TBM

SMART2D—development and contextualization of community strategies to support self-management in prevention and control of type 2 diabetes in Uganda, South Africa, and Sweden

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Abstract

Type 2 diabetes (T2D) and its complications are increasing rapidly in low- and middle-income countries, as well as among socioeconomically disadvantaged populations in high-income countries. Support for healthy lifestyle and self-management is paramount but not well implemented in health systems, and there is need for knowledge on how to design and implement interventions that are contextualized and patient centered and address special needs of disadvantaged population groups. The SMART2D project implements and evaluates a lifestyle and self-management intervention for participants recently diagnosed with or being at increased risk for T2D in rural communities in Uganda, an urban township in South Africa, and socioeconomically disadvantaged urban communities in Sweden. Our aim was to develop an intervention with shared key functions and a good fit with the local context, needs, and resources. The intervention program design was conducted in three steps facilitated by a coordinating team: (a) situational analysis based on the SMART2D Self-Management Framework and definition of intervention objectives and core strategies; (b) designing generic tools for the strategies; and (c) contextual translation of the generic tools and their delivery. This article focuses on community strategies to strengthen support from the social and physical environment and to link health care and community support. Situational analyses showed that objectives and key functions addressing mediators from the SMART2D framework could be shared. Generic tools ensured retaining of functions, while content and delivery were highly contextualized. Phased, collaborative approach and theoretical framework ensured that key functions were not lost in contextualization, also allowing for cross-comparison despite flexibility with other aspects of the intervention between the sites. The trial registration number of this study is ISRCTN11913581.

Keywords

Type 2 diabetes, Prevention, Self-management, Peer support, Disadvantaged settings, Reciprocal learning

INTRODUCTION

Diabetes and prediabetes are increasingly contributing to the global burden of disease [1,2]. The increase disproportionately affects low- and middle-income countries and will be very high in

Implications

Practice: To maintain the effectiveness of lifestyle change and self-management support interventions when transferring from research to routine practice, it is necessary to understand what the active ingredients for change are and to retain those with as much fidelity as possible even when content and (or) delivery have to be contextualized.

Policy: During the implementation of programs for prevention and management of noncommunicable diseases, contextualization is necessary for ensuring feasibility and acceptability, while standardization of functions, that is, retaining active ingredients for change, is necessary to ensure outcome effectiveness.

Research: Future research should focus on how to uncouple the effect of specific active ingredients on specific outcomes within complex interventions and how to adjust for the contextualization factor which is a key aspect of implementation.

Sub-Saharan Africa [3] and socioeconomically disadvantaged communities in high-income countries [4]. The burden is increased by delayed diagnosis and high prevalence of complications [3,4].

Despite evidence showing that self-management, including healthy lifestyle and self-care, are key factors in prevention [5, 6] and control [7] of Type 2 diabetes (T2D), implementation and scaling up of support programs have been a challenge [8]. The challenge is even greater for low- and middle-income settings [9] due to scarce resources, prioritization of communicable diseases and lack of adequate competence in noncommunicable disease prevention and management [10]. In high-income countries, most approaches to chronic disease management

are standardized, uniform, and facility based and fail to account for the special needs of disadvantaged groups [11]. Furthermore, programs are typically informed by behavior change theories that have been developed and tested in western contexts.

An important barrier to wider implementation and scale-up of successful strategies is the lack of knowledge on how to adapt them to new contexts or specific populations while retaining the active ingredients or functions [12] that made the strategies effective. Programs with established effectiveness and feasibility in terms of resources, capacity, and cultural fit are needed [12,13].

The SMART2D project, "A person-centered approach to Self-Management and Reciprocal learning for the prevention and management of Type 2 Diabetes," set out to design a self-management support intervention for T2D and test it through an adaptive implementation trial in multiple disadvantaged contexts. Utilizing diversity for reciprocal learning was our key process-related objective [14,15]. Our aim was to understand the needs and capacities of each site while leveraging core strategies with key functions in a collaborative, phased process promoting cross-learning [14]. In this paper, we will describe the process with the aim to contribute to the implementation knowledge gap of how to transfer evidence-based self-management support interventions into socioeconomically disadvantaged real-world settings. Data from the trial will be reported separately.

METHODS

Setting

The SMART2D intervention was targeted for participants recently diagnosed with or at increased risk for T2D in rural communities in Uganda, an urban township in South Africa, and socioeconomically disadvantaged communities in Sweden. The recruitment algorithm was developed and the sample size for each site was determined by power calculations [16]. After piloting, these were further modified to improve fit with the local context by focusing on locally relevant methods and tests for defining risk status and will be reported in the effectiveness evaluation. All participants were informed of their risk status before enrollment to the study, Characteristics of the settings have been described elsewhere [14−16]. The intervention development was a multidisciplinary team effort by three country teams together with a coordinating team to facilitate the process. The teams represented diverse fields, including medicine, epidemiology, nutrition sciences, exercise physiology, health systems research, behavioral sciences, implementation research, medical anthropology, health policy research, and health economics.

A phased approach to intervention development

The intervention program design was conducted in three phases with methods, the resulting findings and/or output of each described in detail in the following sections.

Phase 1: definition of intervention objectives and core strategies

Phase 1 built on situational analyses performed by each country team as guided by a comprehensive transdisciplinary conceptual model for self-management, the SMART2D Self-Management Framework [15]. The framework, building on several theories and models, such as the Chronic Care Model [17], Self-Determination Theory [18], and Illness Representation model [19], suggests that promoting self-management skills requires a supportive environment, which entails actions by family and friends, community, and health providers that foster individual's basic psychological needs (perceived competence, autonomy, and relatedness), supportive illness representations, and learning.

To assess priority needs, resources, and opportunities to improve self-management, findings from the situational analyses and cross-learning from infectious diseases, stakeholder interaction, and other SMART2D sites were synthesized with key researchers at each site and further discussed in adjoining workshops with local key stakeholders. Phase 1 concluded in a cross-site workshop to discuss findings, learn from each other, and define objectives and core strategies for the intervention protocol [16]. Selected strategies were to address a priority need, have the potential for effectiveness and evaluation, and be feasible and sustainable.

Phase 2: designing generic intervention tools and training for core strategies

The second phase included desk research by the coordination team and country teams to design components of the selected core strategies and tools with appropriate active ingredients (functions). The SMART2D Self-Management Framework [15] and the situational analysis informed us about which theoretical mediators to address. Tools were selected based upon evidence of effectiveness, feasibility, and acceptability and potential for scale-up. The tools and training for their implementation were discussed in a series of teleconferences with the country teams and defined jointly in a tools workshop.

Phase 3: contextual translation of the tools, training, and delivery

For the contextual translation, the country teams, coordination team, and topical experts from the consortium worked together with country stakeholders to find an optimal fit with the strategies and the context. Contextualization implied that materials were made relevant and applicable to the local

context and languages and that the best mode and platform for delivery of the intervention was sought whilst retaining the function. Different teams took a lead for different strategies based on the priority needs in their context and shared their work with other teams. In Sweden, this phase also included piloting of the community strategies.

RESULTS

Phase 1: definition of core intervention strategies

Situational analyses at each site provided rich data, described in detail in several site-specific [20−22] and cross-site publications [15] and reviews [23]. Synthesis of the analyses revealed priority needs and opportunities related to health systems and organization of care, community support, and individual perceptions, which in turn informed the definition of intervention strategies.

Health systems and organization of care

Important challenges for self-management of T2D at health systems level were identified in Uganda. All services in the formal health system were facility based. Mapping the patient processes highlighted limited access influencing subsequent health-seeking behavior. People with symptoms would seek remedies from different community actors, such as mobile drug vendors, traditional healers, and the village health team. If these proved insufficient, they would seek care from health facilities where the minimum level of quality care for T2D was compromised by lack of qualified staff, medication, essential equipment, accurate guidelines, attention to self-management or self-management education, or continuity of care. In South Africa and Sweden, a minimum level of quality care was ensured by staff, equipment, and guidelines, but the implementation of guidelines varied by the health center.

Community support

In Uganda, people were well rooted with strong community ties, but no community health actors and/or activities were identified as being involved with diabetes. The village health team of trained laypersons was overburdened with maternal health promotion and prevention of infectious diseases. In South Africa, community ties were present but weaker due to frequent migration. Community-based T2D support groups existed, but observations suggested that the functions of peer support—practical assistance, social and emotional support, linkage to clinical care, and ongoing availability of support [12]—were by and large not met in the groups. In Sweden, the sense of community in the urban socioeconomically disadvantaged neighborhoods was strong and characterized by heterogeneity in terms of ethnicity, religion, level of education, and occupational status. The links between civil society and formal institutions were weak, however. Several potential contact points with people with T2D or increased risk were identified: public sector (municipal) actors, such as libraries, schools, and citizen offices; nongovernmental organizations (NGOs), for example, patient organizations, women's organization, and sports clubs; and informal groups.

Both South Africa and Uganda had good models for integrating community actors and activities into the prevention and management of infectious diseases, but South Africa was the only site where community actors had been integrated into the care processes for T2D, although this was limited in scope. In cooperation with the Department of Health, NGOs employed trained laypersons as community health workers (CHWs) to perform home visits to patients unable to attend facilities, with tasks such as the distribution of medication and self-management education and support, yet they did not have adequate knowledge for the latter.

Individual perceptions

In Uganda and South Africa, where people often sought care only when facing severe symptoms or even complications, T2D was perceived as life threatening. In Sweden, T2D was regarded as a common part of the aging process in the target population. It was obvious in all country sites that people did not necessarily lack knowledge of the major strategies for T2D prevention and control (the WHAT), but the integration of the strategies into their daily lives, identifying opportunities for healthy behaviors, and getting support were the major challenges (the HOW). Common features across all country sites were low perceived competence (self-efficacy), low perceived autonomy in care-related decisions and matters, and low or controlled motivation for healthy behaviors ("ought to" rather than "want to"). While, in Uganda and Sweden, the family was perceived as the primary source of emotional and practical support, in South Africa, in some cases, family members could be living far away, and the availability of daily support for self-management was more limited.

Validating the syntheses with key stakeholders showed local buy-in to the project with active participation and eagerness to brainstorm potential strategies and to collaborate with the project. In Uganda, health facility heads and the District Health Team members, and the Non-Communicable Diseases Technical Working Group at the Ministry of Health saw an opportunity for improving clinical care with SMART2D. In South Africa, findings highlighted the potentially important role of CHWs and partnerships with their employer NGOs. In Sweden, the municipal Citizen's office and NGOs saw health promotion and T2D prevention as a potential and acceptable entryway to discussions with citizens and members, and primary care centers were keen to collaborate with the community.

To achieve optimal self-management to prevent and control T2D, all country sites recognized the need to intervene at health care and community level. This led to the following intervention objectives: (a) to optimize clinical care using a people-centered approach to enhance patient engagement in management of T2D and its risk factors and (b) to enhance community involvement for practical, emotional, and ongoing support to further increase capabilities, opportunities, and motivation [24] for self-care and healthy lifestyle of people with T2D or increased risk. These common objectives led to definition of two facility and three community strategies: "Organization of care process" and "Strengthened patient role in self-management" (Facility strategies FS1 and FS2); and "Community mobilization," "Strengthened support from the environment," and "Community extension" (Community strategies CS1, CS2, and CS3). Each strategy contained several components. The facility strategies required relatively minor adjustments for standardization in South Africa and Sweden, whereas, in Uganda, they were an important focus of intervention [16], entailing the development of several components that are described in detail elsewhere (Roy Mayega, personal communication). Furthermore, CS1 was primarily used to boost participation in the intervention. In this article, we will only focus on the development of community strategies C2 and C3 since they had the most cross-context adaptation and, thus, are most relevant for informing transfer and scale-up, the main focus of the paper.

Phase 2: designing generic intervention tools and training for community support strategies

For designing generic tools for the two community strategies (Table 1; Phase 1 and Phase 2), the starting point was to identify key functions, that is, "active ingredients needed for change" targeting key mediators from the SMART2D Self-Management Framework [15].

CS2: Strengthening support from the environment aimed to provide social, practical, emotional, and ongoing support for participants in lifestyle change and self-care. The primary component of the strategy was a *Peer Group Program* (PGP). The generic design for the PGP was based on a Motivational Behavioral Coaching (MBC) approach [25] to create a collaborative spirit [26] to fulfill needs for autonomy, competence, and relatedness and to facilitate the adoption of active learning strategies and positive illness representations [15]. A participatory approach to identify existing healthy behaviors that the individual could feel good about would increase motivation for further changes [27], and guide with concrete and realistic goals and plans, starting an upward spiral of behavior change [28] supported by peers. Focus on participants' knowledge and experience as building blocks would allow participants

with different backgrounds to help and support each other, reducing the need for tailoring the intervention by disease status. A generic PGP meeting structure was developed in the joint tools workshop (Supplementary Material 1). Sample activities were provided to the teams to utilize in contextualization for different topics. Based on our earlier experience with peer support programs in LMICs [25] and Peers for Progress peer support programs [12], general guidelines, selection criteria, and recruitment of peer leaders were outlined (Supplementary Material 1).

The second component of CS2, *Care Companion* (CC; Table 1) was designed to systematize and enhance the existing practice of individuals with T2D visiting the health facility with their significant other and to utilize the CC potential for providing emotional, practical, and ongoing support. Key tasks for their role both as a resource and, ideally, a team member, working in parallel with the health providers and the peer group, and being supported in their role [29], were outlined based on earlier research in HIV/AIDS support (Supplementary Material 2).

For practical reasons, the third component of CS2, *Promoting Healthy Physical Environment*, was to be embedded into the PGP. *Community walk with or without PhotoVoice* was a specific activity to empower participants to investigate opportunities for change in their environment [30], especially with regards to a healthy diet and physical activity.

CS3: *Community Extension* was to ensure the flow of information, feedback, and support vital for proper management of T2D between community and facility. Positive outcomes of health care referring patients to community organizations for preventive services have been reported, but there is little evaluation of the linkages or their generalizability to other settings [31]. A new concept of Community Link Teams (CLT) was developed, consisting, ideally, of representatives of patients and care companions, primary care, and local administration and/or NGOs. The CLT tasks were to (a) advocate for and support healthy lifestyles in the community, for example, with information about facilities and other opportunities available; (b) support implementation of community strategies; and (c) form a linkage between the facilities, local administrations, and the community. A generic protocol for training and supervision of the strategies was also developed (Table 1; Phase 2).

Phase 3: contextual translation of the tools, training, and delivery

As regards CS2 (strengthening support from the environment), all sites initially decided to contextualize and implement the PGP (Table 1; Phase 3). In Uganda, the PGP content was modified in a joint workshop with the country team and the

Table 1 | Phased approach of the SMART2D intervention development: from common strategies to generic tools and contextualization

Phase 1: common strategies and components		Phase 2: generic tools for strategies	Phase 3: contextualization of tools and delivery		
Intervention strategy	Component	Tools and training	Uganda	South Africa	Sweden
CS2 Strengthening support from the environment	Peer group program	Peer Group Program manual with set structure and seven topics: starting the group and building rapport; risk factors and complications; healthy eating; physical activity; alcohol and smoking; self-care and medications; community walk	Simplification with fewer activities; more health education; six topics (starting the group and rapport building as part of other topic); all lifestyle behavior guidelines and examples contextualized; translation to local language	Simplification with fewer activities; more health education; nine topics, including sexuality and stress management; all lifestyle behavior guidelines and examples contextualized; translation to local language	Manual adapted to individual support program with focus solely on diet and physical activity; all lifestyle behavior guidelines and examples contextualized
		Delivery	Peer leader selected from the peer group; nine monthly meetings	Community health workers (CHWs) instead of patients as leader; nine monthly meetings	Telephone support by trained researcher + incidental expert/peer meeting; nine sessions over 13 weeks
		Training package for peer group leaders: 1 day skill-building workshop for peer leaders to get groups started; half-a-day mentoring workshops; short face-to-face or teleconference mentoring sessions as per need	2 day initial skill-building workshop; one reflection session and booster training	2 day workshop on motivational interviewing approach; 2.5 days diabetes education; 1 day group coaching approach; mentored mock sessions before each meeting	Training for content and facilitation before each session; four quality assurance meetings
	Care Companion (CC) involvement	CC guide with criteria, screening tool, and practical daily support tasks for healthy lifestyle, medication adherence, self-care, and appointments	CC a family member or neighbor. Criteria, screening tool, and tasks as in generic	CHW as a CC. Screening tool not relevant due to delivery platform; informational and practical support tasks	One or several CCs, a family member or neighbor. Screening tool not feasible; practical support tasks focused on healthy lifestyle
		Delivery	Nurse introduced the concept and encouraged selection; CC invited to accompany at peer group meetings and health care appointments	CHWs as a CC during home visits, support in lifestyle, self-care, and medication	Facilitator introduced the concept and encouraged selection; CC engagement focused on healthy lifestyle support
	Promoting supportive physical environment	Community walk with/without PhotoVoice in peer group guide	Community walk with journaling	Community walk with journaling or photography	–
		Delivery as part of other components	As an additional topic for peer group	As an additional topic for peer group	–

(Continued)

Table 1 | Continued

Phase 1: common strategies and components

	Phase 2: generic tools for strategies	Phase 3: contextualization of tools and delivery
C3 Community extension	Community link team composition: expert patient, health providers, and relevant representatives of community actors Link between peer leaders and nurse to remind and follow up on appointments and peer group meetings	CHWs linked with patients, community (peer groups), and health facility (distribution of medication, reminder, and follow-up of clinic appointments) Community meeting to increase awareness about the project and to encourage participation in support group activities CHWs comprehensive role supported by mentoring activities Participants and their care companions, telephone coaching facilitators, and representatives from primary care and Citizen's offices from the respective localities
Delivery	Introductory meetings between nurse and peer leaders organized by SMART2D team	Inspiration meetings organized in each locality by the SMART2D team in collaboration with primary care and Citizen's offices.

coordination team, together with an external expert in peer group facilitation with contextual knowledge. Six key topics and culturally appropriate activities and relevant content identified by the country team were brainstormed onto the generic structure. Further adaptations included simplification of sessions and inclusion of more content-related information (see Supplementary Material 3: The Ugandan SMART2D Peer Group Program Manual). The CC guidelines with selection criteria and tasks were developed in their generic format in Uganda and, hence, needed no contextualization. Community walk was included in the PGP as an optional activity using journaling instead of photography. All materials for participants were translated into the local language (Luganda). Electing a group member as the peer group leader turned out to be the most feasible option. The Ugandan team facilitated the first PGP meeting and explained the selection criteria verbally to guide group members in selecting their leader. A training program (Table 1) for the elected peer leaders was developed in collaboration between the country team, the coordination team, and the external expert involved in program contextualization. The expert also trained the first batch of peer leaders, as well as the country team, to deliver the first PGP meeting and to train all subsequent batches of peer leaders. Nurses were trained to instruct patients on CC selection and pass an invitation to the CC to accompany the patient at health facility visits and PGP meetings.

In South Africa, the PGP manual was adapted to have a stronger emphasis on health education. The program retained the spirit of motivational interviewing, participatory activities, and goal setting. Sexuality and stress management were identified as important topics based on previous literature [32] and discussion with a diabetes educator leading diabetes training sessions. All materials for participants were translated into the local language (isiXhosa). The leadership of peer groups was taken up by CHWs. Being part of the same community, CHWs were considered "peers," and they were better placed for this role because of the institutional support provided by their employer organization and their wider role and training in supporting people with chronic diseases in their community [33]. Promoting a supportive physical environment was another key component for South Africa, and they took the lead in developing the community walk for the PGP.

As many people in the target group were migrants, selection of a CC from the participants' immediate network was not feasible. Routine home visits by the CHWs to distribute medication to patients with chronic diseases provided an opportunity to implement the CC component. Changing the delivery brought some modifications to the support functions (Table 1) as the CHWs could provide broader

self-management support and help patients with personal goal setting. For delivery of the community support strategy, training program on to the CHWs was designed and further adapted during the trial to improve the fidelity of implementation (Table 1).

In Sweden, the PGP was piloted in two phases. First, the peer group manual was contextualized based on the generic structure and the manual developed in Uganda and piloted on nine participants recruited from primary health care registers in one study district. The interest and attendance dwindled over the subsequent six sessions. During the second phase, several peer groups were initiated; however, only one group of five participants managed to meet regularly in one of the study sites. A key question arising from the pilot was how to facilitate peer support for behavior change given the difficulties in attendance of the peer group sessions. Keeping the peer support as a core element of the intervention, the peer group manual was adapted, retaining the topics and the generic structure, into a telephone-based program with a health coach facilitating behavior change supported by a CC. Considering the diversity in nationality and language skills of the participants and to increase engagement, the telephone coaching sessions were facilitated in Swedish, English, Spanish, Somali, and Arabic. All facilitators were trained (Table 1) and Standard Operational Procedures (SOPs) for facilitation created and regularly updated throughout the intervention. The peer support component was introduced through the CC. The participants were posted a leaflet on CC role and tasks, and they were encouraged to appoint a CC for themselves. The CC's role was facilitated and followed up by the coach (e.g., with goal setting and review of activities with the CC). With the individualized delivery of C2, the community walk component was not feasible.

The third community strategy CS3: Community Extension, needed the most contextualization across the three country sites (Table 1). In Uganda, linking facility care and community support included specific tasks for peer leaders and nurses. In South Africa, the focal role of CHW enabled linking facility and all community activities together. This link was enhanced with specific tasks and skill building, as well as awareness raising in the community. In Sweden, this strategy was implemented as inspiration meetings in the community where study participants and their care companions, representatives of the Citizen's offices, health care providers, telephone coaching facilitators, and experts (diabetes, diet, and physical activity) were brought together. Fig. 1 summarizes the results of the contextualization of both community strategies.

DISCUSSION

The intervention development process described in this study promoted learning across our three different study contexts in socioeconomically disadvantaged real-world settings. It also provides empirical insight on ways to overcome implementation challenges when transferring and scaling up evidence-based self-management support interventions.

Shared functions but contextualized delivery

People in our target group understood the importance of healthy behaviors but struggled with how to put these into practice. They experienced a need for support in their daily lives that could not be met solely by family members or friends, but there were gaps in peer support for T2D in each of the sites. Intervention needs were surprisingly similar; hence, objectives and core strategies could be shared.

However, delivery of the strategies required much more contextualization, which eventually led to some changes in the functions—for example, uptake of the care companion role in South Africa by CHWs instead of family members, limited provision of
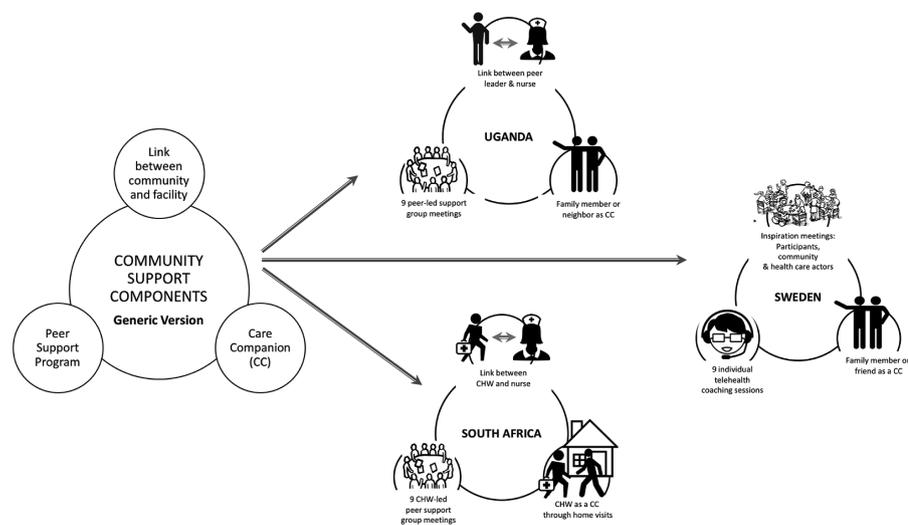
Fig 1 | Generic and contextualized community strategies and their components.

practical assistance and ongoing, and daily support, while enabling provision of informational support and guidance in self-management. Lack of acceptance of peer support interventions has been shown a barrier in western contexts [34] and, in Sweden, major adaptations were required from group-based peer-led to an individual, telephone-facilitated program. While the change from group to individual delivery did not require a major change in the main functions, it had implications for outcome evaluation, with the main emphasis shifting to feasibility and process outcomes rather than effectiveness.

All sites needed improved linkages between community support and facility-based T2D care, but the generic community extension strategy was contextualized both in terms of functions and delivery and largely depended on existing practices and implementation of the other strategies. In Uganda, a linkage between nurses and peer group leaders with the functions to remind and follow-up on patients was introduced by the project. In South Africa, a link between CHWs and facilities already existed, but these and other self-management support functions were enhanced by skills building. In Sweden, a link was established between the primary care, the Citizen's offices and the researchers, bringing all actors together to the inspirational meetings that served a different function: to introduce participants to key stakeholders and activities in their local communities.

The training programs also had to be contextualized and tailored according to the recipients' level of knowledge and skills. In Uganda and Sweden, peer leaders and telephone coaches were offered a training program with both contents and practical, empowering facilitation skills, and they were also offered support during the trial—all factors that have been linked with successful peer support programs [35]. The care companion component did not entail any training in either of the countries as there was no feasible way to deliver it. Our evaluation will show whether their role remains more of a resource rather than a team member [29]. In South Africa, in line with earlier research emphasizing the importance of training for CHWs to be effective [23], they received a comprehensive training package covering T2D, motivational interviewing techniques, and practical program delivery. Working for a local NGO, they are being supported in their role by colleagues and a team supervisor, as well as the research team. They also have direct ongoing contact with the public health care system and, hence, more potential to become a true member of the care team [29]. However, there is still a need for evaluation of the model of care delivery and the CHWs' role and status in the care team [36]. A comprehensive process evaluation will be needed to address the delivery of the different intervention components in each country.

Challenges and benefits related to the process

SMART2D being a research project, all sites were meant to follow the same phases and timeline; however, from the beginning, it was clear that conducting the situational analysis with scientific reporting before synthesizing findings for intervention design was not going to be feasible timewise. This was a major cause of uncertainty during Phase 1. Furthermore, due to unpredictable events (e.g., student protests in South Africa that led to intermittent closure of the university and extended period of piloting in Sweden), it was impossible to work in perfect synchrony. However, this brought also benefits as some countries—especially Uganda—prepared materials that others could adapt with much less work.

Another challenge was the balancing between adaptability and fidelity—the latter being important for cross-comparison. When the project started, "adaptive implementation trial" was a fairly new concept and there was a concern within the country teams that the randomized controlled study design implied that all sites had to implement exactly the same intervention—which the teams knew would not have been feasible. Once the objectives, core strategies, and common functions were clear and the teams could focus on content and delivery fitting each context, the teams also became eager to collaborate and learn from one another. A critical assessment of the implementation strategies benefited from the different teams looking through their lens at the other site's implementation strategy. Furthermore, our strong theoretical awareness was an important source for being able to develop and adapt the intervention over time while largely maintaining the same functions.

Lessons for transfer and scale-up of self-management

Contextualization can be a threat to cross-comparisons, and it can also compromise the effectiveness of the intervention, especially if there is not sufficient clarity of the active ingredients or functions that need to be retained. For example, a stronger emphasis on health education could easily lead to an expert-driven model compromising perceived autonomy, relatedness, and competence, key mediators of self-management [15]. Having a theoretical framework helped to keep the key functions clear and guaranteed they were not lost in contextualization, also allowing for cross-comparison between the sites despite flexibility with other aspects of the intervention. While too much contextualization imposes the risk of throwing the baby out with the bathwater, failing to contextualize adequately would lead to an intervention that is neither acceptable nor feasible to deliver. Finally, while it is premature to conclude whether all the elements of the theoretical framework are, in fact, necessary for change, we

have an opportunity to explore this question as part of the SMART2D intervention evaluation.

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