	Outcome measure(s)	Effect of intervention on HbA1c levels				Risk of bias#
							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)***	
Debussche et al. (2018)[26], Mali	Unblinded randomised controlled trial	1.5-2 hour-sessions 3-monthly for 1 year	People with T2DM, aged between 30-80 years, which were poorly controlled (HbA1c ≥ 8%)	151 participants, mean age 52.5 (±9.8) years, F76.2% / M23.8%	12 months	HbA1c, body weight, BMI, WC, SBP and DBP, anti-diabetic 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)		Intervention group: -1.05% (SD = 2.0) (p 0.006) Control group: 0.15% (SD = 1.7) (p 0.006)	Yes (p = 0.006) The effect size was 0.48 (CI95%: 0.14 to 0.81)	Low-risk

Table 1. Continued

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Essien et al. (2017)[21], Nigeria	Unblinded randomised controlled trial	2-hour sessions 2-weekly for 6 months	Participants aged 18+ years with either T1DM or T2DM, with HbA1c levels >8.5%, 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, F60.2% / M39.8%	6 months	HbA1c	Mean baseline HbA1c (SD): Intervention group: 10.9% (SD = 1.7) Control group: 10.5% (SD = 1.5)	6-month median (95%CI): Intervention group: 8.3% (7.8 to 8.7) Control group: 10.1% (9.5 to 10.7)	Intervention group: -2.6% Control group: -0.4%	Yes ($p < 0.0001$) The mean estimated difference was -1.8 (CI95%: -2.4 to -1.2)	Low-risk

Table 1. Continued

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Gathu et al., (2018)[14], Kenya	Unblinded randomised controlled trial	1-hour sessions 6-weeks; total of 3 sessions	Sub-optimally controlled T2DM (defined as HbA1c levels ≥ 8%), aged between 18-65 years	140 participants, mean age 48 (±9.8) years, F44.3% / M55.7%	6 months	HbA1c, SBP and DPB, 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: 8.8% (SD = 1.89) Control group: 9.3% (SD = 1.75)	Intervention group: -0.98% (SD = 2.29) Control group: -0.60 (SD = 1.54)	Statistically not significant difference of 0.37 (SD = 0.41) (p = 0.37)	High risk

Table 1. Continued

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Paz-Pacheco et al. (2017)[23], Philippines	Cluster randomised controlled trial	1-hour sessions weekly for 4 weeks	T2DM	155 participants, mean age 57.1 (±11.5) years, F70% / M30%	6 months	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

Table 1. Continued

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Flood et al. (2017)[20], Guatemala	Uncontrolled pre-test post-test design	Series of 6 home visits; weekly visits in 1st 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, F82% / M18%	12 months	HbA1c, SBP and BPB, diabetes knowledge and diabetes self-care measures	Mean HbA1c (CI95%) at baseline: 9.9% (9.5%-10.3%)	Mean HbA1c (CI95%) at 12 months: 8.4% (8.0%-8.8%)	Mean HbA1c decreased significantly, with an estimated absolute mean change of −1.5%; CI95%: −1.9 to −1.0 (p < 0.001)	Yes (p < 0.001)	Low risk

Table 1. Continued

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Micikas et al. (2015)[22], 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 ODIM clinic in the past year	104 participants, F 91% / M9%	4 months	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

Table 1. Continued

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Price et al. (2011)[24], 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, F70% / M30%	48 months	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

Table 1. Continued

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**	**Outcome measure(s)**	**Effect of intervention on HbA1c levels**				**Risk of bias#**
							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)***	
Van Zyl et al. (2005)[25], South Africa	Controlled pre-test post-test design	4 sessions held quarterly: duration per session unspecified	People with diabetes visiting one of the tertiary care diabetes clinics	300 participants, mean age in intervention arm: 56.38 (±13.00) years, and 54.72 (±14.46) years in control arm, F63.7% / M36.3%	12 months	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

Risk of bias of RCTs evaluated by use of the revised Cochrane Risk-of-Bias tool for randomised trials (RoB 2).[18] *DSME Diabetes self-management education.

2

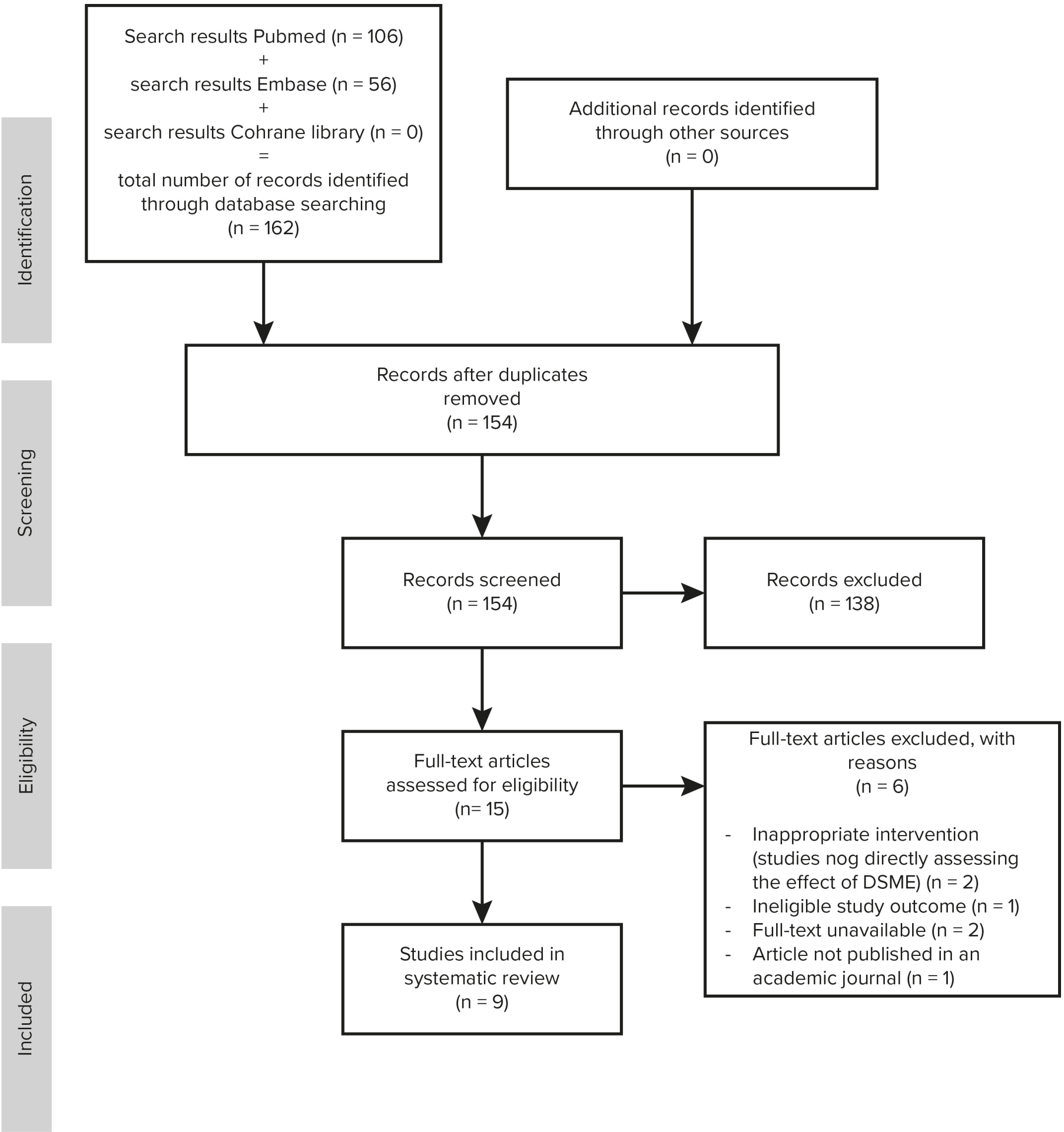


Figure 1 PRISMA flowchart of literature selection process

3

Diabetes self-management education programs and self-management in low-resource settings; a mixed methods study

Roberta Lamptey, Mary Amoakoh-Coleman, Babbel Djobalar, Diederick E. Grobbee, George Obeng Adjei, Kerstin Klipstein-Grobusch

Submitted

Abstract

Introduction

Outcomes of diabetes are closely linked to self-management. However, structured self-management education (DSME) programs are largely unavailable in Africa.

Aim

We sought to characterise DSME programs in two urban low-resource primary settings, and to explore diabetes self-management knowledge and behaviours of persons living with diabetes (PLD).

Research design and Methods

A convergent parallel mixed-methods study was conducted between January to February 2021 in Accra, Ghana. Multivariable regression models were used to study the association between diabetes self-management knowledge and behaviours (the primary outcome). We employed inductive content analysis of informants' experiences and context to complement the quantitative findings.

Results

In total 425 PLD (70.1 % (n=298) females, mean age 58 years (SD 12), mean blood glucose 9.4 mmol/l (SD 6.4)) participated in the quantitative study. Two managers, five professionals, two diabetes experts and 16 PLD participated in in-depth interviews. Finally, 24 PLD were involved in four focus group discussions.

Median diabetes self-management knowledge score was 40 % ((IQR 20-60). Every 1 unit increase in diabetes self-management knowledge was associated with increased scores on diet (5%;[95% CI: 2%-9%, $p<0.05$]), exercise (5%; [95% CI:2%-8%, $p<0.05$]) and glucose monitoring (4%;[95% CI:2%-5%, $p<0.05$]) domains of the diabetes self-care activities scale. The DSME programs were unstructured and limited by resources. Financial constraints, conflicting messages, beliefs, and stigma were themes underpinning behaviours.

Conclusions

DSME programs in low-resource settings should be culturally and linguistically adapted for such settings.

Quantitative analysis enabled us to generate valid unbiased estimates of diabetes self-management knowledge, and self-management practices. The mixed methods design provided additional insights.

The generalisability of the study to the Ghanaian population, however, is limited because the study was conducted only in two facilities within the Greater Accra region.

Key words

Diabetes, Ghana, health resources, self-management, education, self-care.

Introduction

Globally, 536 million people live with diabetes, and this number is projected to rise to 784 million by 2045.[1] Eighty percent of these half a billion people live in low- and middle-income countries like Ghana.[1] Diabetes is a long-standing leading cause of morbidity and mortality[2] in Ghana and among adults with cardiovascular disease, prevalence rates of 6.8% have been reported.[3]

DSMES involves equipping patients with diabetes specific knowledge and offering support for the application of that knowledge in real time. DSME being a bedrock of optimal diabetes care can effectively ameliorate the disease burden. [4,5]

Ryan et al reported a statistically significant in reduction in mean A1c (0.8%) following a 6-month DSME intervention among a predominantly black population. They also found significant improvements in knowledge in glucose monitoring, nutrition, complications, and management of diabetes[25] Similarly, a randomised control trial comparing a culturally tailored DSME intervention in African Americans to usual care reported significant reductions in A1c in the intervention arm at 6months. However, at 12 and 18 months respectively, this difference was lost.

A DSME intervention trial among African Americans which emphasised patient empowerment reported significant improvements in self-care behaviours, quality of life and insulin use even after 2 years.[27] Thus, sustaining improvements in diabetes outcomes may require not only providing information but also empowering patients to utilise the knowledge gained.

Cunningham et al conducted a systematic review and meta-analysis of DSME intervention trials conducted exclusively African Americans. Contrary to the findings Ryan et al and Lynch et al, Cunningham et al reported a non-significant difference in mean A1c and no improvements in quality of life (QoL) between intervention groups and usual care.[28]

Publications of DSME programs in Africa are few and have yielded conflicting results.

An audit of programs in S. Africa found 27 DSME programs with only 5 offering structured education and the rest offering ad hoc education. There were no guidelines specifically dedicated to DSME.[29] An RCT among 140 adults with diabetes attending a Family Medicine clinic in Kenya reported no significant difference in mean A1c between groups. DSME delivered by certified diabetes educators was compared to comprehensive care delivered by Family Physicians.[30] An RCT comparing intensive structured DSME to conventional education in a facility in Nigeria however showed a statistically significant reduction in mean A1c at 6mo in the intervention arm. The use of a structured approach may have contributed to achievement of better glycaemic control in the intervention arm.[31] Currently there are no published papers on DSME programs in Ghana.

It is uncertain which aspects of DSME account for its effectiveness.[6] The effectiveness of any DSME program may depend on several characteristics of the program. These include cultural and linguistic tailoring, theoretical underpinnings, mode of delivery, instructor characteristics, duration, and intensity.[7] Additionally, sustainability and by extension availability of facility-based DSME programs are also influenced by facility-level factors in addition to patient- and provider level factors.[8]

Given the diabetes disease burden, effective and sustainable solutions are urgently needed. Indeed, in high income countries structured DSME is a proven solution for ameliorating the disease burden.[5] On the contrary, the evidence on the effectiveness of structured DSME as a solution for Africa is divided.[9,10] Moreover, in Africa, structured DSME programs are largely unavailable.[10,11]

Structured DSME programs for low-resource settings in Africa must be suited as such. The afore mentioned program characteristics and patient-level factors should influence their design.

We therefore sought to characterise DSME programs in two urban low-resource primary settings, and to explore diabetes self-management knowledge, and understand behaviours of persons living with diabetes (PLD).

Methods

Design

A convergent parallel design[12] with triangulation was used; enabling collection of complementary data (quantitative and qualitative) concurrently (Figure 1). Thus, we merged the two research methods (quantitative and qualitative) to answer our research questions and achieve our study aims. In addition, the two methods converged at the point of analysing the results and interpretating the data. Data for the quantitative study and qualitative study were collected simultaneously, in parallel. Moreover, we placed equal emphasis on qualitative and quantitative data in all aspects of the study. We employed qualitative methods to deepen our understanding (of generalizable) outcomes from the quantitative study. The Good Reporting of a Mixed-Methods Study (GRAMMS)[13] and Consolidated Criteria for REporting Qualitative research (COREQ)[14] checklists were followed.

Setting

The study was conducted in Korle Bu Teaching Hospital polyclinic (KBTH) and Weija Gbawe Municipal hospital (WGMH), two public primary facilities located in Accra, Ghana. Interviews were conducted at the study sites either in offices or large open spaces whilst observing prescribed COVID-19 protocols. Experts were interviewed virtually.

Participant identification, study size and sampling

Participant recruitment and data collection occurred between January and February 2021. Using attendance records, a total enumeration of all eligible clients seen at both study sites from December 2020 to January 2021 was done. Trained staff called all potential participants meeting eligibility criteria and invited them to participate. For each individual, three attempts were made to reach them. Interested participants were given appointments for a screening visit at the study sites and to undergo study procedures. Participants received reimbursement for travel costs and time. On average, each focus group discussion (FGD) lasted an hour.

We assumed a 50% prevalence of diabetes self-management knowledge and 10% non-response rate.[15,16] The level of significance was set at 5%. A sample size of 425 PLD was therefore required for the cross-sectional study. Recruitment for in-depth interviews (IDI) continued until saturation was reached and no new themes emerged.

PLD were identified through convenient sampling and snowballing for the qualitative study. Managers and healthcare professionals (HCPs) were sampled purposively, and judgemental sampling was used to identify experts.

Eligibility criteria

Experts were nationally recognised diabetologists. HCP and PLD were staff and attendants at the study sites respectively. Managers were the respective heads. PLD were 18 years or older and ambulant at the time of recruitment. People known to have type 1 diabetes, or cognitive or psychiatric impairment were excluded.

Instrument development

Investigators anticipated heterogeneity in responses because of the case-mix variation and developed semi-structured interview guides to guide all interviews. RL and MAC, both of whom understand the local culture and norms developed and refined the guides. The questions were informed by results of a literature review of DSME needs in low-resource settings conducted by RL. Participant information guides on the purpose and methods of the study and anonymity was developed by RL and reviewed by MAC and KKG.

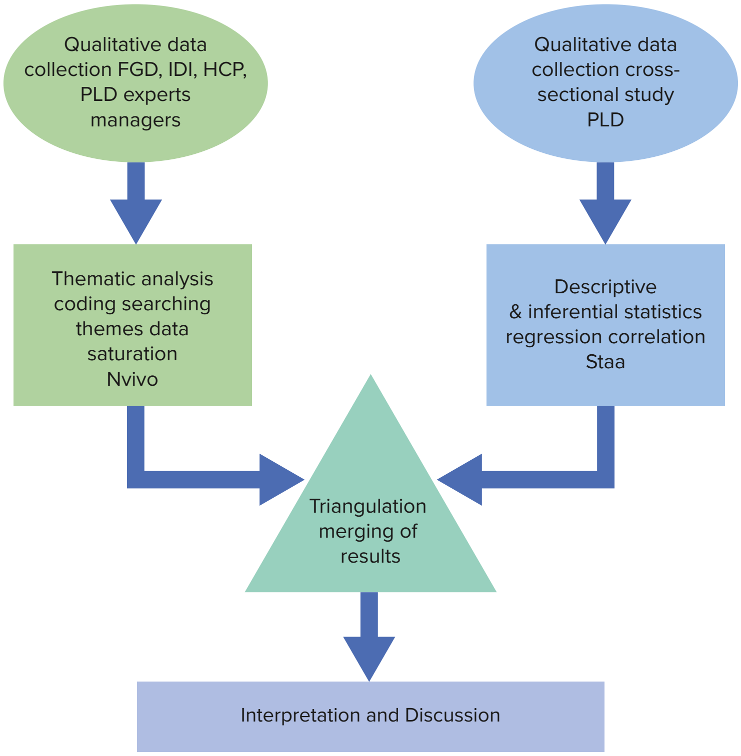


Figure 1. Convergent parallel mixed methods study design. Abbreviations: IDI-in-depth interview FGD-Focus Group Discussion HCP-healthcare professional

Data collection

The study was conducted in line with the principles of the Declaration of Helsinki. Prior to any study procedures, each participant provided written informed consent. Additionally, FGD participants signed non-disclosure statements. Codes were assigned to FGD participants to maintain confidentiality. Access to each facility was granted by their respective heads.

Quantitative

Diabetes self-management knowledge of PLD measured on the spoken knowledge in low literacy persons with diabetes scale (SKILLD), was the primary outcome variable.[17] SKILLD is a 10-item questionnaire with each option giving a score of 0(0%) or 10(100%). Higher scores indicate better diabetes self-management knowledge.

Explanatory variables were random blood glucose, anthropometric measures, sitting blood pressure, duration of diabetes, insulin use, sex, family history of diabetes, income, educational level, occupation and the summary of diabetes self-care activities scores (SDSCA).[18]

Measurement procedures

Following standard recommended procedures, we used StatStrip Xpress glucometer(Onetouch, Taiwan), Omron M7 (Omron, Japan), Omron digital scale, stadiometer, and an inelastic tape measure to measure random blood glucose[19], blood pressure[20] and anthropometry measurements[21] respectively.

Duration of diabetes, insulin use, sex, family history of diabetes, income, educational level, and occupation were obtained from questionnaires. The SKILLD and SDSCA instruments were interviewer administered.

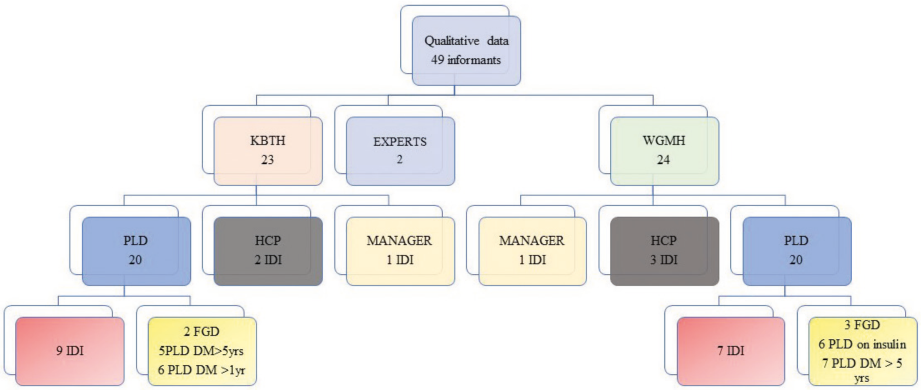


Figure 2. Qualitative data collection procedures and number of informants. KBTH-Korle bu Teaching Hospital; WGMH-Weija Gbawe Municipal Hospital IDI-in-depth interview FGD- Focus Group Discussion DM-duration of diabetes < less than > greater than yrs- years

Qualitative

Figure 2 depicts the informants and qualitative procedures undertaken. RL and BB either conducted or coordinated the IDI and FGD. Interviews were conducted in in English Twi, or Ga. Responses were digitally audio-recorded and handwritten field notes were taken.

Data management and analysis

Quantitative analysis

Total SKILLD score (knowledge) was analysed both as a continuous and categorical variable. The individual SKILLD items were dichotomised into correct and incorrect responses and summarised using counts (percentage).

To test the strength of the association between the total SKILLD score and SDSCA subdomains, the Pearson's correlation was employed. The appropriate regression tests involving ordinary least squares regression or quantiles regression were performed to assess the association between total SKILLD score) and clinically relevant variables. All analyses were conducted with Stata v16.1. Statistical significance was set at a two-sided p-value < 0.05. REDCap data management system was used for data capture.

Qualitative analysis

Data was analysed independently by RL, BB and a research assistant using an inductive thematic approach manually. Audio-recordings were transcribed verbatim. Transcription, initial coding, and thematic analysis were done manually concurrently with data collection. We extracted both latent and manifest content. Transcripts were line searched for recurring words and phrases. Concepts were then used to generate initial codes and further expanded by applying the codes to additional transcripts (open coding). Sub-themes were identified by reviewing the data for repeating patterns in participant's responses. Sub-themes were merged into themes, ensuring themes closely described original content of transcripts. Emerging themes were categorized and compared across the various (informants) groups using colour coded comparative charts. Direct quotes were extracted. Data saturation was reached when no new themes emerged. Subsequently RL used NVivo (released March 2020) to organise the data.

MAC reviewed the themes against the final organisation of the data to ensure that there was agreement in the data collected and its final presentation. Discrepancies and suggestions for review were resolved through dialogue.

Rigour

Data, informant, and investigator triangulation was used to ensure rigor and comprehension of concepts. The transcripts and subsequently thematic analysis were shared with informants to check for accuracy and to provide feedback. Team meetings with co-investigators experienced in qualitative methods enhance credibility of the data. Procedures have been described to allow replicability. Use of NVivo improve transparency and reliability of the coding. Concurrent collection of quantitative and qualitative data improve internal validity.

Ethical approval

Ethical approval was granted by the Institutional Review Board of KBTH (STC/IRB/000175/2020) and the Ethics Review Committee of the Ghana Health Service (GHS-ERC 05/10/20). The head of each facility granted permission for the study after having obtained ethical clearance.

Results

The quantitative results are summarised in tables and the qualitative results are presented by themes.

Quantitative

Participant's flow and baseline characteristics

In total, 1202 participants out of 1735 potentially eligible clients were excluded. Reasons for exclusions were as follows: 54 participants had travelled (zero from WGMH), 1029 were unreachable by telephone (544 from WGMH), 95 declined (one from WGMH), 25 were dead (1 from WGMM). As 110 out of 533 eligible participants invited failed to report, four additional participants (0 from WGMH) were consecutively sampled. Finally, 427 participants were included in the analysis.

Participants' baseline socio-demographic and clinical characteristics are shown in Table 1. Additionally, the mean body weight was 98kg (SD 16). The mean body mass index for males and females was 24 kg/m^2 (SD 8.5) and 29 kg/m^2 respectively. The mean waist circumference for males was 94 cm (SD 16) and for females it was 98 cm (SD 16). The mean systolic and diastolic blood pressure were 133 mmHg (SD 21) and 81 mmHg (SD 12) respectively. The mean random blood glucose was 9.4 mmol/l (SD 6.4) mmol/l.

Table 1. Baseline socio-demographic and clinical characteristics of participants

Variable	Frequency	Percentage
Age(n=425)		
≤39	26	6
40-49	77	18
50-59	132	31
60-69	120	28
70+	70	17
Mean (SD)	581(SD 12)	
Sex (n=425)		
Female	298	70
Male	127	30
Educational level (n=425)		
None	52	12
Primary and middle	194	46
Secondary and vocational	118	27
Tertiary	58	14
Other	3	0.7
Marital Status (n=425)		
Married	245	58
Never married	24	5.7
Living together	1	0.2

Table 1. Continued

Variable	Frequency	Percentage
Widowed	96	23
Divorced	59	14
Occupation (n=425)		
Professionals with university degrees	36	8.5
Professionals without university degree	30	7
Clerks, motor vehicle drivers, mechanic	89	21
Cooks, barbers, domestic staff, gas staff	36	8.5
Labourers and petty traders	86	20
Apprentices, educated youth, unemployed	148	35
Ethnicity (n=425)		
Akan	206	49
Ga/Adangbe	124	29
Ewe	53	13
Other	40	9.5
Religion (n=425)		
Christian	380	89
Islam	42	9.9
Other	3	0.7
Size of your household (n=412)		
1-2	91	22.09
3-4	136	33
5-6	116	28
6+	69	17
Min-Max	1-27	
Mean (SD)	5(3)	
Additional sources of income (n=417)		
No	342	82
Yes	75	18
Years of diabetes illness (n=416)		
≤1	48	12
2-3	95	23
4-9	138	33
10+	135	33
Min-Max	<1-45	
Mean (SD)	7.7 (0.3)	

Table 1. Continued

Variable	Frequency	Percentage
Family history of diabetes (n=418)		
No	179	43
Yes	239	57
Have any device for checking blood sugar at home (n=418)		
No	252	60
Yes	166	40

Abbreviations; SD =Standard Deviation

Diabetes self-management knowledge among PLD

The median SKILLD score was 40 % (IQR 20-60). The results of the individual SKILLD items revealed significant deficits in diabetes self-management knowledge. Only 13 (3%) participants knew the normal HbA1c range and 162 (39%) knew the normal fasting glucose range. In total, 208 (50%) and 196 (40%) knew the signs of hyperglycaemia and hypoglycaemia, respectively. Only 227 (54%) knew how to treat hypoglycaemia. The importance and frequency of foot care was known by 135 (32%) and 126 (30%) participants, respectively. The frequency of eye exams and exercise was known by 176 (42%) and 199 (48%) respectively. Finally, 247 (59%) participants knew the long-term complications of diabetes.

Factors associated with diabetes self-management knowledge

There was no association between SKILLD score and any of the baseline socio-demographic and clinical variables.

Association between diabetes self-management knowledge and self-management behaviour

Pairwise corelations showed that SKILLD score was positively correlated with behaviour (SDSCA). The correlation coefficient was 0.22 ($p<0.01$) for diet, 0.19 ($p<0.01$) for medication, 0.14 for exercise ($p<0.05$), 0.39 ($p<0.01$) for glucose testing and 0.38 ($p<0.01$) for foot care.

Influence of diabetes-self-management knowledge (SKILLD) on Diabetes Self-Care Activities Measure (SDSCA) sub-domains

The effect of total SKILLD on self-management behaviours (SDSCA sub-domains), adjusted for age, education, diabetes duration, family history of diabetes and ownership of a glucometer is displayed in table 2.

Table 2. Influence of Knowledge (spoken language in Low Literacy in Diabetes scale) on Diabetes Self-Care Activities Measure sub-domains

Variable	Diabetes Self-Care Activities Measures				
	OLS		Quantile regression		
	Diet	Medication	Exercise	Blood testing	Foot
	aβ[95%CI]	aβ[95%CI]	aβ[95%CI]	aβ[95%CI]	aβ[95%CI]
SKILLED Knowledge	0.05[0.02-0.09]**	0.01[0.002-0.02]*	0.05[0.02-0.08]**	0.04[0.02-0.05]***	0.02[-0.02-0.05]
Age group					
≤39					
40-49	1.55[-2.39-5.48]	-0.73[-1.99-0.53]	1.00[-1.27-3.27]	1.07[-0.83-2.97]	0.33[-2.55-3.22]
50-59	1.21[-2.57-4.99]	0.37[-0.77-1.52]	2.00[-0.49-4.49]	0.93[-0.96-2.82]	0.17[-2.47-2.81]
60-69	1.03[-2.75-4.82]	0.20[-0.96-1.35]	1.00[-1.09-3.09]	1.07[-0.83-2.97]	0.33[-2.27-2.93]
70+	1.62[-2.46-5.70]	-0.03[-1.25-1.19]	0.50[-1.60-2.61]	2.07[-0.88-3.02]	0.33[-2.36-3.03]
Educational level					
None					
Primary	2.06[-0.93-5.05]	-0.96[-1.69- -0.24]**	1.22[-1.98-5.98]	-0.28[-0.94-0.37]	-0.17[-1.57-1.24]
Middle	1.77[-0.90-4.45]	-1.02[-1.59 -0.45]***	-0.50[-2.33-1.33]	-0.50[-1.05-0.05]	-0.17[-1.46-1.13]
Secondary	3.19[0.33-6.04]*	-1.39[--2.07- -0.71]***	2.50[-0.20-5.20]	0.07[-1.32-1.46]	0.17[-1.48-1.81]
Vocational	2.97[-2.19-4.83]	-1.28[-2.02- -0.36]**	-2.22[-3.32-6.32]	0.78[-2.57-4.14]	0.17[-2.97-3.31]
Tertiary	1.21[-2.19-4.62]	-1.24[-1.98- -0.50]***	0.50[-2.16-3.16]	2.86[0.81-4.90]	1.00[-1.36-3.36]
Other	-2.54[-11.8-6.75]	0.08[-0.76-0.92]	10.0[-17.2-37.2]	7.07[2.85-11.3]***	7.00[1.98-12.0]**
Years of diabetes					
≤1					
2-3	0.38[-2.45-3.21]	0.99[-0.01-1.99]	2.66[-2.18-3.18]	-0.34[-1.01-0.29]	-0.17[-1.48-1.15]
4-9	0.34[-2.41-3.09]	0.93[-0.01-1.89]	3.11[-2.45-6.45]	-0.50[-1.15-0.15]	-0.33[-1.81-1.14]
10+	0.85[-1.98-3.68]	1.25[0.30-2.21]	0.50[-1.85-2.85]	-0.35[-1.19-0.48]	-0.17[-1.83-1.50]

Table 2. Continued

Variable	**Diabetes Self-Care Activities Measures**				
	OLS		**Quantile regression**		
	Diet	**Medication**	**Exercise**	**Blood testing**	**Foot**
Family history of diabetes					
No					
Yes	-1.06[-2.69-0.57]	0.13[-0.31-0.58]	-0.50[-1.92-0.92]	0.00[-0.48-0.49]	-5.55[-1.00-5.99]
Device for checking blood sugar					
No					
Yes	2.34[0.60-4.08]**	0.61[0.20-1.03]**	-1.00[-2.38-0.39]	1.00[0.32-1.67]**	0.17[-0.94-1.27]

NOTE: Abbreviation: SKILLED= Spoken Language in Low Literacy in Diabetes; aβ= adjusted Coefficient estimate. Covariates used age, education, duration of diabetes and family history. *p*-value Notation; *** $p<0.01$, ** $p<0.05$, * $p<0.1$ type of test multiple linear regression

3

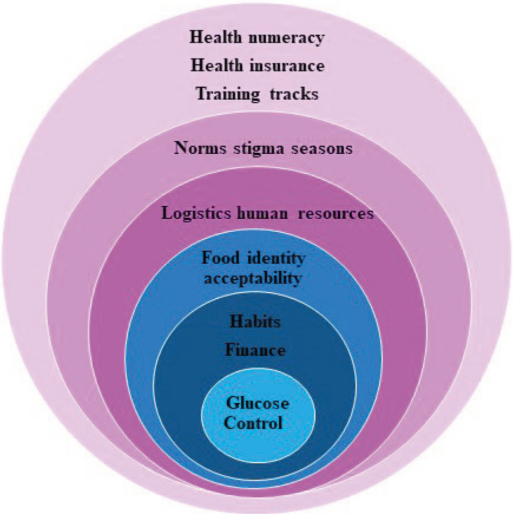
Qualitative results

Participants

Figure 2 depicts the types of informants and data gathering techniques used.

Emerging themes

The themes identified are displayed in Figure 3 and include health numeracy, financing, logistics and norms.



i.DSME programs

PLD receive DSME from nurses, doctors, and or nutritionists. It is un-structured, didactic, group-based and delivered in-person prior to consultations. Groups typically have about 20 PLD per group and sessions on average last 30 minutes. Varied perceptions among informants, resulted in contrasting perspectives on existing DSME programs. PLD generally favoured group over individualised education, placing value on peer-to-peer learning. Individualised education provided prior to a consultation was reported as being inadequate. Group sessions inadvertently provided avenues for newly diagnosed persons to draw on the experience and diabetes self-management knowledge of peers. All patient groups interviewed recommended that peers, together with health workers be used as diabetes educators. PLD described existing DSME programs as beneficial but reported that teaching aids were not culturally or linguistically adapted.

R5 FGD KBTH –"*often the books available on diabetes have examples of food eaten abroad"*

R4 FGD WGMH-*"….we have been given a book that teaches us how to manage the diabetes. The book is normally read to me…. "*

R5 FGD WGMH*: "…..about the pamphlet. It sometimes contains foreign information,… their food and what they need to do in order to take care of themselves…. I think they should be limited to our local activities"*

R3 FGD WGMH: *"……..I prefer all the teachings in a leaflet form…. those who can't read the leaflet personally, can allow our children or friends to help them read"*

In contrast to PLD, providers and diabetes experts thought existing DSME programs were at best parsimonious. Human resource constraints, lack of logistics, unavailability of academic courses, and a policy direction were challenges identified. Except for the doctors, none of the other participant groups were familiar with structured DSME.

The unstructured nature of existing DSME services meant PLD continued with self-management education classes ad-infinitum. Our informants appreciated the knowledge reinforcement.

R IDI KBTH: "…[They] *are doing their best because the doctors really educate the patients on how they can manage the diabetes themselves."*

PLD used DSME interchangeably with health education. They recommended that churches and other community spaces and mass media communication channels be used for DSME.

Most informants preferred the existing in-person format to virtual sessions.

ii. Diabetes self-management knowledge

Knowledge on self-management was deficient and self-care practices among PLD were inadequate.

R4 FGD KBTH: "*I used to inject the insulin in the house but anytime I inject it, my sugar level rises so a doctor friend of mine advised me that, the insulin should be injected in the hospital and by a doctor. So for 5years now I have stop using the insulin.*"

PLDs echoed several myths as truths. Notwithstanding, PLD bemoaned the inconsistencies in nutritional recommendations.

iii. Self-management behaviours

PLD knew more about the importance of medication use, self-blood glucose testing, meal planning, exercise, and routine reviews than about foot care. None of the PLD and HCPs

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mentioned foot care. Contrastingly, foot care, routine investigations and eye screening were mentioned by the experts as being important components of self-management.

Several barriers to self-care, even when diabetes self-management knowledge was apparently adequate, were enumerated by all informants.

iv.Finance

Among persons with low health numeracy in resource constrained settings, there's little choice in lifestyle. Poverty is the common pathway for restricted access to information, food, care, and medication. PLD described dependence on literate relatives to access useful information contained in patient education leaflets.

PLDs and HCPs enumerated the cost constraints faced by PLD and how those influence food consumption patterns. HCPs were empathetic and yet seemingly frustrated by the vicious cycle of high carbohydrate consumption and hyperglycaemia among PLD. Consumption of fresh produce is dependent on seasonality.

PLD described frequent stockout of medications covered by insurance. None of the PLD complained about costs associated with home glucose testing. The experts however noted that patient's inability to afford home glucose monitoring was a barrier to optimising glycaemic control.

v.Norms and belief systems

Finances were not the only determinants of meal patterns. PLD voiced the conflict between their intentions and actions. They recounted the difficulty of executing planned behaviour (such as portion control). They described nutritional recommendations as a deviation from cultural norms. PLD described wanting to 'belong' at social gatherings. HCW and PLD alike alluded to the fact that diabetes (especially among young persons) was stigmatised.

PLD received conflicting messages from traditional herbal and alternative medicine practitioners, religious leaders, and HCPs. Furthermore, there's a belief in destiny and the existence of an external locus of control. These belief systems contributed to poor self-care.

Discussion

We sought to characterize DSME programs and to explore the self-management knowledge and behaviours of persons living with diabetes. The programs studied were unstructured, group-based and delivered in-person mostly by nurses. Self-management knowledge and behaviours were sub-optimal and were influenced by conflicting messaging, financial constraints, culture, beliefs, and stigma.

Existing DSME programs

The existing unstructured group DSME probably reflects health resource constraints and an attempt to increase accessibility of DSME. We identified a of lack of logistics for delivering DSME; more sustainable options may be needed. The participants in our sample proposed the use of "non-internet" mass media to disseminate DSME. This strategy may be suitable for resource-constrained settings and should be studied further. Similar to our findings, the importance of the traditional media in DSME was identified in another African study.[22] Additionally, since most of our informants found repetition of content useful, the mass media channels may well be suited for resource-constrained settings. In contrast, people living with long-standing diabetes in Iran reported that repetition of DSME content was not useful. However, the population studied had significantly higher literacy levels than ours thus accounting for the disparities.[23]

Diabetes self-management knowledge

Our findings of limited diabetes self-management knowledge are consistent with previous studies. Similar to our findings, a multi-centre cross-sectional study in Ghana found diabetes self-management knowledge to be a predictor of self-care: every 1 unit increase in knowledge was associated with 20 times the odds of higher SDSCA scores.

Tertiary education was a predictor of self-care behaviours: it was associated with 12% increase in SDSCA scores. Importantly, the proportion of people with tertiary education was the same in both studies. However, the proportion of people with no education, was 50% higher relative to our study population.[24]

In contrast to our findings, a cross-sectional multi-centre study from Ethiopia, observed, that not having a formal education was surprisingly associated with increased odds of having good self-care behaviours (AOR = 2.6, 95% CI = 1.32-5.25).[25] This estimate of the effect size may be biased because of the absence of a control group.

The extremely low SKILLD scores from the quantitative study reflect the depth of lack of knowledge on self-care. The themes identified in this study provide explanations for and elaborate on the inadequate diabetes self-management knowledge among PLD. In particular, the low literacy levels and inconsistent messaging are plausible explanations for the low SKILLD scores

Diabetes self-management behaviours

In our study poor self-management was indicated by both the low SDSCA scores from the quantitative study and the qualitative results from the IDI and FGDs. Our findings of low scores across all domains of the SDSCA parallel findings from a multi-centre study in the Northern region of Ghana.[26] The socio-demographic and clinical profiles of the participants in both studies were similar except for diabetes duration. The duration of diabetes was longer in the study by Mogre et al.[26], however, despite having had diabetes for longer, the self-management behaviours were sub-optimal, as in our study.

Similar to our findings, a cross-sectional study in a specialist clinic of a tertiary teaching hospital in Nigeria reported low scores on all domains of SDSCA.[27]

Diabetes self-management: knowledge and behaviours

The low diabetes self-management knowledge scores likely contributes to the low adherence to self-care recommendations. Albeit, several of our participants recounted the difficulty of changing behaviours despite adequate diabetes self-management knowledge. Previous behaviour is a predictor of adherence to self-care recommendations.[28]

The qualitative results from our study provide further insight into the low SDSCA scores and parallel findings from other sub-Saharan African countries[29] and other regions of Ghana.[26] Consistent with our findings, a qualitative facility-based study among a predominantly agricultural community reported deficits in diabetes self-management knowledge and self-care behaviours in the domains of nutrition, exercise, and foot care with foot care being the least known and practiced.[30]

The authors also observed formal education to be a positive predictor of adherence to self-care recommendations on diet, exercise, and foot care. Their findings are contrary to our findings on the relation between formal education and foot care, but [26] consistent with findings from the North of Ghana[24]. In Ghana and other sub-Saharan African countries, amputations are major causes of morbidity among PLD.[31] The alarmingly low knowledge scores on and correspondingly poor practice of foot care in this study, suggests that future DSME curricula must emphasise foot care and the relation between amputations, glycaemic control, routines, and daily lifestyle choices.

Our findings indicate high demand for diabetes self-management information, especially, culturally tailored information on nutrition therapy. The unavailability of channels for formal training in DSME for providers, contributes to the inconsistent messaging. Our findings parallel those from a study conducted in specialist clinic in Nigeria which reported confusion about nutritional recommendations, and the unacceptability of nutritional recommendations.[32] Furthermore, the edicts of self-care behaviours particularly in the domain of nutrition deviate from cultural norms and thus contribute to non-adherence.

Financial constraints

Our findings collaborate previous findings from Ghana which indicate that cost is a major and important limiting factor in several aspects of self-management. [33]. Our participants explained that adherence to self-management recommendations, clinic appointments and medications are costly. Medications which are unavailable on the National Health Insurance were largely inaccessible to majority of our informants. Likewise, for many of our informants the accessibility of vegetables was determined by their seasonality.

Norms and belief systems

We found a belief in “divine” influences on outcomes of diabetes and diseases in general as reported by previous studies from Ghana,[33] Malawi and Mozambique[22]. The belief that the locus of control resides outside the individual adversely affects attitude to self-care and self-care behaviours.

Stigma

Our finding that diabetes is stigmatised suggests that DSME programs should include support persons. Peer educators may offer net-working opportunities to PLD and discussing disclosure may improve effectiveness of DSME interventions. The finding of stigma and lack of family support was also reported by Mogre et al. [34] Family non-support is negatively correlated with diabetes self-management behaviours among Ghanaians.[35] Family support has a linear relation with self-care.[36] Finally, our informants indicated that hospital based DSME is more valued because of diabetes-related stigma.

Strengths and limitations

Quantitative analysis enabled us to generate valid unbiased estimates of blood glucose, diabetes self-management knowledge, and self-management behaviours. Our sample was large enough and representative. The mixed methods design provided additional qualitative data and insights into the results of the quantitative study. The data was coded and analysed by researchers well accustomed to the Ghanaian culture. Data was generated from a variety of informants and study participants, managers, PLD, HCPs and experts.

The generalisability of the study to the Ghanaian population, however, is limited because the study was conducted only in two facilities within the Greater Accra region. However, the clientele at the KBTH site come from all over Ghana and neighbouring countries.

Conclusion

Existing DSME services are under-resourced and there are no structured DSME programs available in Ghana. There is a high unmet need for DSME among PLD. Our findings indicate limited diabetes self-management knowledge. Adherence to diabetes self-care recommendations is poor. Knowledge on and practice of diabetes self-management are influenced by multiple factors. Cost is a significant cross-cutting barrier to adherence to self-management recommendations. Cultural norms, belief systems (socio-cultural and religious), and stigma are other barriers.

We recommend structured DSME programs which are culturally tailored and linguistically modified for people with low literacy. This may improve diabetes self-management knowledge, modify self-management behaviour; ultimately reducing the untold suffering of PLD in resource constrained settings.

Acknowledgements

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Part 2

Structured diabetes self-management education programs in glycaemic control in resource-constrained settings

4

Cultural adaptation of a diabetes self-management education and support (DSMES) program for two low-resource urban settings in Ghana, during the COVID-19 era.

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Abstract

Background

Type 2 diabetes is a significant public health problem globally and associated with significant morbidity and mortality. Diabetes self-management education and support (DSMES) programs are associated with improved psychological and clinical outcomes. There are currently no structured DSMES available in Ghana. We sought to adapt an evidence-based DSMES intervention for the Ghanaian population in collaboration with the local Ghanaian people.

Methods

We used virtual engagements with UK-based DSMES trainers, produced locally, culturally and linguistically appropriate content and modified the logistics needed for the delivery of the self-management program to suit people with low literacy and low health literacy levels.

Conclusions

A respectful understanding of the socio-cultural belief systems in Ghana as well as the peculiar challenges of low-resources settings and low health literacy is necessary for adaptation of any DSMES program for Ghana. We identified key cultural, linguistic, and logistic considerations to incorporate into a DSMES program for Ghanaians, guided by the Ecological Validity Model. These insights can be used further to scale up availability of structured DSMES in Ghana and other low- middle- income countries.

Keywords

Cultural adaptation; Ghana; LMICs, Structured diabetes self-management education.

Main text

Background

The COVID-19 pandemic has heightened the need for people living with diabetes (PLWD) to be able to self-care and manage their condition more than ever before.[1] Physical restrictions and social distancing in these unprecedented times, have also highlighted the importance of not only delivering diabetes self-management education and support (DSMES) programs but also the need to do so in a replicable and "safe" manner.[2] In Ghana, COVID-19 infections have been on the increase. As of August 2021, Ghana had 100,383 laboratory-confirmed COVID-19 virus infections and 874 COVID-19-related deaths.[3,4] COVID-19 has disrupted clinical care in various ways. For example, there is a conscious attempt to shorten consultation time for non-urgent care, and several clinical services of Korle Bu Teaching Hospital have been shut down for varying lengths of time following COVID-19 infections among staff. Additionally, the city of Accra was locked down from 30th March 2021 to 19th April, 2020 because of the COVID-19 pandemic. The lockdown further restricted access (physical and economic) to routine diabetes care, fresh produce and group-based outdoor physical activities e.g. street walks/jogs popularly called in local parlance 'Djama'.

Diabetes self-management education and support (DSMES) is the foundation for effective diabetes care.[5,6] Delivering DSMES in low-resource settings and among people with low health literacy and or numeracy skills is challenging[7]; even more so during this pandemic.

DSMES programs must meet quality standards and be accredited.[7] DESMOND (Diabetes education self-management for ongoing and newly diagnosed) is a nationally accredited DSMES program, which supports the self-management of people living with T2D.[8] Originally designed in the UK, this program is evidence- and theory-based, delivered over 6 hours and covers core topics relating to the pathophysiology of type 2 diabetes, glycaemic control, and lifestyle management including monitoring. DESMOND has been shown to improve weight loss and illness beliefs up to 12 months after diagnosis[9] and has been shown to be cost-effective.[10] In recent years, DESMOND was culturally adapted for two cities in LMICs (Lilongwe, Malawi; and Maputo, Mozambique). This adapted version, named the EXTEND program, was tested in a feasibility trial, with results indicating positive biomedical and psychosocial improvements at both sites.[11]

Usual care in public health facilities in Ghana is often based on unstructured group education prior to clinic visits. Despite the significance of DSME programs, evidence on the association between glycaemic control, and structured self-management education programs in low-middle-income settings is poor.[12] In an opportunity to support a DSMES study in Ghana, collaborators from the UK and Ghana worked together to adapt the EXTEND program and produce a program tailored to the needs of the Ghanaian population. This paper aims to describe the adaptations to EXTEND to create a program that is culturally and linguistically sensitive to the Ghanaian community. The objective of this manuscript is to share our learnings from this adaptation process, with fellow colleagues who wish to adapt and implement DSMES in other LMICs.

Methods

The EXTEND study was presented at an international diabetes conference in 2019.[13] This paved the way for collaborators in Ghana and UK to begin discussions on delivering a modified version of EXTEND in Ghana. Several virtual consultative meetings were held between the two parties throughout 2020-2021. The EXTEND resources were sent to the Ghana research team by post and electronically. To ensure that the resources were culturally and linguistically appropriate to the Ghanaian population, work was conducted remotely between the UK and Ghana partners around the adaptation of the content and images of the EXTEND resources. The adaptation was led by the lead author and conducted by the Ghanaian team. This work was informed by prior extensive experience and informal feedback from patients from routine clinics. Once the program was culturally adapted, remote training was then conducted, whereby local nurses and doctors were trained by UK DESMOND trainers on how to deliver the EXTEND resources.

Remote training

Training on EXTEND was delivered virtually to six nurses and two doctors, by two National UK DESMOND trainers. Additional meetings were held to ensure that the two doctors were able to carry out quality assurance (QA). This QA method would assess whether the nurses were delivering the program as intended. Logistical challenges, however, became a barrier to fully allow sessions to be quality assured. In future DSMES delivery, we aim to address these issues, by allocating additional time and resources to deliver a robust QA process.

All six nurses joined the training from one location. This was to guarantee broad band internet connectivity. The nurses did not have access to broad band internet and would have had to rely on mobile data, a service that tends to be unstable and expensive. To overcome these challenges the principal investigator in Ghana (PI) made the necessary arrangements and projected the training sessions at the hospital. There were minimal challenges with technology during the training. One doctor was also physically present at the hospital with the nurses. The other doctor joined remotely.

The core aim of the training was to ensure that the clinicians were equipped with skills to facilitate a group-based self-management program. In particular, the training included key topics around increasing knowledge of the DESMOND philosophy and theories (person empowerment and Social Cognitive Theory[9]), emphasising the importance of a person-centred approach when delivering a self-management program. These areas formed the foundation of the training, to ensure that there was a clear understanding that group-based programs like EXTEND are less didactic and more tailored to the local needs. Furthermore, the virtual training also allowed clinicians to familiarise themselves with core educator skills and behaviours and were provided with the opportunity to 'have a go' at delivering the sessions. This approach fitted with the core DESMOND theory for educators to develop their own self-efficacy and self-belief in delivering sessions, by providing them with the opportunity to master a task in a controlled and safe environment (mastery experience) and observing others around them carrying out the facilitation.

Following the completion of the two-day virtual training by the UK based team, the PI held two 40-minute follow-up virtual meetings with the nurses to address any outstanding queries from the training and to ensure they felt confident to deliver the sessions to the study participants. The pathophysiology of diabetes formed the chunk of the deliberations.

A final virtual training was held after the nurses had delivered two complete sessions of EXTEND. This session was led by the PI and it was mainly to debrief the nurses and provide feedback on the sessions they had already delivered. It also offered the opportunity to introduce additional pictorial modifications to the EXTEND resources and further deepen the nurses understanding of the pathophysiology of T2D. They were introduced to the diabetes remission trials.[14,15]

Adaptations of the EXTEND resources

The resources and materials shared by the UK partners, were culturally adapted as detailed below. These resources included patient handouts, laminated cards of local food items and pictorial versions of these adaptations (Figure 1). Organisational and logistical changes were also made to enable a smooth delivery of the DSMES sessions at two sites in Accra: Korle-Bu Teaching Hospitals (KBTH) and Weija Gbawe Municipal Hospital (WGMH). These changes were mainly due to logistical differences across countries (UK and Ghana), but also due to the social distancing rules during the COVID-19 pandemic:

(a) Adaptation of the set-up of the program

We considered the option of hiring a school classroom located on KBTH campus. This would mean the sessions could only be held on weekends, holidays, or afternoons, in other words when the school was not in session. We also considered that the majority of people used public transport and were elderly. It was therefore agreed that sessions would be delivered in the mornings. As this program was part of a wider trial, the use of a venue outside the hospital setting would have raised questions around future implementation. We therefore had to make modifications, which allowed us to deliver the intervention at the study sites.

(b) Delivery logistics

A magnetic board with a human body outline and magnets of vital human organs is a key part of the EXTEND program to illustrate the breakdown of glucose in the body (Figure 1). One board was posted by the UK partners to Ghana. To ensure it would be possible to implement EXTEND and ensure replicability outside the research settings, it was imperative to create similar resources to the magnetic board for multi-centre delivery of the program. Large white boards and tapes were used to relay these key messages about glucose breakdown. For efficient use of time both sides of the board were used, whereby pictures for the subsequent lessons were taped to the reverse side of the board.

The majority of the DESMOND activities are group-based activities that consist of various resources (i.e. food models or images). These types of activities are often presented on a table to generate group discussions and allow people to reflect on their own experiences. Due to the COVID-19 restrictions, we adapted these activities and presented them as large, laminated pictures (Figure 1). This enabled the facilitators to use the white boards while maintaining social distance.

(c) Adaptation of the delivery of the intervention

DESMOND is a 6-hour program with breaks throughout the day(31). People who attend clinics, typically arrive very early, often before dawn, to get ahead of the queue, which is something that we experienced with our DSMES program. We therefore decided to serve breakfast prior to the start of the sessions and to move the lunch break to the end of the sessions. The intervention was therefore, delivered over about 5 hours instead of 6 hours, without compromising the key messages of each session. We also decided that the food served to participants would be referred to as examples during the delivery of EXTEND sessions around food choices. Breakfast was a bowl of green salad with avocado, flat bread, and an unsweetened hot cocoa beverage. Lunch was Nkontomire sauce with four fingers of boiled green bananas and water (Figure 1).

(d) Cultural adaptation of the DSMES content

Adaptation of metaphors, analogies, and examples

The glucose story as delivered by EXTEND simply states that end-product of ingested carbohydrate is sugar. In Ghana similar to the typical African cuisine, local meals are high in starchy carbohydrates and the typical portions consumed per meal are large.[16] It is not unusual for an average sized person to consume 1 fist sized ball of kenkey in a meal: this being equivalent to about 400g of carbohydrates.

We were aware from clinical experience that patients struggled to reconcile the sugar content of their diets with the amount of carbohydrate in the meal. Identifying carbohydrates in a mixed meal is also challenging. Leveraging on our clinical experience we adapted the EXTEND glucose story and placed emphasis on identification of carbohydrates, carbohydrate counting and portion control. We adapted the 'glucose story' as follows: The local corn mill, called Nikanika is readily identified by locals. It is operated commercially in markets for grinding staple foods/spices e.g.-corn, beans, soyabean, groundnut, shrimps, and pepper. We likened the process of digestion to the functioning of the Nikanika; explaining that all carbohydrate is broken down to sugar. Although corn is put into the corn mill what comes out of the mill is corn powder. In the same way all carbohydrates (e.g. kenkey, plantain, pawpaw or Nkontomire) would come out as sugar. The amount of sugar produced will depend on the type and amount of carbohydrate consumed.

To describe the four main types of carbohydrate, we used a chest of drawers as an analogy. Carbohydrate examples were the starches, milk and milk products, vegetables, and fruits. Even though what is contained in each drawer differs, they are all called carbohydrates because the end product of digestion was sugar. We then used the analogy of hats and shoes, to explain that all carbohydrates break down into sugar. For example, even though there are different types of hats to protect us from the sun, all hats are worn the same way on the head. Similarly, all shoes cover the feet and all carbohydrates become sugar. If the item is not worn on the head, it is not called a hat. If the item is not worn on the foot, it is not called a shoe and if the item is not broken down into sugar, then it is not called a carbohydrate. If it is called carbohydrate, then it means that the end-product will include sugar.

Having understood these basics, it suddenly dawned on the participants that they needed to know the sugar content of food. We explained to participants that carbohydrate was counted in units called grams, however, to ensure this was clear across all literacy levels, these were counted in cedis. Our previous experience with patients with low health literacy and numeracy skills was that abstract counting was difficult. Yet, dealing in currency was somewhat intuitive. We therefore explained that a cube of sugar was equivalent to five Ghana cedis. We proceeded to provide examples of the amounts of sugar in staple foods e.g. a fist size ball of kenkey equalled 400 cedis of sugar, a finger of Apentum plantain equalled 60 cedis of sugar, one soup ladle of nkontomire equalled 10 cedis of sugar.

Adaptation to local foods

As per the DESMOND philosophy, we aimed to share information on food, by using local foods as examples. Nuts are readily available in Ghana, being a tropical country, and therefore, facilitators used nuts as an example to present information around portion control and different types of fats (i.e. saturated, mono-saturated, polyunsaturated). Facilitators also used water as an example to illustrate quantity for oil. In Ghana, water is typically bagged into 500ml sachets (Figure 1). Facilitators portioned the sachet into five 100mls portions. Using the 100mls example, facilitators then explained that 100g of oil was equivalent to 100mls of oil. This visual representation allowed the groups, to reflect on the amount of oil required when cooking. Subsequently, facilitators explained that 100g of coconut oil had 90g/90 cedis of saturated fat; palm oil had 50g/50 cedis of saturated fat and olive oil had 14g/14 cedis of saturated fat. The simple illustration of the different types of fat, provided better understanding for its use.

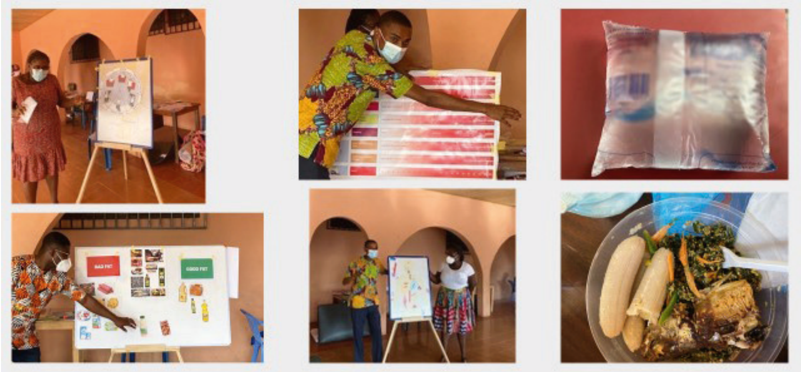

Figure 1. Examples of resources and materials used for the DSMES delivery

Results and Discussion

Recommendations for DSMES cultural adaptation in LMICs like Ghana

This paper described the collaborative work between partners in the UK and Ghana, to develop culturally and linguistically appropriate content to aid the delivery of EXTEND. To our knowledge, this is the first structured DSMES program adapted to meet the needs of Ghanaians with T2D.

The relevance of diabetes self-management education to long-term diabetes outcomes cannot be over emphasised. In the COVID-19 era and possibly beyond, the need to deliver DSMES in a structured manner in Ghana is glaring. Delivering any self-management education to people with low health literacy is challenging especially when compounded by low numeracy, low literacy and low-resource settings. We therefore, sought to build on an existing evidence-based, and theory-guided diabetes self-management program for the Ghanaian community. To do this, we further adapted the curriculum and resources of an a DSMES program, a program that was previously developed and tested in two low- middle- income countries, Malawi and Mozambique.[11]

Limitations

Despite the novelty of this study illustrating the adaptation process of a structured education program in Ghana, it is important to acknowledge its limitations. The team involved in the adaptation process consisted of clinicians, sharing their expertise from a professional perspective. This process would have benefited a formal consultative process, involving stakeholders and community/lay people, who are key to the development of self-management programs. Future studies should consider involving individuals from diverse backgrounds (clinical and non-clinical) to enhance the validity of the adapted materials and the generalisability of the program. This study aimed to adapt a self-management program for urban settings in Ghana. Further research may be required to ensure that self-management programs are adapted appropriately for rural areas also.

Although the UK team followed the standard process to train educators, the pandemic added complexities to the delivery of the training. Overall feedback was positive from those trained remotely, however, in-person training would have allowed for an organic interaction between the trainers and educators. The communication barrier was addressed by ensuring that the Ghanaian and UK team held regular virtual calls to resolve any queries ahead of the delivery of the program.

The ultimate goal from this study, was to test the adapted program in a randomised controlled trial, which is presented in a separate manuscript. Prior to this step, the adaptation process would have benefitted with the opportunity to test the delivery of the program in a feasibility study. The nature of this study did not allow for this to take place; however, future studies should consider piloting the program to refine the adapted material.

Key recommendations

Throughout this development process, we made significant changes and adaptations to the content, logistics and delivery of the program, tailored to people's lifestyle needs and demands. Using the five dimensions of the Ecological Validity Model (EVM), a framework designed to guide culturally sensitive adaptation of programs[17] we summarise key examples of these changes in Table 1; and share recommendations to fellow researchers and stakeholders who wish to culturally adapt DSMES for their communities (see Figure 2):

1. Language: Culturally appropriate language is crucial to ensure that information is relayed in a meaningful way. We have since become aware of the community-based participatory research model and the cultural adaptation process.[18] These are key approaches that allow for coherent documentation of the processes involved in adapting a program thus making it more replicable.
2. Persons: For DSMES programs, it is important to train facilitators who are part of the local communities. Regardless of whether trained facilitators are clinicians or lay people, the training equips facilitators with core facilitation skills to deliver a self-management program. Such training is built on a philosophy that trained facilitators are not perceived as 'experts' to give advice to the group, but rather, to facilitate the group effectively in a person-centred approach.
   Following best practice guidance and international standards for diabetes self-management education[7,19] quality assurance must be an integral aspect of program delivery. This ensures that the fidelity of the program is maintained. We recommend

that initial sessions be kept to the minimum number of 5 participants and to run single sessions instead of concurrent sessions until all logistic challenges have been identified and resolved. Ultimately, standards for quality of structured education programs must be established by the relevant authorities in each country.

3. Metaphors: This is a key dimension to consider when adapting a program. Metaphors can vary across cultures. For example, a pear in the UK refers to a sweet fruit but in Ghana pears refer to avocados; in the UK a tart refers to pastry with sweet or savoury filling, in Ghana it refers to a bun. To overcome such issues, ensure that any international metaphors are replaced with meaningful explanations that would be relevant and relatable to the local community.
4. Content: Consider the traits of the population, including peoples' personal circumstances and traditions, belief systems, socio-economic and educational level. Be aware that your local community may come from a low socio-economic background, with extremely low literacy and health literacy levels. To ensure that key health messages are delivered in a meaningful way, consider further adaptations where needed to replace written text with visual materials, using examples that are relatable to the priority population. Also, ensure that the program is delivered at a venue that is easily accessible and is perceived safe for participants.
5. Methods: Logistics can pose significant setbacks in organising a structured DSMES program in low-resource settings. The planning stage is crucial and it is important to do small trial/test runs prior to the actual roll out of the program. During a time where the COVID-19 pandemic has interrupted the delivery of face-to-face programs, it is important to share our learnings that it is possible to deliver DSMES training to clinicians using live-virtual platforms. However, these virtual sessions must be supplemented by additional virtual sessions delivered by local experts.

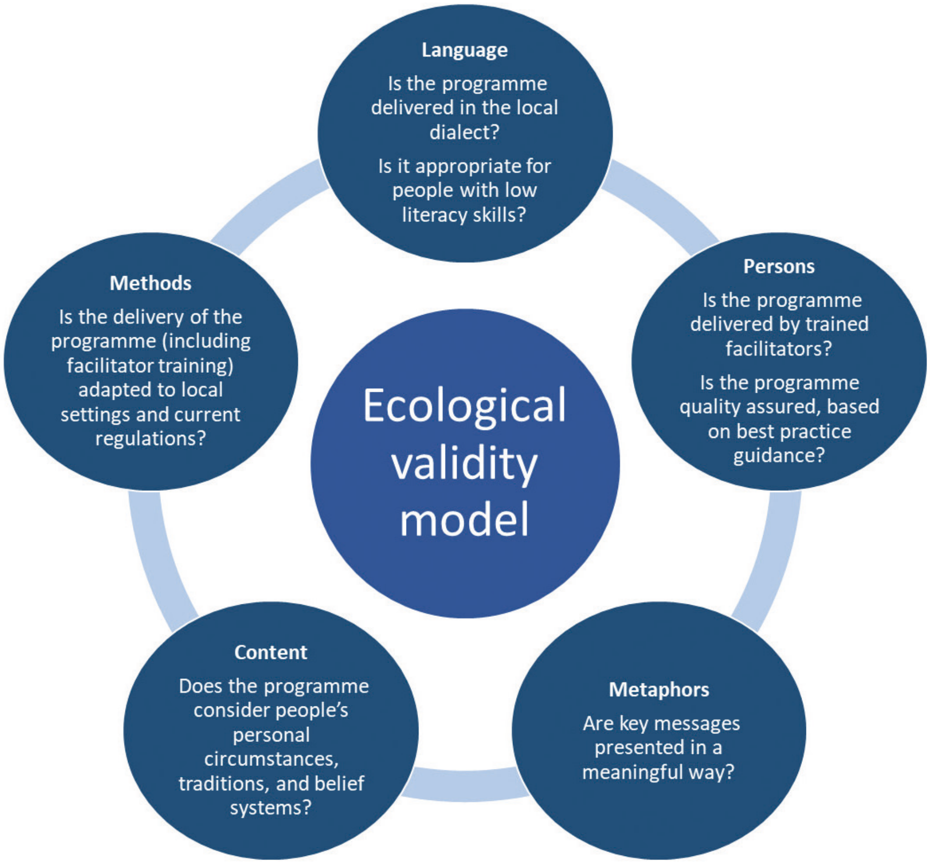

Figure 2. Cultural adaptation of a DMSES program, key factors to consider based on the Ecological Validity Model

Table 1. Examples of adaptation

	EXTEND program	Adapted Ghana program
Language	English, Portuguese and Chichewa	English, Ga, Twi
People	Trained educators were nurses and lay people with T2D.	Trained educators were nurses and a doctor
	Program was targeting adults with T2D from Malawi and Mozambique with low literacy levels	Program was targeting adults with T2D from Ghana with low literacy levels

Table 1. Continued

	EXTEND program	Adapted Ghana program
Metaphor	Lock and key analogy	Corn Mill analogy
		Chest of drawers analogy (to illustrate different groups of vegetables-starchy carbohydrate, vegetables, milk and milk products and fruit)
		Hats and shoes (to illustrate that carbohydrates have different amounts of sugars.
Content	Glucose story (carbohydrates turn into sugar)	Glucose story (carbohydrates are grinded down into sugar)
	Units in grams	Units counted in cedis (1g equivalent to 1 cedi)
	Quantity of oil using examples of oil	Quantity of oil using examples of water sachets (water in 1 sachet divided into 5. One portion used to represent 100g of oil)
	Examples of carbohydrate food used to illustrate key messages (i.e. rice pudding, cola, jam, yam raw, sweet potato)	Examples of carbohydrate food used to illustrate key messages (i.e. plantain varieties, kenkey, banku, fufu, yam varieties, rice, wheat, oats, gari, corn, sweet potato, bread)
	Examples of physical activity examples (i.e. cycling, walking, cleaning house)	Examples of physical activity examples (i.e. hill climbing, aerobics, group street jogging "keep fit club" walking, hand washing, sweeping, cleaning house)
	Examples of good/bad fats (i.e. soya, coconut oil)	Comparison of good/bad fats (i.e. olive, palm and coconut oil)
	Diabetes self-management plan	Verbal discussions on concrete next steps and plans regarding diabetes self-management
Methods	Magnetic board with a human body outline and magnets of human organs	(when the magnetic board was unavailable) Large white boards with masking tape and marker pens
	Use of food models	Use of laminated images of local dishes
	Attended in the morning, no breakfast offered	Attended in morning, breakfast offered
	Self-management program delivered in two 3-hour sessions by two trained educators	Self-management program delivered in one 5-hour session by two trained educators
	Facilitator training was delivered in person	Facilitator training was delivered virtually

Conclusions

To our knowledge, this is the first adaptation of an evidence- and theory- based structured DSMES program tailored to the Ghanaian population. The partnership between UK and Ghana has led to the successful adaptation of a DSMES program. For future implementation of DSMES programs in LMICs, it is fundamental that such programs are appropriately adapted to meet the cultural and personal needs of the local communities. We recommend that widely used adaptation models, such as the EVM, are considered for future DSMES adaptation work in LMICs, to ensure that all factors are included and budgeted appropriately. The Ghana DSMES program has been tested in a randomised controlled trial and the findings will be published in a peer-reviewed journal.

Declarations

Ethics approval and consent to participate:

Ethical approval was provided by the Ghana Health Service Ethics Review Committee (protocol ID no: GHS-ERC 009/11/20) and the Institutional Review Board of KBTH (protocol ID no: KBTH-IRB 000175/2021).

This research was carried out in accordance with relevant guidelines and regulations.

Consent for publication:

Consent for publication was obtained from individuals included in the images.

This study did not recruit research participants, therefore informed consent was not applicable.

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Competing interests:

MJD and KK are the principal investigators on the DESMOND program (Diabetes education and self-management for people with newly diagnosed Type 2 diabetes). The University Hospitals of Leicester (UHL) NHS Trust receives licensing fees to support implementation of the DESMOND program in Clinical Commissioning Groups in the UK, Ireland, and Australia.

KK, MJD, MH are supported by the National Institute for Health Research (NIHR) Applied Research Collaboration East Midlands (ARC EM) and the NIHR Leicester Biomedical Research Centre (BRC). MJD, SS, BS, KK and MH are actively engaged in research and have previously received grants for DESMOND from NIHR, Medical Research Council,

and Diabetes UK to develop and test Diabetes Self-Management Education and Support programs such as DESMOND.
RL has no conflicts of interest to declare.

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Authors' contributions:
RL and MJD led the conceptualisation of the collaboration. RL and MH led the adaptation work and the development of the manuscript, with support from MJD, SS and BS. All authors read and approved the final manuscript.

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5

Change in glycaemic control with structured diabetes self-management education in low-resource settings: randomized trial

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Submitted

What is already known?

- In high-resource settings, structured diabetes self-management education is associated with improved outcomes.

What this study has found?

- A 6-hour structured DSME intervention had no effect on HbA1c at three months.
- HbA1c decreased by 9 mmol/mol [95%CI:-13 to-5, $p<0{\cdot}001$]; 0·9% [95% CI: - 1.2 to -0·5, $p<0{\cdot}001$] in the intervention arm.
- HbA1c decreased by-3 mmol/mol [95%CI:-6 to 1, $p=0{\cdot}172$]; 0·3% [95% CI: -0·6 to 0·0, $p=0{\cdot}002$] in the control arm.

What are the implications of the study?

- The effect size of structured diabetes self-management education on glycaemic control may be limited.
- In low-resource settings, clinician's expectations from diabetes education must therefore be guarded.

Abstract

Aim

To compare structured diabetes self-management education (DSME) to usual care in adults with type 2 diabetes in low-resource settings.

Methods

Design: Single-blind randomised parallel comparator controlled multi-centre trial.

Adults (>18 years) with type 2 diabetes from two hospitals in urban Ghana were randomised 1:1 to usual care only, or a 6-hour tailored evidence-based group structured DSME delivered in-person, plus usual care. Randomisation codes were computer-generated, and allotment concealed in opaque numbered envelopes. The intervention effect was assessed with linear mixed models.
Main outcome: Change in HbA1c after 3-month follow-up.
Primary analysis involved all participants.
Clinicaltrial.gov identifier:NCT04780425.

Results

Recruitment: 22nd until 29th January 2021.

We randomised 206 participants (69% female, median age 58 years [IQR: 49-64], baseline HbA1c median 64 mmol/mol [IQR: 45-88 mmol/mol],7.9%[IQR: 6.4-10.2]). Primary outcome data was available for 79 and 80 participants in the intervention and control groups, respectively. Reasons for loss to follow-up were death (n=1), stroke(n=1) and unreachable or unavailable (n=47). A reduction in HbA1c was found in both groups; -9 mmol/mol [95% CI: -13 to -5 mmol/mol], -0·9% [95% CI: -1·2% to -0·51%] in the intervention group and -3 mmol/mol [95% CI -6 to 1 mmol/mol], -0·3% [95% CI: -0·6% to 0.0%] in the control group. The intervention effect was 1mmol/l [95%CI:-5 TO 8 p=0.726]; 0.1% [95% CI: -0.5, 0.7], p=0·724], adjusted for site, age, and duration of diabetes.
No significant harms were observed.

Conclusion

In low-resource settings, DSME might not be associated with glycaemic control. Clinician's expectations from DSME must therefore be guarded.

Key words

Diabetes, DSME, HbA1c, low-resource, self-care.

5

Introduction

Diabetes is a long-standing epidemic with over half a billion adults affected globally.[1] In Ghana, the overall prevalence of diabetes among the general adult population is 7%.[2] Diabetes is a leading cause of mortality in Accra, the capital of Ghana.[3] However, people living with diabetes (PLD) often have limited knowledge about self-management.[4] This could contribute to poor glycaemic control.

Self-care is essential for PLD. This underpins the need for self-management education. In high-income countries, structured diabetes self-management education (DSME) programmes such as, the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) program, are associated with improved outcomes.[5,6] In low- and middle-income countries, the association between structured diabetes education and diabetes outcomes is however inconclusive.[7,8]

Indeed, DSME services are limited in Ghana, a low-middle-income country.[9] Due to the high disease burden, determinants of glycaemic control are prioritised in Ghana's national health research agenda.[9] We therefore sought to investigate the effect of structured DSME on glycaemic control in two low-resource settings in Accra, Ghana[10].

Materials and Methods

Study design and approval

A multicentre, parallel-group, single-blind randomised controlled trial was conducted at two hospitals (WGMH and KBTH) in Accra, Ghana. Adults living with type 2 diabetes were randomised 1:1 to structured DSME plus usual care, or usual care only.

Ethical approval

Ethical approval was provided by the Ghana Health Service Ethics Review Committee (protocol ID no: GHS-ERC 009/11/20), and the Institutional Review Board of KBTH (protocol ID no: KBTH-IRB 000175/2021).

Study participants and study setting

Eligibility criteria included ability to participate in activities in a group setting, known to have T2DM, and aged 18 years or above.

The study was conducted between January-May 2021, at two public primary facilities in Accra, Ghana. Potential participants were identified by searching electronic medical records of the study sites. Participants were recruited from 22nd to 29th January 2021.

Prior to any study procedures, all participants gave written informed consent in person.

Randomisation and masking

Participants were randomly assigned either to usual care, or usual care plus intervention. Usual care at KBTH polyclinic consisted of informal brief education given by doctors whilst consulting. At WGMH, usual care consisted of unstructured group education, lasting approximately 30 minutes, delivered on clinic days; by nurses.

Enrolled patients were randomised the same day. Stratified randomisation, by participant age (< 40 years or ≥40 years), was carried out in variable blocks with the aid of a centralised computer-generated sequence. Each patient randomised had an electronically generated unique identification number matching the assigned study arm. Allotment was concealed in sequentially numbered opaque envelopes and sealed. Care providers at both hospitals were blinded.

Procedures

Intervention

The intervention tested was a structured DSME program which had been adapted from DESMOND: EXTENDing availability of self-management structured education programmes for people with type 2 Diabetes in low-to-middle income countries (EXTEND). EXTEND has been piloted in Malawi and Mozambique.[11] DESMOND is a cost-effective structured DSME program, originally developed in the United Kingdom.[6,12,13]

We further culturally adapted EXTEND to the Ghanaian community ; citing local cuisine and contextualising examples.[14]

Five community health nurses and one medical officer were trained virtually, by DESMOND trainers to deliver the intervention. The intervention was delivered in-person, while observing all coronavirus infectious disease-2019 (COVID-19) protocols. The intervention consisted of one session of structured DSME, delivered by two educators to groups of six to ten participants in one day, over 6 hours. The delivery of the intervention was completed within 2 weeks of randomisation. The intervention was delivered by providers not directly involved in patient care.

Follow-up intervals and assessments

The first 206 patients were consecutively randomised 1:1 either to structured DSME plus usual care or usual care only (Figure 1). At randomisation (baseline) and three months after randomisation, participants completed an interviewer-administered questionnaire and underwent a clinical assessment. Baseline data was collected on 26th and 27th January 2021 at KBTH, and on 22nd and 29th January 2021 at WGMH. Follow-up data was gathered on 14th and 15th May 2021 at KBTH, and on 20th and 22nd May 2021 at WGMH. The final on-site data collection was conducted at WGMH, on 12th June 2021.

Despite prior acceptance of the invitation to participate in endline data collection, some participants failed to show up by the trial end date. Specifically, 71 participants in the intervention group and 78 in the control group completed follow-up at 3 months. Ten participants completed follow-up between 3 to 5 months : eight in the intervention and two in the control group.

Outcomes

The primary outcome was change in HbA1c. HbA1c was assessed centrally in an accredited laboratory, adhering to international criteria, set out according to International Organisation for Standardisation standards (ISO Standard 15189:2012). HbA1c measurement was conducted using the turbidimetric inhibition immunoassay method, with a ROCHE COBAS intergra 400 plus analyser.

Secondary outcomes were, changes in clinical, psychological, and self-care variables. Specifically, the clinical outcomes were change in weight, waist circumference, and blood pressure respectively; the psychological outcomes were changes in diabetes-related distress scores[15] and WHO quality of life scores respectively[16]; and the self-care outcome was change in diabetes self-care activities (SDSCA) scores.[17]

The SDSCA scale assesses the level of self-care in five domains, namely diet, exercise, glucose monitoring, foot care, and smoking. The WHO Qol Bref instrument assess the quality of life. We assessed diabetes-related distress with, the problem areas in diabetes-5 (PAID-5) scale. Increasing scores indicate increasing distress ; scores of 8 or more suggest diabetes-related emotional distress.[15]

At follow-up, we assessed adverse events using a standardised questionnaire.

Statistical analysis

Sample size calculation

Mean reductions in HbA1c, between baseline and follow-up, were assumed to be 0 mmol/mol (0·0%) in the usual care group, and 4·8 mmol/mol (0·5%) in the intervention group.[8] We assumed mean baseline HbA1c at KBTH to be 72 mmol/l sd 8 (8.7% sd 2.7). To achieve 80% power ($p<0·05$, two-tailed) to detect a (0·5%) difference in mean HbA1c between the intervention and control group, a sample size of 148 participants (74 per group) was required. We assumed 20% loss to follow-up, thus 89 participants per arm were required after screening. It was assumed that 20% of recruited participants would be ineligible at screening, therefore 213 participants (107 per arm) needed to be recruited.

At the time of recruitment, the COVID-19 epidemic was unfolding with vaccines not yet available. Considering the uncertainties surrounding the epidemic, we decided to assess all potentially eligible participants. Subsequently we consecutively randomised the first 206 of those meeting the eligibility criteria.

Comparative analysis

Baseline sociodemographic, clinical, psychosocial, and self-care variables were summarised using median (interquartile range [IQR]) for continuous variables and counts (percentages) for categorical variables. All analysis was by intention to treat.

The study was powered to detect the average response to the intervention, between the two groups. We therefore fitted a model to determine the difference in HbA1c at the end of the study. Specifically, we used linear mixed models to assess the intervention effect for the primary outcome. The models were adjusted for key prognostic factors, site, treatment arm, and follow-up duration.

All analysis was conducted in R statistical package and statistical significance was set at two-sided $p<0{\cdot}05$.

The trial is registered on clinical trials.gov; registration number NCT04780425.

Results

All 206 participants randomised were included in the analysis (Table 1). Importantly, over 10% (N= 21) of participants randomised to the intervention did not receive the intervention. At the time of delivery of the intervention, three participants were unwell including one who had tested positive for COVID-19. One other participant declined the invitation to the structured DSME session, for fear of contracting COVID-19. Aside these four, seven participants were unavailable on the day of the intervention. Four had travelled out of Accra, two were engaged and one was babysitting. The remaining ten out of these 21 participants were unreachable by telephone.

Altogether, 22% (N=46) of the participants randomised were lost to follow-up. The commonest reason for inability to provide follow-up data for the primary outcome was “unreachable by telephone” or “unavailable” during the period allocated for blood sampling. Only 1% (N=2) of the participants randomised had alternative reasons. These reasons are depicted in the trial profile (Figure 1).

Baseline Characteristics

The baseline characteristics show high WHO Qol scores, despite low incomes, low literacy, and high unemployment levels (Table 1 /Supplementary Table 1). Furthermore, in most of the domains of the SDSCA score, the median score was once weekly. At baseline median HbA1c values were higher in the intervention group than in the control group (Table 1 and Supplementary Table 1). Notwithstanding sub-optimal baseline HbA1c values and low SDSCA scores, the overall median baseline PAID score was below eight.

Primary outcome

At endline, HbA1c decreased within both groups. Although this decrease was greater in the intervention group than in the control group, the difference between groups was not significant (Table 2). The primary outcome failed to reach significance. There was insufficient evidence that the intervention had an effect on HbA1c.

Secondary outcomes

Similarly, there was insufficient evidence that the intervention had an effect on any of the secondary outcomes except for an improvement in physical health (Supplementary Table 4d). The within-group differences for both arms were also not significant for most clinical variables and psychological variables. (Supplementary Tables 3c/3d). On the contrary, these differences were significant for self-care activities namely foot care, exercise, and diet. (Supplementary Tables 3a / 3b). The interaction term between the follow-up interval and intervention arm did not reach significance for any of the secondary outcomes.

Adverse events

No significant harms were observed. One participant however, had to be treated for symptomatic hypoglycaemia during delivery of the intervention. The participant's medications included human insulin.

Discussion

Our aim was to study the association between structured DSME, and glycaemic control. Our results show that, in people living with diabetes (PLD) in resource-constrained settings, structured DSME may not be associated with change in HbA1c at 3-months. A clinically relevant reduction in HbA1c was observed in the intervention group but not in the control group.

Reduction in HbA1c is associated with less micro-vascular complications and may also reflect better self-management routines. In sub-Saharan Africa, many PLD have poor self-management skills and poor diabetes outcomes.[1,18] DSME provides knowledge for effective self-management and is thus, especially important for PLD in sub-Saharan Africa. Unfortunately, in resource-constrained settings translating self-management skills into practice can be challenging.

There are multiple and complex barriers to self-management in low-resource settings. These barriers include irregular diabetes supplies, financial constraints, low health literacy and culture.[19] In the African context, culture is a significant barrier to adhering to self-management recommendations.[20,21] Complex cultural belief systems are particularly challenging for Ghanaians living with diabetes.[10,22]

The DSME intervention we tested was culturally tailored for the Ghanaian population, and linguistically suited to low-literacy levels. This may potentially explain the clinically relevant and significant reduction in HbA1c within the intervention group. HbA1c is dependent on self-management routines. The changes in the summary of diabetes self-care activities scores suggest an improvement in self-management routines within the intervention group.

Our findings align with findings from most previous studies.[7,23,24] In a recent systematic review of randomised controlled trials investigating structured DSME in PLD in Africa, seven out of the nine studies found no association between structured DSME and HbA1c. Furthermore, sub-group analysis revealed that, characteristics of structured DSME interventions such as cultural tailoring, duration, and intensity were not associated with HbA1c.

The studies included in this systematic review share some characteristics with our study and this may contribute to the congruence in the findings.[7] In the studies included in the review, the structured DSME interventions tested were culturally tailored, delivered mostly by nurses and the comparator was usual clinical care. The minimum mean baseline HbA1c was over 8% .[7]

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The baseline mean HbA1c was over 10% in Hailu et al's study among participants in Ethiopia. Additionally, 50% of their study population had lived with diabetes for over 10 years and participants received six sessions of DSME over a 9-month period.[24] Compared to participants in our study, participants in Hailu et al's study had relatively higher baseline HbA1c values and longer study duration. Yet, the findings from both studies are congruent. The study by Gathu et al in Kenya is another study included in the systematic review.[7] It was conducted in a single private facility among participants with low deprivation. Our study was conducted in two public facilities among participants with high deprivation. Again, despite the differences, the findings from the two studies are congruent.

In summary, despite the case-mix variation between studies there is homogeneity in the estimates of the association between structured DSME and glycaemic control in PLD in Africa.[7,23,24]

Our findings of a null association between structured DSME and glycaemic control are inconsistent with studies from Kuwait, Nigeria, and our recently published systematic review of structured DSME in low- middle-income countries[8,25,26]. Our study population shares similar characteristics with the study by Alibrahim et al. undertaken in a primary care setting in Kuwait. Alibrahim et al observed that, single 1-hour small group DSME sessions were associated with 1.7% reduction in HbA1c at 12 months.[25] Consistent with these findings from Kuwait, Essien et al also reported a 1.8% reduction in HbA1c at six months among participants in Nigeria living with type 1 or type 2 diabetes.[26]

Our findings on HbA1c are consistent with those of Davies et al in a study undertaken in the UK[6], but differ from the findings from Mozambique and Malawi[11], albeit in all three studies, the intervention tested was underpinned by the same psychological theories of learning. Our study, and the study conducted by Davies et al were randomised control trials; this design maximises internal validity and permits causal inferences. Brady et al[11], performed a feasibility study (with no control group) on a purposively selected sample of 50 people, thus limiting the ability to assess the relationship between structured DSME and HbA1c. Davies et al included only participants who were newly diagnosed with diabetes and used a cluster randomised design. This design may limit contamination between the study groups.

In resource constrained-settings intervention contact time can limit sustainability and scalability of a structured education program. It is not clear what the relation between intervention contact time and reduction in HbA1c is. DSME Interventions with contact time greater or equal to 10 hours, have been shown to be associated with significant reductions in HbA1c in a systematic review of over 100 varieties of DSME programs.[27] However, in a systematic review focusing on studies in African American populations, no association between HbA1c and intervention contact, and provider time was observed.[28] In our study the total contact time was desirably short although the primary outcome did not reach significance.

For most participants in our study, health literacy was low, and the monthly cost of care was greater than half of their monthly income. The average cost of managing one person with diabetes in a clinic in Accra in 2009 was about US$ 28 monthly.[29] There is a positive linear association between health literacy and socio-economic variables.[29] The low income levels, combined with low literacy, possibly denote high deprivation and this could have biased the association between HbA1c and structured DSME.

Our inability to standardise usual care between groups is also a potential source of bias. Due to the nature of the intervention, it was not possible to blind assessors, and this might be responsible for ascertainment bias. However, the primary outcome, change in HbA1c was an objective outcome thus limiting the risk of bias. Higher baseline HbA1c values in the intervention group, may indicate that those in the intervention group had more advanced disease. This difference could also have biased our estimate. Stratification on baseline HbA1c would have resulted in more balanced groups. At the time of randomisation however,, baseline HbA1c values were not known.

The randomised controlled trial design, and the use of a culturally adapted intervention are strengths of this study. This design increases the internal validity of the estimate of the effect of structured education on glycaemic control in the population.

The study was set in Ghana, in two public health facilities, where the national health insurance scheme is the main means of healthcare financing. Our findings may therefore not be generalisable to community-based interventions or private facilities. We excluded participants who were not ambulant, could not participate in group activities and who were not primarily responsible for their care, thus further limiting the generalisability of our findings.

In conclusion, glycaemic control was not associated with DSME in this study, although the reduction in HbA1c was larger in the intervention group compared to usual care. Ideally DSME equips individuals with skills for decision making and taking action.[30] Deprivation as commonly pertains in resource-constrained settings in SSA limits options and thus, the possibility of taking action subsequent to DSME. The difference between persons who receive DSME and those who do not may therefore be minute, relative to the levels of deprivation and thus difficult to enumerate. Importantly, recruitment procedures for this study could have raised awareness on self-management, accruing positive effects in both the intervention and control groups.

We thus recommend larger cluster randomised studies, with longer duration of follow-up, which focus on enumerating the effect of culturally adapted structured DSME on glycaemic control, in resource-constrained settings. Clinicians in low-resource settings should strive to understand the patient's context, culture, and barriers to taking action subsequent to self-management education. This may accrue benefits; reduce the disease burden, and possibly produce solutions for alleviating the difficulties of PLD in resource-constrained settings.

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Conflict of interests: None

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Table 1. Descriptive characteristics of participants, by intervention group, median(Q1*,Q3†) for continuous or N‡ (%)# for categorical variables.

	Control (N=103)	Intervention (N=103)	Total (N=206)
Hospital Site			
N‡	103	103	206
Korle bu Teaching Hospital	55 (53%)	55 (53%)	110 (53%)
Weija Gbawe Municipal Hospital	48 (47%)	48 (47%)	96 (47%)
Sex			
N-Miss¶	0	1	1
N	103	102	205
Male	32 (31%)	32 (31%)	64 (31%)
Female	71 (69%)	70 (69%)	141 (69%)
Age(years)			
N-Miss	0	1	1
N	103	102	205
Median (Q1¶, Q3#)	57 (50, 64)	59 (49, 64)	58 (49, 64)
Education			
N-Miss	1	0	1
N	102	103	205
None	11 (11%)	10 (10%)	21 (10%)
Primary	17 (16.7%)	16 (16%)	33 (16%)
Middle or higher	74(73%)	77 (75%)	151 (74%)
Occupation			
N	103	103	206
Professionals with degrees	5 (5%)	8 (8%)	13 (6%)
other occupation	45 (44%)	60 (58%)	114 (55%)
educated youth, unemployed	44 (43%)	35 (34%)	79 (38%)
Total Income(Dollars)			
N-Miss	10	8	18
N	93	95	188
Median (Q1, Q3)	40(20, 90)	50 (23, 100)	50 (20, 100)
Duration of diabetes (years)			
N	103	103	206
Median (Q1, Q3)	5 (3, 10)	5 (2, 10)	5 (3, 10)
HbA1c** (%)			
N	103	103	206
Median (Q1, Q3)	7.6 (6.3, 6.6)	8.2 (6.5, 10.6)	8 (6, 10)

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Table 1. Continued

	Control (N=103)	Intervention (N=103)	Total (N=206)
HbA1c (mmol/mol)			
N	103	103	206
Median (Q1, Q3)	58 (45, 82)	67 (47, 92)	63 (45, 88)

*Q1 is the lower quartile. † Q2 is the upper quartile. ‡N is number of observations.
#% is percentage of observation. ¶ N-Miss is number of missing observations **HbA1c is glycated Haemoglobin.

Table 2. Effect of the intervention (structured DSME*) on the primary outcome (average change in HbA1c†) after 3-months follow-up.‡

Fixed Effects	**Unit: mmol/mol**			**Units: %**		
Parameters	**Coefficients**	**95% CI**	**P-value**	**Coefficients**	**95% CI**	**P-value**
Intercept	72	56 to 89	< .001	8.8	7.3 to 10.3	< .001
Site (WGMH)¶	9	2 to 15	0.007	0.8	0.2 to 1.4	0.006
Diabetes duration (years)	1	0 to 1	0.023	0.1	0.0 to 0.1	0.021
Age(years)	0	-1 to 0.	0.081	0.0	-0.1 to 0.0	0.071
Arm (Intervention)	1	-5 to 8	0.726	0.1	-0.5 to 0.7	0.724
Follow-up interval#	-2	-3 to -1	< .001	-0.2	-0.3 to -0.1	< .001
			Random Effects			
Parameter		**SD**			**SD**	
Intercept		21			1.9	
Residual		13			1.5	
Intraclass correlation		0.7			0.6	

*DSME is diabetes self-management education intervention. The intervention tested was an adapted version of an evidence based structured DSME: Diabetes Self-Management Education for New and ON-going Diabetes (DESMOND).[6,14] The comparator was usual care.
† HbA1c is glycated Haemoglobin. ‡Data are presented as coefficient estimates from linear mixed models.
¶WGMH is Weija Gbawe Municipal Hospital site. The comparator was Korle Bu Teaching Hospital Polyclinic.
Participants were followed for at least three months.

Supplementary Table 1. Baseline characteristics of participants, by intervention group, median(Q1[*],Q3[†]) for continuous or N[‡] (%)[#] for categorical variables.

	Control (N=103)	Intervention (N=103)	Total (N=206)
Site			
N*	103	103	206
Korle Bu Teaching Hospital (KBTH)	55 (53%)	55 (53.4%)	110 (53.4%)
Weija Gbawe Municipal Hospital (WGMH)	48 (47%)	48 (46.6%)	96 (46.6%)
Sex			
N-Miss[†]	0	1	1
N	103	102	205
Male	32 (31%)	32 (31.4%)	64 (31.2%)
Female	71 (69%)	70 (68.6%)	141 (68.8%)
Age (years)			
N-Miss	0	1	1
N	103	102	205
Median (Q1[††], Q3[¶])	57 (50, 64)	59.00 (49.00, 64.00)	58.00 (49.00, 64.00)
Age Group			
N-Miss	0	1	1
N	103	102	205
< 40 years	8 (8%)	9 (8.8%)	17 (8.3%)
>= 40 years	95 (92%)	93 (91.2%)	188 (91.7%)
Education			
N-Miss	1	0	1
N	102	103	205
None	11 (11%)	10 (10%)	21 (10%)
Primary	17 (17%)	16 (16%)	33 (16%)
Middle or Junior High School	40 (39%)	37 (36%)	77 (38%)
Secondary or Senior High School	22 (22%)	16 (16%)	38 (19%)
Vocational school	1 (1%)	9 (9%)	10 (5%)
Tertiary or higher	11 (11%)	15 (15%)	26 (13%)
Occupation			
N	103	103	206
Professionals with degrees	5 (5%)	8 (8%)	13 (6%)

Supplementary Table 1. Continued

	Control (N=103)	Intervention (N=103)	Total (N=206)
Professionals without degrees	3 (3%)	10 (10%)	13 (6%)
small scale entrepreneurs	19 (19%)	19 (18%)	38 (18%)
small scale farmers	13 (13%)	13 (13%)	26 (13%)
Labourers and petty traders	19 (19%)	18 (18%)	37 (18%)
educated youth, unemployed	44 (43%)	35 (34%)	79 (38%)
Total Income(Dollars)			
N-Miss	10	8	18
N	93	95	188
Median (Q1, Q3)	40 (20, 90)	50 (23, 100)	50 (20, 100)
Duration of diabetes			
N	103	103	206
Median (Q1, Q3)	5 (3, 10)	5 (2, 10)	5 (3, 10)
Blood glucose (mmol/l)			
N	103	103	206
Median (Q1, Q3)	7.8 (6.1, 9.9)	8.0 (6.3, 10.4)	7.9 (6.2, 10.1)
HbA1c (%)			
N	103	103	206
Median (Q1, Q3)	7.6 (6.3, 9.6)	8.2 (6.5, 10.6)	7.9 (6.4, 10.1)
HbA1c (mmol/mol)			
N	103	103	206
Median (Q1, Q3)	58 (44, 82)	67 (47, 92)	64 (45, 88)
Plasma glucose (mmol/l)			
N-Miss	0	2	2
N	103	101	204
Median (Q1, Q3)	7.8 (5.3, 12.3)	7.6 (5.5, 11.8)	7.7 (5.4, 12.0)
Estimated average glucose(mmol/l)			
N-Miss	2	5	7
N	101	98	199
Median (Q1, Q3)	9.3 (7.4, 12.7)	10.5 (7.6, 14.4)	10.0 (7.4, 13.6)
Weight (kg)			
N	103	103	206
Median (Q1, Q3)	78 (68, 86)	77 (66, 85)	77 (66, 85)

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Supplementary Table 1. Continued

	Control (N=103)	Intervention (N=103)	Total (N=206)
Height (cm)			
N-Miss	4	2	6
N	99	101	200
Median (Q1, Q3)	1.66 (1.59, 1.72)	1.62 (1.56, 1.71)	1.64 (1.57, 1.71)
Body mass index (kg/m^2)			
N-Miss	4	2	6
N	99	101	200
Median (Q1, Q3)	28 (24, 32)	28 (25, 33)	28 (25, 33)
Systolic blood pressure (mmHg)			
N	103	103	206
Median (Q1, Q3)	127(116, 141)	128 (113, 138)	127 (115, 139)
Diastolic blood pressure (mmHg)			
N	103	103	206
Median (Q1, Q3)	79 (74, 87)	80 (72, 88)	80 (73, 88)
Problem Areas In Diabetes (PAID-5) score			
N	103	103	206
Median (Q1, Q3)	5 (2, 8)	4 (1, 7)	4 (1, 8)
Summary of Diabetes Self-care Activities (SDSCA), (days/ week)			
Healthy eating			0.345
N	103	103	206
Median (Q1, Q3)	5(2, 8)	6.00 (3.00, 8.00)	6.00 (3.00, 8.00)
General diet			
N	103	103	206
Median (Q1, Q3)	6.00 (1.50, 7.00)	6.00 (3.00, 8.00)	6.00 (3.00, 8.00)
Fruit and vegetable consumption			
N-Miss	2	2	4
N	101	101	202
Median (Q1, Q3)	4.00 (2.00, 6.00)	4.00 (2.00, 6.00)	4.00 (2.00, 6.00)
High fat food consumption			
N-Miss	1	2	3
N	102	101	203
Median (Q1, Q3)	3.00 (2.00, 5.00)	2.00 (1.00, 4.00)	3.00 (1.00, 4.50)
Exercise			
N-Miss	2	4	6
N	101	99	200

Supplementary Table 1. Continued

	Control (N=103)	Intervention (N=103)	Total (N=206)
Median (Q1, Q3)	3.00 (1.00, 7.00)	4.00 (1.00, 6.00)	3.00 (1.00, 7.00)
Engage in specific exercise			
N-Miss	0	2	2
N	103	101	204
Median (Q1, Q3)	2.00 (1.00, 6.00)	1.00 (1.00, 4.00)	1.00 (1.00, 5.00)
Test blood sugar			
N-Miss	1	1	2
N	102	102	204
Median (Q1, Q3)	1.00 (1.00, 2.00)	2.00 (1.00, 2.00)	2.00 (1.00, 2.00)
Test blood sugar as recommended			
N-Miss	0	1	1
N	103	102	205
Median (Q1, Q3)	1.00 (1.00, 1.00)	1.00 (1.00, 2.00)	1.00 (1.00, 2.00)
Foot care			
N	103	103	206
Median (Q1, Q3)	1.00 (1.00, 4.00)	2.00 (1.00, 8.00)	1.00 (1.00, 7.00)
Inspect inside shoes			
N-Miss	0	1	1
N	103	102	205
Median (Q1, Q3)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
Smoked a cigarette			
N-Miss	18	21	39
N	85	82	167
Median (Q1, Q3)	2.00 (2.00, 2.00)	2.00 (2.00, 2.00)	2.00 (2.00, 2.00)
Quality of life domain scores, median (Q1,Q3)			
Physical health			0.056
N-Miss	1	1	2
N	102	102	204
Median (Q1, Q3)	92 (81, 99)	92 (88, 104)	92 (84, 100)
Psychological			0.540
N-Miss	1	2	3
N	102	101	203
Median (Q1, Q3)	80 (76, 88)	80 (76, 88)	80 (76, 88)
Social relationship			
N	103	103	206

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Supplementary Table 1. Continued

	Control (N=103)	Intervention (N=103)	Total (N=206)
Median (Q1, Q3)	44 (36, 48)	44 (40, 48)	44 (36, 48)
Environment			
N-Miss	1	3	4
N	102	100	202
Median (Q1, Q3)	112 (100, 124)	116 (104, 125)	112 (104, 124)

***Q**1 is the lower quartile. † Q2 is the upper quartile. ‡N is number of observations.
#% is percentage of observation. ¶ N-Miss is number of missing observations **HbA1c is glycated Haemoglobin.

Supplementary Table 2. Change in HbA1c ¶ (primary outcome) from baseline to follow-up, by intervention group, mean (CI).**

Arm	Baseline (N=206)		Endline (N=206)	Difference (N=206)	p value
Control	HbA1c-mmol/mol				0.172
	N-Miss†	0	23	23	
	N*	103	80	80	
	Mean (CI)	66 (61 to 71)	60 (55 to 65)	-3 (-6 to 1)	
	HbA1c-%				0.068
	N-Miss	0	23	23	
	N	103	80	80	
	Mean (CI)	8.2 (7.7 to 8.7)	7.7 (7.2 to 8)	-0.3 (-0.6 to 0.0)	
Intervention	HbA1c-mmol/mol				< 0.001
	N-Miss	0	24	24	
	N	103	79	79	
	Mean (CI)	70 (64 to 75)	60 (55 to 65)	-9 (-13 to -5)	
	HbA1c-%				< 0.001
	N-Miss	0	24	24	
	N	103	79	79	
	Mean (CI)	8.5 (8.0 to 9.0)	7.7 (7.2 to 8.1)	-0.9 (-1.2 to -0.5)	

¶HbA1c is glycated Haemoglobin. **Data are presented as estimates from paired t-tests. *N is number of observations.
†N-Miss is number of missing observations.

Supplementary Table 3. Effect of the intervention (structured DSME[#]) on the secondary outcome (average change in SDSCA[¶]) after 3-months follow-up, mean (CI).

Arm	Baseline (N=206)		Endline (N=206)	Difference (N=206)	p value
Control	Healthy eating				0.002
	N-Miss[†]	0	15	15	
	N[*]	103	88	88	
	Mean (CI)	5 (4 to 5)	6 (5 to 6)	1 (0 to 2)	
	Followed eating plan			0.017	
	N-Miss	0	15	15	
	N	103	88	88	
	Mean (CI)	5 (4 to 5)	5 (5 to 6)	1 (0 to 1)	
	Eat Fruits and vegetable				0.261
	N-Miss	2	15	17	
	N	101	88	86	
	Mean (CI)	4 (3.6 to 4.5)	4 (4 to 5)	0 (0 to 1)	
	Eat High fat food				< 0.001
	N-Miss	1	15	16	
	N	102	88	87	
	Mean (CI)	3 (3 to 4)	2 (1.8 to 2.5)	-1 (-2 to -1)	
	Exercise past				0.003
	N-Miss	2	17	19	
	N	101	86	84	
	Mean (CI)	4 (3 to 4)	5 (5 to 6)	1 (0 to 2)	
Intervention	Healthy eating				0.122
	N-Miss	0	14	14	
	N	103	89	89	
	Mean (CI)	5 (5 to 6)	6 (5 to 6)	1 (0 to 1)	
	Followed eating plan				0.162
	N-Miss	0	14	14	
	N	103	89	89	
	Mean (CI)	5 (5 to 6)	6 (5 to 6)	0 (0 to 1)	
	Eat Fruits and vegetable				0.054
	N-Miss	2	14	16	
	N	101	89	87	
	Mean (CI)	4 (4 to 5)	5 (4 to 5)	1 (0 to 1)	
	Eat High fat food				0.019
	N-Miss	2	14	16	

Supplementary Table 3. Continued

Arm	Baseline (N=206)		Endline (N=206)	Difference (N=206)	p value
	N	101	89	87	
	Mean (CI)	3 (2.6 to 3.4)	2 (2 to 3)	-1 (-1 to 0)	
	Exercise past				< 0.001
	N-Miss	4	16	20	
	N	99	87	83	
	Mean (CI)	4 (3 to 4)	6 (5 to 6)	2 (1 to 2)	
Control	Specific exercise				0.351
	N-Miss	0	16	16	
	N	103	87	87	
	Mean (CI)	3 (3 to 4)	3 (2 to 4)	0 (-1 to 0)	
	test blood sugar				0.829
	N-Miss	1	16	17	
	N	102	87	86	
	Mean (CI)	2 (1.7 to 2.3)	2 (1.6 to 2.3)	0 (-0.4 to 0.5)	
	test blood sugar as recommended				0.005
	N-Miss	0	16	16	
	N	103	87	87	
	Mean (CI)	2 (1 to 2)	2 (1.6 to 2.4)	0.6 (0 to 1)	
	check feet				0.003
	N-Miss	0	15	15	
	N	103	88	88	
	Mean (CI)	3 (2 to 3)	4 (3 to 5)	1 (0 to 2)	
	Inspect inside shoes?				0.003
	N-Miss	0	16	16	
	N	103	87	87	
	Mean (CI)	2 (1 to 2)	3 (2 to 3)	1 (0 to 2)	
	smoked a cigarette			0.321	
	N-Miss	18	27	39	
	N	85	76	64	
	Mean (CI)	2 (1.99 to 2.01)	2.00 (2.00, 2.00)	0.02 (-0.02, 0.05)	
Intervention	Specific exercise				< 0.001
	N-Miss	2	14	16	
	N	101	89	87	
	Mean (CI)	3 (2 to 3)	4 (4 to 5)	2 (1 to 2)	
	test blood sugar				0.599

Supplementary Table 3. Continued

Arm	Baseline (N=206)		Endline (N=206)	Difference (N=206)	p value
	N-Miss	1	14	15	
	N	102	89	88	
	Mean (CI)	2 (2 to 3)	2 (2 to 3)	0.1 (-0.3 to 0.5)	
	test blood sugar as recommended				0.096
	N-Miss	1	14	15	
	N	102	89	88	
	Mean (CI)	2 (1 to 2)	2 (1.6 to 2.3)	0 (0 to 1)	
	check feet				< 0.001
	N-Miss	0	14	14	
	N	103	89	89	
	Mean (CI)	4 (3 to 4)	5 (5 to 6)	2 (1 to 3)	
	Inspect inside shoes?				< 0.001
	N-Miss	1	14	15	
	N	102	89	88	
	Mean (CI)	2 (1.5 to 2.3)	3 (3 to 4)	2 (1 to 2)	
	smoked a cigarette				0.321
	N-Miss	21	19	36	
	N	82	84	67	
	Mean (CI)	2 (2.00, 2.00)	2 (1.94, 2.01)	0 (-0.04, 0.01)	
Control	Weight (KG)				0.144
	N-Miss[†]	0	24	24	
	N[*]	103	79	79	
	Mean (CI)	79 (75 to 83)	79 (75 to 83)	1 (0 to 2)	
	Waist circumference (cm)				0.015
	N-Miss	0	24	24	
	N	103	79	79	
	Mean (CI)	95 (91 to 99)	100 (97 to 103)	5 (1 to 8)	
	Average SBP				0.143
	N-Miss	0	24	24	
	N	103	79	79	
	Mean (CI)	129 (125 to 132)	131 (127 to 136)	2.6 (-1, 6)	
	Average DBP				0.262
	N-Miss	0	24	24	
	N	103	79	79	
	Mean (CI)	81 (79 to 84)	79 (77 to 82)	-1 (-4 to 1)	

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Supplementary Table 3. Continued

Arm	Baseline (N=206)		Endline (N=206)	Difference (N=206)	p value
	PAID				0.672
	N		103	103	
	Mean (CI)		6 (5 to 7)	0 (-1 to 1)	
Intervention	Weight (KG)				0.777
	N-Miss	0	25	25	
	N	103	78	78	
	Mean (CI)	77 (75 to 80)	77 (74 to 81)	0 (-1 to 2)	
	Waist circumference (cm)				0.688
	N-Miss	0	27	27	
	N	103	76	76	
	Mean (CI)	97 (94 to 100)	97 (94 to 100)	0 (-2 to 3)	
	Average SBP				0.249
	N-Miss	0	25	25	
	N	103	78	78	
	Mean (CI)	130 (126 to 134)	132 (128 to 136)	2 (-2 to 6)	
	Average DBP				0.902
	N-Miss	0	25	25	
	N	103	78	78	
	Mean (CI)	81 (79 to 84)	81 (78 to 83)	0 (-3 to 2)	
	PAID				0.013
	N	103	103	103	
	Mean (CI)	5 (4 to 5)	6 (5 to 7)	1 (0 to 2)	
Control	Physical health				0.123
	N-Miss	1	15	16	
	N	102	88	87	
	Mean (CI)	90 (87 to 93)	93 (90 to 96)	3 (-1 to 6)	
	Psychological				0.937
	N-Miss	1	15	16	
	N	102	88	87	
	Mean (CI)	80 (79 to 82)	81 (79 to 83)	0 (-2 to 2)	
	Social relationship				0.100
	N-Miss	0	21	21	
	N	103	82	82	
	Mean (CI)	43 (42 to 45)	43 (41 to 44)	-2 (-4 to 0.3)	
	Environment				0.558

Supplementary Table 3. Continued

Arm	Baseline (N=206)		Endline (N=206)	Difference (N=206)	p value
	N-Miss	1	16	17	
	N	102	87	86	
	Mean (CI)	112 (109 to 115)	112 (108 to 115)	-1 (-6 to 3)	
Intervention	Physical health				0.753
	N-Miss	1	14	15	
	N	102	89	88	
	Mean (CI)	94 (91 to 96)	95 (93 to 97)	1 (-3 to 4)	
	Psychological				0.282
	N-Miss	2	14	16	
	N	101	89	87	
	Mean (CI)	81 (80 to 83)	80 (78 to 83)	-1 (-4 to 1)	
	Social relationship				0.884
	N-Miss	0	20	20	
	N	103	83	83	
	Mean (CI)	43 (41 to 44)	43 (41 to 45)	0 (-2 to 2)	
	Environment				0.798
	N-Miss	3	15	18	
	N	100	88	85	
	Mean (CI)	113 (110 to 117)	113 (110 to 116)	-1 (-5 to 3)	

[#]DSME is structured diabetes self-management education. [¶]SDSCA is summary of diabetes self-care assessment.

[**]Data are presented as estimates from paired t-tests. [*]N is number of observations. [†]N-Miss is number of missing observations.

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Supplementary Table 4. Effect of the intervention (structured DSME[*]) on the average change in PAID-5[†] after 3-months follow-up.[‡]

Fixed Effects	PAID 5		
Parameters	**Coefficients**	**95% CI**	**P-value**
Intercept	7	4.5 to 10.3	< .001
Site (WGMH)[¶]	1	-0.1 to 2.1	0.085
Diabetes duration (years)*	0	-0.1 to 0.1	0.777
Age*	0	-0.1 to 0.0	0.056
Arm (Intervention)	0	-1.6 to 0.6	0.361
Follow-up interval[#]	0	0 .0to 0.5	0.054
Random effects			
Parameter	**SD**		
Intercept	3		
Residual	4		
Intraclass correlation	0.3		

Fixed Effects	SBP[†]			DBP[††]		
Parameters	**Coefficients**	**95% CI**	**P-value**	**Coefficients**	**95% CI**	**P-value**
Intercept	97	85 to 108	< .001	82	75 to 90	< .001
Site (WGMH)[¶]	-2.3	7 to 2	0.085	-2.4	-5.3 to 0.5	0.108
Diabetes duration (years)*	0.2	0 to 1	0.777	0.0	-0.3 to 0.2	0.732
Age*	0.6	0 to 1	0.056	0.0	-0.1 to 0.1	0.904
Arm (Intervention)	1.1	-3 to 6	0.361	0.3	-2.6 to 3.2	0.830
Follow-up interval[#]	0.8	-0 to 2	0.054	0.3	-0.8 to 0.2	0.256
			Random Effects			
Parameter	**SD**			**SD**		
Intercept	13			8.5		
Residual	12			8.8		
Intraclass correlation	0.6			0.5		

Supplementary Table 4. Continued

Fixed Effects	**Waist circumference**			**Weight**		
Parameters	**Coefficients**	**95% CI**	**P-value**	**Coefficients**	**95% CI**	**P-value**
Intercept	81	70 to 92	< .001	78	66 to 90	< .001
Site (WGMH)¶	-3.71	-7.8 to 0.4	0.078	0.2	-4.6 to 4.9	0.950
Diabetes duration (years)*	0.0	-0.3 to 0.4	0.912	0.1	-0.3 to 0.4	0.771
Age*	0.29	0.1 to 0.5	0.002	0.0	-0.2 to 0.2	0.933
Arm (Intervention)	0.10	-4.0 to 4.2	0.962	-2.2	-7.0 to 2.5	0.351
Follow-up interval#	0.85	0 .1 to 1.6	0.023	0.2	-0.1 to 0.5	0.246
Random Effects						
Parameter	**SD**			**SD**		
Intercept	13			17		
Residual	9.9			4.2		
Intraclass correlation	0.6			0.9		
Fixed Effects	**Physical Health†**			**Psychological health††**		
Parameters	**Coefficients**	**95% CI**	**P-value**	**Coefficients**	**95% CI**	**P-value**
Intercept	93	87 to 100	< .001	80	75 to 85	< .001
Site (WGMH)¶	2	-1 to 5	0.175	-1.1	-3.0 to 0.8	0.253
Diabetes duration (years)*	0	-0.4 to 0.0 8	0.059	-0.1	-0.2 to 0.1	0.394
Age*	0	-0.2 to 0.01	0.462	0.0	-0.1 to 0.1	0.469
Arm (Intervention)	3	0. to 5	0.035	0.3	-1.7 to 2.2	0.796
Follow-up interval#	1	0 to 1	0.081	-0.2	-0.8 to 0.4	0.487
Random Effects						
Parameter	**SD**			**SD**		
Intercept	4.5			3.2		
Residual	11.4			8.3		
Intraclass correlation	0.1			0.1		
Fixed Effects	**Social relationship†**			**Environment††**		
Parameters	**Coefficients**	**95% CI**	**P-value**	**Coefficients**	**95% CI**	**P-value**
Intercept	45	40 to 50	< .001	104	95 to 114	< .001
Site (WGMH)¶	-0.7	-2.4 to 1.1	0.461	1.3	-2.3 to 4.9	0.253
Diabetes duration (years)*	0.0	-0.2 to 0.1	0.948	0.1	-0.2 to 0.4	0.394
Age*	0.0	-0.1 to 0.0	0.360	0.1	-0.1 to 0.3	0.469
Arm (Intervention)	0.2	-1.6 to, 1.9	0.861	2.1	-1.5 to 5.7	0.796
Follow-up interval#	0.0	-0.5 to 0.4	0.706	-0.1	-1.1 to 0.8	0.487

Supplementary Table 4. Continued

	Random Effects	
Parameter	SD	SD
Intercept	4.2	8.4
Residual	6.4	13
Intraclass correlation	0.3	0.3

[*]DSME is diabetes self-management education intervention. The intervention tested was an adapted version of an evidence based structured DSME: Diabetes Self-Management Education for New and ON-going Diabetes (DESMOND).[6,14] The comparator was usual care.
[†] PAID-5 is Problem Areas in Diabetes Score. It was used to assess diabetes related distress.
[‡]Data are presented as coefficient estimates from linear mixed models.
[¶]WGMH is Weija Gbawe Municipal Hospital site. The comparator was Korle Bu Teaching Hospital Polyclinic.
[#] Participants were followed for at least three months.

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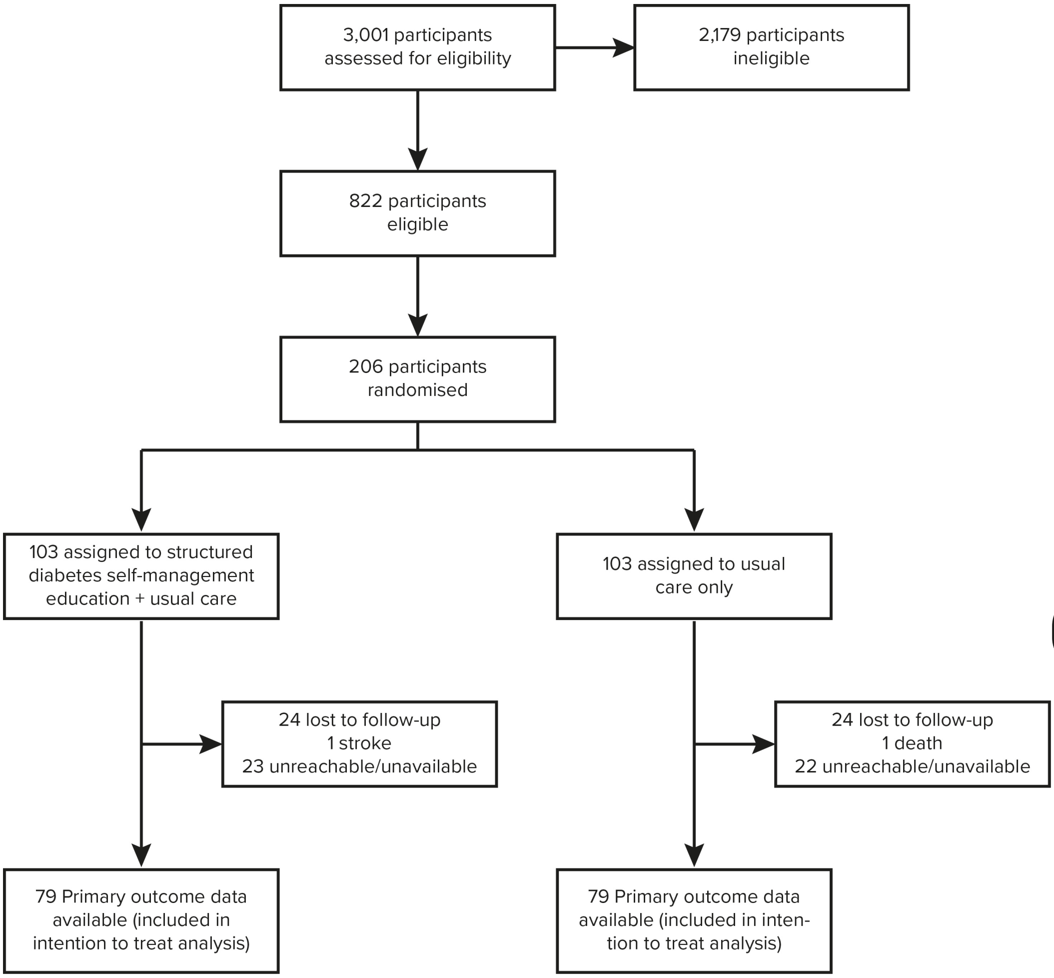

Figure 1. Flowchart of study participants

5

6

Discussion

General Discussion

Diabetes self-management education in sub-Saharan Africa

Increased investment into management of diabetes in sub-Saharan Africa is a current need[1] and may mitigate the rising incidence[2] and burdensome complications.[3,4] We therefore studied the effectiveness of structured diabetes self-management education (DSME) in resource-constrained settings as a potential solution.

Literature on the effectiveness of structured DSME in low-middle income settings is scarce[5] and availability of information on diabetes self-care limited. We observed significant deficits in diabetes specific knowledge and correspondingly poor self-care practices among People Living with Diabetes (PLD) in two facilities in urban Accra in our mixed-methods study (Lamptey et al unpublished work). Existing DSME programs were limited by logistics and human resource. Barriers to self-care were dominated by financial constraints, stigma, and complex socio-cultural belief systems. Knowledge was positively associated with self-care. These findings indicated the need for a culturally adapted diabetes self-management education program for the Ghanaian and similar context.

Our mixed methods study revealed a cultural and religious belief system which interfered negatively with self-care. The combined findings of limited knowledge and limited diabetes self-care practices in the mixed methods study were also replicated in findings from Ethiopia.[6]

Based on our findings from the mixed-methods study, we therefore culturally adapted an evidenced-based structured intervention program – DESMOND – for use in the Ghanaian population. DESMOND is an acronym for Diabetes education and self-management for ongoing and newly diagnosed. It is an accredited DSME program, which supports self-management of PLD[7]. Originally designed in the UK, DESMOND is evidence- and theory-based. It is delivered over six hours and covers core topics relating to the pathophysiology of type 2 diabetes, glycaemic control, and lifestyle management including monitoring[8]. An adapted version of DESMOND has been tested in Malawi and Mozambique and found to be effective in improving glycaemic control .[9] Furthermore, It was also associated with reductions in both systolic and diastolic blood pressures and diabetes related distress.[9]

Subsequently, we tested the effectiveness of this adapted structured DSME in a randomised clinical trial in an urban low-resource setting in Ghana. Structured DSME was associated with a significant improvement in glycaemic control in the intervention group. The difference in glycaemic control between the two study arms at the end of the study, did not however reach statistical significance. The intervention tested was however acceptable to participants who received it. Structured DSME was associated with modification of sedentary behaviour in the intervention arm, and this was corroborated by qualitative feedback from study participants. We postulate that in high deprivation settings, the effect of structured DSME on diabetes control and patient reported outcomes may be small in relation to the impact of financial constraints and norms. Especially in high deprivation settings, a wholistic and individualised approach to managing diabetes may therefore be crucial to diabetes outcomes.

We found that structured DSME was not available in Ghana. Structured DSME programs are not widely available in low-middle income settings. We also found that structured DSME may not be effective in improving diabetes control in high deprivation settings. Our study adds to the limited evidence on the effect size of the association between glycaemic control and structured DSME in such settings. Contrary to our findings, studies from Ethiopia and Malawi have observed the effectiveness of structured DSME in improving glycaemic control.[9] A recent systematic review also reported that DSME was an effective tool in modifying lifestyle choices. [10]

Our findings suggest that structured DSME in low-resource settings may have other advantages beyond glycaemic control when compared to unstructured group education. The intervention tested was acceptable and there was a clinically relevant improvement in self-management behaviours and glycaemic control in the short term for those in the intervention arm. T2DM can go into remission with dietary modification.[11 12] Indeed, successful behaviour modification is crucial to the effectiveness of DSME[13] and patients can be motivated through self-management education to achieve the required modifications.[14] There is ample evidence that T2DM in sub-Saharan Africa will increase dramatically, not only in urban areas but also in semi-rural Africa.[15] The ripple effects associated with a diagnosis of diabetes in an individual spread wide: beyond the core family to the society, and across systems beyond health. In Sub-Saharan Africa, majority of PLD are undiagnosed.[2] Complications are thus often present and established at the time of diagnosis; amplifying the burden of care and associated effects. Structured DSME therefore holds potential benefits for stemming this tide, especially in resource-constrained setting.

We found that inconsistent messaging originated not only from among peers but also from healthcare professionals, alternative herbal medicine practitioners, and religious leaders. Myths are sometimes perpetuated as truth. The situation where PLD receive conflicting messages on what choices constitute good diabetes self-care is unfortunate. People with diabetes want to know how to 'live well' with diabetes and they deserve to know. Knowledge, especially knowledge which can modify disease outcomes should not be a privilege but a right. The unavailability of certified DSME programs for peers, healthcare providers, alternative medicine providers and opinion leaders is the common underlying problem perpetuating this situation. Several articles including ours have highlighted these challenges providers and PLD face in delivering and receiving DSME respectively.

We found that the limited affordability of home blood glucose self-monitoring further hampers self-management. Self-blood glucose monitoring is one of the pillars of diabetes self-care. Too often, in resource constrained settings, feedback from real time glucose monitoring to guide choice of food and medication is a luxury. PLD need accurate and consistent DSME to guide their choices. Blood glucose results provide PLD with feedback and can influence self-care behaviours.[13] . Without self-blood glucose monitoring, PLD risk being oblivious (for extended periods of time) of resultant hyperglycaemia and associated cardiovascular damage following poor meal patterns. They continue to make the wrong self-management choices, mistaking them to be the 'right' choices and believing that they are 'living well with diabetes'.

The status quo must change – a call to action

The need for change

Our findings and several others in published literature have shown that additional factors affect outcomes of NCD including diabetes.[16,17] These additional factors include norms and belief systems.[16,17] Reaching PLD who have low numeracy and or low literacy in low-resource settings with self-management education is a low hanging fruit and can bridge the gap. Thus, to limit the challenges of living with diabetes and the devastating complications, evidence on the effect size of DSME is urgently needed to guide policy in sub-Saharan Africa. The time is ripe for larger studies to validate the findings on effects of structured DSME on diabetes control and patient-reported outcomes. Our findings that structured DSME is acceptable, fills the diabetes specific knowledge gaps and may be associated with improvement in self-care must be validated and this strategy possibly scaled-up subsequently. Unfortunately, the NCD strategies/ policies in most sub-Saharan countries are narrow.[18] They focus on reducing a narrow set of risk factors namely physical activity, diet, tobacco, and alcohol.

How do we change the status quo?

New learnings from this thesis

Awareness creation is the beginning of change. This thesis has generated evidence on the gap in diabetes self-care knowledge and practices, and clinically relevant association between education and behaviour change.

We observed that structured DSME is unfortunately non-existent in public health facilities in low-resource urban primary care settings in Accra. We have also observed in parallel with other published literature the disturbingly low levels of accurate self-management knowledge[19] across all domains of self-care i.e., diet, exercise, blood glucose monitoring, medication, foot care.[20] The abysmal levels of knowledge of PLD in such settings, on potentially life-saving information, such as hypoglycaemia is particularly distressing.

Our findings indicate that cultural and linguistic tailoring of DSME interventions may result in clinically relevant improvements in glycaemic control and self-care behaviours compared to usual care, the 'status quo'. We have shown that behaviour modification can occur subsequent to such DSME programs even amid, seemingly insurmountable challenges of living with diabetes in a resource constrained setting.

This thesis observed that PLD place value on peer-to-peer learning. We observed for example that religion, and cultural belief systems can pose a threat to optimal health. We observed, in parallel with findings from other settings in Ghana and sub-Saharan Africa that, religious and socio-cultural belief systems have a large influence on self-efficacy and self-care behaviour. This was also demonstrated in a study based on the health belief model in Nepal. [21]

We however in this thesis, could not demonstrate the effectiveness for the adapted DSME as compared to standard care. Our study may have been limited by unintended contamination of the two study groups. In the current technologically advanced age, it is difficult to control information sharing. Thus, the structured educational intervention may have accrued benefits for both study arms and diluted the difference between the intervention and control groups. Furthermore, the effects of high (socio-economic) deprivation may dwarf the effect of DSME on diabetes outcomes.

Research outputs can inform strategy and convince policy makers of the need to change the status quo; the need for governments in low-resource settings to prioritise research into the effects of DSME programs when allocating scarce resources among competing interests. Larger and longer cluster randomised studies are urgently needed to assess the size of the problems described in this thesis and to inform strategies aimed at bridging the gaps. It will be important to replicate the results of these thesis in similar settings.

From Evidence to Practice

Outline of guidelines for implementing structured DSME

Based on the learnings from this thesis we present below a proposed outline of how structured DSME may be implemented in resource constrained settings in sub-Saharan Africa:

1. Understand the setting, the cultural norms, belief systems, existing DSME programs and systems for reimbursement of medical services.
2. Adapt an evidence based structured DSME program to the local setting.
3. Train existing personnel to deliver the adapted structured DSME program.
4. Conduct a pilot study of the adapted structured DSME program.
5. Modify the DSME program based on feedback from the pilot.
6. Scale up the DSME program.
7. Regularly undertake quality improvement cycles of the structured DSME program to ensure that the fidelity of the program is maintained.
8. Test the effect size of the DSME program in a research setting.

Celebrate small wins

Translating research into practice begins with disseminating study findings. The results of this thesis will be shared with all stakeholders, starting with the study sites and then beyond. We will do this in a consultative and continuous manner to elicit the interest that will drive further research into these findings.

Stakeholder engagement and dissemination of findings

The size of the silent diabetes epidemic, projections for the future and the amplification of costs once complications set in, will be brought to the attention of stakeholders at all levels: parents, healthcare professionals, facility managers, community leaders and policy makers.

We will initiate discussions with stakeholders at all levels on the need for prioritisation of and budgeting for research into structured DSME programs. We will partner with NGO's and patient support groups to advocate for institutionalisation of more wholistic approach to diabetes care, including culturally sensitive structured diabetes self-management education at primary care levels.

The subsequent strategies outlined below will inform the basis of my overall medium to long-term strategy for translating the results of this thesis into routine practice.

Change at the facility level can be initiated by restructuring the delivery of DSME services. The delivery of DSME programs are linked to effectiveness.[22] We recommend establishment of multi-disciplinary teams at the facility level. Self-care activities are improved when multi-disciplinary approaches are used.[23] Transitioning from unstructured group DSME to structured group DSME will require securing dedicated space for delivering the service, training instructors on how to deliver structured DSME and instituting a quality assurance program to go with the structured DSME service.[24]

We further recommend tapping into community resources such as religious organisations, community pharmacists, alternative herbal practitioners. Crafting a community engagement strategy to understand these established systems and how to influence their messages to the community is likely to be the most challenging solution but also one of the most impactful, if not the most. For example community pharmacists who offer DSME services have been associated with reductions in diabetes related distress.[25] Print and electronic media have a role in achieving community level change.

For changes at the regional level, we will advocate for the standardisation of DSME curricula and teaching aids and training of trainers on their use. At the national and policy level, I will focus on building a team for the development and dissemination of guidelines and policy documents on structured DSME interventions, including reimbursement for structured diabetes education programs.

At the national level, making available formal training in diabetes education for allied health professionals and creating recognition for allied health professionals who undertake these trainings will have multiplicative effects on the availability of trained personnel for structured DSME programs. Regulatory bodies such as medical and dental councils and health facilities regulatory authorities can set standards for accreditation of structured DSME interventions. This will help to regulate the practice and ensure standards. Peer support groups can also be trained to deliver structured DSME as has been done in several places. The role of peer support was evident in both mixed methods study and RCT. Peer support has been associated with effectiveness of DSME in a recently published systematic review and metanalysis.[26] A multi-centre mixed-methods study also corroborated the importance of peer support.[27] We recommend group DSME over individualised programs based on the findings of this thesis. It will be important to emphasise not only peer support but also the training of peers on how to effectively deliver a structured diabetes self-management program.

A person living with diabetes is often thought to have the most influence towards the attainment of good outcomes of care. However, our findings from the mixed-methods study suggest that, the impact of the social determinants of health are not negligible and in settings with high deprivation, the person living with diabetes may not necessarily be the most important stakeholder. Nevertheless, people living with diabetes must be equipped with culturally sensitive self-management knowledge. This will facilitate initiation and maintenance of modifications to daily self-care routines. Trained healthcare providers must be able to offer the support PLD need along their diabetes journey; be it at diagnosis, onset of complications or when remission occurs.

Research

Finally, research drives change. In the light of growing evidence, there is the need for larger and longer studies on sustainability of the effectiveness of structured DSME in resource constrained settings. Studies on how to change behaviour through DSME will provide the evidence needed to recommend changes in practice and policy. Differences in prevalence and demography of affected populations, as well as distribution of explanatory variables, limit the transportability of research findings and models. Validation of existing models and updating them as well as developing new models suitable to PLD in sub-Saharan Africa required funding. Funding for research, especially in low-resource settings, is thus critical in this quest to change the status quo and bridge the inequality gap.

Facing forward - looking to the future

In summary, in the short to medium term, it will be imperative to systematically build the capacity of both healthcare professionals and peers in diabetes self-management education at all levels of care. A structured education program with a quality improvement component will ensure the fidelity of the program is maintained across the health care system.

There will be no quick wins as behaviour modification takes time.[28] Managers must be willing to invest the needed resources for establishing sustainable structured DSME programs.

A robust quality improvement program must accompany structured DSME programs.[24] Routine data collection will provide needed evidence for future modification and upscaling of programs.

Conclusion

Diabetes and its associated complications are no longer rare in sub-Saharan Africa, not even in rural areas. The associated economic and social burden is high. Several challenges further compound the rising prevalence: low numeracy of PLD, stigma, poverty, and cultural norms. DSME can change behaviour and improve glycaemic control in low-resource urban primary care settings. Larger longitudinal studies are needed to demonstrate the impact of structured DSME on outcomes of diabetes in the long-term.

Key messages

- T2DM is a self-managed condition. Diabetes self-management education (DSME) is therefore a need for every person living with diabetes irrespective of health numeracy and or literacy levels.
- Structured DSME programs in sub-Saharan Africa are limited and the effects on glycaemic control have yielded conflicting results.
- Especially in resource constrained settings, knowledge can spark the cycle of change and a cascade of events culminating in better care outcomes
- DSME programs, linguistically adapted for people with low numeracy can change behaviour despite well documented hurdles in these settings. To realise these potential gains investment into structured DSME programs in SSA is needed.

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7

Summary

Summary

Chapter 1 provides a general introduction to the thesis. There are over half a billion people living with diabetes globally. This number is projected to rise to 784 million by 2045 if current trends persist. Sub-Saharan Africa will experience the largest rise in prevalence. Poorly controlled diabetes is associated with serious life-changing complications such as strokes, amputation, and permanent blindness. Diabetes is a leading cause of mortality and morbidity. Microvascular complications are fewer when aggressive glycaemic control is initiated early in the disease process and sustained over prolonged periods. In high-resource countries structured diabetes self-management education has been associated with improved glycaemic control and outcomes.

Part 1: Diabetes Self-Management Education

Part one of the thesis focuses on diabetes self-management education. A systematic review of structured diabetes self-management education and glycaemic control in low- and middle-income countries is reported in chapter two. In chapter three, a mixed-methods study on the diabetes self-management education programs, diabetes self-management knowledge and behaviours of people living with diabetes in low-resource settings is reported.

In **Chapter 2**, PubMed, Embase and Cochrane Library electronic databases were searched from inception up to 30th June 2020, using the following keywords: 'diabetes mellitus', 'structured diabetes self-management education', 'developing countr*', 'glycaemic control' and 'low- and middle-income country'. All intervention studies, published in English, evaluating the effect of structured DSME on glycaemic control in PLD in LMICs were included.

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. Nine studies met the eligibility criteria and were included in this systematic review. One of the studies was judged as having low risk of bias. None of these studies were conducted in Ghana and one was conducted in West-Africa. In all the included studies structured diabetes self-management education was associated with improvement in glycaemic control. The mean/median reduction ranged between 0.5% and 2.6% relative to baseline.

In **Chapter 3** we gained insight and a deeper understanding of the diabetes self-management education programs and assess the diabetes self-management knowledge and behaviours of people living with diabetes in low-resource settings through a mixed methods study. We studied people living with diabetes, diabetes experts, healthcare providers and managers of two primary facilities. Results from the quantitative study showed a preponderance of poor glycaemic control and limited knowledge on diabetes self-care. The mean blood glucose among 425 people living with diabetes was 9.4 mmol/l

(SD 6.4)). Median diabetes-specific knowledge score was 40 % (IQR 20-60). The qualitative study revealed a complex socio-cultural belief system, financial constraints, stigma and inconsistent messaging as factors which limit self-care practices. These findings provide context for and deeper understanding of the quantitative results.

Part 2: Structured DSME programs and glycaemic control in resource constrained settings

Chapter 4 describes the cultural adaptation of a diabetes self-management education and support (DSMES) program for two low-resource urban settings in Ghana. DESMOND is an acronym for diabetes education and self-management for on-going and newly diagnosed diabetes. It is an evidence-based diabetes self-management education, originally developed for the United Kingdom which is widely published. DESMOND EXTEND is an acronym for extending availability of self-management structured education programs for people with type 2 Diabetes in low-to-middle income countries. It has been piloted in Malawi and Mozambique and found to be effective in improving diabetes control and patient reported outcomes. DESMOND EXTEND was culturally tailored to the Ghanaian population and low-resource settings. Based on clinical expertise, experience and results from the mixed methods study, the content, education aids, and delivery of DESMOND EXTEND were adapted. Carbohydrate counting was done in the local currency (Ghana cedis) instead of grams and the program was delivered over five hours rather than six hours in DESMOND EXTEND.

Chapter 5 described a randomised controlled trial on the effect of the adapted structured DSME on diabetes control and patient reported outcomes in adults living with diabetes in urban low-resource settings after 3-month follow-up. The results showed clinically relevant improvements in glycaemic control and self-care behaviours, however the effect of the intervention failed to reach statistical significance. In addition to other factors, the findings could have been limited by contamination of the study arms.

In **Chapter 6** a general discussion of the results, interpretation and implications is provided. In low-resource settings diabetes self-management education programs are largely unavailable. People living with diabetes in low-resource settings are confronted with inconsistent messaging around self-management practices. Financial challenges, complex socio-cultural belief systems and stigma further compound the difficulties faced by people living with diabetes in low-resource settings in navigating diabetes self-management. Despite these challenges, this thesis found that a diabetes self-management education program adapted to low-resource settings was associated with statistically significant improved glycaemic control in the intervention arm albeit the intervention effect did not reach significance. Additionally, there were also significant improvement if diabetes self-care behaviours in the intervention arm.

Appendices

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Structured diabetes self-management education and glycaemic control in low-resource urban primary care settings

Roberta Lamptey

Abstract

Introduction

Diabetes is an epidemic globally though the majority of affected persons live in low-middle income countries. If current trends persists, sub-Saharan Africa will experience the highest increase in diabetes prevalence over the next 20 years. This will have devastating complications, not only for affected individuals and their dependants, but also for health systems.

Majority of people living with diabetes have type 2 diabetes, a largely preventable disease for which complications can also be prevented (or at least delayed). In high income countries diabetes self-management education has been associated with better control of diabetes and thus, less complications. However, there is limited evidence on the effect of diabetes self-managment education in low-income settings. Importantly, the evidence on the association between diabetes self-management education and glycaemic control in Africa is inconclusive. In this thesis, firstly, I sought to characterise diabetes self-management education programs in low-resource settings, such as Ghana. Secondly, to assess and explore the diabetes self-management education knowledge and behaviours of people living with diabetes in low-resource settings. Finally, I sought to adapt an evidence-based diabetes self-management education program for the Ghanaian setting and to test the effect of this adapted program on glycaemic control and patient-reported outcomes in comparision to usual care.

Methods

A mixed-methods study was conducted from January to February 2021 in Weija Gbawe Municipal Hospital and Korle Bu Teaching Hospital; two low-resourced, urban primary care government facilities. We studied 423 people living with diabetes, two nationally recognised diabetes experts, five healthcare professionals and two health care managers. We culturally and linguistically adapted the Diabetes education and self-management for on-going and newly diagnosed (DESMOND) program for the Ghanaian setting and tested the adapted program in a randomised control trial. In total 206 people living with diabetes were randomised 1:1 to the adapted diabetes self-management education program plus usual care or to usual care only and followed for three-months.

Results

There are no structured diabetes self-management education programs in Ghana. Existing programs in other low-resource settings are unstructured, mainly group-based and delivered mostly by nurses. Diabetes knowledge, self-management behaviours, and glycaemic control of persons living with diabetes in low-resource settings were sub-optimal. Financial constraints, culture, beliefs were recurring themes underpinning self-management behaviours. Additionally, we found low income levels, high unemployment rates, and low literacy rates. The intervention tested had no effect on diabetes outcomes at three months.

Conclusions

In low-resource settings, financial contraints and cultural belief systems were found pivotal in relation to self-management behaviours. In high deprevation settings, the effect of diabetes self-management education maybe small, and likely require large samples to demonstrate. A holistic approach to self-management education, incorporating cultural and individual preferences may be beneficial.

Gestructureerde zelfmanagementeducatie en glykemische controle voor diabetes in stedelijke eerstelijnszorginstellingen met weinig middelen

Samenvatting

Inleiding
Diabetes is een wereldwijde epidemie echter de meerderheid van de personen met diabetes leeft in landen met een laag middeninkomen. Als de huidige trends zich aanhouden, zal sub-Saharisch Afrika in de komende 20 jaar de grootste toename in de prevalentie van diabetes meemaken. Dit zal grote gevolgen hebben, niet alleen voor de personen met diabetes en hun families, maar ook voor de gezondheidsstelsels.

De meerderheid van de mensen met diabetes heeft type 2 diabetes; een ziekte die grotendeels te voorkomen is. Daarnaast kunnen complicaties van diabetes ook worden voorkomen, of ten minste uitgesteld. In hooginkomenslanden wordt voorlichting over zelfmanagement bij diabetes in verband gebracht met een betere controle van de diabetes en dus minder complicaties. De bewijslast voor het effect van voorlichting over zelfmanagement bij diabetes in laaginkomenslanden (zoals Ghana) is beperkt. Bovendien is het bewijs voor de associatie tussen zelfmanagementeducatie en glykemische controle in Afrika niet eenduidig. In dit proefschrift heb ik getracht de programma's voor zelfmanagementeducatie bij diabetes in lage-inkomensomgevingen te karakteriseren. Daarnaast, heb ik ook getracht de kennis en het gedrag van mensen met die leven met diabetes in relatie tot zelfmanagementeducatie te onderzoeken. Tot slot heb ik een evidence-based diabetes zelfmanagementeducatie programma aangepast aan de Ghanese setting en het effect van dit aangepaste programma, in vergelijking met de gebruikelijk zorg, getest op diabetescontrole alsmede patiëntgerapporteerde uitkomsten.

Methoden
Van januari tot februari 2021 werd een mixed-methods studie uitgevoerd in het Weija Gbawe Municipal Hospital en het Korle Bu Teaching Hospital; twee stedelijke eerstelijns overheidsinstellingen met beperkte middelen. We bestudeerden 423 mensen met diabetes, twee nationaal erkende diabetesdeskundigen, vijf zorgverleners en twee managers. We pasten het programma "Diabetes Education and Self-management for On-going and Newly Diagnosd (DESMOND)" cultureel en taalkundig aan voor de Ghanese setting en testte het aangepaste programma in een gerandomiseerd onderzoek met controlegroep. In totaal werden 206 mensen met diabetes gerandomiseerd (1:1) naar het aangepaste diabetes zelfmanagementeducatie programma plus gebruikelijke zorg of alleen gebruikelijke zorg. Onderzoeks deelnemers werden gedurende drie maanden gevolgd.

Resultaten

Er zijn geen gestructureerde diabetes zelfmanagementeducatie programma's in Ghana. Bestaande programma's zijn ongestructureerd, voornamelijk in groepsverband en worden meestal door verpleegkundigen gegeven. Diabeteskennis, zelfmanagementgedrag en glykemische controle van mensen met diabetes in een omgeving met weinig middelen waren suboptimaal. Financiële beperkingen, cultuur en overtuigingen waren terugkerende thema's die ten grondslag lagen aan zelfmanagementgedrag. Bovendien vonden wij lage inkomensniveaus, hoge werkloosheidscijfers en een lage alfabetiseringsgraad. De geteste interventie had geen effect op de diabetesresultaten na drie maanden.

Conclusies

In settings met weinig middelen zijn financiële beperkingen en culturele geloofssystemen van invloed op zelfmanagementgedrag. In settings met een groot gebrek aan middelen is het effect van diabeteseducatie over zelfmanagement misschien klein, en zijn waarschijnlijk grotere steekproeven nodig om dit aan te tonen. Een holistische benadering van zelfmanagementeducatie, waarin culturele en individuele voorkeuren zijn verwerkt, kan meerwaarde hebben.

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"It is easy to acknowledge, but almost impossible to realize for long, that we are mirrors whose brightness, if we are bright, is wholly derived from the sun that shines upon us."
C. S. Lewis (1971)

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Curriculum Vitae/About the Author

Roberta Lamptey is a budding researcher and an experienced primary care clinician. Her research is focused on diabetes among people with high deprivation. She has contributed to National guidelines and textbooks on diabetes.

Roberta is the holder of an NIHR grant for research on cardiometabolic disease in Ghana, Kenya and Mozambique. As the Co-PI, she is currently collaborating with colleagues at University of Leicester, University of Nairobi and Eduardo Mondlane University Mozambique to create and test a model for structured self-management education.

Dr Lamptey is a Consultant Family Physician and Diabetologist for Korle Bu Teaching Hospital. As a former deputy director of the Hospital, she led in the establishment of an Institutional Review Board for the hospital. Under her leadership, the hospital successfully migrated from paper to electronic medical records.

Ultimately Roberta aspires empower people living with chronic cardiometabolic conditions by building a sustainable evidence-based model for delivering structured self-management education.

List of publications

Publications in this thesis

Lamptey R, Robben MP, Amoakoh-Coleman M, Boateng D, Grobbee DE, Davies MJ, Klipstein-Grobusch K. Structured diabetes self-management education and glycaemic control in low-and middle-income countries: a systematic review. Diabetic Medicine. 2022 Feb 18:e14812.

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Lamptey R; Amoakoh-Coleman M; Barker MM; Iddi S, Hadjiconstantinou M , Davies MJ; Darko D; Agyepong I; Acheampong F; Commey M; Yawson A; Grobbee DE; Obeng Adjei G; Klipstein-Grobusch K: Change in glycaemic control with structured diabetes self-management education in urban low-resource settings: multicentre randomised trial of effectiveness

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