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Evaluating implementation of Diabetes Self-Management Education in Maryland County, Liberia: protocol for a pilot prospective cohort study

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ABSTRACT

Introduction Achieving glycaemic targets for people living with diabetes (PLWD) is challenging, especially in settings with limited resources. Programmes need to address gaps in knowledge, skills and self-management. Diabetes Self-Management Education (DSME) is an evidence-based intervention to educate and empower PLWD to improve self-management activities. This protocol describes a pilot study assessing the feasibility, acceptability and effect on clinical outcomes of implementing DSME in clinics caring for people living with insulin-dependent diabetes in Liberia.

Methods and analysis Our protocol is a three-phased, mixed-methods, quasi-experimental prospective cohort study. Phase 1 focuses on (a) establishing a Patient Advisory Board and (b) training providers in DSME who provide care for PLWD. In phase 2, clinicians will implement DSME. In phase 3, we will train additional providers who interact with PLWD.

We will assess whether this DSME programme can lead to increased provider knowledge of DSME, improvements in diabetes self-management behaviours, glycaemic control, diabetes knowledge and psychosocial well-being, and a reduction in severe adverse events. Primary outcomes of interest are implementation outcomes and change in frequency of self-management behaviours by patients. Secondary outcomes include change in haemoglobin A1c, psychosocial well-being, severe adverse events and change in provider knowledge of DSME.

Ethics and dissemination Ethical approval was obtained from the University of Liberia Institutional Review Board (IRB) and the Brigham and Women's Hospital IRB. Findings from the study will be shared with local and national clinical and programmatic stakeholders and published in an open-access, peer-reviewed journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Mixed methods will allow for assessment of feasibility, clinical and behaviour outcomes.
⇒ Inclusion of Patient Advisory Board will ensure patient voice and perspectives are centred throughout the study and provide formative feedback on implementation.
⇒ Limited by small sample size, the clinic however only serves a small population of patients living with insulin-dependent diabetes in a remote rural area of Liberia.
⇒ Generalisability of findings limited by a lack of control group.

INTRODUCTION

Background

Diabetes is a chronic condition with increasing impact on individuals and health systems globally. In the African continent, prevalence is projected to increase by 47.6% to 20.8 million people by 2030.[1] Diabetes is a growing public health concern among rural poor populations, who are disproportionally burdened by non-communicable diseases (NCDs).[2 3] Although limited data exist, people living with diabetes (PLWD) in the region experience high rates of severe morbidity and mortality.[3–5] Diabetes management is especially complex when insulin administration is required, presenting additional individual and system-level management challenges.

Achieving glycaemic targets is the cornerstone of diabetes management. For people living with insulin-dependent diabetes (PLWIDD), this can be difficult without significant active engagement by patients in their care.[6] Haemoglobin A1c (HbA1c) is the standard measure for assessing glycaemic management. Current guidelines set the target HbA1c at less than 7.0%–7.5% for most PLWD.[7–9] Even in high-income countries (HICs) where insulin and diabetes supplies and technology are readily available, glycaemic targets are often not met.[10 11] Barriers to glycaemic control (eg, lack of access to insulin/medical supplies, limited literacy and numeracy, food insecurity and lack of multidisciplinary support) are exacerbated in resource-limited settings.[12]

In a recent qualitative survey at the site where this study will be conducted, the only endocrinologist in Liberia identified the need for diabetes education and multidisciplinary care as a priority.[12] These findings were consistent with previous research showing that in addition to barriers presented by social determinants of health, challenges with consistent self-management behaviours are associated with poor glycaemic outcomes in the sub-Saharan Africa (SSA) region.[13–16]

Despite recent efforts to increase access to insulin and self-monitoring blood glucose (SMBG) supplies in low-income countries (LICs), diabetes self-management has not improved.[14 15 17 18] Diabetes Self-Management Education (DSME) is an evidence-based, structured method to educate and empower PLWD to improve self-care activities by focusing on the behavioural aspects of diabetes management and problem-solving to address barriers to self-management. The American Association of Diabetes Educators (AADE) defines seven critical self-management behaviours: healthy eating, being active, monitoring, taking medication, problem-solving, healthy coping and reducing risks.[8 19] DSME is centred on a behaviour change model where the focus is helping patients develop skills that will allow them to engage in health behaviour changes or maintenance to optimise their diabetes care. One of the goals of DSME is to engage patients in their own care and provide an opportunity for shared decision-making between the healthcare team and PLWIDD. DSME focuses on quality of life and well-being and considers individuals' resources and environment. Types of support used in DSME include psychosocial care, addressing barriers to behaviour change and clinical management.[20] Other approaches used include motivational interviewing, use of non-judgemental language and SMART (Specific, Measurable, Achievable, Relevant, Time-bound) goal setting. DSME has been used ubiquitously in HICs, but has not been widely studied in settings with extreme poverty.[19] DSME in HICs has been shown to improve clinical outcomes, diabetes self-management behaviours, quality of life, self-efficacy and feelings about diabetes.[21–24] DSME programmes can lead to decreased diabetes care-related costs to the health system.[25 26]

While the evidence is clear in HICs, it is unclear if DSME will be effective in low/lower middle-income countries (LLMICs). The burden of social determinants of health (high rates of food insecurity, low literacy, low numeracy, shortage of diabetes medication and supplies, long distance from health facilities and lack of access to specialty care) plays a significant role in diabetes self-management in these settings. People living in rural areas, especially in LLMICs, are more likely to lack ancillary support and safety nets and may have limited access to emergency and specialty care services. Diabetes self-management requires daily complex medical decision-making. PLWD in rural settings have less support with this decision-making and may not have access to emergency treatment if errors are made. Self-management, while critical for all PLWD, becomes especially important in this setting where the burden of management of a complex and life-threatening disease falls primarily with the patient and family.

Though the body of evidence on DSME in LLMICs is growing, few studies have examined the effectiveness and acceptability of DSME programmes in SSA, and fewer have focused on type 1 diabetes (T1D). A Nigerian randomised control study of group-based DSME for people living with T1D and type 2 diabetes (T2D) reported a mean reduction of 1.8% (95% CI −2.4% to −1.2%) in average HbA1c in the DSME group compared with the conventional diabetes education group.[27] In Mali, a randomised control trial conducted only in people living with T2D showed a reduction in HbA1c of 1.05% in the DSME group compared with −0.15% in the conventional diabetes education group.[28] The primary outcome of interest in these studies was glycaemic control. No studies in the region have looked at the impact or feasibility of a structured DSME programme on diabetes distress, depression and diabetes self-management behaviours.

This is the first implementation study to evaluate the feasibility of incorporating DSME in the care of PLWIDD in a LLMIC. Our study seeks to fill a significant gap in the literature, while equipping providers who care for PLWD in rural Liberia with the knowledge, skills and tools to support patients to improve self-management activities.

Study objective and aims

This is a protocol for a pilot study that, guided by the Proctor *et al*'s implementation outcome framework, will assess the feasibility, acceptability and clinical impact of implementing structured DSME delivery in clinics caring for PLWIDD in Liberia.[29] The aims of the study are the following:

1. Evaluate change in provider knowledge of DSME delivery through training and mentorship.
2. Assess the feasibility of providers delivering DSME to PLWIDD in a rural region in Liberia.
3. Measure the effect of DSME on self-management behaviours, psychosocial well-being and clinical outcomes among PLWIDD.
4. Determine acceptability of DSME among providers and PLWIDD.

METHODS AND ANALYSIS

Study setting

This pilot study will be conducted at two health facilities in Maryland County, Liberia: JJ Dossen District Hospital (JJD) in Harper City and Pleebo Health Center (PHC) in Pleebo. Both facilities operate under the Ministry of Health (MOH) and receive support from Partners In Health (PIH). JJD is a district hospital serving as a teaching centre. PHC is a community health centre affiliated with JJD. In 2017, an NCD clinic was founded using the Package of Essential NCD Interventions (PEN)-Plus model. The PEN-Plus model builds on the WHO PEN. Mid-level clinicians in LICs are trained to provide

integrated care for severe chronic (causing early death and disability) NCDs such as insulin-dependent diabetes (IDD), rheumatic heart disease and sickle cell disease. Care is provided in rural areas where services were previously only available at tertiary referral facilities.[30–35]

Maryland County is remote and rural—it lies on the border of the Ivory Coast, far removed from Liberia's capital Monrovia and is only accessible by plane or by 2–3 days' travel by car. Qualitative interviews conducted at this site found that challenges to diabetes management include high levels of poverty and food insecurity, low levels of literacy and numeracy, and high temperatures causing insulin damage, increasing the risk of diabetic ketoacidosis hospitalisation.[12] Patients travel long distances to the clinic monthly for consultations and insulin refills. All health services, medications, insulin and diabetes necessities (ie, glucometer, test strips, lancets and syringes) are provided to patients at no cost. Access to HbA1c testing at the clinic level has been inconsistent due to supply chain, cost and machine malfunction. Currently, there is a lack of a robust, structured, diabetes education programme. In 2019, the average HbA1c in PLWIDD was around 10.0%, demonstrating high risk of diabetes-related complications. The standard of care at these facilities is intermediate acting with fixed doses or sliding scale of short-acting insulin. Short-acting insulin doses are less likely to be administered due to fear of hypoglycaemia or uncertainty of when it is needed, especially if not engaging in SMBG. Patients are provided with enough test strips to perform SMBG twice daily, though frequency of SMBG varies by patient. The average amount of time patients spend with clinicians is 10–15 min, not including time with a nurse aide and pharmacist.

Study design

This is an implementation study conducted using Proctor *et al*'s outcomes for implementation research framework.[29] We use a mixed-methods, quasi-experimental prospective cohort design evaluating feasibility, acceptability and effect on clinical outcomes of implementation of DSME in a rural SSA NCD clinic. Clinicians who provide care for PLWIDD will receive DSME training, and then lead DSME delivery over the course of 1 year. We planned phase 1 to start in May 2021, and complete data collection by December 2022.

Intervention

The study will be implemented in three phases summarised below and outlined in table 1.

The three phases of the study are cumulative; they will start at different time points and overlap. Phase 1 study activities and data collection focus on providers. It begins

Table 1 Study logic model

	Timeline	Objective	Study subjects	Interventions
Phase 1a	Months 1–13	Measure impact of training in DSME approaches on provider knowledge and patient interactions	NCD providers	► In-person training ► Case studies and DSME role-play ► Patient Advisory Board
Phase 1b	Months 2–13	Assess impact of continuing education related to diabetes on core NCD providers' ability to manage patients with diabetes		► Virtual continuing education ► Virtual case studies ► Mentorship ► Patient Advisory Board
Phase 2a	Months 2–13	Measure the effect of DSME on self-management behaviours and clinical outcomes	PLWIDD	► DSME delivery by NCD providers ► Patient Advisory Board
Phase 2b	Months 4–13	Assess the impact of DSME and interdisciplinary approach to clinical management on patients' psychosocial well-being		► DSME delivery by NCD providers ► Multidisciplinary collaboration (social work, mental health) ► Patient Advisory Board
Phase 3	Months 7–13	Measure impact of training in DSME approaches on provider knowledge and patient interactions	Providers who interact with PLWIDD	► In-person training ► Case studies and DSME role-play ► Mentorship ► Patient Advisory Board

DSME, Diabetes Self-Management Education; NCD, non-communicable disease; PLWIDD, people living with insulin-dependent diabetes.

by training providers in DSME before delivering DSME to patients in phase 2. Phase 2 focuses on PLWIDD. It begins with the first DSME sessions and continues monthly. Phase 3 study focuses on non-NCD providers who interact with PLWIDD. Providers' and patients' data will be collected until the study concludes.

Phase 1: this phase focuses on the impact of DSME training on provider knowledge and patient interactions and is divided in two subphases. In phase 1a, we will establish a Patient Advisory Board (PAB) to provide guidance concerning modifications to clinic structure and support patient engagement in the project. The PAB will meet with NCD team staff to provide monthly feedback on the project. During this phase, NCD providers will receive in-person training (didactic, cases studies and role-playing) on DSME delivery. A NCD nurse educator and nurse practitioners who are certified diabetes care and education specialists will conduct the training.

Phase 1b will involve provider continuing education and training on advanced management of diabetes following a similar format as in phase 1a. Clinicians delivering the training will serve as DSME mentors and will be observing provider–patient encounters to assess NCD providers' utilisation of DSME to deliver patient care and education, ability to personalise patient education, and frequency of referral for mental health and social support needs.

Phase 2: phase 2 is also divided into two subphases, focused on delivering and monitoring the impact of DSME on patient knowledge and clinical outcomes. Phase 2a focuses on assessing diabetes management knowledge and skills and changes in diabetes self-management behaviours at baseline, 6 months and 12 months of the study. The knowledge assessment measures competency in 10 self-management domains derived from the AADE seven diabetes self-management behaviours: general understanding of diabetes, blood sugar levels, blood sugar monitoring, insulin dosing, nutrition and diet, complications and screening, sick day management, physical activity, general health maintenance and reproductive health.[19] NCD providers will identify gaps in knowledge and skills and design individualised plans to advance patients from basic to intermediate, or intermediate to advanced management skills. Providers will document DSME topics covered during clinic visits and patient progress in their knowledge and skills acquisition. In this phase, clinical data like HbA1c and severe events will be monitored regularly.

Phase 2b will focus on assessing the impact of DSME and the interdisciplinary approach on patients' psychosocial well-being. Based on patients' responses to psychosocial assessments, providers may refer patients to an interdisciplinary team made up of mental health providers and a social worker or social protection officer.

Phase 3: in phase 3, additional providers who interact with PLWIDD will receive training on DSME concepts. This phase will mimic phase 1a, with a focus on training other allied health professionals who care for these patients in inpatient and outpatient settings. This training will be focused on increasing providers' capacity to deliver education on basic diabetes management skills needed for safe discharge from the hospital and therapeutic communication. NCD providers and study staff delivering the training will serve as mentors for these providers. In this phase, we will measure the impact of training in DSME approaches on provider knowledge around basic diabetes management skills and patient interactions.

Recruitment and inclusion and exclusion criteria

Phase 1: we will invite all NCD providers at JJD and PHC to participate. We expect to enrol three to six providers.

Phase 2: all 26 PLWIDD will be invited to participate in this phase of the study. Any patient newly diagnosed or newly started on insulin after the first 2 months of the study, who is pregnant or becomes pregnant during the study, or who does not wish to participate will be included in all study activities but no data for research purposes will be collected. Pregnant patients receive additional care from specialists outside of NCD clinic and have different targets for diabetes management. Similarly, newly diagnosed patients often have rapid reductions in HbA1c; therefore, their data will be excluded from analysis.

All PLWIDD enrolled in the clinics are well known to NCD staff. At the time of their clinic visit, study staff will provide them with information regarding the study. If they agree to participate, informed consent will be obtained at enrolment. Children less than 18 years will provide assent if consent is given by a legal guardian. All participants will be given the option to ask questions and withdraw from the study at any time. Participants will be made aware that their clinical care will not change regardless of whether they choose to participate in the study.

Phase 3: study staff and local MOH and PIH Liberia leadership will collaborate to select providers to invite to participate in phase 3. We expect to enrol 10–15 providers. Any local provider or health worker who may interact with PLWIDD will be eligible to participate.

Effect size calculation

We intend to maximise the sample size by inviting all 26 PLWIDD to enrol in the study. Because we are enrolling the entire patient population, we are unable to perform a sample size calculation. However, for the quantitative clinical secondary outcome HbA1c, given an estimated sample size of 26, we calculate that the study will have over 80% power using a two-tailed test with alpha value of 5% to detect a 1% decrease in HbA1c assuming an SD of 1.7 or less, which is consistent with the randomised control trial performed by Essien *et al* in Nigeria[27] (figure 1).

Data collection

Phase 1: NCD providers will be the first to enrol and will be followed for 13 months. Prior to the training, providers will complete a comprehensive assessment of knowledge on diabetes management, DSME-focused communication techniques and advanced topics in diabetes management. This assessment aligns with competencies for PEN-Plus

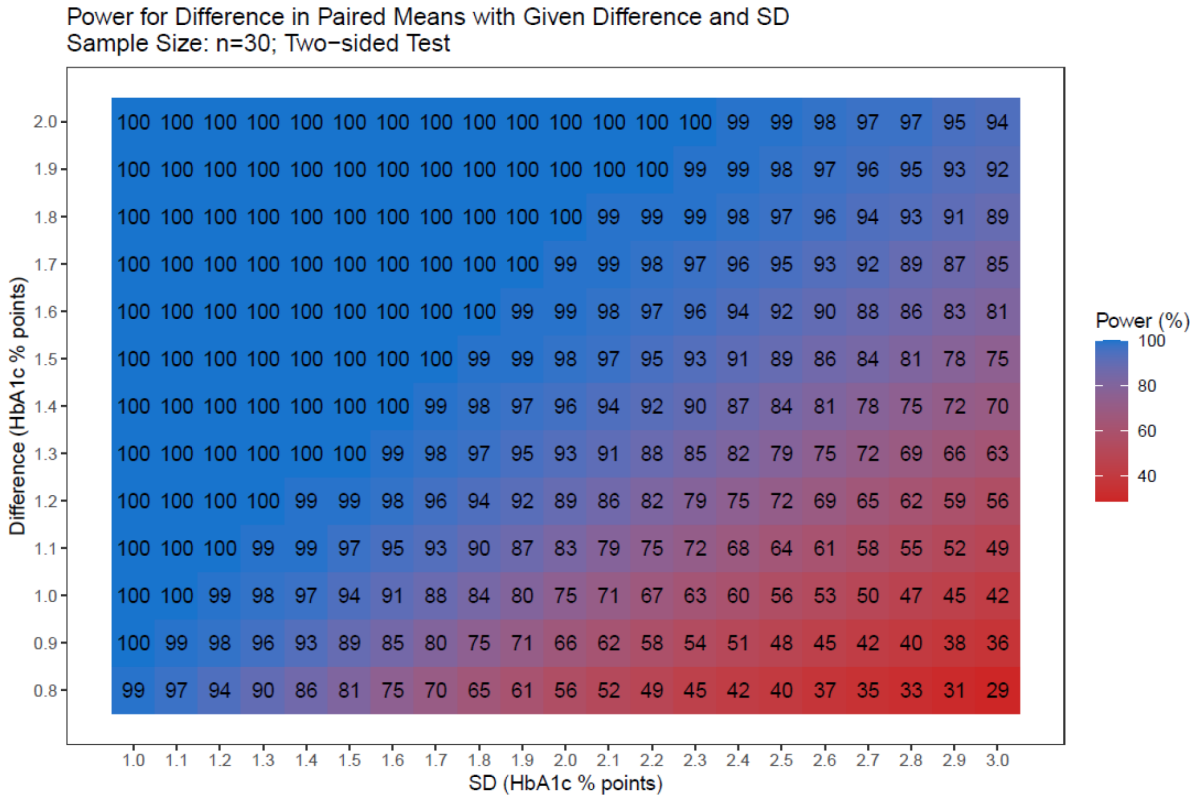

Figure 1 Power table showing expected power for range of changes in haemoglobin A1c levels for different SDs.

providers and AADE guidelines. Post-training, providers will complete qualitative interviews conducted in English (spoken by all Liberian study providers) by study staff with experience working in this location. A trained interviewer will use a semistructured interview guide to learn about their experience, knowledge, and comfort with DSME training and delivery, perceived benefits of DSME, impact of patient–provider interactions, barriers to delivery, acceptability and sustainability. Follow-up assessments and qualitative interviews will be completed at 6 and 12 months post-training.

Phase 2: patients will be enrolled 1 month after provider enrolment and followed for 12 months. At enrolment, patients will complete a questionnaire with demographics, diabetes and health history, access to resources and preferred method of communication. Study staff will assist patients unable to read. Anthropometric measurements and HbA1c will be collected at enrolment and throughout the study. Data on diabetes management knowledge and skills will be collected from patients through an assessment at enrolment, 6 and 12 months. This assessment was developed in alignment with the AADE seven self-care behaviours and adapted with guidance from local providers to fit the context of diabetes management in Liberia.

Two months after the knowledge assessment, patients will complete a psychosocial assessment including the Patient Health Questionnaire-9 (PHQ-9) Scale for depression,[36] the Problem Areas in Diabetes Scale-5 for diabetes distress[37] and the Household Food Insecurity Access Scale for measurement of food access.[38] These scales have all been validated in low resource or SSA settings.[39–41] Psychosocial assessments will be repeated every 3 months. Patients who screen positive will be referred to mental health or social work.

At the conclusion of the study, we will conduct qualitative interviews with 8–12 patients. Recruitment of patients will happen at the time of their last monthly study scheduled appointment. Patients will report their satisfaction with DSME, changes in provider interactions, changes in self-management behaviours, and feelings about self-efficacy and diabetes management. Interviews will be conducted in Liberian English or Grebo (local dialect) by local study staff who speak English, Liberian English and Grebo. All efforts will be made to ensure patients understand that their participation or responses to interview questions will not negatively affect their clinical care.

Throughout phase 2, providers will complete a monthly documentation tool for each patient. This tool tracks topics covered during clinic visits and patients' progress with diabetes self-management knowledge and skills. Data and notes from chart reviews and blood glucose logs will be reviewed monthly to determine frequency of SMBG and missed insulin doses. High rates of food insecurity, lack of food variety and active lifestyle in this setting (eg, walking as transportation, physical labour) present significant barriers to lifestyle modification. Frequency of SMBG and missed insulin doses were identified as priority self-management behaviours by local providers and in the qualitative assessment of T1D care in rural Liberia.[12]

DSME mentors will collect data on core NCD providers' utilisation of DSME, the use of the patient assessment tool, and frequency of referrals for interdisciplinary care by directly observing patient interactions and completing a mentoring checklist. Similar checklists have been effective in promoting retention of learning and improved quality of care for PLWD in rural Rwanda.[33]

Phase 3: at month 5, we will enrol 10–15 additional providers from other departments (ie, mental health, emergency department, outpatient department, primary clinics, medical-surgical ward and paediatric ward) who interact with PLWIDD. Provider knowledge assessment data will be collected before training and 6 months post-training. Mentorship and data collection will mirror phase 1.

Study outcomes

Our outcomes include implementation outcomes following the Proctor *et al*'s framework,[29] as well as clinical and behavioural outcomes. All outcomes are described in detail in table 2. Primary outcomes include the implementation outcomes of acceptability, adoption, fidelity and cost as well as two self-management behaviours: frequency of SMBG and missed insulin doses. Secondary outcomes include clinical outcomes such as HbA1c, severe events (hypoglycaemia requiring assistance or hospitalisation related to diabetes) and psychosocial well-being (depression and diabetes distress). Additional secondary outcomes include provider and patient knowledge retention.

Because the DSME process is individualised based on each patient's resources and personal goals, progression in knowledge and skills around diabetes self-management will be different for each patient. We expect that integrating a structured DSME programme as part of standard diabetes care will lead to increased self-management behaviours resulting in improved HbA1c and decreased frequency of severe adverse events.[19 42]

Data management

Due to limited internet connectivity in the clinic, data will be collected on paper and then transferred to the database REDCap. Qualitative interviews will be audio recorded and transcribed electronically. All paper data collection tools will be de-identified and stored in locked cabinets. All physical data (paper charts, recording devices) will be owned by and stored in Liberia. All online data will be password protected.

Statistical analysis

Quantitative analysis: descriptive statistics will be used to describe primary and secondary quantitative outcomes. T-tests will be used for variables measured pre-intervention and post-intervention. Analysis of variance (ANOVA) will be used for variables measured at multiple time points. We will make every attempt to run repeated measures ANOVA for data collected at multiple time points whenever possible and adjust for confounders.

Table 2 Primary and secondary study outcomes and definitions

Primary outcomes	Definition/tools
Implementation outcomes ► Acceptability	Qualitative interviews Provider: NCD providers will report their satisfaction with DSME, specifically around training and mentorship, implementation, complexity, comfort, delivery and perceived benefits to patients.
	Patient: Patients will report their satisfaction with DSME, changes in provider interactions, changes in self- management behaviours, and feelings about self-efficacy and diabetes management.
► Adoption	Qualitative interviews: NCD providers will reflect on how often they are delivering DSME as they learnt in the training.
► Fidelity	Chart review: we will assess the utilisation of DSME forms, including per cent of DSME documentation tool completed and frequency of the use of the patient assessment to guide DSME. Mentorship/observation: NCD providers will be directly observed through completion of checklists[33] to assess the utilisation of DSME to deliver patient care and education, the use of the patient assessment tool to guide patient education, and frequency of referral mental health and social support.
► Cost	Budget and staffing review: we will measure the increased cost to the programme associated with DSME initiation and maintenance.
Self-management behaviours ► SMBG frequency	Chart review: proportion of patients who bring blood glucose logs and metres to clinic and percentage of blood glucose checks per week versus percentage of blood glucose checks prescribed per week.
► Missed insulin doses	Chart review: we will assess average number of insulin doses missed per week.
Secondary outcomes	
HbA1c	Point-of-care measurement at enrolment and every 3 months. Where possible, we will also include HbA1c from prior years.
Psychosocial well-being ► Depression	The Patient Health Questionnaire-9 (PHQ-9) Scale will be used to screen for depression.[36]
► Diabetes distress	The PAID-5 will be used to screen for diabetes distress.[37]
Severe events	Chart review: any severe hypoglycaemia (patient unable to treat themselves) or hospital admissions related to diabetes will be reported.
Retention of provider knowledge of DSME	Provider knowledge assessment: a comprehensive assessment of provider knowledge of diabetes management and DSME-focused communication techniques will be administered at baseline, 6 months and 12 months.
Retention of patient knowledge of DSME	Patient knowledge assessment: a comprehensive assessment of patient knowledge of diabetes self-management will be administered at baseline, 6 months and 12 months. Patients will be scored on competency within different domains of DSME.

DSME, Diabetes Self-Management Education; HbA1c, haemoglobin A1c; NCD, non-communicable disease; PAID-5, Problem Areas in Diabetes Scale-5; SMBG, self-monitoring of blood glucose.

Qualitative analysis: we will analyse qualitative interviews thematically in two steps. We will start with an a priori thematic analysis, and then move to an indicative analysis

seeking to elicit new themes or unexpected findings through coding and categorising, following the techniques of grounded theory, which include looking for deviant cases and using the constant comparison method by comparing codes and categories.[13] Relevant anonymised quotes representative of the analysis will be incorporated into publications.

Costing analysis: the additional cost of implementing and maintaining DSME beyond current standards of care will be documented. The estimate of the total annual cost of DSME implementation will be based on review of budgets, payroll, support for training and PAB (eg, food and transportation reimbursement), and related administrative costs. The total cost will be divided by the number of patients enrolled in the study to generate an average cost per patient.

Patient and public involvement

As this study is designed to promote a culture shift to patient-centred care, patient voice and local leadership are central to the planning and implementation process. After learning more about the lived experience of PLWIDD in Liberia, local providers and leadership identified the need for a different approach to patient education, and have led the process of adapting DSME to local context and culture.[12] Study outcomes, specifically implementation outcomes, are designed to assess the effectiveness of this adaptation. A PAB will be established in phase 1 of the study, which will provide formative feedback to study staff and lead any process improvement initiatives related to clinic flow and structure. Additionally, this project was developed through a committee that includes five Liberians who have collectively worked in the area for over 15 years, and guided early conceptualisation and protocol development for the study. One of the study coauthors (GF) is living with T1D, and will be involved throughout the design of the protocol, tools, implementation of the study, data analysis and manuscript writing. Study results will be disseminated to the larger community of PLWD served by the clinics, and the advisory board will continue post-study to be involved in decision-making related to continued integration of the intervention into clinic practices.

Limitations of the study

Limited availability of diagnostic tools makes the differentiation between T1D and T2D extremely challenging in LICs. Thus, it is difficult to accurately ascertain how many patients have T1D versus another type of IDD. Due to the small sample size and modifications to clinic structure required to give providers ample time to perform DSME with patients, we are unable to have a control group. It would put too much strain on providers and potential risk to patients to provide two different models of care. As a result, our estimates of effectiveness will be restricted to pre-knowledge and post-knowledge tests and change in clinical and self-management outcomes from enrolment to the end of the study. Wherever possible, we will compare with patient data from prior to the study. As the study runs for a year, we should be able to account for seasonal variations.

Ethics and dissemination

This protocol was approved by the University of Liberia-PIRE Institutional Review Board (Assurance #FWA00004853) and Brigham and Women's Hospital (#2021P001081). We consider this study to be low risk. Participants may need to spend more time in the clinic to complete study activities, which may take time away from work or school. Increased focus on psychosocial burden of diabetes may cause emotional distress. Measures to address emotional distress as a result of the study will be implemented (ie, referral to mental health or social work). The greatest risk would be a breach of confidentiality. No personal identifiable data will be collected on study forms. Data will only be accessible to the study team. Paper data will be stored in a locked filing cabinet. Electronic data will be password protected. All participants will have the option of not being quoted, even anonymously, in the study and subsequent publications; and participants will always be quoted without reference to their exact age or professional status. Participants will be given the option to withdraw anytime. All researchers will undergo research ethics training.

We will share results with the PAB, local clinical teams, the MOH and other national stakeholders for NCD care in Liberia, and publish in a peer-reviewed, open-access journal.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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